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Documenting the Emergence of Electronic Nicotine Delivery Systems as a Disruptive Technology in Nicotine and Tobacco Science

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Abstract

Background—The emergence of the electronic nicotine delivery systems (ENDS, or “e-cigarettes”) has resulted in nicotine and tobacco scientists committing increased resources to studying these products. Despite this surge of research on various topics related to e-cigarettes, it is important to characterize the evolving e-cigarette research landscape as a way to identify important future research directions. The purpose of this review was to broadly categorize published scholarly work on e-cigarettes using a structured, multi-level coding scheme.

Methods—A systematic literature search was conducted to collect articles on e-cigarettes that were published in peer-reviewed journals from 2006 through 2014. Studies were classified through 3 coding waves. Articles were first divided into research reports, literature reviews and opinions/editorials. Research reports were further categorized to determine the proportion of these studies using human participants. Finally, human studies were classified based on their methodologies: descriptive, predictive, explanatory, and intervention.

Results—Research reports ($n = 224$) and opinions/editorials ($n = 248$) were published at similar rates during this time period. All types of articles showed exponential rates of increase in more recent years. 76.3% of human research studies tended to be descriptive in nature, with very little research employing experimental (6.8%) or intervention-based methodologies (5.4%).

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Contributors

Authors JBC, IA, and NSM designed the study. JBC and IA coordinated literature searches and conducted data analysis. All authors assisted in the interpretation of results and manuscript preparation. All authors approved of the final version of the manuscript.

Conflict of Interest

Author THB receives research support from Pfizer, Inc. All other authors declare no conflicts of interest.

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Conclusions—This review reinforces the idea that e-cigarettes are a disruptive technology exerting substantial influence on nicotine and tobacco science. This review also suggests that opinions on e-cigarettes may be outpacing our scientific understanding of these devices. Our findings highlight the need for more e-cigarette research involving experimental, intervention, and longitudinal designs.

Keywords

electronic cigarettes; literature review; research methods; study design

1. Introduction

Electronic nicotine delivery systems (ENDS), also known as electronic cigarettes or e-cigarettes, were introduced into the global marketplace in 2006. Since their introduction, the availability and popularity of these devices have increased exponentially to the point where “vape,” the colloquial term for using ENDS, was chosen as the Oxford English Dictionary’s Word of the Year in 2014. Recent reports estimate that 8.5% of US adults have used these products at least once during their lifetime (King, Patel, Nguyen, & Dube, 2015), and rates of ever-use have been steadily increasing (McMillen, Gottlieb, Shaefer, Winickoff, & Klein, 2015). This increase in use likely stems from greater availability, marketing, and diversity of e-cigarette products, with new brands of ENDS and new flavors of e-cigarette liquids being constantly introduced into the marketplace (Zhu et al., 2014). Growing popularity and expanding availability suggest that ENDS constitute an emerging phenomenon in the global marketplace.

This emergence has raised important questions regarding the safety, efficacy, and population impact of these devices. There are conflicting viewpoints in the public health community on how e-cigarettes may impact smoking: some believe that e-cigarettes may facilitate smoking cessation via harm reduction (Nitzkin, 2014), while others characterize e-cigarettes as a potential “gateway” for a new generation of nicotine-dependent individuals (Grana, 2013). Issues like flavorings and chemical composition of e-cigarette liquids often drive these disagreements in the public health community. To resolve debates like these, many professional organizations have called for systematic research with sound methodologies so that the safety and efficacy of e-cigarettes can be better understood (e.g., Brandon et al., 2015). The nicotine and tobacco research community has consequentially placed emphasis on understanding the role that ENDS play in this scientific domain. Hundreds of scholarly research articles on ENDS have been published since the product was introduced into the general marketplace. Zyoud, Al-Jabi, and Sweileh (2014) used bibliometric methods to describe this emergence of international ENDS research, and they reported that ENDS research output had increased exponentially in more recent years. Pepper and Eissenberg (2014) used a similar strategy to compare the relative growth of ENDS research to that of waterpipe tobacco, and they suggested that nicotine and tobacco scientists may be more interested in studying ENDS than traditional tobacco products. These reviews support the idea that ENDS represent a “disruptive technology” that is rapidly evolving into a central component of nicotine and tobacco research (Abrams, 2014; Fagerstrom, Etter, & Unger, 2015; Pechacek, Nayak, Gregory, Weaver, & Eriksen, 2016).

Despite the proliferation of ENDS research in recent years, many important areas of study remain unaddressed. The need for informative research on ENDS is becoming critical, as regulatory agencies are developing guidelines for monitoring ENDS manufacturing and distribution (Food and Drug Administration, 2016) and professional organizations are releasing position papers and policy recommendations (Bhatnagar et al., 2014). For instance, several professional organizations have suggested sweeping regulations of e-cigarettes, including a complete ban on flavored e-cigarette liquids (Crowley, 2015; Schraufnagel et al., 2014). However, it remains unclear the degree to which flavorings serve to entice youth to initiate nicotine use versus facilitate harm reduction (by encouraging transition from smoking to vaping). As a critical mass of research on ENDS develops, systematic reviews and meta-analyses will continue to be used to summarize important research findings. However, it is also useful to take a “50,000 foot view” of the landscape of ENDS research, as such an approach would help identify unaddressed research questions. To provide such a perspective, the purpose of this review was to systematically compile and classify articles in academic journals that were directly related to ENDS using a structured, multi-level coding scheme. Insight into the broad balance of academic publications on ENDS would be useful in evaluating the potential impact of future research and minimizing “wasted” research resources (Chalmers et al., 2014).

2. Methods

2.1 Acquisition of Articles

A systematic literature search for publications in academic journals was conducted using PubMed, PsycInfo, and Web of Science. Articles published between January 2006 and December 2014 were collected. Searches for the terms “e-cigarette,” “electronic cigarette,” and/or “electronic nicotine” in the title, abstract, or topic identified potentially relevant articles that were reviewed by trained coders.

2.2 Coding of Articles

Duplicate articles, articles not written in the English language, and articles not focused explicitly on ENDS were excluded from the sample. Coding was conducted in three waves, with each successive wave focusing on more specific subsections of the literature. In Wave 1, all included articles were classified into three broad categories: i) primary research reports; ii) literature reviews, meta-analyses, and position papers from research or clinical organizations; iii) opinions, editorials, and letters to editors. In Wave 2, primary research reports that enrolled human participants were differentiated from those that did not.

Finally, in Wave 3, ENDS research articles involving human participants were coded into one of four categories, three of which were adapted from a derivation of study designs described by Bailey (2008): 1) descriptive research, which uses an exploratory design aimed at describing a phenomenon and its common and unique characteristics; 2) predictive research, which identifies factors influencing change in a phenomenon over time without the use of experimental manipulation; 3) explanatory research, which evaluates mechanisms and causes underlying a phenomenon through experimental manipulation. A fourth category, intervention research, was added to capture a small, yet highly important, research area

regarding ENDS—studies evaluating the efficacy of ENDS as aids for smoking reduction and/or cessation. Including this fourth category allowed for the coding scheme to more accurately reflect the traditional goals of the scientific method in health research: “to describe, explain, predict, and sometimes control the world in which we live” (Polgar & Thomas, 2013, p. 7).

Classification criteria for all three waves were agreed upon a priori. Articles were coded by two independent raters, with 87.8% agreement. Discrepant ratings were reviewed by a third rater and assigned a final code.

3. Results

Figure 1 represents a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram of the literature reviewed here. Database searches yielded a sample of 1,063 articles that were considered for inclusion in this review. We removed 534 articles that did not explicitly evaluate ENDS, were not written in the English language, or were not subjected to formal peer or editor review (e.g., conference abstracts). The final 529 articles were coded using the three-wave system described earlier. Of the 529 articles included in this review, 511 (96.6%) were published between 2011 and 2014, and 451 (85.3%) were published in 2013 or 2014.

3.1 Waves 1 and 2

Figure 2 illustrates the results of the three coding waves, with panel A showing results from waves 1 and 2. Wave 1 revealed that opinions, editorials, and letters to editors were the most frequently published type of ENDS article during this 8-year period ($n = 248$, 46.9% of all coded articles), with 84.7% of these types of articles published in 2013 and 2014. Articles coded in this category demonstrated a wide range of tones and messages: some emphasized the potential benefits of e-cigarettes (e.g., Hajek, 2012), some focused on the risks of e-cigarettes (e.g., Chapman, 2013), and others called for empirical research to resolve the differing perspectives (e.g., Hitchman, McNeill, & Brose, 2014). Primary research articles were published at a similar rate ($n = 224$, 42.3% of all coded articles), with 85.3% of these articles published in 2013 and 2014. Reviews, meta-analyses, and position papers were the least frequently coded category in Wave 1 ($n = 57$, 10.8% of all coded articles), with 87.7% published in 2013–2014.

Wave 2 focused on the 224 primary research articles coded in wave 1 and classified these articles based on whether or not human participants were enrolled. Approximately 34% ($n = 76$) of primary research studies did not recruit human participants. Most non-participant research articles addressed one of two general research areas: 1) content analyses of websites, advertisements, and online forums involved with producing, publicizing, or distributing ENDS (e.g., Grana & Ling, 2014); 2) chemical and biological analyses of particles and toxicants in e-cigarette solutions and aerosols (Goniewicz et al., 2014).

3.2 Wave 3

Panel B of Figure 2 shows the results from wave 3 of article coding. The 148 human participants research articles were categorized as descriptive, predictive, explanatory, or

intervention studies based on the criteria described earlier. Panel B shows results from this final wave of article coding during the last five years in the period under consideration, which is when all of these articles were published.

All four categories experienced increases in publication rates during this period, with descriptive experiencing the greatest increase. The majority of articles in this wave were coded as descriptive ($n = 113$; 76.4%), with many of these studies reporting results from surveys on awareness, perceptions, use, and acceptability of ENDS (e.g., Pearson, Richardson, Niaura, Vallone, & Abrams, 2012). The 35 non-descriptive studies fell fairly evenly into the three remaining categories, with 17 predictive studies (11.5%), 10 explanatory studies (6.8%), and 8 intervention studies (5.4%). Many of the predictive studies utilized survey methods to evaluate awareness, use, and perceptions of ENDS; however, these studies differed from descriptive studies in that they collected data at multiple time points and explored the relationship between relevant variables over time (e.g., Choi & Forster, 2014). Many of the explanatory studies comprised experimental designs evaluating acute effects of ENDS use on a variety of general health indicators (e.g., Vardavas, Anagnostopoulos, Kougias, Evangelopoulou, Connolly, & Behrakis, 2012). Finally, many of the intervention studies used non-experimental, prospective designs, with only two articles describing true randomized controlled trial methodology (Bullen et al., 2013; Caponnetto et al., 2013).

4. Discussion

Using a systematic, structured coding system, this review illustrated that, through 2014, peer-reviewed journals published slightly more opinions and editorials about ENDS than primary research articles. Though it is possible that other controversial topics in public health, such as needle exchange programs or controlled drinking interventions, might have produced similar patterns, it is doubtful that such a pattern has been previously seen in the tobacco research area. This pattern also suggests a potentially maladaptive situation in which opinion is outpacing the science that should provide the basis for informed opinion.

This review supports recommendations from organizations like the National Institutes of Health (Walton et al., 2015) and the American Association for Cancer Research (Brandon et al., 2015) that outline viable future directions for ENDS research. Such guidelines encourage implementing predictive, explanatory, and intervention-based designs to answer critical ENDS research questions. The vast majority of human participant research published to date has been descriptive, and this pattern is not particularly surprising. Descriptive research is traditionally conceptualized as the initial step needed when a new research area emerges, and it is usually the simplest and most practical type of research to conduct. More complex and causally-informative designs should follow once foundational descriptions of ENDS use are established.

Our approach builds upon the work of Zyoud et al. (2014) and Pepper and Eissenberg (2014) by characterizing the maturation of ENDS research methodologies across time. The rapidly changing landscape of ENDS research is unusual in that the study topic itself is also rapidly changing. ENDS are evolving as rapidly—or even more so—as any electronic product

available to consumers, with new “generations” introduced to the market after relatively short intervals (Farsalinos & Polosa, 2014). The population of ENDS users is also expanding and evolving rapidly, as are public policies and regulatory actions. It may be tempting for funding agencies to wait until the situation stabilizes before committing large investments to research in this area. However, the potential costs of delaying ENDS research are too great to take a “wait and see” approach. Millions of people are using these products, and there is a vital need for reliable and valid data on their safety and efficacy.

Data are especially needed to understand whether ENDS promote smoking cessation, as this constitutes the area with perhaps the greatest deficit in knowledge. The two randomized controlled trials included in this review both provided suggestive evidence that ENDS may promote smoking cessation, but the role of nicotine was unclear. However, it is difficult to draw generalized conclusions from these results because of the methodological limitations (including small sample sizes) of these early trials. Although there is accumulating support from other research for the efficacy of ENDS for smoking cessation or reduction (McNeill, Brose, Calder, Hitchman, Hajek, & McRobbie, 2015), the quality of the evidence supporting this relationship remains low because of these methodological shortcomings (Malas et al., 2016). And although e-cigarettes cannot be marketed as therapeutic products, many e-cigarette users view them as a way to quit or reduce their smoking (Pepper and Brewer, 2014). It is vital for the research community to overcome barriers—including regulatory ones—that prevent intervention research with ENDS, as these data would serve the public interest to a great degree.

The main limitation of this literature overview is that only articles published between 2006 and 2014 were included. A preliminary search of scholarly articles published in 2015 shows that ENDS publication rates continue to exponentially increase. When using a similar article acquisition approach as the one described in this review, an initial library of 2,959 publications from the year 2015 was produced. This library is nearly three times the size of the one considered for this review, and it reinforces the need for researchers and scientists to consistently scan the landscape of ENDS research for unanswered research questions.

5. Conclusion

In conclusion, this systematic literature overview provides data describing the emergence of ENDS research as a viable enterprise in nicotine and tobacco science. Results from our review demonstrated that ENDS research remains largely descriptive in nature. Future directions that would promote growth of this research area include identifying mechanisms that explain or predict patterns of ENDS use and their consequences, as well as evaluating the efficacy of these devices as smoking cessation aids. We expect that researchers will continue to explore important research questions by utilizing experimental, longitudinal, and controlled clinical methodologies. Such research is needed by multiple stakeholders, including the general public, smokers, “vapers,” and legislators, to make evidence-based decisions regarding ENDS use.

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Highlights

- E-cigarettes represent a “disruptive technology” in nicotine and tobacco science.
- Through 2014, opinion articles on e-cigarettes were published as often as empirical research.
- Human subject research on e-cigarettes has been largely descriptive.
- Experimental and intervention studies of e-cigarettes are needed.

Figure 1.
PRISMA diagram demonstrating categorization of ENDS publications.

Figure 2.

Results from Waves 1, 2, and 3 of article coding for ENDS publications. Panel A shows results from Waves 1 and 2 of coding from years 2007 through 2014. Panel B shows results from Wave 3 of coding from years 2010 through 2014.