Towards the Standardized Documentation of E-Cigarette Use in the Electronic Health Record for Population Health Surveillance and Research

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ABSTRACT
The debate regarding potential negative health effects of electronic nicotine delivery systems (ENDS), which include electronic cigarettes, has received much recent attention. Currently, it is unknown whether ENDS pose a real health risk to users or those passively exposed to their vapor. With the increased use of these devices, the goal of this study was to examine if and how their use is being documented in the electronic health record (EHR) and the associated implications for clinical research. Analysis of five years of progress notes and tobacco use comments revealed that ENDS use is documented at an increasing rate with variable associated information, most often consisting of the status, purpose, and side effects of ENDS use. These results highlight that improved and consistent EHR discrete data entry for ENDS with associated clinical standards for documentation and representation of potential exposures are needed for enabling effective population health surveillance and research.

BACKGROUND AND SIGNIFICANCE
Electronic nicotine delivery systems (ENDS), such as electronic cigarettes ("e-cigarettes"), have been commercially available since 2004. Most recently, advertising efforts have greatly increased and the industry saw over $1.7 billion in sales in 2013.[1, 2] ENDS were originally introduced as a "safer cigarette", an alternative to tobacco use offering reduced harm, and as a potential cessation device for tobacco use.[3] While some studies have shown that ENDS can assist in smoking cessation,[4-6] others have demonstrated that many users use them long term and have shown that the use of e-cigarettes does not discourage and may even encourage traditional cigarette use among adolescents,[7, 8] and that their use is bringing about a "renormalization" of smoking.[9] Criticisms of ENDS devices and nicotine liquids in cartridges ("e-liquids") have centered on the marketing practices of vendors,[10] and some claim that these devices may attract tobacco-naïve individuals to start smoking, especially young people, which has led to concerns that the use of ENDS may be a gateway to conventional cigarette usage.[8, 11, 12]

To date, the health effects of ENDS use have not been well studied. It is unknown what the potential risks are of these devices, including how much nicotine or other harmful chemicals are being inhaled, what the long term affects are, including negative health affects to those passively exposed to the vapor, whether there are environmental concerns regarding the disposal of these devices,[13, 14] and whether these devices truly are a means to tobacco cessation.[14-16] While the nicotinergic effects are similar to traditional cigarettes,[17] studies have shown some specific side effects of ENDS use,[18] poison control centers have seen an increase in reports of exposure to e-cigarettes or their liquid nicotine,[19] and ENDS may contain other products not found in traditional cigarettes such as propylene glycol, glycerol, and flavorings.[20] Since ENDS are not regulated like conventional cigarettes, there is no required disclosure of chemicals that may affect users or passive users. These potential exposures and effects justify the need for surveillance to track adverse events,[21, 22] documentation in the EHR to support inquiry and awareness by healthcare providers into their use by patients,[23] and ENDS use data collection for clinical research.

The ever-changing healthcare environment creates challenges for EHR system vendors as well as standards development organizations to remain current with emerging social and behavioral health issues such as ENDS use to develop consistent and discrete data collection tools for these data.[24, 25] While some standards have been defined for traditional tobacco use and cessation as part of Meaningful Use, EHR Certification Criteria, and Clinical Quality Measures[26], these initiatives have yet to explicitly address and incorporate ENDS devices. Existing models (e.g., HL7[27, 28] and openEHR[29]) and terminology standards (e.g., SNOMED CT[28]) for tobacco use could serve as a foundation for standardizing documentation and guiding design of robust data collection tools, without which clinicians are limited to documenting in unstructured fields, potentially putting it out of reach of providers, clinical decision support tools, and analytics for quality improvement and clinical research. The goal of this study was to

examine current practices of ENDS use documentation in the EHR and to develop an initial representation model for guiding standardized ENDS discrete data collection to support clinical care and research.

METHODS AND RESULTS

Documentation of ENDS use was examined in progress notes and free-text tobacco use comments from the social history module of the Epic EHR at Fairview Health Services (FHS) in Minneapolis, MN. For over a five year period from January 1, 2009 to June 20, 2014. Notes and comments were searched using the following patterns and keywords: "ecig*", "e-cig*", "electronic cig*", "electronic-cig*", "vaping", and "vaper". In addition, a content analysis was performed for a random set of 500 notes and 500 comments from FHS to categorize their contents. The approach used for this analysis was based on our prior work involving the analysis of social history and tobacco use documentation in the EHR.[30-32] In this study, sentences or statements containing any of the keywords from the notes and comments were reviewed and their content categorized, resulting in the development of an initial representation model for ENDS. Results revealed that documentation of ENDS use in progress notes (ambulatory and inpatient encounters) increased from 23 in 2009 to 4,411 in 2014 representing 0.0032% of patients in 2009 and increasing to 0.46% of patients in approximately 6 months of 2014 (Table 1). An examination of tobacco use comments showed an increase in documentation of ENDS use from 0.00071% in 2009 to 0.22% of patients in 2014.

Table 1: Results of Pattern and Keyword Search of Progress Notes (Ambulatory and Inpatient) and Tobacco Use Comments for ENDS Use. * January 1, 2014 to June 20, 2014.

Year	Encounters with ENDS Notes (% Total Encounters)	Patients with ENDS Notes (% Total Patients)	Patients with ENDS Tobacco Use Comments (% Total Patients)
2009	23 (0.00056%)	22 (0.0032%)	2 (0.00071%)
2010	118 (0.0025%)	101 (0.015%)	13 (0.0038%)
2011	386 (0.0080%)	298 (0.041%)	36 (0.0081%)
2012	1,097 (0.021%)	765 (0.10%)	136 (0.025%)
2013	6,718 (0.12%)	4,205 (0.52%)	876 (0.15%)
2014*	4,411 (0.16%)	2,612 (0.46%)	852 (0.22%)

The categorization of contents in notes and comments showed that the majority of statements indicated current use of e-cigarettes, 74.6% and 94.2% respectively. Over half of the notes (52.4%) mentioned details about concurrent tobacco use, and 27.6% of notes and 15.0% of comments indicated e-cigarette use for tobacco cessation (Table 2).

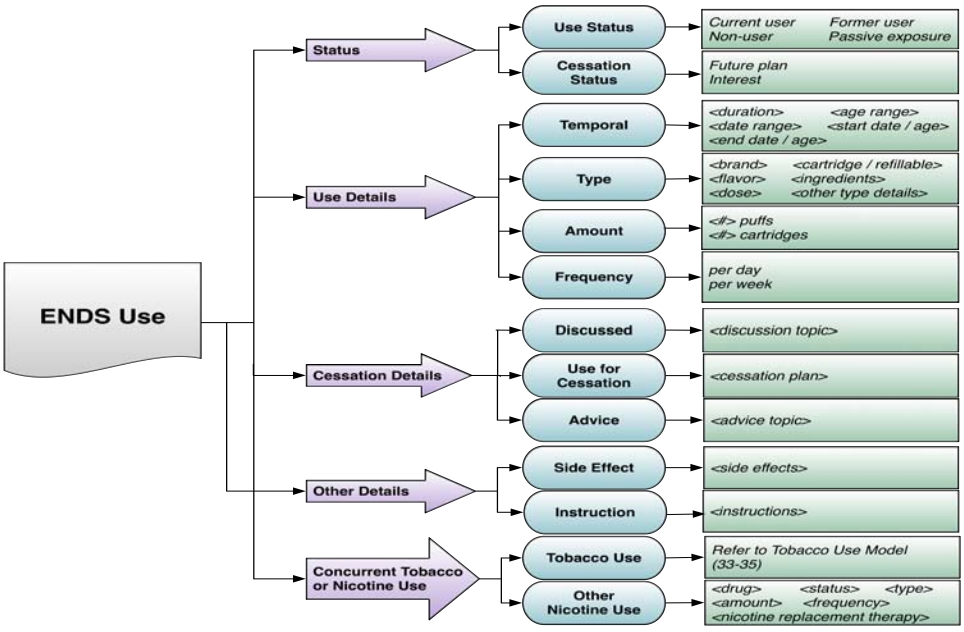
Table 2: Review and Content Categorization of ENDS Use in Notes and Comments.

Category	Notes	Comments	Example Note or Comment Sentences/Statements
Status			
Current user	373 (74.6%)	471 (94.2%)	"Uses E-Cig", "Using electronic cigarette-trying to quit."
Former user	22 (4.4%)	2 (0.4%)	"He stopped all tobacco and E cig 3 weeks ago.", "She also used to use an e-cigarette…"
Non-user	10 (2.0%)	3 (0.6%)	"She has tried e-cigarettes but does not like the taste."
Passive exposure	9 (1.8%)	9 (1.8%)	"…passive exposure from dad- (e cig)", "Grandmother smokes Ecigarettes in the home."
Future plan	19 (3.8%)	9 (1.8%)	"She is still a smoker, but is moving…plans to only smoke e-cigarettes there."
Interest	47 (9.4%)	7 (1.4%)	"…looking into electronic cigarettes to help him quit."
Use Details			
Temporal (duration, start/end date and age)	1.6% (8)	23 (4.6%)	"using electronic cigarettes. Started at age 20."
Device type (flavor, brand, etc.)	5 (1.0%)	1 (0.2%)	"doing e-cigarettes without nicotine- lemon-lime flavor only", "uses ecig 15ml of nicotine titrating down…"
Ingredients / dose	18 (3.6%)	8 (1.6%)	"Smoking e-cig, 10mg", "…using the e-cig. Using the 12 mg nicotine fluid…", "…electronic cigarette – 1.6%..."
Frequency / amount	12 (2.4%)	20 (4.0%)	"He is using an E cigarette 3-4 times/day", "…down to 4 mg e-cigs daily", "electronic cigarette…few puffs a day"

Cessation Details			
Discussed	20 (4.0%)	0 (0.0%)	"Tobacco Cessation…: discussed electronic cigarettes"
Use for cessation	138 (27.6%)	75 (15.0%)	"…and is also using e-cigs to help quit.", "Smoking Cessation: Using the E-Cigarette to help her quit."
Other Details			
Advice / instructions	13 (2.6%)	0 (0.0%)	"Pt councelled that the E Cig is still dangerous…", "*NO tobacco or alcohol for 12 hours prior to your exam (includes E-cigs…)"
Side effect	12 (2.4%)	0 (0.0%)	"…advised him to discontinue E cig as nicotine may be contributing to vasospasm.", "… she believes she is vomiting from her e-cigarette."
Other Tobacco or Nicotine Use			
Status	76 (15.2%)	42 (8.4%)	"quit - now using electronic cigarettes", "Quit smoking in Jan. Using e-cigs."
Type, amount, and/or frequency	262 (52.4%)	175 (35.0%)	"E cig occasional tobacco use", "Using E-cigarette - now down to 5 cigarettes per day."
Other cessation drug/device	39 (7.8%)	11 (2.2%)	"Trying to cut down on smoking - using nicotine patch and e-cigarette..."

The note and comment review provided content to develop an initial model for guiding discrete data collection of ENDS use (Figure 1). This analysis revealed that providers not only document current or former use of these devices, but also information about the frequency, duration, type, side effects, ingredients and concentration of drug, and concurrent use of tobacco or other nicotine delivery methods or cessation drugs.

Figure 1: Proposed Representation Model for ENDS Use. Arrows represent the broad categories from Table 2, rounded rectangles are elements within these categories, and rectangles include examples values that could be documented for each element.



DISCUSSION

The analysis of over five years of EHR data from FHS demonstrated increasing documentation of ENDS use within unstructured notes and free-text tobacco use comment. The same search for ENDS use documentation in free-text tobacco use comments from the Epic EHR at University of Vermont Medical Center supports this trend with documentation increasing from 0.01% of patients in 2011 to 0.12% in 2014. Since the potential health impact of ENDS use is yet unknown, as are the effects of passive exposure to vapor, having standard documentation practices of ENDS use in the EHR could assist providers in facilitating nicotine cessation discussions as well as help identify

adverse events related to these devices which could ultimately be leveraged from a population surveillance and clinical research perspective. In particular, consistent collection of ENDS data might also serve as a foundation for subsequent epidemiological studies that can provide a longitudinal and population-level perspective of the effect of e-cigarettes and related products.

In critically considering ENDS and the EHR, several important questions remain. Where should ENDS use be documented in the chart? Should ENDS be considered a nicotine replacement therapy like a nicotine patch or nicotine inhaler, or should it be included as a substance and exposure similar to tobacco and alcohol? At present, most providers seem to document ENDS use and exposure within tobacco use documentation. It seems appropriate that ENDS use should be discretely recorded, and the associated information visualized alongside traditional tobacco use information.

This study has provided insights into information modeling around ENDS use as well as the type of discrete data that should be collected. Our review and categorization of 500 notes and 500 tobacco use comments provides a solid foundation to propose content for EHR data collection tools for ENDS use. We propose that standard representation of ENDS use should include *Status of Use* and *Cessation*; *Use Details* such as type of ENDS device, frequency and duration of use; *Cessation Details*, *Other Details* such as side effects and instructions; *Concurrent Use* of other devices or drugs; and *Device Cartridge Formulations* (including dose of nicotine, flavor, and manufacturer). As with traditional tobacco use, it is simply not enough, from a population health and individual health perspective, to only document that a patient "uses e-cigarettes." This is a significant amount of new information collection, and its acculturation into routine clinical practice will take education and recognition of its importance from policymakers.

With respect to ENDS and EHR systems, standards are needed that incorporate the use of these devices and important associated information. Engaging stakeholders such as vendors, end users, and ENDS and standards development organizations on how best to document ENDS use will be critical for effective documentation and use. Lastly, rapid implementation of newly developed standards is needed in EHRs that require vendor design and build. The results of this exploratory study provide insights to how ENDS use is currently documented and guidance for improving how nicotine use is represented in EHRs to support clinical care, public health initiatives, and clinical research. Combined with existing standards and our previous work on modeling tobacco use in the EHR[30-32], an enhanced model that incorporates ENDS use could emerge for informing healthcare standards development and future design of EHR systems. Ultimately, EHR systems have the potential to be robust population health surveillance and research tools if they are well designed for data collection and are flexible enough to be able to track emerging public health issues and support clinical research. The social history section of the EHR, in particular, needs to be flexible enough to allow for documentation of social determinants of health in a central location, in a manner such that the data are accessible to analytic and clinical decision support tools.

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