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A Cross-sectional Survey of California Pharmacists' Knowledge and Perceptions about Electronic Nicotine Delivery Systems (ENDS)

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Introduction

Tobacco use in the US causes more than 480,000 fatalities each year, accounting for nearly one in five deaths.[1,2] On a population level, tobacco cessation efforts have been complicated by the development of new alternative tobacco products, including electronic nicotine delivery systems (ENDS), which some smokers view as a method to help them quit smoking combustible cigarettes.[3] In the US, use of ENDS, primarily electronic cigarettes (e-cigarettes), increased from 1.8% to 13% of the population between 2010 and 2013.[4] E-cigarettes consist of a battery, vaporizer, and nicotine solution; as the device heats the nicotine solution, it delivers an aerosol that the user inhales. Nicotine solution is usually packaged in a cartridge and is typically comprised of nicotine, propylene glycol, and flavoring agents (although the specific composition of nicotine solution can vary across different products and brands).[5] Although ENDS were initially unregulated, in August 2016 the US Food and Drug Administration (FDA) made a deeming provision that subjected these products to federal regulation, which could include the creation of product quality standards and disclosure of the ingredients used in nicotine solutions.[6,7]

Although the health risks of combustible cigarettes are well known, research on the health risks of ENDS is ongoing.[6-8] ENDS appear to generate lower levels of toxicants than combustible products that contain tobacco.[8,9] However the US Centers for Disease Control and Prevention (CDC) reported that the aerosol generated by e-cigarettes is not harmless and not as safe as clean air.[6] ENDS decompose the contents of nicotine solution during heating, potentially transforming them into toxic compounds that could pose health threats to the user.[10] Safety concerns have also been raised about e-cigarette flavorings; although some have been considered safe for food consumption, little is known about the long-term effects of inhaling these substances into the lungs in aerosol form.[6,11] The nicotine contained in ENDS is a highly addictive substance that can be detrimental to fetal brain development during pregnancy and to youth.[6,7] Because the health effects of ENDS use are not well-understood, ENDS are not officially indicated for use as a smoking cessation aid.[6] Studies comparing ENDS and traditional nicotine replacement therapy (NRT) for smoking cessation have found inconsistent results.[3] Despite the lack of definitive data to prove their efficacy, ENDS are marketed as safer alternatives to combustible cigarettes.[6]

Pharmacists are uniquely well-situated to promote smoking cessation due to their daily interactions with the public.[12-14] In California, the scope of pharmacy practice expanded with the passage of SB 493 in 2013, which allows pharmacists to furnish prescription NRT and other medications that can help smokers quit, and the passage AB 1114 in 2016, which allows pharmacists to be reimbursed under Medi-Cal for furnishing medications.[15-18] In

the US, both NRT and ENDS are available over the counter at many community pharmacies and may be sold in close proximity. Pharmacists, particularly community pharmacists, can initiate smoking cessation counseling and NRT use and provide patients with accurate information about the safety and use of ENDS.[4,16] However, there is limited data regarding pharmacists' knowledge and perceptions regarding ENDS, their health risks, and their potential role in cessation.

This study sought to assess California pharmacists' awareness and approaches regarding ENDS to gain insight into what information is offered to patients, and to determine whether there is a need for continuing professional education about ENDS targeted to pharmacists. We hypothesized that pharmacists would be aware of the regulatory status of ENDS and that their recommendations regarding cessation would be consistent with CDC guidelines, which state that "evidence is insufficient to recommend e-cigarettes for smoking cessation in adults."[19]

Methods

To assess pharmacist knowledge and attitudes toward ENDS, we conducted an online, cross-sectional, exploratory survey of California pharmacists. Eligible respondents were California-licensed pharmacists with no exclusions based on area or years of practice. We received institutional review board approval on June 15, 2016 (*redacted #16-19851*), and began disseminating the survey via email to licensed pharmacists affiliated with California Pharmacy Student Leadership, California schools of pharmacy, the California Society of Health-System Pharmacists (CSHP) listserv, and the American Society of Health System Pharmacists' (ASHP) residency directory. Each potential participant received a single email, and respondents were self-selected. The survey was fielded between June 22 and August 6, 2016. The FDA changed its regulatory stance on e-cigarettes as of August 8, 2016, at which point the survey was closed.

The survey was created using Qualtrics software and housed on the UCSF Research Electronic Data Capture system, which provides secure and Health Insurance Portability and Accountability Act of 1996 compliant data storage and anonymized the survey responses. Our 17-item instrument (see Appendix) relied on validated questions assessing e-cigarette awareness and use as well as demographics, drawn from existing studies of tobacco product use, and the time estimated to complete the survey ranged from three to five minutes.[20-23] Measures of perceived harm used Likert-scaling to assess pharmacists' opinions and level of comfort. Measures of knowledge and practices focused on ENDS tracking and regulation. To resolve issues of missing data, we excluded incomplete surveys. We conducted tests of statistical significance using contingency tables to understand distinguishing characteristics associated with California pharmacists' knowledge and attitudes toward ENDS.

Results

Although the sample was self-selected, general characteristics of the study were representative of California pharmacists. A total of 336 surveys were received; 81 (24%) of these surveys were incomplete and removed from the analysis. Results are reported from the remaining 255 (76%) completed surveys. The sample was compared to population data on the total numbers of California pharmacists (although the totals differed by source, ranging from 28,300 to 35,526).[24] Demographic data of this sample, relative to the population of California pharmacists, is provided in Table 1; no statistically significant differences were identified.

Table 1. Comparison of Characteristics of Pharmacy Survey Respondents (n=255) to the General Population of California Pharmacists

Characteristic	Respondent characteristics, N (%)	Population characteristics, N (%)
Gender		
Female	154 (60)	20,772 (58)
Male	101 (40)	14,754 (42)
Age		
18-44 y	159 (62)	17,978 (51)
45-64 y	62 (24)	12,230 (34)
65+ y	34 (13)	5,316 (15)
Unknown		2 (<1)
Time in practice		
<5 years	92 (36)	No data
5-10 years	42 (16)	No data
>10 years	121 (47)	No data
Practice setting		
Hospital	96 (38)	9,622 (34)
Ambulatory care	42 (16)	3,679 (13)
Community	61 (24)	13,018 (46)
Other (self-report)	56 (22)	1,981 (7)

Knowledge

Respondents were asked if they believed that the FDA was regulating ENDS. Most respondents (60%, n=152) were aware that the FDA was not regulating the use and safety of ENDS at the time of the survey. The remaining respondents either believed that the FDA was regulating at the time of the survey (23%) or were unaware of ENDS' regulatory status (17%). Results are shown in Figure 1. This awareness did not appear to be associated with general experience or with exposure to ENDS; no significant correlations were found between knowledge of ENDS regulatory status and years in practice (P=0.07, $\chi 2=8.51$), working in a practice that tracked nicotine product use (P=0.43, $\chi 2=3.84$), or practice setting (P=0.87; $\chi 2=2.41$).

Table 2. ENDS Knowledge and Perceptions (Reported as Percentages)

	Agree/Yes	Disagree/No	Don't know
Does using ENDS help people quit smoking?	20	46	34
Are ENDS regulated by the FDA?	23	60	17
ENDS are just as addictive as cigarettes	87	4	8

Note: Data drawn from 2016 California pharmacist survey (N=255).

Table 3. Perceptions of Health Risks for ENDS and Combustible Cigarettes (Reported as Percentages)

	Is using ENDS less harmful, about the same, or more harmful than smoking cigarettes?	Do you think the vapor from other people's ENDS is harmful to you?
Not harmful	–	3
Less harmful than cigarettes	26	39
About the same/equal to cigarettes	49	37
More harmful than cigarettes	12	3
Don't know	13	18

Note: Data drawn from 2016 California pharmacist survey (N=255).

FDA, Food and Drug Administration.

Perceptions of Health Risks

At the time of the survey, studies assessing the health risks of ENDS demonstrated mixed results. Nonetheless, most pharmacists surveyed had drawn conclusions about their effects. Nearly 9 in 10 respondents (88%, n=222) reported opinions regarding the health risks of ENDS relative to combustible cigarettes, and 82% (n=208) reported opinions about the health risks of exposure to secondhand aerosol from ENDS.

There was widespread agreement regarding the addictiveness of ENDS; 224/255 (88%) respondents believed that ENDS were just as addictive as cigarettes (see Figure 2). There was less agreement about the potential harms of ENDS use; only half of the respondents viewed ENDS and combustible cigarettes as equally harmful (49%, n=126), while a quarter (26%, n=65) viewed ENDS as less harmful (see Figure 3). Nearly all pharmacists who perceived that ENDS were more harmful than cigarettes (n=31) also believed that ENDS were as addictive as cigarettes (93%, n=29).

Respondents reported a range of perceptions regarding the risks of secondhand ENDS aerosol exposure. Only 3% stated that secondhand ENDS aerosol was "not harmful," while 39% stated that it was "less harmful" than secondhand smoke. Another 37% of respondents stated that secondhand ENDS aerosol and secondhand smoke were "equally" harmful, and 3% of respondents stated that secondhand ENDS aerosol was "more harmful." The remaining 18% of respondents stated that they did not know whether ENDS vapor was harmful to non-users.

Years in practice (P=0.09, $\chi 2=13.81$) and knowledge of FDA regulation (P=0.59, $\chi 2=4.62$) had no significant influence on perception of ENDS harmfulness relative to combustible cigarettes. However, working in a non-community practice

setting was associated with the belief that the health risks of using ENDS were comparable to combustible cigarettes (P=0.01, $\chi 2=26.59$).

Smoking Cessation Practices

Respondents were asked whether they assessed smoking behavior, offered smoking cessation services for smokers and/or ENDS users, felt comfortable providing smoking cessation counseling, and tracked smoking behavior in patient medical records in their practices.

Most respondents did not consistently assess smoking behavior. Overall, few pharmacists reported that they always (17%, n=42) or often (20%, n=51) asked patients about their smoking status; nearly two-thirds only sometimes (35%, n=90) or never (28%, n=72) asked patients if they smoked (see Table 4). Asking patients about their smoking status was significantly correlated with practice setting (P=0.01, $\chi 2=40.8$); while 45% of inpatient pharmacists reported that they never asked about smoking status, only 18% of managed care pharmacists and 21% of community practice pharmacists reported never asking.

To assess the possibility that pharmacists relied on medical records in lieu of asking patients about their smoking status, we also asked respondents to report on whether their practice tracked tobacco use by patients. Most respondents (82%, n=209) reported that they had a computerized medical records system at their practice. When asked about the tracking of tobacco product usage, 36% reported that their clinic tracked patients who smoked combustible cigarettes, while 10% tracked patients who used ENDS. Many respondents were not aware whether their practice tracked combustible cigarette use (30%) or ENDS use (40%) (see Table 5).

With respect to smoking cessation counseling, 22% (n=56) always provided it, 16% (n=40) often did, 38% (n=96) sometimes did, and 25% (n=63) stated that they never provided smoking cessation counseling. When asked to report their confidence about providing smoking cessation counselling, only 25%

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Table 4. Smoking Cessation Practices: Tracking (Reported as Percentages)

	How often do you ask patients if they smoke?	How often do you provide counselling for patients who want to quit smoking?
Always do	17	22
Often	20	16
Sometimes	35	38
Never	28	35

Note: Data drawn from 2016 California pharmacist survey (N=255).

Table 5. Tracking of Tobacco Product Use (Reported as Percentages)

	Does your clinic currently track patients who smoke cigarettes?	Does your clinic currently track patients who use ENDS?
Yes	36	10
No	34	59
Don't know	30	40

Figure 1 Knowledge and Preceptions of ENDS

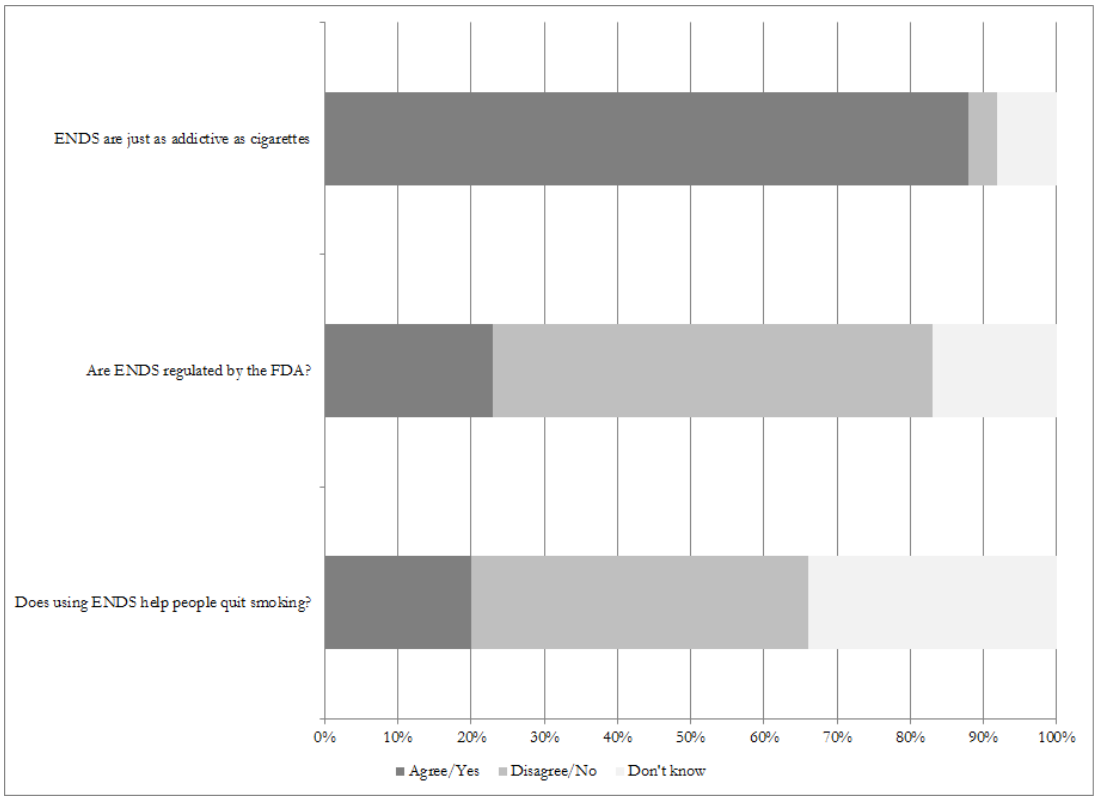
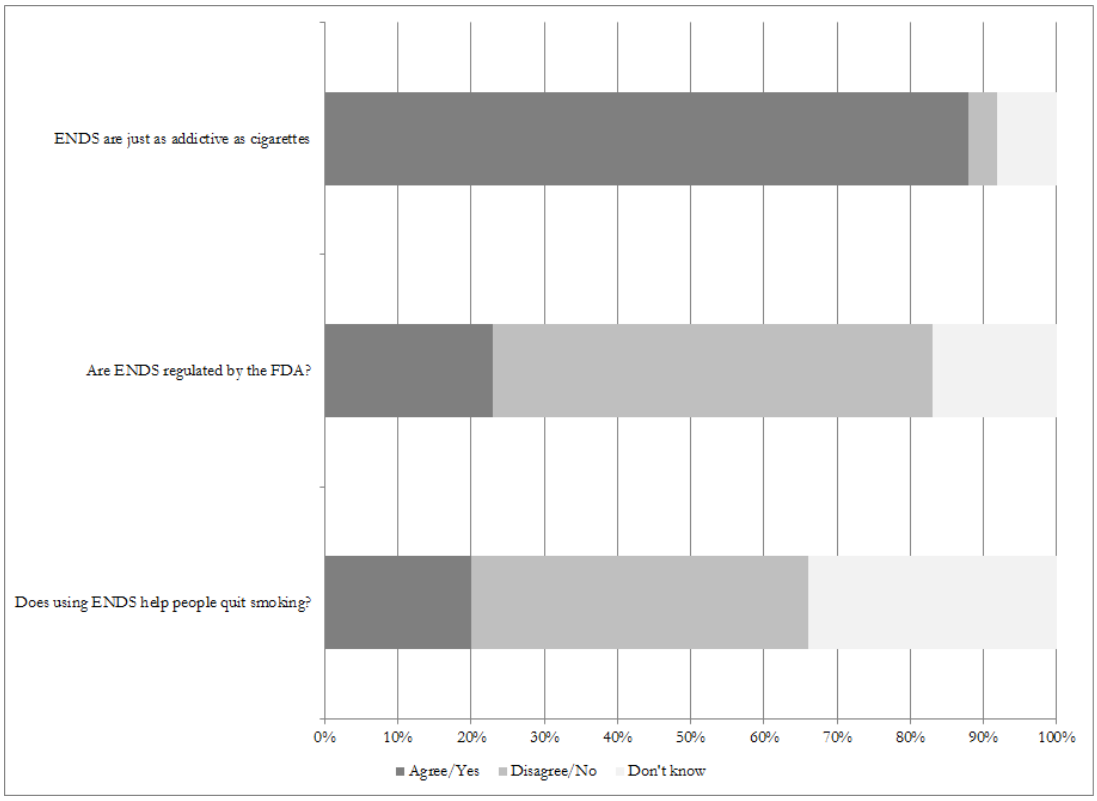


Figure 2 Perceptions of Health Risks for ENDS and Combustible Cigarettes



(n=64) reported that they were extremely comfortable counseling on smoking cessation, 49% reported they were somewhat comfortable, 20% reported they were somewhat uncomfortable, and 6% (n=15) reported that they were extremely uncomfortable. When asked about recommending ENDS for cessation, nearly half (48%) stated that they would be extremely uncomfortable making this recommendation; only 15% said that they would be extremely or somewhat comfortable making this recommendation (see Table 6).

Advice About ENDS and Smoking Cessation

Despite inconsistent findings about the value of ENDS for cessation at the time of the study, 15% (n=39) of respondents reported feeling somewhat or extremely comfortable recommending ENDS as a smoking cessation aid. However, among the 39 pharmacists that were comfortable recommending ENDS for cessation, 72% (n=28) perceived them to be just as addictive as cigarettes and nearly half (46%, n=18) believed that ENDS were equally or more harmful than combustible cigarettes.

Discussion

Results indicate that pharmacists generally had accurate knowledge about the regulatory status of ENDS, and their advice about cessation reflected national guidelines. However, although California pharmacists have been encouraged to focus on tobacco cessation, only one-third tracked combustible cigarette use by patients and only 10% tracked ENDS usage. Counselling for ENDS cessation was not reported by pharmacists in any practice setting. Although our study did not assess the perceived reasons for the failure to assess tobacco use or counsel for cessation, this could reflect system-level factors that interfere with pharmacists' ability to provide smoking cessation including time constraints due to understaffing or workflow. Further research on this question is warranted.

Pharmacists in our survey expressed little enthusiasm for the popular perception of ENDS as a reduced-harm product that could serve as a smoking cessation aid. Our results suggest that expectations about ENDS may have mirrored respondents' understanding of the health risks of combustible cigarettes. The overwhelming majority of surveyed pharmacists believed that ENDS and combustible cigarettes were equally addictive, and most believed they were equally or more harmful. The majority of respondents also believed that ENDS users exposed non-users to health risks created by secondhand aerosol; extensive evidence indicates that exposure to secondhand smoke from combustible cigarettes is a health risk.[1] Consistent with these results, few pharmacists felt comfortable recommending ENDS for patients who wanted to quit smoking.

We found no correlation between knowledge of FDA regulation and perceptions of ENDS risks. Typically the FDA seeks to protect the health of the public by reviewing the safety and effectiveness of products before they are marketed to consumers.[25] The fact that ENDS were marketed without FDA prior approval may explain why no correlation was observed between knowledge of FDA regulation of ENDS and pharmacists' beliefs about the safety of the products.

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Table 6. Smoking Cessation Practices: Comfort (Reported as Percentages)

	Comfort level on counseling patients about smoking cessation	Comfort level on recommending ENDS for patients who want to quit
Extremely comfortable	25	4
Somewhat comfortable	49	11
Somewhat uncomfortable	20	37
Extremely uncomfortable	6	48

Note: Data drawn from 2016 California pharmacist survey (N=255).

This study has limitations: survey respondents may not have accurately represented California pharmacists. The population of potential respondents involved pharmacists involved in professional organizations such as CSHP and ASHP; moreover, those who did participate may have done so because they were more informed about ENDS or more concerned about their potential health risks. However, findings revealed that knowledge about ENDS was limited and that pharmacists did not consistently encourage smoking cessation; if participants had self-selected for greater knowledge, our findings would imply that most pharmacists were even less engaged. The structure of our survey questions may have prompted pharmacists to select options that underestimated their knowledge; for instance, each institution could have different protocols about whether a technician or pharmacist should be the first point of contact in interviewing patients and inquiring about their smoking status. Even if the patient intake workflow in each institution did not have a pharmacist as the "primary" interviewer, however, it would still be their responsibility to review and assess smoking status once it was entered into the patient's electronic medical record, suggesting that low awareness of tobacco use is still a problem. Finally, given that the study was cross-sectional, it was unable to assess possible changes in pharmacists' perceptions over time.

These findings suggest that there is widespread agreement among California pharmacists about the addictiveness of ENDS, which was perceived as comparable to combustible cigarettes, reflecting the nicotine in both types of products. However, they have not yet developed consistent views about the safety of ENDS and proposals to use them as a strategy to quit combustible cigarette use. Independently, pharmacists who responded were not consistently assessing tobacco use or offering smoking cessation into their practices, despite professional and policy encouragement. Our results suggest that professional organizations may wish to provide guidance for pharmacists that would address these questions; previous work has determined that doing so can affect practice.[26] Although the pharmacists we surveyed were relatively informed about the regulatory status of ENDS, some advised patients to use ENDS for tobacco cessation, contrary to CDC recommendations. Continuing education addressing new alternative tobacco products such as ENDS might improve practice in this area. However, the effectiveness of such efforts may be limited by structural barriers, including systems that do not currently collect data on use.

Key Points

- Despite encouragement by professional associations and policymakers, assessing the smoking status of patients and providing smoking cessation counseling is not yet part of most California pharmacists' regular practice.
- California pharmacists were aware of the regulatory status of ENDS, their addictiveness, and that their use posed other health risks.
- Although most respondents were aware of the potential health risks of ENDS and that they were not recommended for cessation, some pharmacists advised ENDS use as a strategy to quit combustible cigarettes. ○

Pharmacists Perception of E-Cigarettes

Definition of E-Cigarettes

We are asking you to take part in a research study being done by the CAPSLEAD team at the University of California, San Francisco. Being in this study is optional. If you choose to be in the study, you will complete a survey. This survey will help us learn more about current pharmacists' perceptions of electronic nicotine delivery systems. The survey will take about 3-5 minutes to complete. You can stop the survey at any time. The survey is anonymous, and no one will be able to link your answers back to you. Please do not include your name or other information that could be used to identify you in the survey responses. Questions? Please contact the UCSF CAPSLEAD team at CAPSLEAD@listsrv.ucsf.edu. If you have questions or concerns about your rights as a research participant, you can call the UCSF Institutional Review Board at 415-476-1814.

If you want to participate in this study, click the Next button to start the survey.

E-cigarettes or Electronic Nicotine Delivery Systems (ENDS) can look like regular cigarettes, but are battery-powered and produce vapor instead of smoke. ENDS can be bought as one-time, disposable products, or as re-usable kits with a cartridge. Some people refill their own cartridges with nicotine fluid, sometimes called "e-juice" or "e-liquid". Disposable ENDS, ENDS cartridges, and e-liquid come in many different flavors and nicotine concentrations.

Cigarette Safety

Electronic Nicotine Delivery Systems (ENDS)

Q1 Is using ENDS less harmful, about the same, or more harmful than smoking cigarettes?

- ❍ Less harmful (1)
- ❍ About the same (2)
- ❍ More harmful (3)
- ❍ Don't know (4)

Q2 Do you agree or disagree with the following statement: ENDS are just as addictive as cigarettes?

- ❍ Agree (1)
- ❍ Disagree (2)
- ❍ Don't know (3)

Q3 Do you think the vapor from other people's ENDS is harmful to you?

- ❍ Not harmful (1)
- ❍ Less harmful than cigarettes (2)
- ❍ Equally as harmful as cigarettes (3)
- ❍ More harmful than cigarettes (4)
- ❍ Don't know (5)

Q4 Do you believe that the United States Food and Drug Administration (FDA) regulates ENDS products in the U.S.?

- ❍ Yes (1)
- ❍ No (2)
- ❍ Don't know (3)

Cessation

Q5 Electronic Nicotine Delivery Systems (ENDS)

Q6 Rate how often you do the following:

	Never (1)	Sometimes (2)	Often (3)	Always (4)
Ask patients if they smoke (1)				
Provide counseling for patients who want to quit smoking (2)				

Q7 Rate how comfortable you are with the following:

	Extremely uncomfortable (1)	Somewhat uncomfortable (2)	Somewhat comfortable (3)	Extremely comfortable (4)
Counseling patients about smoking cessation (1)				
Recommending ENDS for your patients who want to quit (2)				

Q8 Using ENDS helps people to quit smoking cigarettes

- ❍ Yes (1)
- ❍ No (2)
- ❍ Don't know (3)

Tracking E-Cigarette Usage

Electronic Nicotine Delivery Systems (ENDS)

Q9 Does your clinic currently track patients who smoke cigarettes (i.e., actively asking and recording their status)?

- ❍ Yes (1)
- ❍ No (2)
- ❍ Don't know (3)

Q10 Does your clinic currently track patients who uses ENDS (i.e., actively asking and recording their status)?

- ❍ Yes (1)
- ❍ No (2)
- ❍ Don't know (3)

Q11 Does your main practice location have a computerized medical records system (also known as an electronic health record or an electronic medical record)?

- ❍ Yes (1)
- ❍ No (2)
- ❍ Don't know (3)

Demographics

Q12 Gender:

- ❍ Male (1)
- ❍ Female (2)

Q13 Age range:

- ❍ 18-44 (1)
- ❍ 45-64 (2)
- ❍ 65+ (3)

Q14 Race:

- ❍ Caucasian (1)
- ❍ Asian (2)
- ❍ Black/African American (3)
- ❍ Hispanic/Latino (4)
- ❍ Native Hawaiian/Pacific Islander (5)
- ❍ Two or more races (6)

Q15 Main practice setting:

- ❍ Hospital Inpatient (1)
- ❍ Ambulatory Care (2)
- ❍ Managed Care (3)
- ❍ Community and Hospital Outpatient (4)
- ❍ Other (5)

Q21 California region of practice:

- ❍ Northern (1)
- ❍ Central (2)
- ❍ Southern (3)

Q17 Years of pharmacy practice:

- ❍ Less than 5 (1)
- ❍ 5-10 (2)
- ❍ More than 10 (3)

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