# Parental tobacco use

# Parental Tobacco Use:
# Dual use of e-cigarettes and cigarettes, and interventions to help them quit

**DISSERTATION**

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# CHAPTER 1

# General Introduction and Outline of the Thesis

# Introduction

According to World Health Organization (WHO),[1] tobacco use is the single greatest preventable cause of mortality, killing more than 8 million people each year. More than 7 million of those deaths are the result of direct tobacco use while around 1.2 million are the result of non-smokers being exposed to tobacco smoke.[1] Cigarettes are the most common form of tobacco products but there are many other forms of using tobacco like cigars, cigarillos, roll-your-own tobacco, bidis, kreteks, waterpipes and various smokeless tobacco products.[2] Tobacco products are made up of thousands of chemicals, including many that are known to cause cancer.[3] Nicotine is a highly addictive chemical that naturally occurs in the tobacco plant and is therefore present in all tobacco products. Some tobacco products, like cigarettes, are designed to deliver nicotine to the brain within seconds, making it easier to become dependent on nicotine and more difficult to quit these products.[3,4] Once a tobacco product is lit, many more harmful chemicals are formed in the burning process that weren't present in the growing and manufacturing stages. These chemicals are then inhaled by smokers or those exposed to secondhand smoke.[3,5] There is no safe level of exposure to any form of tobacco and all tobacco products are harmful.[4]

In the recent years, the use of electronic cigarettes (e-cigarettes) or electronic nicotine delivery systems (ENDS) has increased globally.[6] E-cigarettes are devices that operate by heating a liquid solution to a high enough temperature so that it produces an aerosol that is inhaled and exhaled.[7] With growing popularity, these devices have undergone dramatic changes in design and have been called by different names including cig-a-likes, e-hookahs, JUUL, tank systems, mods, and vapes. E-cigarettes were originally marketed as a safer alternative to traditional combustible cigarettes although they still expose users to known toxins and carcinogens. The e-cigarette liquid typically contains nicotine, propylene glycol, glycerin, flavorings, and other chemicals.[7,8] Research shows that e-cigarette aerosol is not harmless and often contains potentially harmful chemicals, including ultrafine particles that can be inhaled deep into the lungs; flavoring such diacetyl, a chemical linked to a serious lung disease; volatile organic compounds such as

benzene, which is found in car exhaust; and heavy metals, such as nickel, tin, and lead.[8] In particular, e-cigarettes exposure has been shown to impair muco-ciliary function[9] and the alterations in alveolar macrophage functions which can lead to lung inflammation and tissue damages.[10] There is some evidence to suggest that use of e-cigarettes may predispose users to cardiovascular diseases though more research is needed to study short-term and long-term effects of e-cigarettes on the cardiovascular system.[11,12]

E-cigarettes have also been marketed as cessations aids to help smokers who use combustible tobacco to quit smoking.[13–15] The U.S. Preventive Services Task Force,[16] and the latest U.S. Surgeon General's report on smoking cessation,[17] have all concluded that the current evidence is insufficient to recommend e-cigarettes for smoking cessation. Research has also shown that overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.[7] Despite inconclusive evidence to support e-cigarettes as cessation products, many smokers who are trying to quit smoking combustible tobacco products use them. [18,19] However, most of these smokers are unable to quit smoking completely, instead becoming dual users of cigarettes and e-cigarettes.[14,20]

Smoking parents are a unique and special population as their smoking exposes their children to tobacco smoke. Tobacco smoke is a well-documented toxic air contaminant that contributes to increased morbidity and mortality in children.[21] Children exposed to tobacco smoke are more likely to have respiratory infections, ear infections, and increased severity of asthma symptoms.[21] These children are also at an increased risk of initiating smoking at a later age.[22,23] With dual use of cigarettes and e-cigarettes becoming an increasingly common phenomenon, parents who use e-cigarettes and continue to smoke cigarettes may be exposing their children to the harmful chemicals present in both tobacco smoke and e-cigarette vapor.[8,24–26] Despite known harmful effects of using e-cigarettes around children, one study showed that parents who used e-cigarettes were unaware of the potential health and safety hazards associated with their use and storage.[27]

Many adult smokers who have children who are seen in the pediatric setting and pediatric health care providers are uniquely positioned to motivate parents and provide effective evidence-based cessation assistance to quit smoking. When parents quit smoking, their life expectancy is increased by over 10 years,[28] tobacco-related poor pregnancy outcomes are eliminated,[29] children have lower risk of becoming smokers,[30–34] and children are less likely to suffer the diseases caused by tobacco smoke exposure. Parents who smoke are often medically underserved and visit their child's doctor more often than their own doctor. Despite this evidence, systematic tobacco cessation interventions to help parents quit smoking are not implemented in most pediatric settings.[35] The pediatric health care delivery systems should facilitate the identification, and treatment of tobacco dependence in parents.

# Outline of the Thesis

The research purpose of this PhD is to understand the existing evidence on dual use and smoking cessation in the long-term, dual use in parents, and delivery of smoking cessation interventions to parents in the context of their child's healthcare setting. The dissertation will answer the following research questions:

- *Research Question 1: What are the factors associated with dual use of cigarettes and e-cigarettes in the parent population and what is their intention to quit compared to cigarette only smokers?*

We address this question in Chapter 2 by conducting exit interviews of parents who currently report smoking cigarettes and also, of those who report using both cigarettes and e-cigarettes after their child's doctor's visit to a primary care pediatric practice. The survey asked these parents questions about their smoking behavior including frequency of use, readiness to quit, quit attempts in the past 3 months.

The results of this analysis suggests that dual users of cigarettes and e-cigarettes may have higher rates of contemplating smoking cessation than those who smoke only cigarettes. This evidence, in the context of the widespread marketing of e-cigarettes as a smoking cessation aid, led to our research question 2:

- *Research Question 2: What is the current evidence about long-term smoking cessation between dual-users of e-cigarettes and cigarettes and cigarette only smokers?*

We answer this research question in Chapter 3 with a systematic review and meta-analysis of studies to assess the association between dual use of e-cigarettes and cigarettes and smoking cessation after at least 1 year among adult cigarette smokers.

The second and third chapter of this thesis suggested that dual users of cigarettes and e-cigarettes maybe a unique population who probably start using e-cigarettes as they are contemplating smoking cessation but in the long-term end up not quitting smoking but becoming dual users of cigarettes and e-cigarettes. These findings led to our research question 3:

- *Research Question 3: What are the rates of receipt of smoking cessation treatment among parents who are dual users of cigarettes and e-cigarettes compared to cigarettes only smokers when a smoking cessation treatment is delivered by their child's healthcare provider?*

We address this question in Chapter 4 by conducting a secondary analysis of parent survey data collected from pediatric practices in five U.S. states as part of the the CEASE trial. The data suggests that dual users who were offered the smoking cessation treatment were more likely to receive a cessation treatment than parents who smoke only cigarettes. These results led us to think of the final research question 4:

- *Research Question 4: Can a smoking cessation intervention like Clinical Effort Against Secondhand Smoke Exposure (CEASE) be implemented and sustained in pediatric practices and what are the factors that influence the implementation of a smoking cessation intervention in the pediatric setting?*

We address this question in Chapters 5 and 6. Chapter 5 outlines the results of a qualitative study with interviews with a variety of key informants i.e., clinicians and practice staff who participated in a randomized clinical trial about delivering smoking cessation treatment (CEASE) to parents in the pediatric setting. This chapter presents factors that influenced the implementation of CEASE in five pediatric intervention practices in five states that participated in a cluster randomized clinical trial of the CEASE intervention.

Chapter 6 presents the results of a 2-year cluster randomized clinical trial to test a practice-change intervention (CEASE) to routinely identify tobacco use in families and delivery of tobacco cessation treatment to smokers. This chapter assessed the implementation and sustainability of the CEASE intervention in five pediatric practices (intervention arm) and comparing the rates of tobacco dependence treatment in five usual care pediatric practices which were not trained in the CEASE intervention (control arm) at baseline and 2-years post-intervention implementation. The results from the analysis are presented in chapter 6 along with a look at the practice-level smoking prevalence over the 2-years of intervention implementation in the intervention vs. control arm.

Finally, Chapter 7 discuses and reflects on the results of the research questions and also, suggests some clinical implications, policy considerations and future directions based on the results of this thesis.

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# CHAPTER 2

# Parental Dual use of E-cigarettes and Traditional Cigarettes

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**Abstract**

**Background:** E-cigarettes are growing in popularity. Dual use of e-cigarettes and cigarettes is an increasingly common practice, but little is known about patterns of dual use in parents.

**Objectives:** To describe smoking-related behaviors among dual-users.

**Methods:** Parent exit surveys were conducted following their child's visit in five control pediatric practices in five states participating in the CEASE trial. We examined factors associated with dual use of e-cigarettes and cigarettes vs. cigarette-only smokers, assessed by self-report.

**Results:** Of 1382 smokers or recent quitters screened after their child's visit between April-October 2017, 943 (68%) completed the survey. Of these, 727 parents reported current use of cigarettes; and of those, 81 (11.1%) also reported e-cigarette use, meeting the definition of dual use. Compared to cigarette-only smokers, dual users were more likely to have a child younger than 1-year old, planned to quit in the next 6 months, and had tried to quit in the past (had a quit attempt in the past 3 months, called the quitline or used medicine to quit in the past 2 years; $P<.05$ for each).

***Conclusion***: Parents who use both e-cigarettes and cigarettes may have higher rates of contemplating smoking cessation than parents who only smoke cigarettes. These parents may be using e-cigarettes for harm reduction or as a step towards cessation. Identification of these parents may provide an opportunity to deliver effective treatment, including nicotine replacement therapies that do not expose infants and children to e-cigarette aerosol.

**Background:**

Electronic cigarettes (e-cigarettes) include a diverse group of devices that allow users to inhale an aerosol, which typically contains nicotine, flavorings, and other additives.[1] These devices are referred to as “e-cigarettes,” “e-cigs,” “cigalikes,” “e-hookahs,” “mods,” “vape pens,” “vapes,” “tank systems”, and JUUL. For this paper, the term e-cigarettes is used to represent all such products in this diverse category. E-cigarettes vary widely in design and appearance, but generally operate in a similar manner and have similar components. They heat the liquid in the cartridge to create an aerosol that users inhale.[2] The concentration of nicotine can vary across cartridges and in “e-liquids” across different brands.[2,3] A 2014 study showed that current e-cigarette users have systemic nicotine and/or cotinine concentrations similar to those seen in traditional cigarette users.[3]

E-cigarettes are easily available and growing in popularity in adults.[4–6] When used as a replacement for cigarettes, e-cigarettes may serve as a potential smoking cessation aid[7,8] and are perceived by users as a less harmful alternative to cigarette smoking.[9,10] Although e-cigarettes could help with cigarette smoking cessation,[11] there is limited evidence regarding long-term adverse effects and their long-term impact on tobacco smoking reduction or cessation.[12,13] Recommendations from the United States (U.S.) Preventive Services Task Force,[14] and an expert committee of the National Academies of Sciences, Engineering, and Medicine[9] concluded that the current evidence is insufficient to recommend e-cigarettes for tobacco cessation and as of 2019, the US Food and Drug Administration (FDA) has not approved e-cigarettes as a cessation aid.

Although data from the 2016 NHIS survey showed that current e-cigarette use declined among current smokers since 2014, it increased among former and never smokers.[15] This trend is particularly worrisome as it could indicate that e-cigarettes are renormalizing smoking behavior for former smokers[16] and becoming gateways of nicotine use for never smokers.[17] Long-term prospective data is needed to understand the patterns and trends of e-cigarette use in current, former, and never smokers.

Importantly, most adults who use e-cigarettes continue to smoke cigarettes (referred to as dual users). In 2015, National Health Interview Survey data showed that 58.8 percent of adult e-cigarette users also smoked cigarettes in the U.S.[4] and the 2016 BRFSS reported similar findings, estimating that 54.6 percent of current e-cigarette users were also current smokers.[6] A recent study showed that dual users exhibited higher concentrations of nearly all biomarkers of nicotine and toxicants compared to cigarette only smokers.[18]

Parental use of traditional cigarettes is strongly associated with later use of cigarettes by their children[19] but it is not yet known whether this association holds true for parental e-cigarette use. E-cigarette use by parents may facilitate adolescent use of nicotine products through behavioral role modeling, direct effects of increased nicotine exposure on the developing brain, and increased access to the products themselves in the home.[20,21] Additionally, the concentrated nicotine present in e-liquid can be toxic if absorbed through the skin or ingested accidentally, posing a particular risk to children.[22] Despite the increasing dual use of cigarettes and e-cigarettes in adults, and the implications for child health, there is limited data on dual use in parents.[21,23] This is the first study to explore the readiness to quit smoking and use of FDA approved tobacco treatments by parents who are dual users of cigarettes and e-cigarettes vs. cigarette-only smokers.

**Design/Methods:**

Data were collected between April-October 2017 from five practices in five states (TN, IN, VA, NC, OH) randomized to the control arm of the Clinical Effort Against Secondhand Smoke Exposure (CEASE) study.[24] This trial tested the effectiveness and sustainability of an intervention to address parental tobacco use in the pediatric office setting. It was conducted in partnership with the American Academy of Pediatrics Julius Richmond Center of Excellence. The study protocol was approved by the Institutional Review Boards (IRB's) of the AAP and Massachusetts General Hospital, and by individual practice IRBs where required.

Participant enrollment

Exit surveys were conducted with parents following their child's visit to the pediatric office. The exit screener survey gathered the following information: parent's demographic information (age, gender, race and ethnicity, and level of education); parent's current and past smoking status; the age of the youngest child present at the visit; and how the visit was paid for. Parents were eligible for inclusion in the study if they reported smoking at least 100 cigarettes in their lifetime and if they had smoked a cigarette, even a puff, in the last 7 days or had quit smoking within the past 2 years. Eligible parents were invited to complete a detailed survey. Exclusion criteria included: (1) parents under age 18; (2) parents whose child had a medical emergency; (3) non-English speakers; or (4) completion of the detailed survey during a previous visit. Eligible parents who agreed to do a detailed survey signed a consent form and received $5 for completion. Screening continued until approximately 200 eligible parents completed the detailed survey at each practice. The detailed survey asked additional questions about their tobacco use and behavior, readiness to quit, quit attempts in the past 3 months, smoke-free and e-cigarette-free home and car rules, if someone had used cigarettes or e-cigarettes in their home and car in the last 3 months, use of other tobacco products including e-cigarettes, and if the child's healthcare provider asked them about their smoking status and discussed using medications or quitline enrollment to help them quit smoking.

Parents were considered to be dual users of cigarettes and e-cigarettes if they reported smoking a cigarette, even a puff, in the past 7 days and using e-cigarettes within the past 30 days. Bivariate analyses were conducted using chi-square tests to explore the association between parent and child characteristics and dual use.

Variables that were significant ($p<0.10$) in the bivariate analysis and those that had theoretical plausibility (infant seen at the visit, gender and education of the parent, number of cigarettes smoked per day) were added step-wise to a logistic regression model. We combined the people who reported making a quit attempt in the past 3 months, or reported using NRT or calling the quitline to help them quit smoking in the past 2 years and created a variable 'tried to quit in the past'. Odds ratios (OR) and 95% Confidence Intervals (CI)

were reported for each variable from the final model. All p values are 2-sided and were considered significant at $p<0.05$. Analyses were conducted using Stata statistical software (StataCorp, 2017. Stata Statistical Software: Release 15. College Station, TX: Stata Corporation).

**Results:**

Of 1382 eligible smokers and recent quitters screened after their child's office visit between April-October 2017, 943 (68%) completed the detailed survey. Of these, 727 parents reported current use of cigarettes and of these, 81 (11.1%) also reported e-cigarette use, meeting the definition of dual use. In our sample of 216 parents who quit smoking in the past 2 years, 34 (15.7%) reported current e-cigarette use.

Of the 81 dual users, 73% were in the age group 25 to 44 years, 46% were high school graduates, 36% had some college education or had graduated college, 83% smoked everyday, and 84% and 70% intended to quit smoking in the next 6 months and 30 days, respectively. As well, 56 (69%) of dual users had made an unsuccessful quit attempt in the previous 3 months, 23 (28%) had tried FDA approved medications to help them quit smoking, and 8 (10%) had called a quitline in the previous 2 years (Table 1).

Of the 81 dual user parents, 32% and 72% reported that someone had smoked in their homes and cars respectively in the past 3 months. Of the 646 cigarette only smokers, 35% and 56% reported that someone had smoked in their home and car respectively in the past 3 months. Of the dual users, 62% and 63% reported that someone had used an e-cigarette in their home and car respectively in the past 3 months. Of the cigarette only smokers, 11% and 8% reported that someone had used an e-cigarette in their home and car respectively in the past 3 months.

Figure 1 shows that 84% of dual users planned to quit smoking in the next 6 months, compared to 67% of cigarette only smokers; and 70% of dual users planned to quit smoking in the next 30 days, compared to 61% of cigarette only smokers. Of the dual

users, 69% had already attempted to quit in the last 3 months, compared to 47% of cigarette only smokers.

Of the 81 dual users, 28 (34.5%) reported either calling the quitline or using NRT in the last 2 years to help them quit smoking, whereas out of the 646 cigarette only smokers, 157 (24.3%) reported calling the quitline or using NRT in the last 2 years to help them quit smoking ($p<0.05$). Of those parents who reported calling the quitline or using NRT in the past 2 years, 82.1% dual users and 59.9% cigarette only smokers reported making a quit attempt in the past 3 months ($p=0.02$).

Bivariate analyses (Table 1) demonstrated an association between being a dual user and intention to quit in the next 6 months, having made a quit attempt in the past 3 months, having called a quitline in the past 2 years, smoking cigarettes in the car in the past 3 months, and smoking e-cigarettes in the home and the car in the past 3 months. We did not find any association between parent's age, race and ethnicity, education, intention to quit smoking in the next 30 days, or smoking cigarettes inside the home, with parental dual use.

The final multivariable logistic regression model (Table 2), adjusting for parent gender and education, showed that dual users, compared to cigarette smokers only, had 1.7 times greater odds of having a child less than one year old (infant) at the visit, 1.99 times greater odds of having the intention to quit smoking in the next 6 months and 1.85 times greater odds of having tried to quit in the past (called the quitline or used medicine in the past 2 years to help them quit or made a quit attempt in the past 3 months) compared to cigarette only users. Parent gender, education or numbers of cigarettes smoked per day were not associated with dual use.

In our sample of cigarette smokers, we found that 114 (17.6%) cigarette only users and 21 (25.9%) dual users were asked about their smoking status; however medication to help them quit smoking was discussed with 16 (2.4%) cigarette only users and 0 (0%)

dual users. Similarly, 13 (2.0%) cigarette only users and 2 (2.5%) dual users were advised enrollment in the quitline.

***Discussion*:**

In our sample of current cigarette smoking parents, we found that almost 11% were dual users of cigarettes and e-cigarettes. Dual users are more likely to have a child less than one year old at home, have the intention to quit smoking in the next 6 months and tried to quit in the past (called the quitline or used medicine in the past 2 years to help them quit smoking or made a quit attempt in the past 3 months) relative to cigarette only users.

Having a child less than one year old was associated with dual use of cigarettes and e-cigarettes. Data shows that two-fifths of US adults believe that children's exposure to e-cigarette aerosol causes some or little harm, while one-third do not know whether it causes harm.[25] Such beliefs may also be the reason that dual users had relatively high rates of smoking e-cigarettes in their home and car.[21,23] A recent paper from the CEASE trial examined parents' strict rules about prohibiting e-cigarette and regular tobacco use in homes and cars, concluding that dual users were less likely than cigarette only smokers to report a variety of child-protective measures for the home and car.[23] The particles and toxicants released in e-cigarette aerosols although in much lower concentrations than in combusted cigarettes,[26] may still pose health risks to users and bystanders.[12,13] Another report entitled the Public Health Consequences of E-Cigarettes, an expert committee of the National Academies of Sciences, Engineering, and Medicine[9] reported that there is conclusive evidence that e-cigarette use increases airborne concentrations of particulate matter and nicotine in indoor environments compared with background levels. The report also concluded that in addition to nicotine, most e-cigarette products contain and emit numerous potentially toxic substances. Additionally, just like combusted tobacco smoke, the nicotine from e-cigarette aerosol can remain on indoor surfaces for weeks to months, causing thirdhand exposure to toxicants.[28] Nicotine exposure is particularly harmful to the developing brains of children and adolescents.[29,30] Considering recent evidence highlighting the harms of e-cigarette aerosols,[9] there is a need for clinicians to deliver appropriate education and advice to e-cigarette users and dual user parents.

Dual users in our study were more likely to have tried to quit smoking than cigarette only smokers. Almost 7 in 10 dual users had made a quit attempt in the past 3 months compared to less than 5 in 10 cigarette only smoking parents. This finding is consistent with studies that have shown that dual users are significantly more likely than exclusive cigarette smokers to have made a quit attempt.[31,32] This finding could suggest that these parents may have started using e-cigarettes as a method of harm reduction or a path to smoking cessation but since our data is cross-sectional, we cannot derive that inference. However, these data are consistent with existing evidence that current smokers report using these products to help reduce the number of cigarettes smoked or to quit smoking,[13] despite insufficient evidence to recommend e-cigarettes for tobacco cessation.[9]

Significantly higher percentages of dual users in our study reported calling the quitline or using NRT in the past 2 years to help them quit smoking compared to cigarette only smokers. These findings reinforce the opportunity for pediatric clinicians to promote the use of evidence-based treatment for nicotine dependence in the growing population of dual user parents.[33]

Parents who use both e-cigarettes and cigarettes appear to have higher rates of contemplating quitting.[34] This finding is consistent with studies that have shown that higher proportions of dual users have high intention to quit compared to cigarette smokers,[35] further suggesting that this group may be more likely to accept effective cessation assistance treatments offered by their child's pediatrician.

In our sample, the majority of e-cigarette users (70%) also smoked cigarettes and almost one in six recent quitters of combusted tobacco were vaping e-cigarettes. Even though a comparison between the harmful substances released by cigarettes and e-cigarettes suggest that e-cigarettes are likely safer than cigarettes,[36] their overall effect on population health depends on how e-cigarettes are used.[37] Recent research suggests that even though vaping may reduce or partially replace cigarette use, e-cigarette

dependence may increase over time without further reductions in smoking among those who maintain dual use.[38]

Our data shows that although some pediatric offices may have systems to prompt clinicians to screen for parental tobacco product use, few routinely deliver evidence-based tobacco control treatments to help parents quit. Pediatricians are in a unique position to help parents who use e-cigarettes and cigarettes[39,40] in the following ways:

- Screening: Pediatric clinical settings could use systems like the CEASE intervention to routinely screen all families for combusted and non-combusted tobacco use.
- Motivational messaging: Pediatric settings have an opportunity to deliver evidence-based messages to parents about the harmful effects of nicotine and other toxins in both e-cigarette aerosol and combusted tobacco smoke.
- Advising strict smoke-free and vape-free environments: Considering the recent research about harms from e-cigarette aerosol,[1,9,30] parents should be advised to protect their children from second- and third- hand tobacco smoke and e-cigarette aerosol by having strict smoke-free and e-cigarette aerosol-free homes and cars.
- Treating with medications: Pediatricians should prescribe evidence-based,[33] non-aerosolized, FDA-approved nicotine replacement therapy (NRT) in the form of patch, lozenge and gum to help parents completely replace combusted tobacco and e-cigarettes.
- Enrolling: Pediatric offices should enroll tobacco product users in free resources like tobacco quitlines, cessation support websites, and texting services like smokefreeTXT.[40]

*Limitations*

The results presented in this paper were generated from a secondary analysis of the data collected for the CEASE trial[24] and therefore the statistical tests were not specifically powered for the research questions posed in this paper. The sample size of dual users is small so the results should be interpreted cautiously. Although surveys were administered in-person and directly following the pediatric office visit, the results are based on parental

self-report and thus, are subject to recall and response bias. In addition, the results are based on cross-sectional exit-survey data and no causal inferences should be made for the observed associations. Despite these limitations, the statistically significant results add to the limited knowledge base about dual use of cigarettes and e-cigarettes in the parent population.

**Conclusion:**

In this study, 11% of parents who smoked cigarettes were dual users of cigarettes and e-cigarettes, and the majority had made a quit attempt in the past 3 months. This study suggests that parents who smoke may view e-cigarettes as a cessation tool or as a harm reduction aide despite insufficient evidence to support the efficacy or safety of e-cigarettes as a tobacco dependence treatment product. The fact that 70% of e-cigarette users were still smoking combusted cigarettes, highlights the need for providing specific messaging and evidence based tobacco dependence treatment to parents in this prevalent dual user group. Early identification of dual user parents could be helpful in identifying smokers who have recently tried quitting and may be particularly motivated to accept referral for effective treatment and prescription of safe forms of nicotine replacement therapy that do not expose infants and children to e-cigarette aerosols. Finally, this research study highlights the need for pediatric clinicians to provide a new message to parents about keeping homes and cars completely smoke-free and vape free.

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**Table 1: Characteristics of parental dual users and cigarette only users seen in pediatric practices (N=727)**

| Characteristic | Dual users N=81 n (%) | Cigarette-only users N=646 n (%) | p-value |
|---|---|---|---|
| Parent Age | | | 0.581 |
| 18-24 | 16 (20) | 99 (15) | |
| 25-44 | 59 (73) | 474 (73) | |
| ≥ 45 | 6 (7) | 73(11) | |
| Relationship to the child | | | 0.855 |
| Father | 12 (15) | 100 (15) | |
| Mother | 62 (77) | 501 (78) | |
| Other | 45 (9) | 45 (7) | |
| Race and Ethnicity | | | 0.615 |
| Hispanic | 3 (4) | 8 (1) | |
| Non-Hispanic Black or African American | 5 (6) | 67 (10) | |
| Other or > 1 race | 3 (4) | 29 (5) | |
| Non-Hispanic White | 70 (86) | 540 (84) | |
| Education | | | 0.338 |
| <High school | 14 (18) | 85 (13) | |
| High school graduate | 37 (46) | 303 (47) | |
| Some college | 24 (30) | 176 (27) | |
| College graduate | 5 (6) | 79 (12) | |
| # Cigarettes/Day | | | 0.754 |
| 1-10 cigarettes/day | 38 (47) | 315 (49) | |
| ≥11 cigarettes/day | 43 (53) | 331 (51) | |
| Plan to Quit | | | |
| Next 6 months | 65 (84) | 411 (67) | 0.002 |
| Next 30 days | 44 (70) | 233 (61) | 0.172 |
| Quit attempt in the last 3 months | | | 0.000 |
| Yes | 56 (69) | 303 (47) | |
| Daily smoker | 66 (83) | 528 (82) | 0.215 |
| Youngest Child seen Age | | | 0.437 |
| ≤1 year | 30 (37) | 199 (31) | |
| 2-4 years | 16 (20) | 114 (18) | |
| 5-9 years | 19 (23) | 155 (24) | |
| ≥10 years | 16 (20) | 178 (28) | |
| Home and Car Smoking Policy | | | |
| Someone smoked in their home in past 3 months | 26 (32) | 224 (35) | 0.625 |
| Someone smoked in their car in past 3 months | 52 (72) | 327 (56) | 0.009 |

| | | | |
|---|---|---|---|
| Someone used e-cig in their home in past 3 months | 50 (62) | 69 (11) | 0.000 |
| Someone used e-cig in their car in past 3 months | 45 (63) | 49 (8) | 0.000 |
| Assistance used the last 2 years | | | |
| NRT | 23 (28) | 142 (22) | 0.199 |
| Quitline | 8 (10) | 23 (4) | 0.008 |
| Child's insurance Coverage | | | 0.707 |
| Medicaid | 46 (57) | 385 (60) | |
| Self Pay | 2 (3) | 26 (4) | |
| Private insurance/HMO | 32 (40) | 231 (36) | |

* Note: Missing data not included. Car items limited to parents who reported they have a car.

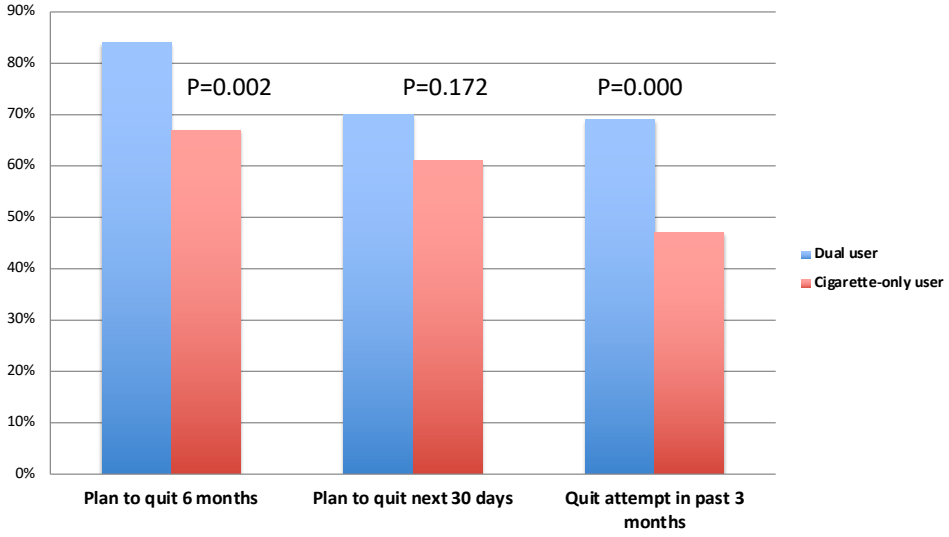
**Table 2: Characteristics associated with e-cigarette use among current cigarette smoking parents (N= 727)**

| **Characteristic** | **OR** | **95% CI** | **p-value** |
|---|---|---|---|
| Infant at home (<1 year old) | 1.68 | 1.01, 2.79 | 0.044 |
| Male | 1.01 | 0.55, 1.86 | 0.953 |
| Attended college | 0.94 | 0.57, 1.54 | 0.813 |
| Smokes >10 cigarettes per day | 1.42 | 0.85, 2.37 | 0.172 |
| Plan to quit in next 6 months | 1.99 | 1.08, 3.67 | 0.027 |
| Tried to quit* | 1.85 | 1.05, 3.25 | 0.031 |

*Parent is classified as 'tried to quit' it if they reported making a quit attempt in the past 3 months, using medication for quitting, or calling the quitline in the past 2 years for assistance

** Results from multiple logistic regression analysis

**Figure 1: Readiness to quit and use of assistance to quit among parental dual users and parental cigarette only users (N=727)**



# CHAPTER 3

# Do dual users of e-cigarettes and cigarettes quit smoking in the long-term: A systematic review

**This chapter is currently under review at Journal of Smoking Cessation journal:**

Nabi-Burza E, Jenssen BP, Willemsen M, Winickoff JP Zeegers MF. Do dual users of e-cigarettes and cigarettes quit smoking in the long-term: A systematic review. Under review at Journal of Smoking Cessation.

# CHAPTER 4

# Smoking Cessation Treatment for parents who dual use E-Cigarettes and Traditional Cigarettes

**This chapter has been published as:**

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**Abstract**

**Introduction:** An increasing number of parents use both e-cigarettes and cigarettes (dual users). Previous studies have shown that dual users may have higher rates of contemplating smoking cessation than parents who only smoke cigarettes. This study aims to assess the delivery of tobacco cessation treatment (prescription for nicotine replacement therapy and referral to the quitline) among parents who report being dual users vs. cigarette-only smokers. **Methods:** A secondary analysis of parent survey data collected between April-October 2017 at 10 pediatric primary care practices participating in a cluster-randomized controlled trial of the Clinical Effort Against Secondhand Smoke Exposure (CEASE) intervention was conducted. Parents were considered to be dual users of cigarettes and e-cigarettes if they reported smoking a cigarette, even a puff, in the past seven days and using an e-cigarette within the past 30 days. Parents were asked if they received a prescription for nicotine replacement therapy and referral to the quitline to help them quit from their child's clinician. Multivariable logistic regression examined factors (dual use, insurance status, relationship to the child, race and education status of the parent) associated with delivery of smoking cessation treatment (receiving prescriptions and/or enrollment in quitline) to smoking parents. Further, we compared the rates of tobacco cessation treatment delivery to dual users in the usual-care control practices vs. intervention practices. **Results:** Of 1007 smokers or recent quitters surveyed in the five intervention practices, 722 parents reported current use of cigarettes-only and 111 used e-cigarettes. Of these 111 parents, 82(73.9%) reported smoking cigarettes. Parents were more likely to report receiving any treatment if they were dual users vs. cigarette-only smokers (OR 2.43, 95% CI 1.38, 4.29). Child's insurance status, parents' sex, education, and race were not associated with parental receipt of tobacco cessation treatment in the model. No dual users in the usual-care control practices reported receiving treatment. **Discussion:** Dual users who visited CEASE intervention practices were more likely to receive treatment than cigarette-only smokers when treatments were discussed. An increased uptake of tobacco cessation treatments among dual users reinforces the importance of discussing treatment options with this group, while also recognizing that cigarette-only smokers may require additional intervention to increase the acceptance rate of cessation assistance.

**Background:**

Parental smoking exposes children to thousands of harmful chemicals and toxins in tobacco smoke, increasing the risk of ear infections and respiratory infections such as bronchiolitis and pneumonia in infants and young children.[1] In addition to the increased risk of infections, exposure to tobacco smoke is associated with an increased risk of learning problems and attention-deficit/hyperactivity disorder (ADHD) in children.[2] Despite the strong evidence of harm to children from exposure to tobacco smoke, almost 500 million children worldwide are exposed to secondhand smoke at home.[3] According to National Health and Nutrition Examination Survey (NHANES) data from 2013–2016, 38.1% of children aged 3–11 years were exposed to tobacco smoke in the United States (U.S.).[4]

There is no safe level of tobacco smoke exposure and the only way to prevent children from this exposure is for parents to quit smoking.[1] According to the 2008 update of the US Public Health Service Guideline for the Treatment of Tobacco Use and Dependence,[5] behavioral counseling, and cessation medications like nicotine replacement therapy (NRT) are each more effective than placebo or no treatment and even more effective when used in combination. NRT is the preferred pharmacological treatment that should be offered to parents by a pediatric healthcare provider as it is available over the counter, has an excellent safety profile and is effective in achieving abstinence.[6–8] Nicotine is the main addictive substance in tobacco but each puff of a cigarette also contains a mixture of thousands of compounds, including more than 60 well-established carcinogens.[1,9] NRT helps to increase abstinence by replacing the nicotine – in the form of gum, patches, sprays, inhalers, or lozenges – while not containing the other harmful chemicals in tobacco smoke.[8] With a written prescription from a licensed practitioner, NRT is also covered by most insurance plans in the United States, including Medicaid. The evidence also suggests that proactive quitline counseling, when provided alone or in combination with cessation medications, increases rates of smoking cessation.[10,11]

Electronic cigarettes (e-cigarettes) are increasing in popularity and their use is rapidly growing. They are perceived by some as a less toxic alternative to traditional cigarettes

or used as a smoking cessation aid.[12] The U.S. Preventive Services Task Force,[13] the latest U.S. Surgeon General's report on smoking cessation,[11] a 2016 Cochrane review on the use of electronic cigarettes for smoking cessation,[14] and the latest Public Health England report[15] have all concluded that the current evidence is insufficient to recommend e-cigarettes for smoking cessation. Despite inconclusive evidence to support e-cigarettes as cessation products, many smokers who are trying to quit smoking use them.[16,17] Many smokers who use e-cigarettes have reportedly continued to smoke cigarettes (hereafter referred as dual users).[18] Data from the 2016 Behavioral Risk Factor Surveillance System survey estimated that 54.6 percent of current e-cigarette users were also current smokers.[19]

Parents who use e-cigarettes and continue to smoke cigarettes may be exposing their children to the harmful chemicals present in of both tobacco smoke and e-cigarette vapor.[20,21] E-cigarette aerosol contains nicotine and other potentially harmful chemicals including ultrafine particles that can be inhaled deep into the lungs, volatile organic compounds, and heavy metals, such as nickel, tin, and lead.[22] Nicotine exposure is known to harm the developing brains of children and adolescents.[23,24] E-liquid for e-cigarettes usually contains a high concentration of nicotine which can be toxic if absorbed through the skin or ingested, posing a poisoning risk to children.[25,26] Despite these known harmful effects of using e-cigarettes around children, one study showed that parents who used e-cigarettes were unaware of the potential health and safety hazards associated with their use and storage.[27]

Research has shown that higher proportions of dual users have the strong intention to quit compared to cigarette smokers.[28] A 2019 paper showed that parents who use both e-cigarettes and cigarettes may have higher rates of contemplating smoking cessation than parents who only smoke cigarettes, suggesting that these parents may be using e-cigarettes for harm reduction or as a step towards cessation.[29] Since some dual users seem to have taken their first step towards smoking cessation by initiating e-cigarettes, there may be an opportunity to facilitate smoking and e-cigarette cessation using evidence-based treatments.

Child healthcare practices are ideal settings to identify parents who smoke and or use e-cigarettes and offer them evidence-based cessation treatments.[30] No previous studies have assessed the receipt of evidence-based smoking cessation treatments among this motivated group of parental dual users in the child healthcare setting. Therefore, this study aims to assess the receipt of evidence-based tobacco cessation treatments among parents who use both cigarettes and e-cigarettes compared to cigarettes only by their child's healthcare provider in the pediatric practices that delivered the Clinical Effort Against Secondhand Smoke Exposure (CEASE) intervention. Further, we compared the rates of tobacco cessation treatment delivery to dual users in the usual-care control practices vs. intervention practices.

**Methods:**

A secondary analysis of data collected from ten pediatric practices in five U.S. states (TN, IN, VA, NC, OH) randomized to the usual-care control and intervention arms of the CEASE trial was conducted between September-December 2019.[31] The CEASE intervention consists of training child healthcare providers to routinely screen for parental tobacco use and offer evidence-based assistance to parents who smoke (enrollment in the state tobacco quitline, prescribing NRT, and advising families to establish smoke-free homes and cars).[31] Parental exit interviews were conducted between April and October 2017, two years after implementation of the intervention.

Study sample

Research assistants conducted interviews with parents after their child's visit to the pediatric office between April-October 2017. Parents were eligible to enroll in the study and answer a detailed survey about their tobacco use and smoking characteristics if they reported smoking at least 100 cigarettes in their lifetime and if they had smoked a cigarette, even a puff in the last 7 days or had quit smoking within the past 2 years. Exit interviews continued until approximately 200 eligible parents completed the detailed survey at each practice, resulting in a study sample of 1,007 parents in the intervention practices and 943 in the control practices.

Measures

Parents were considered to be dual users of cigarettes and e-cigarettes if they reported smoking a cigarette, even a puff, in the past seven days and using an e-cigarette within the past 30 days. The primary outcome, as assessed by parental self-report at the exit interview, was rate of receipt of tobacco cessation treatments among dual users vs. cigarette only smokers. Parents were asked the following questions about receipt of tobacco cessation treatments as part of the detailed survey:

*During your visit today, did a doctor, nurse, or other healthcare provider:*

1. *Ask if you smoke cigarettes*
2. *Advise you to quit smoking or stay quit*
3. *Discuss medicine to help you quit smoking or stay quit*
4. *Give you a prescription for medicine to help you quit smoking or stay quit*
5. *Discuss using a telephone "quitline" or other program*
6. *Enroll you in a telephone "quitline" or other program*

Rates of parents asked about smoking, advised to quit smoking, advised about how the free tobacco control quitline could help them quit smoking, assisted with smoking cessation by discussing medications to help quit smoking and offering a prescription for NRT, and referral to the quitline were compared between dual users vs. cigarette only smokers, as well as between intervention practices and usual-care control practices. Parents were considered to have received tobacco cessation treatment if they answered ‘yes’ to receiving a prescription for medicine to help them quit and/or being enrolled in the telephone quitline. Rates of delivering tobacco cessation assistance were compared between dual users vs. cigarette only smokers and also, between intervention practices and usual-care control practices. Parents were considered to have received tobacco cessation treatment if they answered ‘yes’ to receiving a prescription for medicine to help them quit and/or being enrolled in the telephone quitline. Rates of delivering tobacco cessation assistance were compared between dual users vs. cigarette only smokers and also, between intervention practices and usual-care control practices.

Statistical analysis

Bivariate analyses were conducted using chi-square tests to explore the association

between parent and child characteristics for parents who visited an intervention arm practice who received tobacco cessation treatment vs. those who did not receive any treatment. This analysis was limited to practices randomized to the intervention arm of the trial since assistance delivery was almost negligible in the control arm. Variables that had theoretical plausibility were added step-wise to a logistic regression model. Odds ratios (OR) and 95% Confidence Intervals (CI) were reported for each variable from the final model. All p values are two-sided, and were considered significant at $p<0.05$. Analyses were conducted using Stata statistical software (StataCorp, 2017. Stata Statistical Software: Release 15. College Station, TX: Stata Corporation).

**Results**

Of the 1007 parents who completed the detailed survey after their child's visit in the intervention practices, 804 (79.8%) were current cigarette smokers (including 722 parents who reported current use of cigarettes only) and 203 (20.2 %) were recent quitters. Overall, 111 parents (28.3%) reported currently use of e-cigarettes and of these, 82 parents (73.9%) also reported using cigarettes. These 82 parents met our definition of dual use.

Of the 943 parents who completed the detailed survey after their child's visit in the control practices, 727 (77.1%) were current smokers (including 646 parents who reported current use of cigarettes only) and 216 (22.9 %) were recent quitters. Overall, 115 parents (12.2%) reported current use of e-cigarettes and of these, 81 parents (70.4%) also reported using cigarettes. These 81 parents met our definition of dual use.

In the intervention practices, of the total 804 parents who were current smokers and answered questions about discussing and receiving treatment at that day’s visit, 113 (14.1%) reported receiving tobacco cessation treatment at that day’s visit. Table 1 shows that 50% of parents who received tobacco cessation treatment were high school graduates compared to 43% who did not receive any treatment. Almost 88% of the parents who received treatment were planning to quit in the next 6 months compared to 75.4% who did not receive treatment. Similarly, almost 80% of the parents who received treatment were planning to quit in the next 30 days compared to 64% parents who did not

receive any treatment.

The overall rates of screening parents for tobacco use, discussing using NRT, discussing referral to the quitline and receipt of tobacco cessation treatments (NRT prescription and quitline referral) were higher among parents who were dual users of e-cigarettes and cigarettes compared to cigarette only smokers in the intervention arm.(Table 2). Of the 82 dual users, 50% reported that their child's healthcare provider discussed medicines to help them quit smoking, compared to 29% of cigarette only smokers. Of these parents who reported that their child's healthcare provider discussed medicines to help them quit, 49% dual users and 39% cigarette only smokers received a prescription for medicine to help them quit smoking. In addition, 33% of dual users reported that their child's healthcare provider discussed referral to a telephone quitline to help them quit smoking, compared to 19% of cigarette only smokers. Of these parents who reported that their child's healthcare provider discussed referral to a telephone quitline, 50% dual users and 38% cigarette only smokers received referral to a quitline.

The multivariable logistic regression model (Table 3) shows that parents were more likely to receive cessation treatment if they were dual users compared to cigarette only smokers (OR 2.43, 95% CI 1.38, 4.29). Child's insurance status, parents' sex, education, and race were not associated with parental receipt of tobacco cessation treatment in the model.

Table 4 shows that in the usual-care control practices, 0 dual users reported discussing a prescription for NRT with their child's clinician in control practices compared to 41 (50.0%) in the intervention practices and 2 (2.50%) dual users reported discussing enrollment in a quitline compared to 27 (33.3%) in the intervention practices. No dual users reported receiving either a NRT prescription or an enrollment in the quitline in the control arm compared to 19 (23.8%) dual users reporting receiving a NRT prescription and 15 (18.5%) dual users reporting enrollment in the tobacco quitline in the intervention practices.

***Discussion***:

Data from this study shows that dual users who visited CEASE intervention practices were more likely to receive a cessation treatment than parents who smoke only cigarettes two years after intervention implementation after controlling for child's insurance, parents' sex, education, and race. The data also shows that dual users in the usual-care control practices reported not receiving any treatment.

As displayed in Table 1, almost 51% of smoking parents who received treatment have tried quitting smoking in the past three months and failed. Smokers who made prior quit attempts typically feel more motivated to quit than those parents who have not made a quit attempt.[32] Data in Table 2 shows that dual users are more likely to have made a quit attempt in the past 3 months and more likely to be planning to quit in the next 6 months compared to cigarette only smokers. It is critical that these motivated parents get evidence-based smoking cessation treatments[33] to help them quit both smoking combustible tobacco and using e-cigarettes in order to protect their children from further tobacco smoke exposure and from exposure to potentially harmful byproducts produced by e-cigarettes.

CEASE practices were trained to ask all parents about tobacco use and to provide advise and assist every parent who smoked by discussing and providing evidence-based cessation treatment, but in this study, we found that clinicians in the intervention practices were more likely to screen dual users for tobacco use. As a result, clinicians in the intervention practices were more likely to discuss evidence-based treatment options with dual users than cigarette only smokers. It is not clear why the providers screened or discussed treatment more often with dual users than cigarette only smokers. It could be that the dual users may be more receptive to screening for tobacco use and discussing various treatments to help them quit smoking. Another reason for this may be that clinicians may perceive that e-cigarette use among cigarette smokers is motivated by a desire to quit smoking[34] and may think that these parents have already taken a step towards smoking cessation by using e-cigarettes. It has been previously reported that dual user parents may have higher rates of contemplating smoking cessation than

parents who only smoke cigarettes.[29] Another possibility is that the clinicians may perceive that dual users and their children are at a higher risk of exposure to toxicants in tobacco smoke and e-cigarette aerosols[35] and may need help to quit. Additional research is needed to better understand the variation in smoking cessation screening and assistance delivery to dual users compared to cigarette only smokers in the pediatric setting when a tobacco cessation intervention is implemented.

The rates of screening and discussing treatment options was higher in dual users compared to cigarette only smokers, but the rates of acceptability of NRT prescriptions or quitline referral was also higher in dual users compared to cigarette only smokers when any treatment was discussed with them. Of the parents with whom medicine was discussed in the intervention practices, dual users were significantly more likely to accept prescriptions for NRT compared to cigarette only smokers. Similarly, of the parents with whom quitline enrollment was discussed, dual user parents were significantly more likely to be enrolled in the quitline compared to cigarette only smokers (Table 2). This data suggests that these dual user parents might be more receptive than cigarette only smokers to cessation treatments when discussed and offered by their child's clinician. These dual user parents seem to be contemplating smoking cessation and it has been previously reported that parents who are contemplating quitting in the near future are more likely to connect with the quitline and use the service.[36] This reinforces the important role of child healthcare providers in screening families for tobacco use and connecting them with the evidence-based treatments and resources to help them quit smoking.[37]

When parental smokers quit smoking, they improve their own health,[11] eliminate most of their children's exposure to tobacco smoke,[1] and decrease the chances of their children starting smoking.[38] Despite clinical guidelines recommending that pediatric clinicians should address parental tobacco use and address children's tobacco smoke exposure,[33,39] the research showed that less than 1 percent smokers received tobacco cessation treatment and no dual users in control practices received tobacco cessation treatment (Table 4). A US national parent survey data also showed low rates of recommending and prescribing cessation therapies.[40] These data suggest that significant

opportunities exist to improve the rates of treating parents for tobacco use in the pediatric setting and reduce children's' exposure to tobacco smoke. In light of persistent tobacco use by parents and the emerging epidemic of e-cigarettes, it is critical that all parents who use tobacco be offered evidence-based tobacco cessation treatments to help them quit smoking. Interventions like CEASE[31] have proven to be effective in creating a simple, innovative, and efficient way to screen families for tobacco use and get them treatment in the form of prescriptions for nicotine patches and gum, and referral to the state's free tobacco quitline.

Limitations

The sample size of dual users is relatively small so the results should be interpreted cautiously. In addition, results are based on cross-sectional exit-survey data and no causal inferences should be made for the observed associations. Finally, self-reported data are subject to recall and response bias. However, the administration of the survey, immediately following the clinical visit, decreased the likelihood of recall bias of the tobacco control services received at the office visit.

**Public Health Implications**

Dual users may have higher rates of contemplating smoking cessation than cigarette-only smokers and are more likely than cigarette-only smokers to receive tobacco cessation assistance after having discussions about NRT and/or the tobacco quitline with clinicians. An increased uptake of tobacco cessation treatments among dual users reinforces the importance of discussing treatment options with this group, while also recognizing that cigarette-only smokers may require additional intervention to increase the acceptance rate of cessation assistance.

**Table 1. Characteristics of currently smoking parents who received treatment* to help them quit vs. who did not receive treatment, 2-years post CEASE implementation in the intervention arm (N=802)**

| Characteristic | Received treatment N=113 n (%) | Did not receive treatment N=689 n (%) | p-value |
|---|---|---|---|
| Parent Age | | | 0.544 |
| 18-24 | 15 (13.27) | 129 (18.72) | |
| 25-44 | 86 (76.11) | 490 (71.12) | |
| ≥ 45 | 12 (10.62) | 70 (10.16) | |
| Relationship to the child | | | 0.197 |
| Father | 25 (22.12) | 142 (20.61) | |
| Mother | 84 (74.34) | 489 (70.97) | |
| Other | 4 (3.54) | 58 (8.42) | |
| Hispanic | 3 (2.65) | 25 (3.63) | 0.601 |
| Race | | | 0.057** |
| Non-Hispanic Black or African American | 8 (7.08) | 27 (3.92) | |
| Other or > 1 race | 3 (2.65) | 65 (9.43) | |
| Non-Hispanic White | 103 (91.15) | 641 (93.03) | |
| Education | | | 0.030** |
| <High school | 13 (11.50) | 93 (13.50) | |
| High school graduate | 57 (50.44) | 297 (43.11) | |
| Some college | 42 (37.17) | 242 (35.12) | |
| College graduate | 1 (0.88) | 57 (8.27) | |
| # Cigarettes/Day | | | 0.257 |
| 1-10 cigarettes/day | 46 (40.71) | 320 (46.44) | |
| ≥11 cigarettes/day | 67 (59.29) | 369 (53.56) | |
| Plan to Quit | | | |
| Next 6 months | 93 (87.74) | 478 (75.39) | 0.005** |
| Next 30 days | 67 (79.76) | 271 (64.22) | 0.006** |
| Quit attempt in the last 3 months | | | |
| Yes | 57 (50.89) | 332 (48.40) | 0.624 |
| Daily smoker | 97 (85.84) | 565 (82.36) | 0.363 |
| Youngest Child seen Age | | | 0.398 |
| <1 year | 30 (26.79) | 240 (34.83) | |
| 1-4 years | 24 (21.43) | 141 (20.46) | |
| 5-9 years | 28 (25.00) | 150 (21.77) | |
| ≥10 years | 30 (26.79) | 158 (22.93) | |
| Child's insurance Coverage | | | 0.377 |
| Medicaid | 90 (80.36) | 527 (76.71) | |
| Self Pay | 4 (3.57) | 14 (2.04) | |
| Private insurance/HMO | 17 (15.18) | 143 (20.82) | |
| Dual user | 22 (19.47) | 59 (8.56) | 0.000** |
| Asked about smoking status | 104 (92.04) | 281 (40.78) | 0.000** |

* Parents were considered to have received tobacco cessation treatment if they answered 'yes' to receiving a prescription for medicine to help them quit and/or being enrolled in the telephone quitline. **p-value<0.05

**Table 2: Intention to quit and smoking cessation assistance delivery among dual user parents vs. cigarette only smokers 2-years post CEASE implementation in the intervention arm (N=804)**

| | Dual User (N=82) n (%) | Cigarette only smoker (N=722) N (%) | p-value |
|---|---|---|---|
| Parent Age | | | 0.630 |
| 18-24 | 15 (18.3) | 129 (17.9) | |
| 25-44 | 62 (75.6) | 516 (71.5) | |
| ≥ 45 | 5 (6.1) | 77 (10.67) | |
| Relationship to the child | | | 0.012 |
| Father | 26 (31.7) | 142 (19.7) | |
| Mother | 54 (65.9) | 520 (72.0) | |
| Other | 2 (2.4) | 60 (8.3) | |
| Hispanic | 2 (2.4) | 26 (3.6) | 0.586 |
| Race | | | |
| Non-Hispanic Black or African American | 2 (2.4) | 33 (4.6) | 0.370 |
| Other or > 1 race | 4 (4.9) | 21 (2.9) | 0.330 |
| Non-Hispanic White | 77 (93.9) | 669 (92.7) | 0.680 |
| Education | | | 0.538 |
| <High school | 15 (18.3) | 91 (12.6) | |
| High school graduate | 33 (40.2) | 322 (44.6) | |
| Some college | 28 (34.2) | 257 (35.6) | |
| College graduate | 6 (7.3) | 52 (7.20) | |
| # Cigarettes/Day | | | 0.139 |
| 1-10 cigarettes/day | 31 (37.8) | 335 (46.4) | |
| ≥11 cigarettes/day | 51 (62.2) | 387 (53.6) | |
| Plan to Quit | | | |
| Next 6 months | 69 (88.5) | 504 (75.9) | 0.012* |
| Next 30 days | 47 (75.8) | 293 (65.7) | 0.113 |
| Quit attempt in the last 3 months | | | |
| Yes | 57 (69.5) | 332 (46.2) | 0.000* |
| | 48 (58.54) | 339 (46.95) | 0.047* |
| Advice to quit | 43 (52.44) | 270 (37.40) | 0.008* |
| Discuss medicine to quit | 41 (50.00) | 209 (29.03) | 0.000* |
| Received Prescription | 19 (23.75) | 83 (11.53) | 0.002* |
| Prescription acceptance ratio when offered by the pediatric staff (received prescription/discuss medicine) | 19 (48.7) | 81 (38.9) | 0.254 |
| Discuss quitline | 27 (33.33) | 134 (18.61) | 0.002* |
| Referred to the quitline | 15 (18.52) | 51 (7.08) | 0.000* |
| Quitline referral ratio when offered by the pediatric staff (referred to the quitline/discuss quitline) | 13 (50.0) | 50 (37.6) | 0.237 |

- p-values<0.05

**Table 3: Multivariable logistic regression model predicting delivery of smoking cessation treatment (receiving prescriptions and/or enrollment in quitline) 2-years post CEASE implementation in the intervention arm (N=734)**

| Variable | OR (95% CI) |
|---|---|
| Dual Use of Cigarettes and e-cigarettes | |
| Yes | 2.43 (1.38,4.29) * |
| No (cigarette only smoker) | 1.0 [a] |
| Insurance Status | |
| Medicaid | 1.37 (0.92, 2.06) |
| Private insurance or self-pay | 1.0 [a] |
| Relationship to the child | |
| Mother | 1.08 (0.72, 1.62) |
| Father | 1.0 [a] |
| Race | |
| White | 0.72 (0.47, 1.11) |
| Non-White | 1.0 [a] |
| Education | |
| Less than high school | 0.69 (0.40, 1.20) |
| Completed high school or College | 1.0 [a] |
| | |

[a]Indicates reference group,
*p<0.05

**Table 4: Smoking cessation assistance delivery among dual user parents vs. cigarette only smokers 2-years post CEASE implementation in the control vs. intervention arms (N=1531)**

| Characteristic | Current cigarette only smokers | | | Dual users | | |
|---|---|---|---|---|---|---|
| | Control N= 646 N (%) | Intervention N= 722 N (%) | p-value | Control N= 81 N (%) | Intervention N= 82 N (%) | p-value |
| Discuss medicine to quit | 16 (2.5) | 209 (29.0) | < .001 | 0 (0) | 41 (50.0) | < .001 |
| Discuss enrollment in state quitline | 13 (2.0) | 134 (18.6) | < .001 | 2 (2.5) | 27 (33.3) | < .001 |
| Prescribe NRT | 2 (0.3) | 83 (11.5) | < .001 | 0 (0) | 19 (23.8) | < .001 |
| Enroll in quitline | 0 (0) | 51 (7.1) | < .001 | 0 (0) | 15 (18.5) | < .001 |

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# CHAPTER 5

# A qualitative study of factors influencing implementation of tobacco control in pediatric practices

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**Abstract**

**Introduction**

Clinical Effort Against Secondhand Smoke Exposure (CEASE) is an evidence-based intervention that prepares child health care clinicians and staff with the knowledge, skills, and resources needed to ask family members about tobacco use, provide brief counseling and medication assistance, and refer to free cessation services.

**Aim**

This study sought to identify factors that influenced the implementation of CEASE in five pediatric intervention practices in five states that participated in a cluster randomized clinical trial of the CEASE intervention.

**Methods**

Guided by questions from the Consolidated Framework for Implementation Research (CFIR) interview guide, semi-structured qualitative interviews were conducted with 11 clinicians and practice staff from five intervention practices after the practices had implemented CEASE for two years. Interviews were conducted by a trained qualitative researcher, recorded with permission, and transcribed verbatim. An interview codebook was inductively developed; two researchers used the codebook to code data. After coding, data was analyzed to identify factors, as described by the CFIR domains, that influenced the implementation of CEASE.

**Results**

The implementation of CEASE in practices was influenced by the adaptability and complexity of the intervention, the needs of patients and their families, the resources available to practices to support the implementation of CEASE, other competing priorities at the practices, the cultures of practices, and clinicians' and office staffs' knowledge and beliefs about family-centered tobacco control.

**Conclusion**

Identifying and influencing certain critical factors guided by information gathered through interviews may help improve implementation and sustainability of family-centered tobacco control interventions in the future.

**Implications**

Healthcare organizations can improve the health of families by implementing an evidence-based family-centered tobacco control program, such as CEASE. This research showed that the implementation of CEASE was shaped by a variety of factors, including the complexity and adaptability of the program, the needs of patients and their families, the resources available to support implementation, conflicting priorities, and practice staff engagement. Strengthening or modifying factors that influence implementation may result in more successful implementation of evidence-based family-centered tobacco control programs.

## INTRODUCTION

National Health and Nutrition Examination Survey (NHANES) data shows that 35.4% of children aged 3–17 years in 2013-2016 were exposed to tobacco smoke in the US,[1] despite well documented risks from tobacco smoke exposure to children's health.[2,3] Pediatric clinicians are uniquely positioned to address family tobacco use and reduce children's exposure to tobacco smoke by helping families quit smoking.[4,5] While clinical practice guidelines recommend that clinicians and staff in child healthcare settings, such as pediatric offices, screen families for tobacco use and provide guidance to reduce tobacco use and exposure,[6–8] few pediatric practices routinely ask about tobacco use and offer evidence-based cessation assistance.[9,10]

### Clinical Effort Against Secondhand Smoke Exposure (CEASE)

Research has shown that many child healthcare clinicians and staff lack the skills and confidence needed to address family tobacco use and exposure, revealing gaps in knowledge and in practice.[11] The Clinical Effort Against Secondhand Smoke Exposure (CEASE) intervention was developed to address such gaps.[11] The development of CEASE was and continues to be informed by evidence-based tobacco control guidelines,[7,12] smoking cessation strategies and tools,[13,14] and insights from tobacco control specialists, public health professionals, and clinicians.[15–17]

Through CEASE, child healthcare clinicians and staff are trained to address family smoking and family tobacco smoke exposure. The CEASE capacity building efforts are centered around two training calls (a peer-to-peer training call for practice champions and a training call for the whole office), [18] with opportunities for additional training through an online CME program in tobacco control[19] and the American Academy of Pediatrics' Maintenance of Certification online course in tobacco control.[18,20]

In line with Ask, Assist, Refer,[21] the core components of CEASE consist of screening families for tobacco using using an iPad-based pre-visit screener and assisting with cessation by providing evidence-based tobacco cessation treatment and referral to free cessation support services to those who smoke. The pre-visit screener, which is used exclusively for the intervention, is given to the adult family member accompanying the child at the visit. The adult family member, commonly a parent or legal guardian (hereafter

referred to as *parent*), completes the pre-visit screener before the parent and child are seen by the clinician; this often happens during check-in at the front desk, in the exam room, or at another pre-visit moment. The pre-visit screener identifies families exposed to tobacco smoke with this question: “Does any member of your household use any form of tobacco?”. If the parent indicates that no members of the household use tobacco, no further questions are asked. Parents who report having a household tobacco user are asked additional questions. These questions include information about their child’s name, relationship to the child, and the parent’s own tobacco use status. If the parent is a current smoker, the screener is programmed to ask them about their interest in nicotine replacement therapy (NRT) patch and gum prescriptions and referral to the free state quitline and SmokeFreeTXT program.[22] After the parent who smokes completes all questions, a member of the front desk staff gives the parent pre-printed NRT prescriptions. If the parent indicates on the screener that he or she would like to be referred to the quitline, the front desk staff are prompted to give the parent a tobacco quitline enrollment form. When available from the state’s tobacco quitline, the pre-visit screener includes information about when to expect a call from the quitline and/or how the phone number would likely appear on their caller ID.

CEASE has been shown to be effective at helping parents quit smoking.[10] The economic evaluation of the CEASE intervention showed an incremental cost-effectiveness ratio of $1132 per quit.[23] However, less is known about the factors that influence the implementation of CEASE in pediatric office settings. Understanding the factors that influence the implementation of CEASE is crucial for the scale-up, sustainability, and dissemination of evidence-based family tobacco cessation interventions in child healthcare settings.

## METHODS

As part of a hybrid effectiveness/implementation study of CEASE in five intervention pediatric practices in five states (OH, NC, TN, VA, IN) (ClinicalTrials.gov identifier: NCT018823480)[10], interviews were conducted with pediatric clinicians and staff gain insight into the factors that influenced the implementation of CEASE in study practices.

**Ethical approval and consent**

The study protocol was approved by Institutional Review Boards at the American Academy of Pediatrics, Massachusetts General Hospital, and individual practice IRBs when required. In addition, all respondents were consented before data collection and verbal permission was given to record the interview.

**Design**

Practices were recruited into the hybrid effectiveness/implementation study through the American Academy of Pediatrics. Practices were eligible if they had parent smoking prevalence >15%, average patient flow >50 families/day, >four full-time clinicians, and used an electronic health record (EHR). Eligible practices that expressed interest conducted three-day practice population surveys (PPS) to confirm parent smoking and patient flow rates.

As part of the study, intervention practices were asked to identify a pediatrician to serve as a practice champion, who would support the implementation of CEASE in their practice. Also, a member of the office staff, such as an office manager, was asked to serve as a coordinator for the CEASE study, and the implementation of CEASE in their practices. The practice champion and the coordinator at each practice were asked to participate in interviews about implementation of CEASE in their practices.

Interviews were conducted two years after the start of CEASE implementation, which is defined as two years after clinicians and staff were trained in the intervention and after practices began using the iPad-based pre-visit screener to screen families for tobacco use and exposure. The semi-structured interviews were conducted via telephone between November 2017 and January 2018 by a PhD-level researcher who was a part of the CEASE research team (BHW).

**The use of the Consolidated Framework for Implementation Research**

The Consolidated Framework for Implementation Research (CFIR) is a comprehensive, theory-informed, and adaptable implementation research framework consisting of five domains that have been shown to shape the implementation of interventions; these domains are intervention characteristics, the outer setting, the inner setting, the

characteristics of individuals, and the process of implementation.[24,25] Each of these domains consists of a variety of subdomains, which help provide further details for each of the domains. In the CEASE study, the CFIR was used to develop the interview guide and to analyze data collected through interviews.

**Interview guide**

Clinicians and staff were interviewed using questions from an interview guide, which consisted of tailored questions from the CFIR interview guide[26,27] and questions specific to the CEASE intervention. The interview guide was reviewed by the study's Steering Committee and further improved based on feedback from an external qualitative researcher who reviewed it for potential leading questions, relevance, and clarity.

**Interview process**

The phone interviews lasted between 45 to 60 minutes. In the pre-interview briefing, respondents were encouraged to be open and honest, that there were no right or wrong answers, that the focus of the interview was to learn about their experiences with implementing CEASE, and that respondents had the right to stop the interview at any time or to skip questions. The respondents were assured that the data would be anonymized.

**Data Analysis**

The interview recordings were transcribed verbatim using an external service. The transcriptions were read closely and anonymized by BHW. She then shared the cleaned transcripts with ENB. Both coders (BHW and ENB) closely read all transcripts before coding.

Once the transcripts had been cleaned and read, BHW began inductively coding five transcripts. The codes that were uncovered during this initial coding process were used to develop the codebook. The codebook included key terms (codes), definitions of the codes, inclusion and exclusion criteria for each code, and an example quote that was representative of each code. After this initial development, the codebook was shared with the second coder (ENB), who coded a sample of the transcripts and added to the codebook. The revised codebook was then reviewed by both coders; both coders then

met to discuss any questions about the codebook. After this meeting, the codebook was approved and finalized. The final codebook contained 33 codes. The final codebook was used as a guide for coding all transcripts.

The transcripts were coded independently by the two investigators. Coding was done in Word. Each code was documented onto its respective code page. The coder copied relevant quotes from the transcript into the relevant code page. If a quote met the inclusion criteria for two codes, the quote was copied into the relevant code pages for both codes. This was done for all transcripts. After all of the transcripts were coded, the coders had a series of five to six hour-long meetings in which they compared their code pages for each of the codes. During these meetings, the coders discussed any differences in coding and resolved them based on the contents of the quote, each code's definition, each code's inclusion criteria, and each code's exclusion criteria. At the end of these meetings, all coded data had been reviewed and agreed upon by both coders, resulting in a final set of coded data.

The coded data was analyzed using a thematic approach.[28] Themes and included categories were organized into a thematic framework. Major themes were mapped to the domains of the CFIR.[24,29] Table 1 presents the CFIR domains with definitions, relevant constructs with definitions and major themes from the data mapped to the domains.

## RESULTS

The interviews were conducted with 11 respondents from the five intervention practices. Of these, four respondents were MDs, one was a receptionist, five were office managers, and one was a practice nurse. In one practice, the office manager was also a clinical provider (nurse) at the practice and was the most involved in the intervention implementation, so she was the only one interviewed at that practice.

### Intervention characteristics that influence CEASE implementation

The CFIR defines intervention characteristics as "key attributes of interventions that influence the success of implementation. The core components and characteristics of CEASE included screening for tobacco use using the iPad, referring parents to the free state smoking cessation telephone support service using a fax-to-quit form, and

prescribing NRT to parents using pre-printed prescriptions. These "key attributes"[24] of CEASE shaped, in part, how practices implemented the CEASE intervention. Interview data provided insight into practice implementation and the adaptability of CEASE, as well as the complexity of CEASE.

*The adaptability of the CEASE intervention*

The adaptability (the degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs) of the CEASE intervention was a recurring theme in the interviews. During trainings and communication with the CEASE study team, practices were encouraged to tailor the adaptable periphery of CEASE[24], such as health education materials and the use of the iPad screener, to work within existing practice workflows and to meet the needs of the practice's patients and their families.

Respondents reported adapting CEASE to work within their practice's existing workflow and processes. The Practice 2 Office Manager stated that "*we looked at our processes and changed things, tweaked it a little bit… we were able to kind of overcome a lot of those things and get back to this being part of the workflow instead of this added thing*". Other practices reported changing the process of using the iPad to screen parents for tobacco use and exposure; the Practice 1 Pediatrician explained "*instead of doing [the iPad] at all visits, we did it only at well-child visits*".

Adapting CEASE included tailoring the provided parental health education materials, as well as creating additional, practice-specific health education materials to help parents quit smoking. The Practice 1 Pediatrician noted that "*we put the handouts together about how to use patches correctly, and we also put in the information for the quitline and we put information in [about] tobacco classes, free classes from (inaudible) hospital that were offered so that you get free nicotine patches. So we tried to, ourselves, do some education for our patients*".

*The complexity of the CEASE intervention*

During the interviews, many pediatricians and office staff shared that using iPads to routinely screen for parental tobacco use was a complex aspect of the CEASE intervention, as it could involve the use of a new tool (the iPad), a different or longer

check-in process for families, additional tasks for staff, and/or resistance from parents. Some of the complexity of using the iPad screener was related to how families reacted to the intervention; the Office Manager at Practice 4 mentioned that *"I think the only issue we had was people taking it over and over again that weren't interested in it".* In other cases, the complexity of the screener was related to the process of using it routinely in practice. The Pediatrician at Practice 4 noted that "*handing out the iPad at the front desk, I think, was not an easy thing to implement*".

While using the iPads may have been complex for practices, some respondents noted their pride in being able to screen most of their families for tobacco use. The Practice 3 Office Manger noted that "*some days we were really busy, and we were trying to catch them with all the iPads, and it maybe slowed down a little bit. But at the end, we were happy that we could manage to do it with every family".*

**The role of outer setting in the implementation of CEASE**

The implementation of the CEASE intervention was shaped by factors outside of the pediatric practices. The factors included the needs of patients and their families, external policies governing the care provided by practices, and external incentives for clinicians and office staff.

*The needs and resources of patients and their families*

Interview respondents noted that their communities and their patient populations were in need of an intervention to address tobacco use and children's exposure of tobacco smoke. The CEASE intervention was seen as a potential way of addressing the needs of families with regard to tobacco use and exposure. The Practice 2 Office Manager explained that "*I think (it was needed) within our population just because it's largely tobacco using. I think it was definitely needed in our area for sure*". Further, a pediatrician in Practice 3 noted that "*we have 30, 20-25 percent of patients per day (with) parents that smoke so definitely we get secondhand and thirdhand smoke, (which) we can decrease. And it's going to definitely going to help the children, their sickness, their getting repeatedly sick, those asthma patients*". The perceived need for such an intervention may

have influenced how, to what extent, and with which families practices used the CEASE intervention.

Many of the practices in the study served high need, low-income families with high rates of tobacco use; during the interviews, practice staff and clinicians reported that their practices had high number of patients insured through Medicaid, which is commonly associated with higher levels of tobacco use.[30] The Practice 5 Office Manager stated that "*at least 50 percent of our patients are Medicaid patients".* While many of the children seen at the practices were insured through Medicaid, interview respondents noted that many parents lacked health insurance for themselves. The Practice 4 Pediatrician noted that "*it was eye-opening to me to realize how many of our parents do not have insurance*". In addition to many parents having no insurance, respondents also noted that parents did not have the financial resources to pay for cessation medication out-of-pocket. The Practice 4 Office Manager explained that "*there were people that wanted to quit; they just really couldn't afford the patches or the gum, and they didn't have any insurance*".

*External Policies and Incentives*

Interview respondents noted that it could be difficult for parents to access smoking cessation medication due to financial constraints. However, at various time during the implementation of CEASE, some of the state quitlines offered free nicotine replacement therapy to those enrolled in quitline services. This free NRT served as an external incentive for the practices to enroll parents in the quitline; the Practice 2 Office Manager noted that *"sometimes they (quitline) would offer two free weeks of NRT for anyone no matter what their insurance status…. So that was a great support".* Practices were motivated and indirectly incentivized to enroll parents in the quitline by this external policy of free NRT.

**The role of the inner setting in the implementation of CEASE**

Respondents described how the structure of the practices, the context and culture of the practices, the organizational incentives for implementing CEASE, and the other programs and care provided by the practices influenced the implementation of CEASE in their practices.

*Implementation Climate: Organizational Incentives*

Organizational incentives to implement an intervention include tangible and intangible incentives, such as increased opportunities for payment and potential for advancement or professional development.[24]

During the interviews, a few respondents noted that payment (or the hope of payment) from insurance companies helped their practice implement CEASE. The Practice 4 Office Manager explained that "*it's not a large amount by any means, the ones [insurance providers] that do pay on it. But it was just that extra incentive to get $10 to $20 a visit extra because you spent some time counseling with the patient… So that was a pretty big incentive, and like I said, when we figured that out that was when the doctors, kind of, took ownership of it because of the financial incentive as well".* The additional funds served to support implementation and motivate some pediatricians to spend more time talking about smoking cessation with parents. However, many practices were not able to successfully bill insurance companies for the services that they provided, even when payment for those services was legally obligated.[31]

Not all incentives to implement CEASE were directly financial. As one respondent noted, the Maintenance of Certification (MOC) course offered through CEASE was an incentive in and of itself. While the MOC course does have a monetary value, the added value for participants was seen to be in the overlap between the CEASE training and the MOC course; as part of CEASE, pediatricians were already learning and practicing much of the content of the MOC. The Practice 4 Pediatrician stated that "*it was for MOC credit and all of us are scrambling for that MOC 4 credit because MOC 4 is the hardest to get… So that was a good incentive to get everybody".* The course served as both a resource and an incentive to implement CEASE. As MOC credits are required to maintain certification, this aspect of CEASE can be seen as an indirect "organizational incentive".[29]

*Implementation Climate: Relative Priority*

Many respondents described facing conflicting priorities and demands on their time, which impacted the implementation of CEASE. The Practice 3 Pediatrician stated "*we're doing a study on asthma. We're doing a study on digestion. We're doing a study on breastfeeding. And when you do so many things, time was a constant (problem)",* while the Practice 1 Pediatrician noted that "*we've got to do all the regulatory stuff that is being asked of us in well-visits and sick-visits. So, adding this extra CEASE component really was kind of a juggling act for us, if you can imagine that".* The *Office Manager at Practice 4 noted that,* "*Probably the biggest obstacle for us was the amount of presumed work it was to get the iPad component embedded in what we were doing because when patients come to the front desk to check in they're already confronted with a variety of things they have to fill in each time, whether it's the developmental screening, or changes in their insurance information, or whatever, or verification of those things".* Many respondents noted that sometimes they had other priority tasks to complete which were seen as a barrier to the implementation of CEASE.

*Culture*

The culture of an organization – "the norms, values, and basic assumptions"[24] – influences how an intervention is implemented. The respondents noted that the alignment of the goals of the intervention with the organizational culture affected the intervention implementation in a positive way. This was reflected in Practice 1 Office Manager's quote, *"I think we're very involved in the community and making sure that our population and community is healthy …. [I] feel like ethically, that's what we have to do";* the Practice 1 Office Manager went on to say that *"we were able to make a positive impact on not only the health of our parents, but also our children that we see. So I feel like culturally, it [CEASE] fit right in with what we do".* Interventions that align with the overarching culture of an organization tend to be more successfully implemented.[29]

**Characteristics of individuals**

During the interviews, pediatricians and office staff described how their personal beliefs and knowledge about parental tobacco use and the tobacco smoke exposure of children motivated them to implement CEASE. They also described the ways in which their knowledge and beliefs shaped the way that they worked with other staff members to implement CEASE in their practices.

*Knowledge and beliefs about family-centered tobacco control*

Many respondents described their belief that addressing parental tobacco use and the tobacco smoke exposure of children was an important responsibility of child healthcare clinicians. The Practice 1 Pediatrician stated that "*I feel very, very strongly that there are certain things that we should be doing as healthcare providers to keep certain general healthcare parameters high on the radar because if we don't tell our patients that we're concerned and think these things are important, they're not going to see that as an important thing. So, if we don't have smoking as something that we talk about, to try and educate and to let them know that we think that this is an important issue to address, just like obesity and healthy lifestyle -- if we're not actively promoting those things, then I think we're not fulfilling our mission".* The implementation of CEASE, then, helped the pediatrician and their practice to fulfil their sense of mission.

Respondents described how CEASE gave them the motivation, tools, and knowledge needed to address parental tobacco use. The Practice 5 Pediatrician stated that *"I am proud that we've actually talked -- because it did get us to discuss more of secondhand smoke for kids, and thirdhand smoke, and what that meant. I am proud that we actually did talk to parents about that… So, I think that was good because it got awareness out there, so parents actually know that we were serious".* Through CEASE, clinicians were able to share their knowledge to increase awareness of second and thirdhand smoke while also sharing their beliefs in the seriousness of parental smoking and the tobacco smoke exposure of children.

**Process of Implementing CEASE**

Through the interviews, pediatricians and office staff were asked to describe how the practice prepared for implementing CEASE, the workflows and step-by-step actions conducted by different staff members used to implement CEASE in their practices, and to share insight into how staff worked together to implement CEASE.

*Preparing for and engaging with CEASE*

Respondents described how working together, such as brainstorming as a team, was a part of their practices' implementation process. The Practice 1 Receptionist said that *"we actually had a meeting -- a staff meeting with the nursing staff, clerical staff, and the providers, and I think we were just brainstorming ways of how to make this process run smoother".*

In addition to brainstorming and planning at the beginning of the CEASE project, pediatricians and office staff described how they adapted the workflow and different staff roles over time, engaging with one another to improve the process of implementing CEASE in their practices; the Practice 4 Office Manager noted that "*In the beginning, I think, the doctors thought it would be more of a nurse-and-reception thing and it -- it wasn't going so well, so we switched up, and they took a lot more ownership in it, I guess, and that was when we saw more success*". Engaging with CEASE – "involving appropriate individuals in the implementation and use of the intervention" – was a process that evolved and adapted over time to meet the changing needs and realities of practices.[24]

*Practice champions for CEASE*

During the interviews, pediatricians and office staff noted that having a supporter of the intervention helped in motivating other staff. The Practice 3 Office Manager said that *"somebody who is motivated be behind you and tell you, 'Just keep going. We're not going to stop.'…. 'How many do we want to do today? How many … people (are) coming to us today?' So, to have that motivation is very good"* while the Practice 1 Office manager noted that *"he was up there talking about why it's important; I think it made people understand how, yes, this is something they need to do….. So I feel like those are things that helped encourage people to become more involved".*

## DISCUSSION

This qualitative study explores the factors that influenced the implementation of CEASE, an evidence-based family-centered tobacco control intervention, in five pediatric practices in the US. Interviews using questions from the Consolidated Framework for Implementation Research provided insight into the implementation of CEASE; the domains and subdomains of the CFIR provided a structure to understand the factors that may have influenced the implementation of the CEASE intervention in pediatric office settings. Through the interviews, pediatricians and staff indicated that the implementation of CEASE was shaped by:

- the adaptability and the complexity of the intervention (CFIR domain: intervention characteristics),
- the needs and resources of the patients and their families (CFIR domain: outer setting),
- incentives for implementing CEASE and practice's culture (CFIR domain: inner setting),
- knowledge and beliefs about family-centered tobacco control (CFIR domain: characteristics of individuals), and
- engaging staff with CEASE, and practice champions for CEASE (CFIR domain: process).[24,25]

*Perceived complexity of (implementing) CEASE*

As described by the CFIR, interventions (and implementing these interventions) can be understood as complex when they have both core components and an adaptable periphery - elements of the intervention and of the implementation of the intervention that can be adapted by staff at the practice to meet the practice's needs.[29,32] Interventions are also considered complex when they have a number of interacting components and involve (potentially) difficult changes to behaviors and activities by those conducting the intervention.[33] In their guidance on how to evaluate complex interventions, Moore et al noted that programs to help people quit smoking are often complex.[34] Using these conceptualizations, the CEASE intervention and its implementation can be seen as

complex. Data from the interviews revealed that having the ability and flexibility to adapt components of CEASE and its implementation was seen as an opportunity to adapt CEASE to the practice, using an iPad to routinely screen for tobacco use and exposure was often viewed as difficult and disruptive. This complexity may influence how CEASE is scaled up to non-research practices, as well as to what extent practices can engage with and sustain CEASE over time.

*Needs and resources of patients and their families*

The implementation of CEASE was shaped by factors outside of the pediatric clinicians and office staff. The overall effect of factors in the outer setting is similar to what Pettigrew et al[35] called the "receptive context for organizational change", which emphasizes identifying the external factors that that influence intervention implementation and the importance of interventions to adapt to these factors. Implementation can be positively influenced by the degree to which an intervention meets the perceived needs of patients and their families.[36] Studies have also shown that smokers with lower incomes are less likely to use evidence-based smoking cessation treatments like pharmacotherapy than smokers with higher incomes.[37,38] Although Medicaid covers NRT patch and gum,[31] many insurance companies do not cover it, and many parents do not have any insurance. While CEASE has been designed to use existing evidence-based counseling programs and covered medications to help parents quit smoking, this relies on the programs and medications being easily and feasibly available to parents. Without enforcement of required medication coverage at the insurance company level and availability of free tobacco quitline and texting programs, it may be difficult for parents to access the treatments prescribed by pediatricians as part of the CEASE intervention.

*Incentives for implementing CEASE and the practice's culture*

The inner setting of practices also played a key role in the implementation of CEASE. Financial incentives, such as receiving payments from insurance companies for the time spent in addressing the tobacco smoke exposure of children, was seen as an incentive by some respondents. Other non-financial incentives included the opportunity to earn MOC credits required to maintain certification and a CME-awarding course on tobacco

control. These findings are consistent with literature that suggests that incentives, including financial incentives and performance evaluations, positively influenced intervention implementation.[39]

*Knowledge and beliefs about family-centered tobacco control*

The respondents' knowledge of CEASE and beliefs about tobacco use influenced its implementation. These beliefs are important to understand at the individual and practice level to assess quality of implementation and prospects for sustainability.[40] Adequate knowledge of the intervention affects the adoption of the intervention and often, opinions based on personal beliefs and experiences are convincing and help to generate enthusiasm about the intervention.[41]

*Engaging staff with CEASE and practice champions for CEASE*

The interview data showed that having individuals who are internally motivated to support implementation influenced how the intervention was implemented in their practices as they served as a driver of motivation. Engaging staff in a meaningful problem-solving manner is a critical element to transform patient care.[42] Data also showed that engaging staff and reflecting on the reasons for doing the intervention was key to implementation. Dedicating time for reflecting or debriefing during, and after implementation was one way to promote shared learning and motivation along the way.[43]

Table 2 presents the main challenges faced that were learned from this qualitative study and the implications and improvements for dissemination and sustainability of the intervention.

*Limitations*

The small sample size may limit generalizability of results, though the themes identified were consistent across five practices and enhance the likelihood that the findings are not unique to a specific pediatric practice.[44] Results are limited to respondents who agreed to take part in interviews, which could have resulted in selection bias. Respondents other than those interviewed may have had different responses than those reported here and

may not be representative of other pediatric clinics. However, we aimed to interview both clinical and administrative staff from each practice to get the overall picture of intervention implementation. Since the interviews were conducted with respondents from five pediatric practices in five states across the US, the diversity of the sample gives us greater confidence that the findings of this study may be applicable and potentially transferable to other US pediatric clinics.[44]

**Conclusion**

This study examined the implementation of an evidence-based tobacco control intervention, CEASE in pediatric outpatient settings. We identified certain factors that may help improve implementation and sustainability of tobacco control interventions in the future. Findings from this paper emphasize the importance of intervention characteristics (more adaptable, less complex), inner setting (incentives for implementing CEASE and practice's culture), outer setting (addressing the needs and resources of patients and their families), characteristics of individuals (knowledge and beliefs about the intervention) and the process of implementing an intervention (engaging all staff roles with CEASE, and having practice champions for CEASE). By attending to these factors, future tobacco control interventions will have the best possible chance of sustainable integration into routine care delivery and enhanced likelihood of effective dissemination.

| **Table 1: Major study themes mapped to the CFIR domains**[24,25] | | |
|---|---|---|
| **CFIR Domains and definition** | **Constructs and definition** | **Themes** |
| **Intervention Characteristics** *(Key attributes of an intervention that may impact implementation success)* | • **Complexity of CEASE** *(Perceived difficulty of the intervention, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement)*<br><br>• **Adaptability of CEASE** *(The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs)* | • Screening all families at every visit for tobacco use with an iPad<br>• Ability to adapt or make changes to CEASE |
| **Outer Setting** *(Includes the features of the external context or environment that might influence implementation)* | • **Patient and family needs and resources** *(The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization)* | *Patients and their families:*<br>• Need for tobacco control<br>• Patient population characteristics<br>• Parents barriers to CEASE<br>• Parents response to CEASE<br><br>*External cessation support*<br>• Access and coverage for NRT<br>• Free help and resources from the quitline |
| **Inner Setting** *(Includes features of the implementing organization that might influence implementation)* | • **Implementation Climate**<br>• **Organizational Incentives** (*Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect*)<br>• **Relative Priorities** (*Individuals' shared perception of the importance of the implementation within the organization*)<br>• **Culture** *(Norms, values, and basic assumptions of a given organization)* | *CEASE implementation in the office*<br>• Extent to which the practice was able to bill for these services<br>• CEASE vs other priorities<br>• MOC Credits as an incentive<br><br>*Organizational culture*<br>• Culture of the practice |
| **Characteristics of Individuals** (*Characteristics of individuals* | • **Knowledge and Beliefs about the Intervention** | *CEASE and staff* |

| | | |
|---|---|---|
| *involved in implementation that might influence implementation*) | (*Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention*) | • Second and thirdhand smoke beliefs and knowledge<br>• Beliefs and motivation of the staff to address tobacco use in families<br>• Feeling proud for helping smoking family members quit |
| **<u>Process</u>**<br>(Includes strategies or tactics that might influence implementation) | • **Engaging**<br>(*Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities*)<br><br>• **CEASE champions**<br>(*Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]" [101] (p. 182), overcoming indifference or resistance that the intervention may provoke in an organization*) | • Engaging staff with CEASE<br>• CEASE champions as drivers or motivators for other staff members |

| **Table 2: Challenges and implications for sustainability and disseminability of the intervention** | |
|---|---|
| **Challenges faced** | **Implications and Improvements** |
| The pre-visit screener identifies parents who smoke and offers them treatment but does not sign them up. | The pre-visit screener could go a step further and automatically connect parents who smoke with resources to help them quit smoking to further reduce any burden on practice staff. |
| The pre-visit screener was not integrated with other screeners and paper work leaving the front desk juggling multiple pre-visit tasks in different platforms at check-in. | Integrate the pre-visit tobacco use screener with other pre-visit surveys in a single platform that would all populate the appropriate sections of the child's medical record. |
| The pre-visit screener was offered too frequently | The pre-visit screener should screen all families once a year for tobacco use, following up with only those families that have a smoker at scheduled time intervals. |
| Billing for services is a good financial incentive for the clinicians and practices but did not happen routinely. | Billing for tobacco use counselling should be easy and automated in the child's medical record. |

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# CHAPTER 6

# Treating Parents for Tobacco Use in the Pediatric Setting: The CEASE Cluster Randomized Control Trial

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## Key Points

**Question:** Can the CEASE intervention help parents quit smoking in the context of pediatric practices?

**Findings:** In this RCT, after initial intervention implementation, 44% of parents received cessation assistance in intervention practices compared to <1% in control practices. Over the two year study period, intervention practices had a 2.7% decrease in parent smoking rate compared to a 1.1% increase in control practices.

**Meaning:** In this trial, implementing a program to treat parents for tobacco use within pediatric offices was associated with markedly higher rates of tobacco treatment delivery and a decline in practice-level parent smoking rate compared to usual-care controls.

## Abstract

**Importance:** Despite availability of free and effective treatment, few pediatric practices identify and treat parental tobacco use.

**Objective:** To determine if the CEASE intervention can be implemented and sustained in pediatric practices and test whether implementing CEASE led to changes in practice-level parent smoking prevalence over two-years.

**Design:** Cluster RCT, conducted from April 2015 to October 2017.

**Setting:** Ten pediatric practices in five states were randomized to either CEASE or usual-care control.

**Participants:** All parents who screened positive for tobacco use by exit survey after their child's clinical visit two-weeks (April-October 2015) and two-years post-intervention implementation (April-October 2017).

**Intervention:** CEASE is a practice change intervention designed to facilitate, in pediatric settings, both routine screening of families for tobacco use and delivery of tobacco cessation treatment to household tobacco users.

**Main outcomes and measures:** The primary outcome was delivery of meaningful tobacco treatment, defined as prescription of nicotine replacement therapy or quitline enrollment. Further, we assessed change in practice-level smoking prevalence and cotinine-confirmed quit-rates over two-years of intervention implementation.

**Results:** Of 8,184 parents screened after their child's visit two-weeks post-intervention implementation, 961(27.1%) and 1,103(23.9%) were identified as current smokers in intervention and control practices, respectively. Among 822 and 701 eligible smoker parents completing the survey in intervention and control practices, 44.3% vs. 0.1% received meaningful treatment at that visit, respectively (risk-difference 44.0%, 95%CI [9.8%, 84.8%]). Two years later, of 9,794 parents screened, 1,261(24.4%) and 1,149(25.0%) were identified as current smokers in intervention and control practices, respectively. Among 804 and 727 eligible smoker parents completing the survey in intervention and control practices, 14.1% vs. 0.3% received meaningful treatment at that visit, respectively (risk-difference 12.8%, 95%CI [3.3, 37.8]). Change in smoking prevalence over the two-years of intervention implementation favored the intervention (-2.7% vs. +1.1%, difference -3.7%, 95%CI [-6.3%, -1.2%]), as did the cotinine-confirmed quit-rate (+2.4% vs. -3.2%, difference 5.5%, 95%CI [1.4%, 9.6%]).

**Conclusions and Relevance:** In this trial, integrating screening and treatment for parental tobacco use in pediatric practices showed both immediate and long-term increases in treatment delivery, a decline in practice-level parental smoking prevalence, and an increase in cotinine-confirmed cessation of parents compared to usual care.

## Introduction

Tobacco use and involuntary smoke exposure cause an estimated 480,000 premature deaths annually.[1,2] Pediatric office visits represent an opportunity to deliver tobacco cessation assistance to parents.[3] The 2015 American Academy of Pediatrics (AAP) tobacco policy recommends that healthcare systems facilitate identification of children exposed to tobacco and treat parental tobacco dependence.[1] In addition to improving parents' health, parental cessation improves children's health,[2,4,5] reduces teens' smoking initiation,[6–10] and ensures future smokefree pregnancies.[11]

Clinician counseling, telephone quitlines, and nicotine replacement therapy (NRT) improve the likelihood of quitting.[12] Combining treatments is more effective than individual interventions alone.[13] Despite this evidence and recommendations, systematic parental tobacco cessation treatments are not delivered in most pediatric settings. A 2013 study found that only 3.5% of smoking parents received meaningful treatment (discussing quit-strategies, prescription for pharmacotherapy, or quitline referral) in pediatric practices.[14]

CEASE (Clinical Effort Against Secondhand Smoke Exposure) is a practice-change intervention aimed at routinely screening families for tobacco use and delivering cessation assistance in pediatric offices.[3,14–17] Early versions of CEASE were paper-based; barriers to implementation and sustainability included lack of systems-level integration of the intervention into routine care, visit-time limitations, inability to efficiently identify parents requiring cessation assistance, and lack of easy methods for referral to cessation resources.[15] For this study, a tablet was used in pediatric offices to screen families for tobacco use with the goal of increasing the proportion of families screened and offered assistance.

The study tested the effectiveness and sustainability of the enhanced CEASE intervention versus usual-care for smoking cessation assistance to parental smokers in pediatric practices and assessed the change in practice-level smoking prevalence and cotinine-confirmed quit-rates between groups over two years.

**Methods:**

**Practice Enrollment and Randomization**

Practices were recruited through AAP. To enhance generalizability, we recruited and enrolled a control, intervention, and replacement practice in each of five states, as well as a replacement state with a control, intervention, and replacement practice. The initial criteria to help ensure that an adequate number of smoking parents would be enrolled in each practice were: parent smoking prevalence ≥15%, average patient flow ≥50 families/day, ≥four full-time clinicians, and used an electronic health record (EHR). Due to slow recruitment, the criteria of ≥four FTE was removed to adhere to study timeline and two practices with three FTE clinicians were recruited to assess for eligibility. Practices that expressed interest conducted three-day practice population surveys (PPS) to confirm eligibility for randomization. Practices were eligible if they saw a minimum of nine smoking families (proxy for parent smoking rate) and a minimum of 40 families per day (proxy for practice flow rate). Figure 1 outlines the study design. Eighteen pediatric practices were eligible from six states and were randomized to the CEASE intervention, usual-care control, or replacement group using a random number generator. The practices were not blinded to group assignment. The final five study states were North Carolina, Tennessee, Virginia, Ohio, and Indiana. Prior to intervention implementation, the intervention practice in NC withdrew due to staff turnover and was replaced by the NC replacement practice. The control practice in VA was replaced by the VA replacement practice after administrative delays in starting data collection. The study protocol was approved by the Institutional Review Boards at the AAP, Massachusetts General Hospital, and individual practice IRBs when required.

**Parent Eligibility**

Research assistants (RAs) at intervention and control practices attempted to screen all parents after their child's visit using the screener survey, starting two weeks after the intervention implementation and again two-years later. Parents were eligible for a detailed survey if they indicated that they were the child's parent/legal guardian ("parents"), and reported having smoked a cigarette, even a puff, in the past seven days (current smoker) or having quit smoking in the past two years (former smoker).

Exclusion criteria included: (1) parent age <18; (2) parents whose child had a medical emergency; (3) non-English speakers; or (4) prior completion of the detailed survey. Eligible parents who agreed to do the detailed survey provided consent and received $5 upon completion. Parents who reported not smoking in the last seven days were asked to provide a saliva sample to confirm quit-status and received an additional $20. At two-weeks and two-years post-intervention, RAs screened parents until approximately 200 eligible parents per practice completed the detailed survey. Due to slow recruitment in the NC control practice, an additional pediatric office affiliated with the practice was included. Recruitment at these two practices was stopped at 137 surveys total to adhere to the study timeline. The same procedures were used for the two-years post-intervention measurements.

**Intervention**

CEASE is integrated into existing systems of care to routinely address parental smoking and smoke exposure of all family members using the Ask, Assist, Refer (AAR) approach.[18] The majority of clinical and support staff training was conducted via phone, online learning courses, a training video, and a training manual (provided for reference).[18] On-going training of new staff, assistance and materials were tailored to individual practices.

Staff distributed the tablet-based household tobacco use screener to parents at each visit during check-in or before they saw the healthcare provider. Screener information was managed using REDCap data-capture tools hosted at Partners HealthCare.[19] The CEASE study team monitored parent screening by the practice for two years. Electronic screening allowed for real-time monitoring; the team alerted practices when screening numbers dropped below their average numbers-per-day determined by the PPS flow rate, prompting a discussion of strategies to increase screening rates. Office staff handed a CEASE Action Sheet to families that reported having a smoker, even when the smoker was not at the visit. This sheet included prescriptions for NRT, information about a free cessation support text-messaging service (SmokefreeTXT),[20] and reminders for the clinician to recommend quitline enrollment. Parents interested in the

quitline had their enrollment forms faxed to their free state quitline by practice staff; a quitline coach subsequently made proactive attempts to contact the parent.

Participating clinicians were trained to help interested smokers set a quit date, set smokefree home and car rules, and encourage NRT use. A member of the CEASE team contacted pharmacies near the intervention practices to inform them about the program and update them on NRT coverage changes from the Affordable Care Act.[21] The electronically-collected tobacco use screening information was used to create a registry of children exposed to tobacco smoke, with monthly reports sent to each clinician to enhance documentation of parental smoking, confirm that requests for assistance were fulfilled, and foster follow-up with smokers.

**Measures/Outcomes and Data Analysis**

Cross-sectional exit survey data were collected two-weeks (April-October 2015) and two-years (April-October 2017) post-intervention implementation. Exit interview data was chosen over medical chart review as it has been shown to be more accurate than chart review [22,23] and almost as accurate as direct observation of clinician behavior.[24,25] Parents reported their child's age, reason for visit and demographics, and their own tobacco use, intention to quit, home/car smoking rules, and whether the child's healthcare provider delivered cessation assistance at that visit.

We assessed meaningful tobacco treatment delivery, defined as parents responding "yes" to one or both of the following exit survey questions used in our prior studies:[14,26,27]

*During your visit today, did a doctor, nurse, or other healthcare provider:*

1. *Give you a prescription for medicine to help you quit smoking (e.g., nicotine replacement gum, patch, lozenge, or other medicine)?*
2. *Enroll you in a telephone quitline or other program to help you quit smoking?*

To assess implementation and sustainability of the intervention, we examined meaningful tobacco treatment delivered at two-weeks and at two-years post-intervention

implementation. Only parents who were current smokers are included in this analysis. We compared rates of treatment delivery using multivariable logistic regression with generalized estimating equations (GEE) to account for physician clustering within practices. We included parent and child characteristics that showed imbalance (defined as $p<0.1$) from the bivariate analyses in the models.

To assess the intervention's effect on tobacco use, we compared change in current smoking prevalence from two-weeks to two-years post-intervention implementation, as assessed by the exit-survey screener. Parents were considered current smokers if they answered 'yes' to the following question:

*"Have you smoked a cigarette, even a puff, in the past 7 days?"*

To assess cotinine-confirmed quit-rate and validate comparability of self-reported smoking status between the groups, we tested salivary cotinine in parents who reported quitting in the past two years. Parents were considered to be quit if they reported smoking at least 100 cigarettes in their life, smoking a cigarette, even a puff, in the past 2 years but not in the past 7 days. Parents were considered cotinine-confirmed quit if their cotinine level was $\leq$10ng/mL or if they reported using NRT in the past seven days. Parents with missing cotinine data were considered current smokers.

Since we expected a much smaller effect from the cotinine-confirmed quit rate outcome than from the primary outcome of cessation assistance delivery, our sample size calculation was conducted based on the quit rate difference at two-years post implementation. We assumed alpha=0.05, 80% power, 2-tailed test of significance, and 10 total practices (5 intervention, 5 control) completing the full study protocol and recruiting the necessary parent subjects. We assumed a cotinine confirmed quit rate of 7.5% in the control group and 12.5% in the intervention group, which requires a total sample size of 1190. With the assumptions of an intra-class correlation of 0.017 (based on the mean value from a previous study[28]) and a total of 60 providers, we estimated we need a total of 1844 participants to take into account of the clustering effect.

After observing a non-neglectable group difference in smoking prevalence at the first time period, we used difference-in-differences analyses for both cotinine-confirmed quit-rate and self-reported smoking status by testing the group and time interaction in logistic regression models adjusting for state, parent (age, gender, race) and child (age and insurance) characteristics. For the cotinine-confirmed quit-rate, we also conducted sensitivity analysis accounting for provider clustering. Analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC).

**Results**

Research assistants screened 8,184 parents exiting pediatric practices two-weeks post-intervention implementation. Of these, 961 (27.1%) were current smokers in intervention practices and 1,103 (23.9%) were current smokers in control practices. Among eligible current smokers, 822 (89.0%) in intervention practices and 701 (67.0%) in control practices agreed to participate in the detailed survey. Two-years later, 9,794 parents were screened when exiting the pediatric practices. Of these, 1,261 (24.4%) were current smokers in intervention practices and 1,149 (25.0%) were current smokers in control practices. Among current smokers, 804 (68.4%) in intervention practices and 727 (68.0%) in control practices agreed to the detailed survey (Figure 1).

Table 1 presents characteristics of current-smoking parents who completed the survey at two-weeks and two-years post-intervention implementation. Overall 69.1% of parents were 25-44 years old at two-weeks post-intervention implementation; 72.6% were 25-44 years old at two-years post-intervention implementation period. The intervention group had more non-Hispanic white parents and more children on Medicaid than the control group at both time-periods. Overall 45.0% and 40.3% currently smoking parents plan to quit in the next 30 days at two-weeks and at two years respectively.

For the primary outcome of meaningful treatment delivery, 44.3% of current smokers in the intervention group vs. 0.1% in the control group ($P$ <0.001) reported receiving a prescription for NRT or being enrolled in the quitline at two-weeks post-intervention implementation and 14.1% vs. 0.3% ($P$ <0.001) at the two-years post-intervention

implementation period (Table 2). These differences remained statistically significant after adjusting for differences in parent characteristics. A larger proportion of smoking parents in the intervention vs. control group reported discussing any cessation assistance (NRT/quitline) at two-weeks (59.0% vs. 1.1%) and two-years post-intervention implementation period (32.0% vs. 3.3%). Among the 485 currently smoking parents who were provided any assistance at two-weeks post-intervention implementation period in the intervention group, 364 (75.1%) accepted treatment (got prescription/quitline enrollment) when it was discussed in the intervention practices, and 113 out of 257 (43.9%) parents accepted treatment at the two-years post-intervention implementation period.

Table 3 shows a 2.7% reduction in intervention practice population-level smoking prevalence over the course of two years compared to a 1.1% increase in usual-care control practices (absolute rate difference -3.7%, 95%CI [-6.3%, -1.2%]). The number needed to treat to reduce one smoker is 27. Table 3 also demonstrates the 2.4% increase in cotinine-confirmed quit-rate in intervention practices vs. 3.2% decrease in usual-care control practices seen at 2 years post-intervention implementation (absolute rate difference 5.5%, 95%CI [1.4%, 9.6%]). Sensitivity analysis showed that group and time interaction remained statistically significant (P=0.037) for changes in cotinine-confirmed cessation. The number needed to treat to produce one confirmed quit is 18.

**Discussion**

In this cluster RCT in pediatric practices in five states, implementation of the tablet-based CEASE intervention facilitated far higher rates of meaningful parental tobacco treatment than usual-care both two-weeks and two-years post-intervention implementation. Two years after implementation, a significant decrease in practice-level smoking prevalence and a significant increase in cotinine-confirmed quit-rates was seen in intervention vs. control practices.

A large proportion of parents in our study planned to quit in the next 30 days; this is considered the preparation stage for quitting smoking.[29] This number is much higher

than seen in the general population,[30] suggesting that the pediatric visit is a teachable moment for cessation.[31] A large number of parents accepted assistance when it was discussed at two-weeks and at the two-years post-intervention implementation period. This data supports results from other studies[32,33] which show that parents who smoke are willing to accept cessation assistance when it is offered by their child's healthcare provider.

Sustained rates of routinely screening families for household tobacco use, and subsequent delivery of meaningful treatment to parents who smoke [34] in intervention practices demonstrates a true systems-level implementation of the intervention. We observed a decrease in the proportion of parents reporting receiving meaningful treatment at two-years post-intervention implementation, though clinicians in the intervention group were still providing significantly higher rates of meaningful treatment compared to usual-care control clinicians. The drop in meaningful treatment delivered in the intervention group after two-years of implementation demonstrates that there are some challenges to sustaining meaningful treatment delivery. Although the intervention was designed to minimize burden on office flow, it did increase workload for administrative staff. In addition, data captured by the CEASE household tobacco use form were not automatically integrated into the child's EHR, possibly reducing effectiveness and sustainability. Despite ACA-mandated insurance coverage for NRT and communication with local pharmacies, some parents were unable to obtain NRT for free or for the cost of co-pay. Additionally, some insurance providers required pre-authorization, decreasing clinician enthusiasm for providing NRT prescriptions. Addressing these challenges could increase the intervention's sustainability. Some intervention improvement opportunities include better integration of household tobacco screening and assistance into pediatric EHRs, improving insurance coverage of NRT and for providers' time spent on parental tobacco control, and making delivery of parental cessation assistance a component of clinicians' credentialing/evaluation process.[35]

Compared to the low percentage of parents who used NRT in the past two years pre-CEASE implementation (22.9%), a higher percentage (39.6%) of parents received an NRT prescription at two-weeks post-intervention implementation visits in intervention practices. A similar finding was observed for enrollment in the quitline (6.9% enrolled in the past two years vs. 30.1% enrolled at the two-week visit just after CEASE implementation). These results suggest an unmet demand for tobacco cessation assistance among parents; CEASE increased delivery of assistance to parents who may not have otherwise received it. A significant number of parents (31%) in the intervention group who reported quitting and using NRT in the past two years to help them quit reported that they got the NRT prescription from their child's doctor compared to 0% in the control group. This data suggests that the higher quit rate in the intervention practices maybe due to the tobacco dependence treatment received in the pediatric practice.

Several components of the tablet-based CEASE intervention may have contributed to its improved performance compared to previous paper versions of the CEASE program.[36] Non-smoking families were identified with the first question, which prompted the survey to end with a single screening question making the screening process more efficient. This CEASE intervention was successful at facilitating proactive referrals to state quitlines. The tablets displayed relevant and time-sensitive quitline promotions for free cessation resources, such as NRT. The automated process of prompting staff to distribute quitline enrollment forms to all smoking parents who indicated interest ensured they had the opportunity to enroll in the quitline immediately.

The study showed an overall moderate decrease in practice-level smoking prevalence in intervention practices compared to control practices. Study practices were chosen in states, which had, a higher smoking rate compared to the national US smoking rate. Even though the adult cigarette smoking rate in the US decreased from 15.5% to 14% from 2015 to 2017,[37,38] only one of the five states (NC) where the study was conducted showed a decrease in adult smoking rate. The smoking rate in the other states either stayed the same or increased, consistent with our control practice parent smoking

prevalence in these states. The parent smoking prevalence in the intervention practices showed consistent reduction in four states, indicating the potential of pediatric healthcare setting interventions to reduce smoking prevalence in some of the most challenging tobacco control environments. The parent smoking prevalence for the intervention practice in one state (VA) increased by 2.3%, which was less than the increase in the control practice (3.7%) in the same state. Overall, decreasing family-level smoking prevalence could yield major health benefits to the U.S. population if the intervention were implemented nationally.

The significant increase in parents' cotinine-confirmed cessation over the two-years study period in the intervention practices compared to usual-care control practices demonstrates that improved cessation can be achieved if pediatric offices screen parents for tobacco use and routinely offer tobacco dependence treatment.

The study had several limitations. Volunteer practices who enrolled in the study may have been more motivated than general pediatric practices to participate in the CEASE intervention. The RA's were not blinded to the practice's study arm assignment, but they were trained to use the same standard protocol and language to approach all parents exiting practices to ensure validity of the collected data. We do not have data on the total visits during the data collection period but the RA's attempted a complete sequential capture of every parent who exited the pediatric practice with their child after the visit. The use of a difference in differences analysis allows each clinic to serve as its own control for demographic and visit type variables. Although the same protocol was used to approach all parents, larger percentages of current smokers consented in intervention compared to control practices at two-weeks post-intervention implementation period, possibly due to unplanned priming as a result of the intervention. However, consent rate did not appear to have any correlation with the change in smoking prevalence. As the question about current smoking status was asked before consenting the parent, we do not believe consent to participation has any implication on current smoking prevalence data. We did not observe difference in consent rate during the two-years post-intervention implementation period. Intervention practices received

regular data monitoring and feedback from the study staff and it is unknown if the meaningful treatment delivery would be sustained without this support. To faithfully replicate the intervention protocol, accountable care organizations may have to undertake the task of monitoring practice's parental tobacco use screening and assistance data to sustain the intervention and reduce population level tobacco use rates.[39] Providing program management support for the intervention may help ensure a substantial return on investment.[40] Smoking prevalence at two-weeks post-intervention implementation was slightly higher in the intervention group but current smoker characteristics between intervention and control practices at two-week period indicates randomization generally resulted in good balance between the two groups.

**Conclusion**

Using an innovative electronic screening system to address household tobacco use, the CEASE intervention produced markedly higher rates of screening parents for tobacco use and delivering effective tobacco cessation assistance, compared to usual-care, and these effects were sustained two-years after the intervention implementation. A decrease in parent smoking prevalence and increase in cotinine-confirmed cessation was measured in practices that implemented the CEASE intervention while changes occurred in the opposite direction in the usual-care practices. If implemented in pediatric practices nationally, this intervention could reduce the prevalence of tobacco use among U.S. parents and protect children from exposure to tobacco smoke.

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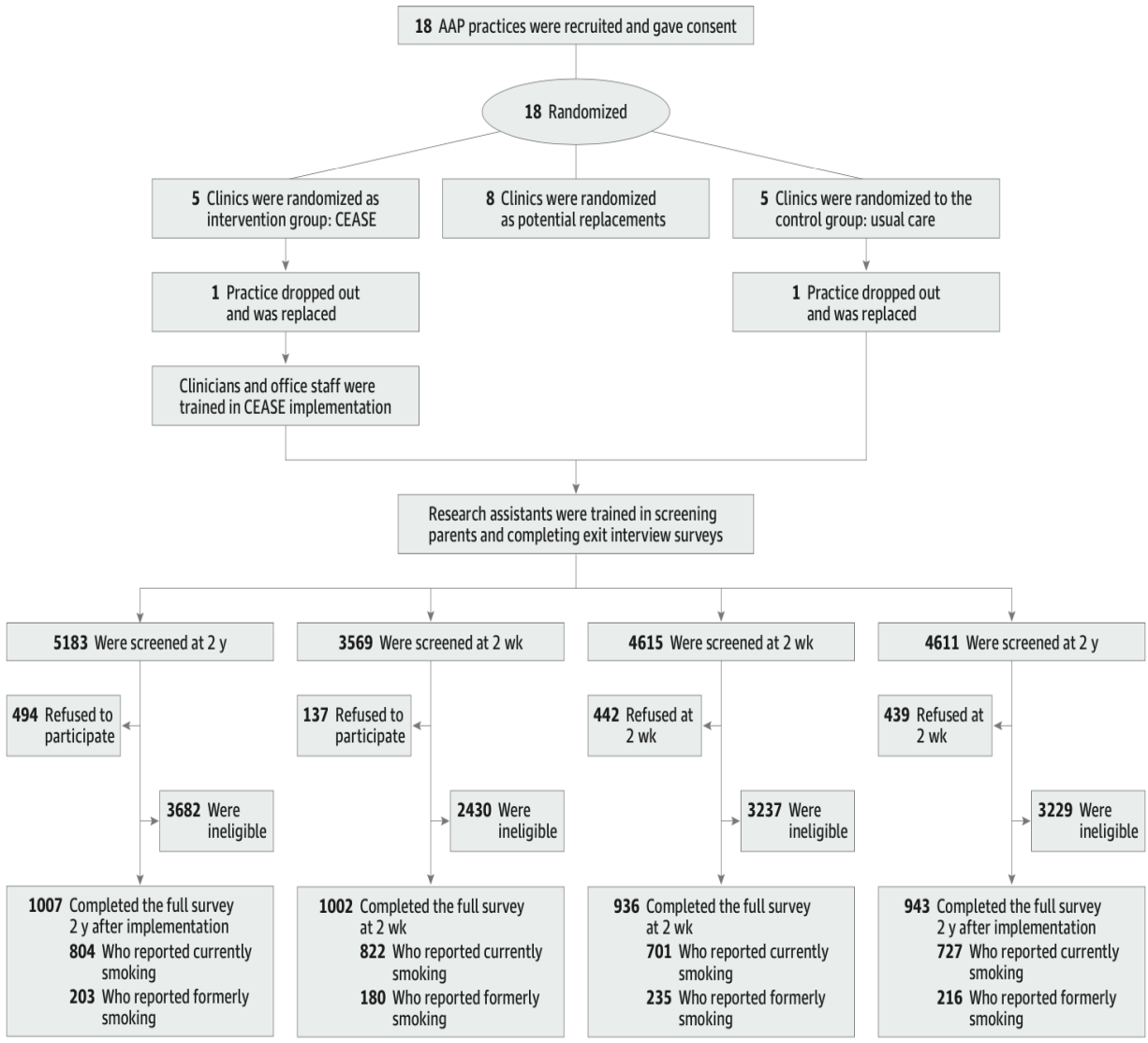
## Figure Legends:

## Figure 1: Randomization Design




AAP indicates American Academy of Pediatrics; CEASE, Clinical Effort Against Secondhand Smoke Exposure.

**Table 1: Characteristics of current smoker parents at two-weeks and two-years post-intervention implementation office visit**

| Characteristic | Two-weeks post-implementation | | Two-years post-implementation | |
|---|---|---|---|---|
| | Control N= 701 N (%) | Intervention N= 822 N (%) | Control N= 727 N (%) | Intervention N= 804 N (%) |
| Age | | | | |
| 18-24 | 138 (19.7) | 159 (19.3) | 115 (15.8) | 144 (17.9) |
| 25-44 | 486 (69.3) | 566 (68.9) | 533 (73.3) | 578 (71.9) |
| > 45 | 77 (11.0) | 97 (11.8) | 79 (10.9) | 82 (10.2) |
| Gender | | | | |
| Male | 109 (15.5) | 164 (20.0) | 123 (16.9) | 177 (22.0) |
| Female | 592 (84.5) | 658 (80.0) | 604 (83.1) | 627 (78.0) |
| Race and Ethnicity | | | | |
| Hispanic | 16 (2.3) | 25 (3.0) | 11 (1.5) | 28 (3.5) |
| Other | 19 (2.7) | 11 (1.3) | 18 (2.5) | 24 (2.9) |
| Non-Hispanic Black or African American | 78 (11.1) | 23 (2.8) | 72 (9.9) | 25 (3.1) |
| Non-Hispanic Asian | 2 (0.3) | 4 (0.5) | 0 | 2 (0.2) |
| Non-Hispanic Native Hawaiian or other | 19 (2.7) | 7 (0.9) | 16 (2.2) | 15 (1.9) |
| Non-Hispanic White | 567 (80.8) | 752 (91.5) | 610 (83.9) | 710 (88.3) |
| Education | | | | |
| <High school | 79 (11.3) | 145 (17.6) | 99 (13.6) | 106 (13.2) |
| High school graduate | 310 (44.2) | 340 (41.4) | 340 (46.8) | 355 (44.2) |
| Some college | 239 (34.1) | 261 (31.8) | 200 (27.5) | 285 (35.4) |
| College graduate | 73 (10.4) | 76 (9.2) | 84 (11.6) | 58 (7.2) |
| # Cigarettes/Day | | | | |
| 1-9 cigarettes/day | 270 (38.5) | 236 (28.7) | 287 (39.5) | 280 (34.8) |
| ≥10 cigarettes/day | 430 (61.3) | 582 (70.8) | 438 (60.2) | 520 (64.7) |
| Plan to Quit | | | | |
| Next 30 days | 312 (44.5) | 374 (45.5) | 277 (38.1) | 340 (42.3) |
| Next 6 months | 211 (30.1) | 213 (25.9) | 199 (27.4) | 233 (29.0) |
| No plan to quit next 6 months | 138 (19.7) | 150 (18.2) | 215 (29.6) | 169 (21.0) |
| Unknown | 40 (5.7) | 85 (10.3) | 36 (5.0) | 62 (7.7) |
| Quit attempt in the past 3 months | 388 (55.3) | 344 (41.8) | 359 (49.4) | 389 (48.4) |
| Daily smoker | 595 (84.9) | 732 (89.1) | 594 (81.7) | 664 (82.6) |
| Age of the youngest child seen | | | | |
| <1 years | 162 (23.1) | 179 (21.8) | 148 (20.4) | 189 (23.5) |
| 1-4 years | 215 (30.7) | 267 (32.5) | 211 (29.0) | 247 (30.7) |
| 5-9 years | 167 (23.8) | 175 (21.3) | 174 (23.9) | 179 (22.3) |
| 10-14 years | 114 (16.3) | 134 (16.3) | 153 (21.0) | 137 (17.0) |
| ≥ 15 | 43 (6.1) | 67 (8.2) | 41 (5.6) | 51 (6.3) |
| Strict smokefree policies in home and car | | | | |
| Strict smokefree home policy | 407 (58.1) | 486 (59.1) | 444 (61.1) | 523 (65.0) |
| Strict smokefree car policy | 213 (30.4) | 261 (31.8) | 265 (36.5) | 251 (31.2) |

| | | | | |
|---|---|---|---|---|
| Any other forms of tobacco used | | | | |
| Pipe | 4 (0.6) | 7 (0.9) | 5 (0.7) | 15 (1.9) |
| Chew tobacco | 13 (1.9) | 31 (3.8) | 20 (2.8) | 36 (4.5) |
| e-cigarettes | 95 (13.6) | 147 (17.9) | 81 (11.1) | 82 (10.2) |
| Hookah | 1 (0.1) | 8 (1.0) | 7 (1.0) | 7 (0.9) |
| Assistance used the last 2 years to help quit | | | | |
| NRT | 158 (22.5) | 188 (22.9) | 165 (22.7) | 268 (33.3) |
| Quitline | 41 (5.8) | 57 (6.9) | 31 (4.3) | 115 (14.3) |
| Website | 25 (3.6) | 32 (3.9) | 21 (2.9) | 54 (6.7) |
| Child's insurance Coverage | | | | |
| Medicaid | 489 (69.8) | 684 (83.2) | 431 (59.3) | 617 (76.7) |
| Private insurance/HMO | 202 (28.8) | 119 (14.5) | 263 (36.2) | 162 (20.1) |
| Other/self-pay | 9 (1.3) | 14 (1.7) | 28 (3.8) | 22 (2.7) |
| Type of visit | | | | |
| Well child | 338 (48.2) | 413 (50.2) | 394 (54.2) | 406 (50.5) |
| Follow-up | 79 (11.3) | 71 (8.6) | 59 (8.1) | 77 (9.6) |
| Sick visit | 226 (32.2) | 268 (32.6) | 181 (24.9) | 221 (27.5) |
| Other | 58 (8.3) | 69 (8.4) | 93 (12.8) | 100 (12.4) |
| No. of visits to pediatric office in the past 2 years, including today's visit: Median (IQs) | 8 (4-15) | 7 (4-15) | 8 (4-15) | 6 (4-12) |
| No. of visits to own doctor in past 2 years: Median (IQs) | 4 (2-10) | 4 (2-13) | 4 (2-10) | 4 (2-12) |

* Total N's vary slightly among items due to missing data

**Table 2: Current smoker parents who received any tobacco treatment at two-weeks and two-years post-intervention implementation office visit**

| Characteristic | Two-weeks post-implementation | | | Two-years post-implementation | | |
|---|---|---|---|---|---|---|
| | Control N= 701 N (%) | Intervention N= 822 N (%) | aRD§ (95% CI) | Control N= 727 N (%) | Intervention N= 804 N (%) | aRD§ (95% CI) |
| **Meaningful treatment*** | 1 (0.1) | 364 (44.3) | 44.0 (9.8, 84.8) | 2 (0.3) | 113 (14.1) | 12.8 (3.3, 37.8) |
| Any assistance (discuss NRT/quitline) | 8 (1.1) | 485 (59.0) | 50.1 (25.5, 74.2) | 24 (3.3) | 257 (32.0) | 33.1 (13.2, 59.1) |
| Ask smoking status | 156 (22.3) | 617 (75.4) | 52.4 (40.5, 61.5) | 135 (18.7) | 387 (48.1) | 29.1 (17.5, 41.0) |
| Ask smoke-free home status | 198 (28.3) | 570 (69.8) | 43.1 (31.6, 52.4) | 168 (23.2) | 378 (47.1) | 27.7 (14.6, 40.6) |
| Ask smoke-free car status | 126 (18.1) | 534 (65.4) | 48.2 (35.4, 59.0) | 119 (16.5) | 319 (39.7) | 26.4 (14.7, 38.9) |
| Advise smoker to quit | 95 (13.6) | 521 (63.7) | 44.5 (31.0, 56.9) | 85 (11.7) | 313 (38.9) | 26.2 (12.7, 41.8) |
| Advise to have Smoke-free home | 149 (21.3) | 532 (64.9) | 43.2 (30.1, 54.5) | 118 (16.3) | 319 (39.7) | 25.0 (13.4, 37.7) |
| Advise to have Smoke-free car | 123 (17.6) | 516 (62.9) | 43.8 (30.5, 55.6) | 104 (14.4) | 296 (36.9) | 24.5 (12.8, 37.6) |
| Discuss medicine to quit | 3 (0.4) | 466 (56.8) | 46.3 (20.0, 74.6) | 16 (2.2) | 250 (31.2) | 29.1 (10.8,56.0) |
| Discuss enrollment in state quitline | 7 (1.0) | 414 (50.6) | 40.7 (20.0, 64.7) | 15 (2.1) | 161 (20.1) | 17.3 (5.1, 41.0) |
| Prescribe NRT | 1 (0.1) | 325 (39.6) | 38.3 (7.9, 81.6) | 2 (0.3) | 102 (12.8) | 11.4 (2.9, 34.9) |
| Enroll in quitline | 1 (0.1) | 246 (30.1) | 29.4 (5.4, 74.9) | 0 (0) | 66 (8.2) | 8.2¶ (6.3, 10.1) |

* Defined as either prescription of Nicotine Replacement Therapy or enrollment in the state quitline during that day's visit

§ Adjusted risk differences, adjusted for parent sex, race, education, cigarette per day, plan to quit, quit attempt, daily smoker, e-cigarette use, and child insurance.

§§ Adjusted risk differences, adjusted for parent age, sex, race, education, cigarette per day, plan to quit, and child age and insurance.

¶ Unadjusted risk difference

**Table 3: Changes in cotinine-confirmed cessation and practice-level smoking prevalence from two-weeks to two-years post-intervention implementation**

| | Two-weeks post implementation | | Two-years post-implementation | | |
|---|---|---|---|---|---|
| | **Control** | **Intervention** | **Control** | **Intervention** | **RD (95%CI)** |
| **Total parents screened** | 4615 | 3569 | 4611 | 5183 | |
| **Current Smokers** | 1103 (23.9%) | 961 (27.1%) | 1149 (25.0%) | 1261 (24.4%) | |
| **Change in practice-level current smoking prevalence at 2 years** | | | +1.1% | -2.7% | -3.7% (-6.3%, -1.2%)** |
| **Total current and former smokers* who completed full survey** | 936 | 1002 | 943 | 1007 | |
| **Cotinine-confirmed Cessation** | 135 (14.4%) | 99 (9.8%) | 106 (11.2%) | 123 (12.2%) | |
| **Change in Cessation % at 2 years** | | | -3.2% | +2.4% | 5.5% (1.4%, 9.6%)§ |

*Former smokers: people reporting quitting in the past two-years
** Group and time interaction P=0.047 adjusting for state, parent age, gender, race, child age and insurance.
§ Group and time interaction P=0.019 adjusting for state, parent age, gender, race, child age and insurance.

# CHAPTER 7

# General Discussion

While tobacco use been as considered and recognized as one of the biggest public health threats,[1] the public health community is now faced with new products like e-cigarettes which are growing in popularity and use.[2–4] Even though e-cigarettes have been marketed as a smoking cessation aid,[5] the use of e-cigarettes has led to increased dual use of both cigarettes and e-cigarettes.[6] This pattern of dual use may suggest that some of these dual users may be supplementing their cigarette smoking with e-cigarettes instead of replacing it or that the use of e-cigarettes may prolong their dependance on cigarettes and delay cigarettes smoking cessation in the long term. This is a dangerous trend as dual users of e-cigarettes and cigarettes has been found to have higher odds of developing respiratory symptoms than either product alone although the precise level of risk in the long-term is not currently known.[7,8] A recent study also showed that dual users exhibited higher concentrations of nearly all biomarkers of nicotine and toxicants compared to cigarette only smokers.[9]

This thesis involved the culmination of five studies that examined the existing evidence on dual use and smoking cessation in the long-term, dual use of e-cigarettes and cigarettes in parents and the need for evidence-based tobacco cessation treatment interventions in the child healthcare setting. This chapter provides a summary of the findings of the thesis, the clinical implications, policy considerations and future directions based on these results.

Chapter two illustrates that the majority of e-cigarette users (70%) also smoked cigarettes and that seven in ten dual users had made a quit attempt in the past three months compared to less than five in ten cigarette only smoking parents. Pasquereau and Messer have also shown that cigarette smokers who also use e-cigarettes are more likely to have tried to quit,[10,11] but may not be more likely to quit smoking than exclusive smokers. This finding was confirmed in the chapter three where the systematic review results showed that most (86%) dual users continue to smoke or be dual users after at least one year follow-up. The meta-analysis showed that the dual users of cigarettes and e-cigarettes are not more likely to quit smoking after one year than those who use only cigarettes. Similar findings were reiterated in the real-world and clinical settings systematic review of

dual users by Kalkohran,[12] where the authors concluded that e-cigarettes are associated with significantly less quitting among smokers.

Chapter four of this thesis assessed the receipt of evidence-based tobacco cessation treatments among dual users compared to cigarettes only and demonstrated that dual users were more likely to receive a smoking cessation treatment than parents who smoke only cigarettes when treatment was offered in the child healthcare setting. It is not clear why dual users were more receptive to discussing and eventually receiving various smoking cessation treatments but maybe their higher rates of contemplating smoking cessation may have led to increased receptivity to evidence-based smoking cessation treatments.

Chapters five and six report results from a 2-year cluster randomized clinical trial to deliver smoking cessation treatment to parents and promote parental tobacco cessation conducted in ten primary care practices in five US states. In chapter five, we reported interview data from key informants i.e., clinicians and practice staff who participated in the trial. We found that the implementation of CEASE in practices was influenced by the adaptability and complexity of the intervention, the needs of patients and their families, the resources available to practices to support the implementation of CEASE, other competing priorities at the practices, the cultures of practices, and clinicians' and office staffs' knowledge and beliefs about family-centered tobacco control. Chapter six reported the main results from the trial. At exit interview, we found that 44.3% smoking parents in the intervention arm received meaningful treatment at that visit vs. 0.1% in the control arm (risk difference, 44.0% [95% CI, 9.8%-84.8%]). We also found that the change in smoking prevalence over the 2 years of intervention implementation favored the intervention (−2.7% vs 1.1%; difference −3.7% [95% CI, −6.3% to −1.2%]). These results proved that interventions that screen families for tobacco use and offer tobacco cessation treatments to smoking parents can be implemented in the child healthcare setting and can be effective in helping parent quit smoking.

In summary, the results of this thesis conclude that the prevalence of dual use is increasing[13,14] and as research has shown, dual use exposes its users to not only the harms from continued smoking but also has additional adverse health effects from dual use of e-cigarettes and cigarettes. [2,7,8] Hence, dual use could pose a significant public health risk if it perpetuates nicotine addiction, and in turn, delays or inhibits full cessation among those who might have otherwise quit.

Tobacco use has been identified as a well established public health problem with cigarette smoking as the leading cause of preventable disease among and disability throughout the world among smokers and non-smokers.[15] In the last two decades, substantial effort has been devoted globally to control the tobacco epidemic with tobacco control policies and treatments recommended by the World Health Organization's Framework Convention on Tobacco Control (FCTC).[16] Effective strategies to curb this epidemic have relied on creating awareness about harm caused by using tobacco products, implementing policies that regulate tobacco sales, pictorial warnings on tobacco product packages, policies that counter tobacco industry efforts to market to children and bans on using these products in public spaces. With the introduction of e-cigarettes and their increased use among youth and young adults, there is a fear of renormalizing smoking.[17] There is a concern that these electronic products may serve as a gateway for nicotine addiction[18] and tobacco use in people who have never smoked. Additionally former smokers or current smokers who use e-cigarettes might become accustomed to the nicotine intake and become dual users thus undermining years of tobacco control efforts.[17,19] The 2019 Lancet's editorial[20] which stated that there is no firm evidence to claim that e-cigarettes are healthier than cigarettes or can support quitting smoking and concluded that it maybe time to align the public health approach to e-cigarettes with that of cigarettes.

In view of the concerns of public health officials and tobacco control advocates around the use of e-cigarettes with cigarettes, dual use as a behavior needs to be better understood to help develop effective clinical interventions and health policies. Below, we

present clinical implications, policy considerations and future directions based on the results of this thesis.

***Clinical Implications:***

Healthcare providers have played an important role in creating awareness about the harms of tobacco use and treating tobacco dependance. The health care setting is an ideal place to educate people of all ages on the potential risks of e-cigarette use and exposure to secondhand aerosol from e-cigarettes.[2] In order to truly make a meaningful difference in complete tobacco use cessation including e-cigarettes in the long term, dual users of e-cigarettes and cigarettes needs to be addressed in all community health and healthcare settings including the child health care setting by:

- Educating healthcare professionals about various types of e-cigarettes, and the safety and harms associated with the use of these products. This will help them feel comfortable in discussing and educating their patients and families about the harms of e-cigarettes and the risk of a potential lifetime of nicotine addiction.
- Training healthcare professionals in preventing and treating both cigarette and e-cigarettes use.
- Creating awareness about the importance of not only having indoor environments like homes and cars completely tobacco-free but also free from the use of e-cigarettes.
- Identifying people using cigarettes and/or e-cigarettes and educating them about the effects of using these products and also, offering evidence-based cessation treatments to help them quit smoking.

***Policy Considerations:***

Regulatory bodies have been looking at regulation of e-cigarettes but there is a need to consider the dual users of e-cigarettes and cigarettes as well since this group who seems to use e-cigarettes have shown high intention to quit smoking but eventually somehow end up exposing themselves and people around them to more harmful chemicals than in cigarettes alone. Beyond strengthening service delivery and healthcare provision, major reforms are needed with respect to e-cigarettes, including the following:

1. Sale of e-cigarettes needs to be better regulated globally. Some countries have taken steps to ban the sales of e-cigarettes and some countries are considering banning or regulating the sales of e-cigarettes. Owusu and his colleagues[6] reported continued high prevalence of dual use in current smokers and increased prevalence of current e-cigarette use among never smokers. Considering that the youth and young adults are the highest consumers of e-cigarettes, strict regulations about the sale of e-cigarettes are a public health emergency especially to avoid an increasing number of people becoming dual users of e-cigarettes and cigarettes.
2. Prohibiting the sales of e-cigarettes to anyone under the age of 21 should be enforced and implemented.
3. E-cigarettes have also been marketed as a way to circumvent smoke-free policies.[21,22] E-cigarettes should be included in public smoke-free laws as this could help decrease the use of e-cigarettes as a cigarette substitute when smoking is not allowed. In turn, this may help increase the effectiveness of e-cigarettes for smoking cessation.
4. E-cigarettes have been marketed as an attractive product with a variety of flavors to attract consumers. Policy makers should consider banning the colorful, attractive packaging for e-cigarettes and implement restrictions on packaging, advertising and promotion of these products.
5. With many different types of e-cigarettes in the market and a rapidly evolving e-cigarette technology, regulation has been challenging. E-cigarette products need to be standardized and product types need to be better regulated. Health warnings about nicotine and the harms from these products should be required on packaging and in advertisements.
6. Since e-cigarettes have been marketed as a tool for smoking cessation despite regulatory authorities like FDA not having approved them for smoking cessation, regulatory authorities should not allow marketing of these products for use to reduce harm or risk of tobacco-use related disease or smoking cessation unless they are approved or authorized for this use.

***Future Directions:***

1. While looking at the e-cigarettes literature and dual use, it was tough to quantify the quantity and frequency of e-cigarettes use as we came across many different kinds of e-cigarettes with variable nicotine content. Further research is needed to determine the standard definitions of e-cigarette use.
2. Long-terms studies are needed to study the effect of dual use of e-cigarettes use not only in the people who are dual users but also for those who are exposed to the smoke and/or aerosol.

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# Summary

According to the 2019 Global Burden of Disease study, the tobacco epidemic kills about 8.71 million people a year around the world. There is no safe level of tobacco smoke exposure. In the recent years, new products have emerged in the market like the electronic nicotine delivery systems (ENDS), commonly referred to as e-cigarettes. These products are promoted as cessation aids without any proven evidence of their effectiveness in cessation. Most smokers who start these products, end up using both e-cigarettes and cigarettes (becoming dual users). This thesis explores the existing evidence on dual use and smoking cessation in the long-term, dual use in parents, and delivery of smoking cessation interventions to parents in the context of their child's healthcare setting.

The second chapter of the thesis describes the use of a new product, e-cigarettes which is growing in popularity globally. Dual use of e-cigarettes and cigarettes is an increasingly common practice, but little is known about patterns of dual use in parents. We sought to describe smoking-related behaviors among dual-users. We found that parents who use both e-cigarettes and cigarettes may have greater rates of contemplating smoking cessation than parents who only smoke cigarettes. These parents may be using e-cigarettes for harm reduction or as a step toward cessation. Identification of these parents may provide an opportunity to deliver effective treatment, including nicotine-replacement therapies that do not expose infants and children to e-cigarette aerosol.

Chapter 3 is a systematic review of literature to study the association between dual use of e-cigarettes and cigarettes and long-term smoking cessation among adult cigarette smokers. Despite limited evidence regarding the long-term impact of e-cigarettes on cigarette smoking cessation, they are sometimes used and promoted as a potential smoking cessation aid. Our review of the literature found that dual-users of cigarettes and e-cigarettes are not significantly more likely to quit smoking after one-year compared to those who smoke only-cigarettes. Most dual-users continue to smoke or be dual-users after at least one-year follow-up.

The fourth chapter of the thesis assesses delivery of evidence-based tobacco cessation treatment among parents who use both e-cigarettes and cigarettes (dual users) vs. cigarette-only smokers. Dual users who visited CEASE intervention practices were more likely to receive treatment (a prescription for nicotine replacement therapy and referral to the quitline to help them) than cigarette-only smokers.

Chapter 5 outlines the results of a qualitative study with interviews with a variety of key informants i.e., clinicians and practice staff who participated in a randomized clinical trial about delivering smoking cessation treatment to parents in the Pediatric setting. Structured interviews were conducted and two investigators employed analyzed the transcribed data. A codebook was developed (below) and codes were applied to the transcripts, which were analyzed using a thematic analysis. This paper study sought to identify factors that influenced the implementation of CEASE in five pediatric intervention practices in five states that participated in a cluster randomized clinical trial of the CEASE intervention. The main findings were that the implementation of CEASE in practices was influenced by the adaptability and complexity of the intervention, the needs of patients and their families, the resources available to practices to support the implementation of CEASE, other competing priorities at the practices, the cultures of practices, and clinicians' and office staffs' knowledge and beliefs about family-centered tobacco control.

Finally, chapter 6 outlines the results of a 2-year cluster randomized clinical trial to promote parental tobacco cessation conducted in 10 primary care practices in 5 US states. This trial tested a practice-change intervention designed to facilitate both routine screening in Pediatric settings of families for tobacco use and delivery of tobacco cessation treatment to individuals in screened households who use tobacco. This trial showed that integrating screening and treatment for parental tobacco use in Pediatric practices showed both immediate and long-term increases in cessation treatment delivery, a decline in practice-level parental smoking prevalence, and an increase in cotinine-confirmed cessation, compared with usual care control.

In the general discussion (chapter 7), we review and reflect on the results of the research questions and also, suggest some clinical implications, policy considerations and future directions based on the results. In summary, the results of this thesis conclude that the smokers who start using e-cigarettes to possibly quit smoking, end up continuing to use both cigarettes and e-cigarettes and becoming dual users. These dual users were more likely to receive a smoking cessation treatment than parents who smoke only cigarettes when treatment was offered in the child healthcare setting. Hence, evidence based treatments should be offered in the healthcare settings to smokers to help them quit and the feasibility and effectiveness of one such intervention in the child healthcare setting was demonstrated in this thesis.

To conclude, at the clinical/healthcare level, all healthcare professionals need to be educated about the various types of e-cigarettes and the existing evidence around their short-term and long-term use of e-cigarettes on health and smoking cessation. If smokers are ready to quit smoking, evidence-based treatments should be offered to them in the healthcare settings to help them quit smoking and healthcare providers need to be equipped with the right tools to screen and deliver the treatment to the smokers. Further long-term studies are needed to establish the long-term safety and harms of using e-cigarettes alone or in combination with cigarettes and the long-term smoking cessation rates of dual users of cigarettes and e-cigarettes. In the meantime, at the policy level, the marketing and sale of e-cigarettes needs to be better regulated and vape-free laws need to be implemented along with the smoke-free laws to reduce their use and exposure of non-users to the e-cigarette aerosol in public spaces and indoor settings.

# Impact

The use of e-cigarettes has been increasing globally among both smokers and nonsmokers. E-cigarettes have been marketed as safer alternatives to cigarettes or as smoking cessation aids. However, most e-cigarette users continue to smoke and becoming dual users of cigarettes and e-cigarettes rather than switching to e-cigarettes or quitting both products. These dual users eventually end up exposing themselves to not only the harmful substances in cigarettes but additionally to the harmful substances in e-cigarettes as well. Recent studies have shown that dual users are associated with a higher risk of respiratory disease and potentially cardiovascular symptoms than cigarette-only smokers but there is limited evidence on long-term effects of using both cigarettes and e-cigarettes on the user and people exposed to the smoke or aerosol from these products. Also, there is limited evidence regarding dual use and smoking cessation in the long-term.

The aim of this dissertation is to explore the existing evidence on dual use and smoking cessation in the long-term, dual use in parents, and delivery of evidence-based smoking cessation interventions to parents who smoke in the context of their child's healthcare setting. The five papers presented in this thesis suggest that dual users of both e-cigarettes and cigarettes may have greater rates of contemplating smoking cessation than cigarette-only smokers, and that dual-users are not significantly more likely to quit smoking after one-year or more compared to those who smoke only-cigarettes. The results from the systematic review also showed that dual-users continue to smoke or be dual-users after at least one-year follow-up. The last two chapters of the thesis outline the results from a randomized controlled trial to test the implementation of a smoking cessation intervention that delivered evidence-based cessation treatments to parents who smoke in the child health care setting. The results from these two chapters highlighted the factors that influenced the implementation of the intervention and showed that integrating screening and treatment for parental tobacco use in pediatric practices showed both immediate and long-term increases in cessation treatment delivery, and a decline in practice-level parental smoking prevalence over the two-years of intervention implementation.

The results of this thesis has some social and policy relevant implications. Global efforts to control the tobacco epidemic led to a decrease in smoking rates and de-normalize smoking making it socially less acceptable but with the increased use of e-cigarettes, there is a risk that e-cigarettes may facilitate renormalization of smoking. Also, due to the perception that using e-cigarettes or e-cigarette aerosol is safer than smoking cigarettes or exposure to cigarettes smoke, e-cigarettes have been used as a way to circumvent smoke-free policies. This highlights the need for policy makers to consider adding e-cigarettes to smoke-free policies and better regulation of the sales of e-cigarettes. Smokers who seek to quit smoking should be able to receive evidence-based smoking cessation treatments at all points of health care delivery including child healthcare practices.

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# Curriculum Vitae

Emara Nabi was born in Srinagar, Jammu and Kashmir, India on July 5, 1981. She grew up in India and obtained her Bachelor of Medicine and Bachelor of Surgery degree from M.S. Ramaiah Medical College, India. After obtaining her medical degree, she worked as a Internal Medicine resident doctor in India. Emara moved to the United States and completed a Master of Science degree in International Health Policy and Management from The Heller School for Social Policy and Management. After obtaining her Masters degree, she joined the Center for Child and Adolescent Health Policy at Massachusetts General Hospital (MGH), Boston in 2008. While working with MGH, Emara worked on several preventive health research studies including obesity and mostly, tobacco use and smoking cessation interventions. The growing use of e-cigarettes and the eventual dual use of cigarettes and e-cigarettes sparked an interest to explore this further through a PhD. In 2019, Emara officially enrolled as an external PhD candidate at the Department of Health Promotion, Maastricht University under the supervision of Professor Maurice Zeegers.

As she was completing her PhD virtually from India and the United Kingdom, Emara was also working as a Clinical Program Manager at Massachusetts General Hospital, Boston MA (US). She was managing different aspects of NIH grants related to tobacco control in the pediatric setting.

## Publications in this thesis:

1. **Nabi-Burza E,** Jenssen BP, Willemsen M, Winickoff JP Zeegers MP. Do dual users of e-cigarettes and cigarettes quit smoking in the long-term: A systematic review. Under review at Journal of Smoking Cessation.

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