

# Sustainability of a Parental Tobacco Control Intervention in Pediatric Practice

**AUTHORS:** Jonathan P. Winickoff, MD, MPH,<sup>a,b,c</sup> Emara Nabi-Burza, MBBS, MS,<sup>a,c</sup> Yuchiao Chang, PhD,<sup>c,d</sup> Susan Regan, PhD,<sup>e,d</sup> Jeremy Drehmer, MPH,<sup>a,c</sup> Stacia Finch, MA,<sup>e</sup> Richard Wasserman, MD,<sup>e,f</sup> Deborah Ossip, PhD,<sup>g</sup> Bethany Hipple, MPH,<sup>a,c</sup> Heide Woo, MD,<sup>e,h</sup> Jonathan Klein, MD, MPH,<sup>b</sup> and Nancy A. Rigotti, MD<sup>c,d</sup>

<sup>a</sup>Center for Child and Adolescent Health Research and Policy, Division of General Academic Pediatrics, Massachusetts General Hospital for Children, Boston, Massachusetts; <sup>b</sup>AAP Richmond Center of Excellence, and <sup>c</sup>Pediatric Research in Office Settings, American Academy of Pediatrics, Elk Grove Village, Illinois; <sup>d</sup>Tobacco Research and Treatment Center, and <sup>e</sup>General Medicine Division, Massachusetts General Hospital, Boston, Massachusetts; <sup>f</sup>Department of Pediatrics, University of Vermont, Burlington, Vermont; <sup>g</sup>University of Rochester Medical Center, Rochester, New York; and <sup>h</sup>University of California—Los Angeles, Los Angeles, California

## KEY WORDS

parental smoking, smoking cessation, secondhand smoke

## ABBREVIATIONS

AAP—American Academy of Pediatrics  
CEASE—Clinical and Community Effort Against Secondhand Smoke Exposure  
CI—confidence interval  
EMR—electronic medical record  
NRT—nicotine replacement therapy  
OR—odds ratio  
PROS—Pediatric Research in Office Settings  
TSE—tobacco smoke exposure

Dr Winickoff conceived of and conducted the trial as principal investigator, conceived of and designed the study, drafted and revised the manuscript, and takes full responsibility for the final submission; Dr Chang advised on and conducted data analyses and participated in the interpretation of results; Dr Nabi-Burza made substantial intellectual contributions to the study design, analysis and interpretation of data, and editing of and submitting the manuscript; Dr Regan supervised the designing of the data collection instruments and data collection, managed the database, made significant contributions to the design, and critically reviewed the manuscript; Mr Drehmer, Ms Finch, and Mrs Hipple made substantial intellectual contributions to the design and editing of the manuscript; Drs Wasserman, Ossip, and Rigotti made substantial intellectual contributions to the conception and design of the study, analysis and interpretation of data, and editing of the manuscript; Drs Woo and Klein made substantial intellectual contributions to the conception and design of the study and editing of the manuscript; and all authors approved the final manuscript as submitted.

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(Continued on last page)



**WHAT'S KNOWN ON THIS SUBJECT:** Parental smoking cessation helps eliminate children's exposure to tobacco smoke. A child's visit to the doctor provides a teachable moment for parental smoking cessation. Effective strategies to help parents quit smoking are available for implementation.



**WHAT THIS STUDY ADDS:** Evidence-based outpatient intervention for parents who smoke can be delivered successfully after the initial implementation. Maximizing parental quit rates in the pediatric context will require more complete and sustained systems-level integration.

## abstract



**OBJECTIVE:** To determine whether an evidence-based pediatric outpatient intervention for parents who smoke persisted after initial implementation.

**METHODS:** A cluster randomized controlled trial of 20 pediatric practices in 16 states that received either Clinical and Community Effort Against Secondhand Smoke Exposure (CEASE) intervention or usual care. The intervention provided practices with training to provide evidence-based assistance to parents who smoke. The primary outcome, assessed by the 12-month follow-up telephone survey with parents, was provision of meaningful tobacco control assistance, defined as discussing various strategies to quit smoking, discussing smoking cessation medication, or recommending the use of the state quitline after initial enrollment visit. We also assessed parental quit rates at 12 months, determined by self-report and biochemical verification.

**RESULTS:** Practices' rates of providing any meaningful tobacco control assistance (55% vs 19%), discussing various strategies to quit smoking (25% vs 10%), discussing cessation medication (41% vs 11%), and recommending the use of the quitline (37% vs 9%) were all significantly higher in the intervention than in the control groups, respectively ( $P < .0001$  for each), during the 12-month postintervention implementation. Receiving any assistance was associated with a cotinine-confirmed quitting adjusted odds ratio of 1.89 (95% confidence interval: 1.13–3.19). After controlling for demographic and behavioral factors, the adjusted odds ratio for cotinine-confirmed quitting in intervention versus control practices was 1.07 (95% confidence interval: 0.64–1.78).

**CONCLUSIONS:** Intervention practices had higher rates of delivering tobacco control assistance than usual care practices over the 1-year follow-up period. Parents who received any assistance were more likely to quit smoking; however, parents' likelihood of quitting smoking was not statistically different between the intervention and control groups. Maximizing parental quit rates will require more complete systems-level integration and adjunctive cessation strategies. *Pediatrics* 2014;134:933–941

Smoking is the single major preventable cause of mortality and morbidity.<sup>1,2</sup> Parental smoking exposes children to tobacco smoke, increasing the risk of respiratory and other illnesses, as well as the risk that the child will start smoking.<sup>3,4</sup> Quitting smoking adds an average of 7 years to a parent's life,<sup>5</sup> eliminates the majority of their children's tobacco smoke exposure (TSE),<sup>6-8</sup> and eliminates smoking-related poor pregnancy outcomes for all future pregnancies.<sup>9</sup> Earlier parental quitting is associated with a decreased prevalence of adolescent smoking and increased rates of smoking cessation among young adults.<sup>10-12</sup> The child health care setting provides teachable moments for the provider to influence parental smoking behavior and advance parents' motivation to quit smoking.<sup>13-16</sup> Healthy parents who smoke may not see a doctor frequently<sup>13,17-19</sup> but see their child's doctor more than once each year.<sup>20</sup> Therefore, tobacco cessation assistance delivered in the pediatric context is particularly important because, for a large percentage of parents, it is the only setting in which they will encounter a health care provider.

The effectiveness of smoking cessation strategies is well established. According to meta-analyses from the 2008 update of the US Public Health Service Guideline for the Treatment of Tobacco Use and Dependence, counseling, use of a quit-line, and nicotine replacement therapy (NRT) are each more efficacious than placebo or usual care.<sup>21</sup> Combining these therapies has shown more effectiveness than individual components alone.<sup>21</sup> Furthermore, a meta-analysis recently revealed the effectiveness of parental smoking cessation initiated in the pediatric context compared with control practices; yet, the difference in parental quit rates was small, which suggests that more comprehensive interventions need to be implemented.<sup>22</sup> Effective strategies to help parents quit

smoking are available,<sup>15,23</sup> and it has been shown that a comprehensive evidence-based tobacco control program can be routinely implemented in the pediatric outpatient setting.<sup>23</sup> Whether tobacco cessation assistance to parents who smoke can be sustained in pediatric practices after its initial implementation is not known. Therefore, we determined to what extent an evidence-based outpatient intervention for parents who smoke persisted after the initial successful implementation. Furthermore, we used biochemical validation to determine if smoking cessation rates were different between control and intervention practices 12 months after intervention implementation. Predictors of successful cessation were also identified.

## METHODS

### Practice Enrollment

We analyzed 12-month telephone survey data collected between May 14, 2010, and May 30, 2012, as part of the Clinical and Community Effort Against Secondhand Smoke Exposure (CEASE) cluster randomized controlled trial. The study was conducted in partnership with Pediatric Research in Office Settings (PROS), a practice-based research network of the American Academy of Pediatrics (AAP). PROS includes >700 practice sites throughout the United States.<sup>24</sup> Twenty-two PROS practices, located in 16 states (Arkansas, Virginia, Connecticut, New Mexico, Pennsylvania, Missouri, South Carolina, Tennessee, Massachusetts, Oregon, Ohio, Oklahoma, Illinois, West Virginia, Maryland, and South Dakota) were randomized equally to the intervention and control arms. One practice in each group was dropped from the study due to slow parent enrollment. The study protocol was approved by the institutional review boards of the AAP and Massachusetts General Hospital and by individual practice institutional review boards, where required.

### Parent Enrollment

At each practice, research assistants enrolled ~100 smoking parents as they exited the pediatric office after their child's visit. At the baseline interview, parents were asked questions about their child's age and reason for the visit, demographic characteristics, tobacco use, smoking rules in the car and/or at home, smoking behaviors, and if the child's health care provider delivered any tobacco cessation assistance at that visit. Parents were eligible for study enrollment if they indicated on the baseline survey that they were the parent or legal guardian of the child seen that day (hereafter referred to as "parents"); indicated that they had smoked a cigarette, even a puff, in the past 7 days; were English-speaking; and were at least 18 years old. Eligible parents were invited to enroll in the study to participate in 3- and 12-month telephone surveys. Participating parents were given \$5 at the conclusion of baseline enrollment and were offered \$10 and \$25 gift cards for completing the 3- and 12-month telephone surveys, respectively. At the 3- and 12-month surveys, parents were asked about their tobacco use and behavior, smoking rules in the car and/or at home, and if they had a visit to their child's doctor's office since the baseline enrollment visit. If parents reported at least 1 visit since their enrollment into the study, they were asked to report if their child's health care provider delivered any tobacco cessation assistance at any of the visits after enrollment. They were also offered a \$50 gift card to send their saliva sample to confirm their quit status at the 12-month follow-up survey time.

### Intervention

This trial tested the implementation of an intervention to address parental tobacco use in the pediatric office setting.<sup>23</sup> The intervention included the following:

1. Routine screening for parental tobacco use using a document called the CEASE Action Sheet. The CEASE action sheet was handed to all of the parents during their child's visit by the front desk staff at check-in and it helped the office staff identify each smoking family member and document their smoking status in the child's medical record.
2. Motivational messaging delivered by the child's health care provider (clinician, nurse), which was based on the parents' own concerns as well as potential teachable moments that may be cued by the child's illness.
3. Recommendation and possible provision of a nicotine patch and gum by the clinician and enrollment in the free state quitline.

The intervention was designed to function within existing systems of care, and the research staff did not deliver any of the clinical tobacco dependence treatment. Practice leaders in the intervention practices participated in a one-on-one training call with research staff, which was followed up by a whole-office training conference call with the entire practice staff. Control practices received no training in tobacco control from the research staff, but the practice staff was aware that they were participating as a control practice in a tobacco control study. Maintenance of the intervention was encouraged by phone calls with the intervention practice leaders approximately once per month and by sending monthly intervention-related material such as posters for the office or small motivational items such as CEASE pens or CEASE tote bags that we asked them to hand out to parents visiting the practice.

### Measures/Outcomes and Data Analysis

The primary outcome of the study was provision of meaningful tobacco control assistance in the 12 months after the initial intervention implementation. We

asked each parent at the 12-month follow-up survey if they had visited their child's doctor's office in the past 12 months. For the analyses on service delivery, we presented data from the parents who reported having at least 1 visit to their child's doctor's office after their study enrollment. Parents were considered to have been provided meaningful tobacco control assistance by the child's health care provider if they answered "yes" to any of the following questions on the 12-month follow-up survey:

During your visit(s) after enrollment, did a doctor, nurse, or other health care provider:

1. Discuss medicine to help you quit smoking (eg, nicotine replacement gum, patch, lozenge, or other medicine)?
2. Discuss methods and strategies (other than medicine) to help you quit smoking?
3. Suggest you use a telephone quitline or other program to help you quit smoking?

Salivary swabs were mailed to parents who reported quitting smoking at 12 months to determine biochemically validated parental smoking cessation rates. We used a predetermined cotinine cutoff of 10 ng/mL as the threshold level for confirming abstinence and identified the factors associated with cessation in parents.<sup>25,26</sup> Secondary outcomes included specific "ask," "advise," and "assist" items based on parental report of receipt of tobacco control assistance services at baseline and follow-up times. We excluded from this analysis parents who had not had a visit to their child's doctor's office in the past 12 months.

We also explored the association between treatment effect, demographic and behavioral factors, and cotinine-confirmed quit rates at 12 months. All parents lost to follow-up and who did not return the cotinine swabs were classified as "current smokers." We performed the

analysis by using both bivariate and multivariable approaches. Variables that were significant at  $P < .05$  in the bivariate analysis or had theoretical plausibility were included in the multivariable logistic regression models. We conducted 2 separate multivariable logistic regression models to determine the effect of intervention group and the effect of provider assistance. Any assistance by the provider was defined as parents reporting yes to receiving any 1 of the 3 types of effective tobacco control assistance from the child's health care provider at any time during the study period after the baseline enrollment. In both models, we controlled for the child's age, insurance type, parent's gender, parent's race, and parental baseline smoking characteristics (number of cigarettes smoked per day, frequency of smoking, and stage of change [assessed by asking if they were planning to quit in the next 30 days or 6 months]). Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) were reported for each variable from the final models. In addition to the binary provider "any assistance" variable, we also examined the amount of assistance delivered to a parent within the study period by using a 5-level variable, as follows:

1. No assistance delivered at baseline or within the subsequent 12-month time period
2. Some assistance delivered at 1 time point and no assistance delivered at the other time point
3. The maximum amount of assistance (defined as having been enrolled in a state quitline plus receiving any of the following from the health care provider: discussing various strategies to quit smoking or discussing smoking cessation medication) delivered at 1 time point and no assistance delivered at the other time point
4. The maximum amount of assistance delivered at 1 time point

and some assistance given at the other time point

- The maximum amount of assistance given at both baseline and within the subsequent 12-month time period

All analyses were conducted by using generalized estimating equation techniques to take into account physician clustering. SAS version 9.3 (SAS Institute, Cary, NC) was used for all analyses.

## RESULTS

A total of 1980 parents were enrolled at baseline between June 1, 2009, and March 7, 2011, after they exited from the pediatric office after their child's visit. Table 1 presents characteristics of all parents enrolled at baseline. The average age was 30 years, and 22% of the parents were men. The intervention group had more whites, fewer black non-Hispanics, fewer Hispanics, and fewer college graduates; smoked more cigarettes per day; and had lower rates of private insurance coverage for children compared with the control group.

A total of 1355 parents (68.4%) completed the 12-month telephone survey: 64.6% and 72.4% in the intervention and control practices, respectively. Of the parents who completed the 12-month follow-up telephone survey, 635 (89.4%) in the control practices and 556 (86.2%) in the intervention practices reported having a visit to their child's doctor at least once after the baseline enrollment in the study. The average age of parents who completed the 12-month follow-up survey was 31 years, and 81% of them were women. On the basis of the report of parents who had a visit to their child's doctor at least once after the baseline enrollment in the study, pediatricians' rates of screening parents for their smoking status and smoke-free home and car rules (triple tobacco screen) were all higher in the intervention practices compared with the control practices (Table 2). The

**TABLE 1** Characteristics of Enrolled Parents

Characteristic	Control (N = 981)	Intervention (N = 999)
Age, mean (range), y	30.6 (18–65)	30.0 (18–78)
Age group, %		
18–24 years	25.8	27.1
25–44 years	67.7	66.5
>45 years	6.4	6.4
Gender, %		
Male	22.0	21.3
Female	77.9	78.6
Race/ethnicity, %		
Hispanic	13.7	8.2
Non-Hispanic, >1 race	2.5	3.0
Non-Hispanic black or African American	19.8	11.3
Non-Hispanic, other	1.7	3.9
Non-Hispanic white	61.5	72.9
Education, %		
Less than high school	14.5	16.4
High school graduate	45.0	47.5
Some college	26.8	29.0
College graduate	13.5	6.6
Mean child's age, mo	17.5	11.5
Child's age group, %		
<1 year	29.1	23.8
1–4 years	34.4	39.0
5–9 years	18.8	20.0
≥10 years	16.5	16.4
Mean number of cigarettes/day	10.3	11.7
1–9 cigarettes/day, %	46.7	38.8
≥10 cigarettes/day, %	52.4	60.5
Daily smoker, %	82.3	87.3
Child's insurance coverage, %		
Medicaid	64.5	69.8
Private insurance/HMO	27.1	20.2
Other/self-pay	7.1	9.9
Type of visit		
Well child	43.5	41.9
Sick visit/other	56.5	58.1
Practice characteristics, %	N=10	N=10
Practice size		
≤4 clinicians	20.0	40.0
>4 clinicians	80.0	60.0
Overall smoking rate in the practice		
<15%	40.0	10.0
15%–20%	20.0	30.0
>20%	40.0	60.0
EMR	30.4	50.2

Total N = 1980. HMO, health maintenance organization.

intervention practices also had higher rates of advising parents to quit smoking and to have smoke-free home and cars. Pediatricians' rates of discussing smoking cessation medication, recommending using the quitline, and discussing other strategies to quit smoking (all  $P < .001$ ) were all higher in the intervention group compared with the control group during the 12 months after initial intervention implementation. Overall, pediatricians'

rates of providing any tobacco control assistance were higher in the intervention practices compared with the control practices (54.7% vs 19.2%,  $P < .001$ ).

In the 12-month smoking cessation analyses, all parents lost to follow-up and who did not return the cotinine swabs were classified as current smokers. A total of 107 and 123 parents reported quitting in the intervention and control practices, respectively, and 82 and 89 of

**TABLE 2** Parental Smoking Cessation Assistance Delivery After Initial Intervention Implementation

Characteristic	Intervention (N = 556), n (%)	Control (N = 635), n (%)	P
<b>Ask</b>			
Parent smoking status	330 (59.4)	207 (32.6)	<.0001
Smoke-free home	364 (65.5)	255 (40.2)	<.0001
Smoke-free car	313 (56.3)	208 (32.8)	<.0001
Any tobacco triple screener <sup>a</sup> question	397 (71.4)	288 (45.4)	<.0001
All tobacco triple screener questions	263 (47.3)	157 (24.7)	<.0001
<b>Advise</b>			
Quit smoking	281 (50.5)	171 (26.9)	<.0001
Smoke-free home	329 (59.2)	237 (37.3)	<.0001
Smoke-free car	292 (52.5)	208 (32.8)	<.0001
To reduce any SHS exposure of child	359 (64.6)	264 (41.6)	<.0001
To reduce all SHS exposures of child	229 (41.2)	131 (20.6)	<.0001
<b>Assist</b>			
Discuss smoking cessation medication	229 (41.2)	68 (10.7)	<.0001
Give prescription for smoking cessation medication	103 (18.5)	15 (2.4)	<.0001
Recommend a quitline program	207 (37.2)	59 (9.3)	<.0001
Enroll in a quitline	23 (4.1)	7 (1.1)	.003
Discuss other methods and strategies to help quit smoking	140 (25.2)	61 (9.6)	<.0001
Any assistance	304 (54.7)	122 (19.2)	<.0001

Excluded all the parents who did not have a visit to their child's pediatric office in the last 12 mo; N = 1191. SHS, secondhand smoke.

<sup>a</sup> Tobacco triple screener: screen parents for smoking status, smoke-free home rules, and smoke-free car rules.

them agreed to send in their saliva sample for cotinine testing in the intervention and control practices, respectively. Of the parents who agreed to send in their saliva sample, 68% and 72% returned the samples in the intervention and control practices, respectively. The rates of cotinine-confirmed quitting were 4.3% and 4.1% ( $P = .88$ ) in the intervention and control practices, respectively. After controlling for child's age, insurance type, parent's gender, parent's race, and parental baseline smoking characteristics (number of cigarettes smoked per day, frequency of smoking, and stage of change), the adjusted OR for cotinine-confirmed quitting in the intervention versus control practices was 1.07 (95% CI: 0.64–1.78).

Bivariate analyses revealed associations between parent's gender, race, smoking frequency and quantity, and planning to quit in the next 30 days at baseline enrollment with confirmed quitting at the 12-month follow-up time period (Table 3). In the multivariable logistic regression model, 2 factors had significantly lower odds of confirmed quitting at 12 months: parents who reported at baseline enrollment that they belonged to a race

other than white (OR: 0.37; 95% CI: 0.21–0.65) and parents who smoked  $\geq 10$  cigarettes/day versus  $< 10$  cigarettes/day (OR: 0.25; 95% CI: 0.16–0.37). Parents who reported receiving "any assistance" at either the baseline visit or within 12 months after the baseline visit, on the other hand, had significantly higher odds of confirmed quitting 12 months after enrollment in the study (OR: 1.89; 95% CI: 1.13–3.19) (Table 4). When examining the amount of assistance delivered at baseline and during subsequent visits within the following 12 months by using the 5-level variable, the level 5 assistance (maximum amount of assistance given at both baseline and within the subsequent 12-month time period) was associated with a 13.9 times (95% CI: 2.3–83.3) increased likelihood of parents quitting at 12 months compared with level 1 (no intervention delivered at all).

## DISCUSSION

This follow-up study of a clinical trial of a tobacco control intervention in pediatric practices revealed significantly higher postintervention tobacco cessation assistance delivery rates in intervention

practices compared with the control practices after initial implementation. However, we did not see a significant difference in the rates of cotinine-confirmed parental quit rates between the intervention and control practices. Parents who reported at baseline enrollment that they smoked  $< 10$  cigarettes/day, who were white, and who received any assistance at either the baseline visit or within 12 months after the baseline visit were more likely to quit after 12 months.

Specifically, this study showed that an evidence-based outpatient tobacco control intervention implemented in the pediatric setting will persist after implementation as shown by the fact that the pediatricians' rate of providing tobacco control assistance was 42.5% after initial intervention implementation<sup>23</sup> and was 54.7% during the 12 months after initial intervention implementation. The sustainability of the intervention may be attributable to the fact that it was designed to function using existing systems of care within each practice. These findings support implementation of tobacco cessation interventions with the use of existing systems of care in routine pediatric practice for the successful delivery of smoking cessation assistance to parents.

Although it is important to intervene with all parents regarding their children's tobacco smoke exposure, parents who smoke fewer cigarettes may have less difficulty abstaining and be more likely to quit smoking, as our results suggest. White parents were more likely to quit smoking than parents of other races. Studies have shown that black adults smoke at lower rates than whites,<sup>27</sup> and some studies have shown that parents who are not white are less likely to receive cessation services from their own clinicians.<sup>28,29</sup> Better parental health education regarding the harms to children's health due to exposure to secondhand smoke and third-hand smoke could help motivate more parents to quit smoking.<sup>30</sup> We also found that parents who reported

**TABLE 3** Predictors of Parental Confirmed Quits in the Total Randomized Population

Characteristic	Total, <i>N</i>	Quit, <i>n</i> (%)	<i>P</i>
Arm			.88
Control	981	40 (4.1)	
Intervention	999	43 (4.3)	
Age of the parent			.28
<30 years/unknown	1059	49 (4.6)	
≥30 years	921	34 (3.7)	
Gender			.009
Male	429	10 (2.3)	
Female	1551	73 (4.7)	
Race			.019
White	1331	67 (5.0)	
Other	649	16 (2.5)	
Education			.22
Less than high school	1222	45 (3.7)	
High school graduate or higher	758	38 (5.0)	
Child's age			.16
<1 years	523	16 (3.1)	
≥1 year/unknown	1457	67 (4.6)	
Medicaid			.21
Yes	1330	50 (3.8)	
No	650	33 (5.1)	
Private insurance/HMO			.13
Yes	511	29 (5.7)	
No	1469	54 (3.7)	
Frequency of smoking at baseline			.008
Everyday	1680	59 (3.5)	
Some days	300	24 (8.0)	
Number of cigarettes/day at baseline			<.0001
<10 cigarettes/day	862	61 (7.1)	
≥10 cigarettes/day	1118	22 (2.0)	
Other smokers in home			.92
Yes	1176	49 (4.2)	
No	804	34 (4.2)	
Stage of quitting at baseline			.048
Plan to quit in 30 days	841	46 (5.5)	
Plan to quit in 6 months	564	22 (3.9)	
No plan to quit within 6 months	574	15 (2.6)	
Strictly enforced home smoking policy at baseline			.40
Yes	1041	47 (4.5)	
No	939	36 (3.9)	
Strictly enforced car smoking policy at baseline			.51
Yes	393	19 (4.8)	
No	1587	64 (4.0)	
Any assistance <sup>a</sup>			.024
Yes	950	51 (5.4%)	
No	1030	32 (3.1%)	

*N* = 1980. HMO, health maintenance organization.

<sup>a</sup> At either the baseline visit or within 12 months after the baseline visit.

**TABLE 4** Predictors of Confirmed Quits in the Total Randomized Population

Characteristic	OR	95% CI	<i>P</i>
Assistance: any assistance versus no assistance at all	1.89	1.13–3.19	.016
Age of the child: ≥1 year/unknown versus <1 year	1.71	0.97–3.01	.065
Private insurance/HMO: yes versus no	1.48	0.81–2.70	.20
Parent gender: male versus female	0.61	0.37–1.04	.067
Race: other versus white	0.36	0.22–0.60	<.0001
Frequency of smoking: everyday/unknown versus some days	0.74	0.47–1.18	.20
Cigarettes per day: ≥10 versus <10	0.24	0.16–0.35	<.0001
Stage of quit: quit 30 days versus quit 6 months	1.74	0.86–3.50	.12
Stage of quit: quit 6 months versus no plan to quit	1.52	0.86–2.68	.15

*N* = 1980. HMO, health maintenance organization.

receiving any assistance at either the baseline visit or within 12 months after the baseline visit had significantly higher odds of confirmed quitting after 12 months. Furthermore, we found an even stronger association with confirmed quitting when the maximum amount of assistance was delivered over multiple visits to smoking parents. This finding supports the need for universal screening for parental tobacco use so that assistance can be offered to everyone who uses tobacco at every visit.

We identified a number of barriers to significant parental quit results despite successful intervention implementation. A few factors may have either weakened the study's finding of a difference between intervention and control groups or blunted the differential impact of the intervention. The differential follow-up rates in the intervention versus control practices (64.5% vs 72.4%, *P* = .1133) could be 1 of the reasons for lower than expected confirmed quit rates in the intervention group. To put this effect in perspective, 5 control practices had higher follow-up rates than the intervention practice with the highest follow-up rate. Low follow-up rates in the intervention group bias results to the null because all those who are not reached are assumed to be current smokers using an "intention to treat" analysis. In a future study,<sup>31</sup> this loss to follow-up can be prevented by using a serial cross-sectional design with exit interviews at baseline and at 1 or 2 years to look at the sustainability of the intervention and population-level cessation effects.

The use of NRT has been shown to be 1 of the most effective strategies to help increase people's chances of quitting smoking.<sup>21</sup> NRT is expensive, and at the time we conducted this trial it was not covered by some insurers and not even by Medicaid in all states. Physicians' overall enthusiasm for the intervention could have been diminished when they were not able to get NRT into the hands of smoking parents for free or for the price

of a copay. This important study result highlights the need for better funding of NRT through state quitlines and better coverage through Medicaid and private insurance companies. In the future, NRT will be covered by Medicaid,<sup>32</sup> and hopefully more people can use it for free or for the price of a copayment.

The intervention was initially designed to help practices that use paper records but most of the pediatric practices now use electronic medical record (EMR) systems. The CEASE intervention could be strengthened by EMR integration. During the pediatric visit, the child health care provider would be prompted by the EMR to ask the parent about the child's TSE, which would lead to universal screening of parents for tobacco use and also prompt the provider to offer smoking cessation assistance to the parents at subsequent visits. This concept has been demonstrated in pilot work.<sup>33</sup>

The lack of a disease registry of children exposed to tobacco smoke made it difficult for practices to know which families to intervene with regarding offering cessation assistance. Electronic tablets are increasingly being used in pediatric offices to collect intake information from the parents, and their use is likely to persist and grow in the future.<sup>34</sup> The use of these tablets at check-in for screening and documentation of a child's TSE will eventually lead to the creation of a useful disease registry to guide intervention with high-risk families. In summary, maximizing parental quit rates in pediatric offices will require more complete systems-level integration.

Addressing parental smoking needs to be emphasized to all child health care providers in the context of offering a workable and effective office system for them to take serious action against TSE in children. Future studies might consider using cotinine levels in children to document the extent of a child's exposure and

enhance systems-level integration of tobacco control assistance for parents.<sup>35,36</sup>

The results are based on parental self-report and thus are subject to response bias. Those parents who quit may have also been more likely to report receipt of assistance as a result of recall bias. The sample of parents who self-selected to enroll in the study may have differed from the eligible parents who refused enrollment. Despite these limitations, the use of a large sample size across 16 US states allows greater confidence in reporting of the results. Also, the PROS practices that volunteered to enroll in the study and were randomized to the control group may have already been concerned about parental smoking and may have had a higher baseline rate of assistance than the average practice. The control group clinicians were aware they were in a tobacco control intervention, and it is unknown if this knowledge influenced their tobacco control behaviors in any way.

The differential follow-up rates between control and intervention practices may have blunted the final intervention effect because all those lost to follow-up were assumed to be smokers. Factors that could have led to suboptimal intervention implementation in some practices include that the intervention was designed to help practices using paper records but at the time of the trial many of the pediatric practices were transitioning to EMR systems and NRT was not covered for all parents by Medicaid or some insurances. The long-term sustainability of this intervention has not been established beyond a year. An additional limitation is that there was variability in the frequency and timing of pediatric office visits since enrollment into the study, thus limiting our ability to determine if the sustainability of the intervention lasted the entire 12-month period.

## CONCLUSIONS

This study shows that an intervention to help parents quit smoking can be successfully delivered as part of routine child health care outpatient practice nationally after the initial implementation period. However, our study highlights the need for better universal screening for parental tobacco use to identify parents who smoke, more intensive cessation approaches for parents who smoke, better integration of tobacco exposure documentation in the EMR, and universal coverage for cessation medications to maximize parental quit rates.

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Address correspondence to Jonathan P. Winickoff, MD, MPH, Center for Child and Adolescent Health Research and Policy, Division of General Academic Pediatrics, Massachusetts General Hospital for Children, 15th Floor, Suite 1542A, 100 Cambridge St, Boston, MA 02114. E-mail: [jwinickoff@partners.org](mailto:jwinickoff@partners.org)

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