An Office-Initiated Multilevel Intervention for Tobacco Smoke Exposure: A Randomized Trial

Bradley N. Collins, PhD,^{a,b} Stephen J. Lepore, PhD,^a Jonathan P. Winickoff, MD,^c Uma S. Nair, PhD,^a Beth Moughan, MD,^b Tyra Bryant-Stephens, MD,^d Adam Davey, PhD,^e Daniel Taylor, DO,^f David Fleece, MD,^b Melissa Godfrey, MPH^a

abstract

BACKGROUND: Provider adherence to best practice guidelines (ask, advise, refer [AAR]) for addressing child tobacco smoke exposure (TSE) motivates parents to reduce TSE. However, high-risk, vulnerable populations of smokers may require more intensive treatment. We hypothesized that a pragmatic, multilevel treatment model including AAR coupled with individualized, telephone-based behavioral counseling promoting child TSE reduction would demonstrate greater child TSE reduction than would standard AAR.

METHODS: In this 2-arm randomized controlled trial, we trained pediatric providers in systems serving low-income communities to improve AAR adherence by using decision aid prompts embedded in routine electronic health record assessments. Providers faxed referrals to the study and received ongoing AAR adherence feedback. Referred participants were eligible if they were daily smokers, >17 years old, and spoke English. Participants were randomly assigned to telephone-based behavioral counseling (AAR and counseling) or nutrition education (AAR and attention control). Participants completed prerandomization and 3-month follow-up assessments.

RESULTS: Of providers, >80% ($n = 334$) adhered to AAR procedures and faxed 2949 referrals. Participants ($n = 327$) were 83% women, 83% African American, and 79% low income (below poverty level). Intention-to-treat logistic regression showed robust, positive treatment effects: more parents in AAR and counseling than in AAR and attention control eliminated all sources of TSE (45.8% vs 29.9%; odds ratio 1.99 [95% confidence interval 1.44–2.74]) and quit smoking (28.2% vs 8.2%; odds ratio 3.78 [95% confidence interval 1.51–9.52]).

CONCLUSIONS: The results indicate that the integration of clinic- and individual-level smoking interventions produces improved TSE and cessation outcomes relative to standalone clinic AAR intervention. Moreover, this study was among the first in which researchers demonstrated success in embedding AAR decision aids into electronic health records and seamlessly facilitated TSE intervention into routine clinic practice.

Departments of ^aSocial and Behavioral Sciences and ^bEpidemiology and Biostatistics, College of Public Health, and ^cDepartment of Pediatrics, Lewis Katz School of Medicine, Temple University, Philadelphia, Pennsylvania; ^dDepartment of Pediatrics, Massachusetts General Hospital, Boston, Massachusetts; ^eDepartment of General Pediatrics, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; and ^fDepartment of Pediatrics, College of Medicine, Drexel University, Philadelphia, Pennsylvania

Dr Collins was a principal investigator, conceptualized and designed the study, oversaw all aspects of the trial in collaboration with the co-principal investigator, led the development of the counseling intervention, protocols for intervention delivery, and counselor training, oversaw the implementation and maintenance of the interventions, interpreted study results, and drafted the initial manuscript; Dr Lepore was a principal investigator, conceptualized and designed the study and interventions in collaboration with the principal investigator, led the development of the attention control intervention, oversaw data collection, quality

Tobacco smoke is a carcinogen^{1,2} that causes preventable illnesses, disease, and death in children.^{1,3–6} Parental smoking is the primary source of child tobacco smoke exposure (TSE),⁷ and young children bear an increased susceptibility to its consequences.^{8,9} This vulnerability is disproportionately high among impoverished children.^{1,10–12} Of US adults, ~18% smoke,¹³ but in low-income and minority groups, smoking rates often exceed 30%, and child TSE rates can exceed 50%.^{14,15} Therefore, addressing parental smoking and child TSE remain public health priorities, particularly in underserved populations.¹⁶

Although empirically validated cessation interventions exist, treatment uptake is low among underserved smokers.^{17,18} Most adult smokers are motivated to quit.¹⁹ However, low-income and racial minority smokers who initiate cessation demonstrate lower quit rates^{19–21} than the overall population because they face more barriers to access and uptake of evidence-based treatments and confront more challenges to quitting.^{22–24} Because such challenges exist, underserved families could benefit from harm-reduction approaches that immediately address child TSE while continuing to encourage smoking cessation rather than focusing entirely on smoking cessation. For example, adopting indoor residential smoking restrictions would immediately benefit children's wellbeing even when parents have not quit smoking.

The American Academy of Pediatrics best practices guidelines (ask, advise, refer [AAR])²⁵ recognize the priority of child TSE reduction and underscore providers' role and responsibility to boost parents' TSE knowledge, increase their motivation to protect children from TSE, and facilitate access to nicotine replacement therapy (NRT) and cessation counseling. AAR

effectiveness depends on consistent adherence.²⁵ However, studies suggest a wide adherence variability that is attributed to differences in training, confidence, and systems-related barriers.^{26,27}

Among other limitations,²⁸ TSE interventions overemphasize single-mode, 1-size-fits-all treatment approaches^{29–32} that disregard individuals' needs. Such approaches tend to focus on 1 level of smoking behavior determinants (eg, motivation to change smoking behavior around children), which may not address other relevant determinants (eg, interpersonal barriers to implementing residential smoking restrictions). Therefore, in populations demonstrating the greatest challenges to smoking behavior change, brief provider advice alone may be an important but inadequate approach to promoting behavior change in smokers. In particular, providers may motivate parents to change as a gateway to accessing evidence-based smoking treatment that will provide more intensive and ongoing support and skills training that are necessary for successful smoking behavior change.^{30,32}

Because tobacco smoking and cessation processes are driven by multiple, interacting factors across individual, interpersonal, and metasocial levels of influence, the failure to develop a multilevel approach remains a critical barrier to effectively addressing child TSE.³³ Although currently underused,³⁴ multilevel approaches may be more effective than current approaches because they can capitalize on potential synergistic effects of repeated doses of advice and support across multiple sources of health messaging.³⁵ Resource and logistical challenges that contribute to the underuse of multilevel interventions can be addressed, in part, by embedding assessment prompts and clinical decision aids into routine

electronic health records (EHRs) and clinical workflow. Integrating assessments and decision aids within the EHR could improve the quality and standardization of clinic interventions for tobacco.^{36,37}

Moreover, linking such enhanced, clinic-level care to individualized behavioral health services via electronic referral can improve the current standard of care. To test this hypothesis, we examined the effects of a multilevel program (Kids Safe and Smokefree [KiSS]) that linked a primary care, clinic-level intervention with individual telephone counseling for child TSE reduction and parent smoking cessation. The clinic intervention was intended to provide a credible source of TSE information and motivational advice during teachable moments. Behavioral health phone counseling was designed to bolster clinic-level messaging while providing personalized skills training and support for smoking behavior change. We hypothesized that compared with an attention control intervention with just the clinic-level intervention (AAR and control), the multilevel KiSS intervention that combines clinic- and individual-level behavioral counseling (AAR and counseling) would demonstrate a greater reduction in child TSE (primary outcome) and higher parent quit rates (secondary outcome) at 3-month follow-up.

METHODS

Study Design Overview

In this study, we used a randomized, 2-group (experimental versus attention control) design with measurement at baseline and 3-month follow-up. Both groups received a clinic-level intervention following best practice guidelines. After referral, eligible participants completed consent and a structured, interviewer-administered baseline assessment by phone. Participants

were randomly assigned to a 12-week treatment in either (1) an experimental group (AAR and counseling), in which they received print materials and up to 5 sessions of telephone counseling, or (2) an attention control group, in which they received print materials and telephone nutrition education. Study design was guided by Consolidated Standards of Reporting Trials criteria³⁸ and approved by the appropriate institutional review boards.

Study Population

The study population included tobacco-smoking parents living in low-income, urban communities with children <11 years old exposed daily to tobacco smoke in the home. Population access was facilitated through partnerships with pediatric services in 3 large hospital systems in Philadelphia, Pennsylvania (Temple University Health System, Children's Hospital of Philadelphia, and St Christopher's Hospital for Children). Additional inclusion criteria included being a daily smoker, >17 years old, and speaking English. Exclusion criteria included pregnancy, psychiatric diagnosis, and daily consumption of >2 alcoholic beverages. Participants were enrolled from September 2012 to June 2015. The projected sample size was calculated by using ≥ 0.80 power with $\alpha = .05$ and assuming $\leq 25\%$ attrition.

Clinic-Level Intervention (AAR Prerandomization)

Clinic intervention objectives stressed the importance of AAR adherence to improve the quality of tobacco-exposed patients' care. The intervention aligned with the health systems' meaningful use of EHR and experts' calls for pragmatic EHR implementation.^{39,40} To achieve objectives, investigators did the following: (1) augmented providers' tobacco intervention training around TSE advice and the provision of NRT prescriptions to smoking parents; (2)

embedded assessment and decision aid prompts (AAR) in the routine, EHR-guided workflow to simplify actions for AAR adherence and link clinic operations with research protocols; (3) offered providers easily accessible, printed resources and direct fax referrals to evidence-based telephone counseling for smokers; and (4) provided feedback to clinic liaisons about providers' AAR adherence and participant successes with treatment.

Before intervention adoption and implementation, the principal investigators (PIs) and a pediatrician liaison at each site reviewed clinic operations, patient flow, and existing AAR practices to guide tailored modifications of clinic procedures. Then, EHR systems were modified. PIs initiated intervention adoption with training and clinic detailing by using KiSS branded posters, flyers, and brochures with AAR cues to action to promote adherence and social norms supporting child TSE protections. Intervention steps included asking all parents if their children were exposed to tobacco smoke, advising parents on TSE dangers and benefits of TSE protection, and providing self-help print materials and referral resources. Materials included the Environmental Protection Agency (EPA) brochure "Secondhand Smoke and the Health of Your Family" and an insert with referral resources (eg, Pennsylvania quitline number and information to access free NRT). Providers then faxed interested parents' contact information to the study staff.

Participant Assessment and Randomization Procedures

Trial assessments were conducted by telephone with bachelor's degree-level research assistants who were trained and supervised by a master of public health-trained project director. Research assistants completed ≥ 20 hours

of training and achieved $\geq 90\%$ fidelity on data protocols before conducting supervised assessments. The director monitored taped interviews to ensure $\geq 90\%$ fidelity maintenance. Referred smokers were screened for eligibility by telephone. Consented participants completed baseline assessment interviews by telephone before randomization. Randomization used a permuted block design of varying lengths with 2 strata (clinic site and race) and was seeded by the project statistician by using values obtained from www.random.org. Envelopes organized by strata concealed information until immediately before intervention assignment. Various procedures were used to reduce attrition, including reminder postcards and text messages, flexible scheduling, and financial incentives for completing the assessments. Assessment staff were blind to treatment assignment.

Telephone Interventions

Counselor Training and Supervision

Intervention staff included master's degree-level health counselors. They completed at least 1 month of training and live supervision around evidence-based cessation counseling methods and the KiSS TSE-reduction intervention with a doctoral-level intervention director and PI. Trained counselors participated in weekly supervision with the director and PI to review cases and record sessions against a treatment fidelity checklist to maintain $\geq 90\%$ protocol fidelity.

AAR and Behavioral Counseling (Experimental Condition)

The experimental (KiSS) intervention included the clinic-level AAR and manualized counseling over 12 weeks. Before beginning counseling, staff provided program orientation in participants' homes. Materials included a treatment binder, schedule, and copy of the EPA brochure with resource information to ensure its receipt even if clinics

did not provide a copy. The timing, structure, and content of sessions were guided by quitline best practices⁴¹ (eg, up to 5 sessions) and our previous child TSE-reduction counseling intervention (Family Rules for Establishing Smoke-free Homes).⁴² Session content consisted of evidence-based cognitive behavioral therapy strategies, including goal setting, self-monitoring, skills training, social support to guide child TSE-reduction efforts, and motivational interviewing techniques to facilitate a collaborative and personalized cessation plan.

Key counseling process objectives included (1) enhancing parents' perceived support for smoking behavior change, (2) developing smoking urge management coping skills, (3) building self-efficacy for child TSE protections and smoking cessation, and (4) navigating participants to acquire and properly use NRT. The intervention process was guided by the Family Rules for Establishing Smoke-free Homes intervention,⁴² associative learning principles, and ecological theories (eg, social cognitive theory and the behavioral ecological model).^{43,44} In this framework, counselors used behavioral shaping techniques to emphasize and reinforce effort toward TSE-reduction goals, maintain motivation, and build confidence in achieving more challenging, long-term cessation goals. For example, when praising a participant's recent TSE-reduction efforts, counselors described how those efforts not only met immediate child protection goals but also improved preparation for cessation later in treatment. Therefore, the emphasis of short-term goals progressed sequentially across sessions from early harm-reduction efforts to strategies promoting the maintenance of a smoke-free lifestyle.

AAR and Nutrition Education (Attention Control)

The control group received AAR and telephone-based nutrition education. The session structure was modeled after the experimental arm. At the home-visit orientation, staff provided to participants the EPA brochure, cessation referral, and NRT information to ensure its receipt. Participants also received Sesame Street's tool kit "Food for Thought: Eating Well on a Budget."⁴⁵ This kit included DVDs on nutrition guidelines, recipe cards, colorful books, activity suggestions, and videos on fruit and vegetable consumption for children.

Measures

Clinic-Level Intervention

At baseline, parents reported provider AAR adherence by responding "yes" or "no" to 3 questions about their last clinic visits: did the provider (1) advise about the dangers of TSE and benefits of reducing their children's exposure, (2) advise them to protect their children by avoiding smoking in their homes and cars, and (3) offer self-help print materials, including a brochure with information about secondhand smoke reduction, NRT, and smoking cessation resources?

Treatment Outcome Variables

Interviewers collected baseline and 3-month follow-up data via structured telephone interviews. TSE elimination and cessation outcome data were collected with validated time line follow-back methods that have been used in previous studies.^{46,47} Outcome variables were operationalized by using 7-day point prevalence abstinence criteria (eg, 0 child TSE from any sources inside or outside of the home; 0 cigarettes smoked during the 7 days before assessment). TSE elimination was coded 1 (successful elimination from all sources) or 0 (unsuccessful elimination). Point

prevalence abstinence was coded as 1 (quit success) or 0 (quit failure). In addition, prolonged abstinence was assessed to determine group differences in sustained abstinence⁴⁸ (defined as sustained abstinence after a 2-week post-quit-day grace period through the date of the 3-month assessment; coded as 1 [abstinence success] or 0 [abstinence failure]).

Potential Covariates and Counseling Process Variables

Interviewers collected baseline participant demographics (eg, age), smoking history (eg, nicotine dependence⁴⁹), and psychosocial variables (eg, depressive symptoms⁵⁰). Measures to assess the achievement of KiSS counseling objectives (manipulation check) were collected at 3-month follow-up. They included the following: (1) perceived counselor support for smoking behavior change was assessed by using a modified subscale of the Partner Interaction Questionnaire.^{51,52} This 11-item subscale assessed the frequency (1 [never] to 4 [often]) of perceived counselor support during treatment. Items were summed to create a composite score. (2) Urge management coping skills were assessed by using a modified version of O'Connell et al's scale⁵³ asking how often in the last week (1 [never] to 4 [often]) participants used any of 12 coping strategies instead of smoking when they felt an urge or craving. These 12 strategies corresponded to cognitive behavioral coping skills that counselors encouraged participants to practice and yielded 2 variables (the total number of coping strategies used [0–12] and the mean frequency with which they used them [1–4]). (3) Self-efficacy to quit smoking was assessed by using a version of DiClemente's cessation scale.⁵⁴ Participants indicated their level of confidence (1 [not at all sure] to 4 [very sure]) in resisting smoking in 12 tempting situations. Self-efficacy

to protect one's child from TSE was similarly assessed with a 3-item scale (eg, "How sure are you that you can create a smoke-free home?"). For both self-efficacy scales, items were summed to create a self-efficacy score. (4) Residential smoking restrictions were assessed by using a 4-item scale rating the degree of smoking rules in the home and car that were recoded 0 (no restrictions) or 1 (smoking restrictions enforced). (5) NRT acquisition and use was assessed by asking participants if they received an NRT prescription, used any NRT during treatment, and if so, whether they used NRT for least 2 consecutive weeks (yes or no).

Data Analysis

First, descriptive statistics were generated. After an evaluation of the missing data mechanism, we generated 100 multiple imputations to account for the missing data.⁵⁵ Baseline TSE, treatment condition, and variables associated ($P \geq .10$) with the probability of missing response variables (male sex, low income, younger child age, fewer previous quit attempts, and being the only smoker in the home) were included as covariates in the models, which were adjusted for clustering by hospital system. The number of cigarettes smoked per day and cigarettes a child was exposed to in the past 7 days from all sources were log transformed to normality. The primary hypothesis was tested by using multiple regression analyses with the intervention group as the predictor and adjusting for baseline TSE and appropriate control variables as well as treatment $\times$ baseline TSE interaction. Intention-to-treat analyses were used with 2-tailed $\alpha = .025$ because of the 2 primary outcomes, with results combined by using Rubin's rules for multiple imputation inference.⁵⁶ Sensitivity analyses⁵⁷ using listwise deletion were conducted and yielded identical substantive conclusions,

FIGURE 1
Participant flowchart through 3-month follow-up.

as did further models incorporating baseline adjustment for covariates.

RESULTS

Prerandomization, Clinic-Level Intervention Outcomes

Across clinics, 334 providers faxed 2949 referrals. Regarding AAR fidelity, 80.4% of participants reported that their referring providers advised them about TSE harms and the benefits of reducing TSE, 84.4% reported that their providers advised them to avoid indoor smoking, and 51.2% reported receiving print self-help and cessation resources in the clinics. Clinic liaisons reported sustained postenrollment AAR practices that had been implemented during the KiSS trial, with clinics referring smoking parents to the Pennsylvania state quitline instead of the trial quitline.

Participant Enrollment, Retention, and Baseline Characteristics

Figure 1 shows participant flow through 3-month follow-up. We were able to stop recruitment with a final sample size of 327 ($n = 163$, AAR and counseling; $n = 164$, AAR and control) because attrition (8.9% of total sample) was less than original projections. This sample size ensures ≥ 0.80 power to detect an r^2 change ranging from 0.03 to 0.05 (moderate effect size). When adjusting for clustering, there was not differential between-group attrition.

Table 1 shows participants' baseline characteristics. Even without Bonferroni correction for multiple comparisons, there were no between-group differences. Most parents were single, women, African American, living below the national poverty level, and had completed at least a high school education. Approximately half the sample reported significant depressive symptoms. Parents were moderately heavy smokers, with approximately half living with

TABLE 1 Baseline Participant Characteristics by Condition (*N* = 327)

Characteristic	AAR and Control (<i>N</i> = 164)	AAR and Counseling (<i>N</i> = 163)	<i>P</i>
Parent age, y, mean ± SD	33.9 ± 9.2	32.7 ± 7.9	.06
Female sex, %	81.1	85.9	.37
African American, %	84.1	83.2	.23
Married or living with partner, %	38.4	43.6	.07
Less than high school education, %	28.0	26.4	.77
Income below poverty level, %	78.7	78.5	.97
Significant depressive symptoms (CESD), %	50.0	52.1	.65
Other smokers in home (yes), %	47.0	45.4	.64
Nicotine dependence (FTND), mean ± SD	4.0 ± 1.9	4.2 ± 2.0	.14
Cigarettes smoked per day, mean ± SD	10.7 ± 5.8	12.2 ± 8.9	.13
Age started smoking, y, mean ± SD	17.4 ± 3.5	17.4 ± 4.3	.78
No. previous quit attempts ^a	2.3 ± 2.0	2.6 ± 2.7	.46
Child age, mo, mean ± SD	64.0 ± 33.9	64.5 ± 31.6	.51
Child female sex, %	47.0	51.5	.63
Cigarettes child exposed to (past 7 d, all sources) mean, ± SD	7.7 ± 7.8	8.6 ± 9.6	.32
Indoor smoking restrictions (yes), %	29.3	31.3	.58

CESD, Center for Epidemiologic Studies Depression Scale; FTND, Fagerström Test for Nicotine Dependence.

^a Winsorized.

another smoker and approximately one-third reporting indoor smoking restrictions. The sample of target children had nearly an equal number of boys and girls and a median age of 5 years. No adverse events were reported.

Children's TSE

Complete case analysis demonstrated that compared with control parents (29.9%), significantly more parents in the experimental condition (45.8%) eliminated their children's exposure to all sources of tobacco smoke both inside and outside their homes (odds ratio [OR] = 2.14 [95% confidence interval (CI) 1.61–2.85]; *P* = .001) at 3-month follow-up. Intention-to-treat logistic regression analysis was consistent with complete case analysis and demonstrated a significant effect of treatment on TSE reduction; parents in AAR and counseling were twice as likely to eliminate their children's TSE compared with parents in AAR and control (OR = 1.99 [95% CI 1.44–2.74]; *P* < .001). A sensitivity analysis suggested reliability of imputation methods and robustness of the between-group effect on elimination of TSE.

Parent Quit Status

A complete case analysis demonstrated that compared with control group parents (8.2%), significantly more parents in AAR and counseling (28.2%) reported 7-day point prevalence quit success (OR = 4.38 [95% CI 2.45–7.84]; *P* < .001) at 3-month follow-up. Intention-to-treat logistic regression analysis demonstrated a significant treatment effect; specifically, parents receiving AAR and counseling showed 3.78 greater odds of quitting smoking at 3 months compared with parent receiving AAR and control (OR = 3.78 [95% CI 1.51–9.52]; *P* = .005). A sensitivity analysis suggested reliability of imputation methods and robustness of the intervention effect. In addition, prolonged abstinence rates during treatment provided consistent evidence of between-group differences in smoking cessation; compared with control group parents, significantly more parents in the AAR and counseling group achieved prolonged abstinence (22.1% vs 6.3%; *P* < .001). Intention-to-treat and sensitivity analyses demonstrated a reliability and robustness of the treatment effect on prolonged abstinence (OR = 3.56 [95% CI 1.82–6.97]; *P* < .001).

Treatment Adherence and Counseling Manipulation Check

A nearly equivalent percentage of randomly assigned participants received treatment in the AAR and counseling group (90.2%) and the AAR and control group (87.8%). Most AAR and counseling participants achieved the adherence goal of completing ≥3 sessions (*M* = 3.35 ± 1.81), with 64% completing 5 sessions. Table 2 highlights the counseling process variables showing significant group differences; relative to the control group, the AAR and counseling group was more likely to implement home and/or car smoking restrictions and report a greater number of urge coping strategies used, greater frequency of coping strategy use, greater TSE protection, and higher cessation self-efficacy. There were no between-group differences in the low percentage of participants using NRT or obtaining NRT via prescription. However, among the 108 participants who reported any NRT use, more participants in AAR and counseling versus controls used NRT for at least 2 weeks.

DISCUSSION

The multilevel KiSS intervention (AAR and counseling) demonstrated efficacy in promoting child TSE reduction and parental smoking cessation in a low-income sample with significant psychosocial distress. Results suggested that a multilevel model integrating EHR-prompted, pediatric provider AAR with individualized telephone counseling is more likely to promote child TSE elimination and parent smoking cessation than clinic-level AAR only, which is the recommended, standard care (provider advice, self-help materials, and passive referral to cessation services). Importantly, study hypotheses were supported in a sample of smokers who were known to experience numerous

TABLE 2 Counseling Process Factors Affected by AAR and Counseling

Factor	AAR and Control	AAR and Counseling	P
Adopted smoking restrictions in home and/or car, %	82.3	96.3	<.001
Positive support from counselor, mean $\pm$ SD	2.74 $\pm$ 0.98	2.81 $\pm$ 1.14	.332
No. urge coping strategies used, mean $\pm$ SD	7.96 $\pm$ 4.82	9.23 $\pm$ 2.06	.001
Frequency of using coping strategies, mean $\pm$ SD	29.07 $\pm$ 9.75	33.30 $\pm$ 6.44	<.001
TSE protection self-efficacy, mean $\pm$ SD	9.94 $\pm$ 2.25	10.28 $\pm$ 1.83	.008
Cessation self-efficacy, mean $\pm$ SD	28.77 $\pm$ 10.32	31.51 $\pm$ 14.45	.013
Received NRT prescription, %	15.2	19.6	.447
Used any NRT, %	34.6	38.0	.490
Used NRT for $\geq$ 2 wks, %	35.2	55.6	.026

challenges to access to, engagement, and success in smoking interventions.

To our knowledge, this trial is the first in which researchers test the efficacy of a multilevel tobacco intervention in pediatric primary care that takes advantage of EHR systems. The EHR-driven, clinic-level intervention seems highly feasible and acceptable, as indicated by the high number of referrals in a short period of time and generally good compliance with the AAR protocol among clinicians. The relatively low adherence to the passive referral protocol (EPA brochure with resources) may have been a training issue: during clinic debriefings, we discovered that some providers misunderstood instructions on how to offer the material to all smoking parents and offered it only to parents who were not interested in being referred to the study. However, study procedures ensured that every parent in the study received these print materials at the treatment orientation.

The counseling process data and low participant attrition suggest that the KiSS intervention was acceptable to participants and consistent with previous research on quitlines targeting broader populations.^{58,59} KiSS telephone counselors achieved most process objectives to promote greater social support, self-efficacy, urge management skills, and indoor smoking restrictions. Together, our successful clinic treatment implementation, low attrition, counseling process data, and smoking

outcome results suggest that our clinic and telephone counseling intervention strategies could inform improvements in pediatric practice and state quitline services. The KiSS multilevel intervention put a minimal burden on providers but offered counseling, support, and skills training in a pragmatic package that simultaneously addressed pediatric- and adult-related public health priorities. As such, the KiSS model could become an effective standard of care for smoking parents.

Results also suggested that ongoing treatment improvements are needed to boost providers' NRT prescription practices and facilitate parents' NRT acquisition. These results are consistent with previous research demonstrating a low uptake of NRT in similar populations.^{60,61} However, among parents who did acquire NRT, the KiSS intervention participants were more likely than controls to use NRT for at least 2 weeks. Because NRT is effective for smoking cessation^{62,63} and adding counseling to NRT further bolsters success,⁶⁴ researchers in future interventions with underserved smokers should consider a direct provision of NRT, an approach that is consistent with quitline best practices guidelines.⁴¹

Our study had some limitations. Timing and funding capacity precluded the opportunity to assess baseline AAR practices and whether our provider training and EHR decision aid boosted AAR adherence. However, other research has demonstrated how the strategic use

of EHR systems can improve clinical practice and patient care,⁶⁵ and our previous trial suggests that provider training similar to the KiSS clinic intervention improves AAR adherence and boosts smokers' quit rates.⁶⁶ Other limitations include the short-term follow-up and lack of resources to bioverify TSE reduction and quit status at 3 months. Although other research supports the validity of self-reported smoking data,⁶⁷ the bioverification of self-report would strengthen results. Despite these limitations, our results are highly encouraging given the parallels between the KiSS multilevel treatment model and the emerging standard of care. Moreover, the future completion of our posttreatment, 12-month follow-up data and analysis will include child cotinine and parent cessation bioverification. These data will also facilitate theory-driven secondary analyses of factors that could moderate (eg, employment status and other smokers in the home) or mediate (eg, self-efficacy and social support) the effects of the KiSS intervention on TSE and cessation outcomes.

Future advances in multilevel tobacco interventions could build on our formative efforts and strategies used in the KiSS trial. For example, the KiSS model was designed to be consistent with the National Institutes of Health roadmap to advance the science of behavior change by testing multilevel approaches that address multifactorial influences on nicotine dependence simultaneously and over time.^{33,44} Our trial was informed by a decade of work examining pediatric providers' guideline adherence,^{26,27,29} testing individualized counseling and behavioral shaping strategy for TSE reduction and cessation among underserved smoking parents,⁴² and applying theory-based intervention strategies within the clinical trial methodology.⁶⁸ Finally, the

integration of health education and messaging across intervention levels in the KiSS multilevel intervention was guided by research⁶⁹ suggesting that coordinated efforts across different levels of influence (eg, systems, clinic, individual levels) can encourage cross-systems health messaging, thereby increasing the dosage of advice and support that can lead to improved intervention access, engagement, and outcomes compared with single-level intervention approaches. Importantly, by re-emphasizing and intertwining providers' AAR messaging within the KiSS multilevel intervention, the AAR and behavioral counseling interventions complement and strengthen one another. Such actions could result in additive treatment effects through their integration, as our results suggest.

CONCLUSIONS

There is no safe level of TSE,⁷⁰ and low-income, underserved

populations of smokers require intensive intervention. The multilevel KiSS intervention demonstrates efficacy in affecting smoking behavior change in a low-income, distressed sample of adult smokers. It represents a portable, multilevel intervention model that improves the quality of pediatric patient care and informs quitline best practices. It is also a sustainable model, as evidenced by the KiSS partnering clinics' maintenance of AAR processes initiated by the KiSS trial but continued with referral to the state quitline. Therefore, the KiSS model could become a new standard of care for underserved populations of smokers. It could also be implemented more broadly through mutually advantageous partnerships between publicly supported smoking cessation providers (eg, state quitlines) and large community health systems (eg, the Supplemental Nutrition Program for Women, Infants, and Children and Head Start) that serve vulnerable families.

Implementing the KiSS model nationally in pediatric health systems could lead to significant public health benefits by reducing the health and cost burdens associated with child TSE in populations that are known to have excess tobacco morbidity and mortality, thereby fulfilling the goals of Healthy People 2020, the American Academy of Pediatrics, and the National Institutes of Health.

ABBREVIATIONS

AAR: ask, advise, refer
 CI: confidence interval
 EHR: electronic health record
 EPA: Environmental Protection Agency
 KiSS: Kids Safe and Smokefree
 NRT: nicotine replacement therapy
 OR: odds ratio
 PI: principal investigator
 TSE: tobacco smoke exposure

control, and research staff training protocols, and reviewed and revised the manuscript; Dr Winickoff contributed to the conceptualization and design of the clinic-level intervention, assisted with efforts to implement the intervention at partnering sites, and reviewed and revised the manuscript; Dr Nair assisted with the implementation of intervention protocols and the training and supervision of health counselors; Dr Moughan facilitated clinic intervention adoption, implementation, and maintenance at Temple University Health System's pediatric clinic; Dr Fleece oversaw modifications to Temple University Health System's electronic health record and assisted in the implementation of the clinic intervention; Dr Bryant-Stephens facilitated the adoption, implementation, and maintenance of the clinic intervention at Children's Hospital of Philadelphia clinics and facilitated modifications to their electronic health records; Dr Taylor facilitated the adoption, implementation, and maintenance of the clinic intervention at St Christopher's Hospital for Children (Drexel University) clinics and facilitated modifications to their electronic health records; Dr Davey designed the analysis plan, oversaw randomization procedures, and conducted statistical analyses; Ms Godfrey facilitated and managed the adoption and maintenance of data collection, data entry, and data-quality protocols; and all authors approved the final manuscript as submitted.

This trial has been registered at www.clinicaltrials.gov (identifier NCT01745393).

DOI: <https://doi.org/10.1542/peds.2017-1026K>

Accepted for publication Sep 6, 2017

Address correspondence to Bradley N. Collins, PhD, Department of Social and Behavioral Sciences, 1301 Cecil B. Moore Ave, 949 Ritter Annex, Philadelphia, PA 19122. E-mail: collinsb@temple.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Supported by Temple University. Funded by the National Cancer Institute, National Institutes of Health, grant CA158361. Funded by the National Institutes of Health (NIH).

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

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