Title:	**Electronic Pediatric Office Systems to Support Treatment for Parental Tobacco Use**
Short Title	eCEASE
Drug or Device Name(s):	N/A
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Statistical Analysis plan.

Primary outcome: Parental 7-day quit rates, as assessed by validated surveys and biochemically- confirmed at 12-months, compared between iEHR+Navigator and usual care control arms. The study is powered for this outcome.

The primary outcome will compare the parental combusted tobacco cessation, biochemically confirmed between the intervention arm (iEHR + Navigator) vs. usual care control. For cotinine confirmed quitting, only self-reported non-smokers who have cotinine values <10 ng/ml, a consensus cutoff level, will be considered quit. Parents on NRT, or e-cigarettes, or who fail the cotinine test will be asked to have their carbon monoxide (CO) levels tested, to confirm self-reported smoking cessation. For CO confirmed quitting, expired-air CO cutoff level of < 5ppm will be considered quit. E-cigarette use will be noted and analyzed separately as the literature emerges.

In our intention-to-treat analysis, all participants lost to follow-up will be considered smokers. We will also use multiple imputation techniques, as appropriate to impute missing data. We will used generalized linear mixed-effects models (Gaussian, logistic, or Poisson, as appropriate) to compare the primary outcome between arms. To the extent allowed by the sample, we will build a logistic regression model that includes potential confounding factors, particularly those that are unbalanced between iEHR+Navigator vs usual care control groups to compare the parental 7-day quit rates. We will attempt to identify predictors of parental quitting to determine whether any of these factors modify intervention effect. To determine whether the intervention effect differs among subgroups, we will test the interaction between intervention group and these predictors. Specifically, to the extent allowed by our sample size, exploratory analyses will compare quit rates in subgroups of smokers characterized by cigarettes per day, e-cigarette use, number of smokers in the home, demographic variables (parent sex, age, race, education, child age) and treatment use. We will conduct a difference in difference analyses from baseline to follow up to evaluate the effect of the intervention on changes in smoking related factors like mean cigarettes per day and daily smoking rates.

Secondary outcomes

1. **Rates of smokefree homes and cars, use of NRT and duration of use, and quitline enrollment, as assessed by validated surveys of parents, will be compared between iEHR+Navigator and usual care control arms.** Change in parental smoking inside homes and cars, use of NRT, and receiving services from cessation programs will be based on the baseline and 12-months enrollment visit, comparing change from baseline to 12 months between intervention groups and usual care control practices. We will follow a similar analysis strategy to that stated above in primary outcome analysis.

2. **Establish the incremental cost per quit of intervention.** The healthcare system's perspective is central to establishing the interventions' disseminability and sustainability. As a secondary analysis, we will consider costs from a societal perspective to pave the way for future cost-utility analyses. We will calculate the incremental cost per quit of the iEHR+Navigator intervention relative to usual care, as we have done in prior studies: (Total cost at 12 months $_{arm[i]}$-Total costs $_{arm[j]}$)/(Total biochemically confirmed quits at 12 months $_{arm[i]}$-Total biochemically confirmed quits at 12 months $_{arm[j]}$). Development costs for iEHR will not be included in primary analyses as the iEHR will be fully developed and ready for dissemination by the time the intervention begins. Direct costs include iEHR set-up, customizing, implementing, and sustaining the systems changes that support service delivery and cessation, electronic tablets, and related clinician work. Direct costs further include: the CEASE intervention staff time to support the practice leader and the time clinicians and office staff take to learn and use the online module. Time use will be tracked by administrative records, direct observation by the RA, and surveys. For the iEHR+Navigator arm, we will create a log to note the types of CHN outreach efforts, time spent, and the type of services delivered to smoking parents. Personnel costs will reflect national average wages for each personnel type. We will use Monte Carlo simulation methods to develop confidence bounds on our cost-per-quit estimates. Following standard methods of economic evaluation in prior studies, we will also perform parameter-specific sensitivity analyses in which individual parameters are varied singly and in combination, through plausible ranges to assess the relative impact different elements of the program have on overall cost-effectiveness.

3. Assess the implementation and sustainability of the intervention in the iEHR + Navigator arm **NRT prescription, quitline referral, and smokefree homes and cars will be compared between iEHR+Navigator vs. usual care control, as assessed by parental surveys at 12-months, and by EHR documentation data at, before, and immediately following implementation at 6,12, 18, 24, 30, and 36 months (documentation of screening and services delivery fidelity, coding, and billing).** We will follow a similar analysis strategy to that stated above in primary outcome analysis. We will compare cessation assistance delivery at 6 months intervals for 3 years using EHR documentation data. We will analyze qualitative interview data from the combined RE-AIM/CFIR interviews conducted at before and following implementation, and at 12, and 24 months. The interview data will be coded and thematically analyzed in order to gain clarity on implementation processes and intervention sustainability. The interview data will inform future implementation and sustainability efforts.