Helping the Poor Quit Smoking: Specialized Quitlines and Meeting Basic Needs

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Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.

Aim 1: For each group, descriptive statistics will show the proportion of baseline participants reached by the quitline, number of quitline sessions completed, and additional services (Print, Text2Quit, WebCoach) used. Differences by group will be compared using chi-square tests or logistic regression for categorical variables and by t-tests, linear regression or appropriate non-parametric tests for continuous variables. Secondary analyses will explore any differences by covariates such as gender, age, rural/urban residence, and unmet basic needs. Significant intervention and/or covariate effects will be included in all further analyses.

Aim 2: We will calculate quit rates for each group by dividing the number of participants who meet this criterion by the number of participants randomized to that group. Analysis will follow intent-to-treat (ITT) principles; all participants who completed a baseline assessment and were randomized will be included in analysis. Those lost-to-follow-up, refusing interviews, or otherwise unreachable will be assumed to be smokers. We will use logistic regression to compute odds ratios and 95% confidence intervals for group differences in quit rates, comparing Standard and Specialized Quitlines with and without a Basic Needs Navigator, with the "standard quitline, no navigator" group as the referent.

We will conduct analyses of secondary outcomes (7 and 30 day point prevalence abstinence, >24 hour quit attempt, use of pharmacotherapy, participation in cessation counseling) at 3 and 6 month follow up. Consistent with other reports in the literature, we also will compare the results from self-reported smoking cessation to results that adjust for biochemical validation.215 First, we will consider all participants who fail the biochemical validation and those that did not return a saliva sample to be smokers and recalculate abstinence rates by group. Second, we will recalculate abstinence rates by group, assuming that the true smoking cessation rate of participants who do not complete a follow up survey or do not return their saliva samples is the same rate as for those who did return a sample.216,217 Additionally, we will explore differences between people who do and do not agree to receive a kit and do and do not return a saliva sample. Analyses will be repeated with multiple logistic regression to include

potential baseline covariates (e.g., socio-demographics, rural/urban residence, nicotine dependence, readiness to quit). Cases with missing data on covariates will be excluded from analyses.

We also will conduct a series of sensitivity analyses to evaluate the robustness of our findings. To assess effects of protocol deviations, we will compare results of per-protocol analyses to ITT analysis. We will examine quit rate differences by intervention "dose" (i.e., number of completed quitline calls, number of navigator contacts), number of unmet basic needs, demographics, and smoking variables assessed at baseline, and extent of problem resolution at 3- and 6-month follow-up. We will assess the effect of missing data by comparing ITT results to a complete case (all data available at 6-month follow-up) analysis.

1.23 Provide the rationale or power analysis to support the number of participants proposed to complete this study.

To be consistent with national reporting guidelines and evidence reviews, the primary cessation outcome will be 7-day point prevalence abstinence measured at 6-months post-baseline. With a baseline sample of 2000 smokers (500 per group) we will have sufficient power for detecting a 5% difference in quit rates between our most intensive condition (Specialized Quitline with Basic Needs Navigator) and least intensive (standard quitline without basic needs navigator) condition for a range of possible quit rates in the sample as a whole. Quit rates were based on the range of 6-month cessation rates from previous Alere clients. We conservatively expect to reach at least 60% of baseline participants at 6-month follow-up, leaving a total sample of at least 1,200 smokers. We would still have sufficient power to detect a 5% difference between groups if OR=1.8 with a total quit rate of 10%, and even greater power for lower quit rates and for intent to treat analyses that include all randomized participants, because non-respondents are assumed to have continued smoking thus overall quit rates would be lower.