Title:	BE Smokefree: Behavioral Economics Incentives to Engage Adolescents in Smoking Cessation
Short Title	BE Smokefree
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ABBREVIATIONS AND DEFINITIONS OF TERMS

NCI	National Cancer Institute
PeRC	Pediatric Research Consortium
WTH	Way to Health Platform
EHR	Electronic Health Record
DBHi	Department of Biomedical and Health Informatics

ABSTRACT

Context:

Cigarette smoking remains a leading preventable cause of death in the US with substantial morbidity, mortality, and financial costs each year. More than 90% of adult smokers initiate tobacco use before age 18, making prevention and treatment of adolescent smoking a critical health priority. Behavioral economic interventions utilizing financial incentives can promote smoking cessation in adult populations. No studies have evaluated financial incentives among adolescents to promote engagement in effective smoking cessation programs through primary care settings.

Objectives:

Primary Objective: To compare, through a pilot, randomized controlled trial, an intervention incentivizing contact with the Quitline, an intervention incentivizing quitting, or no financial incentive intervention on adolescent smoker enrollment and depth of engagement in a smoking cessation program (Free Smoker Quitline).

Secondary Objective: To compare cotinine-confirmed 2-month quit rates across the 3 groups, among users who report abstinence.

Study Design:

This is a randomized controlled trial of a quitline incentive vs smoking cessation incentive vs no financial incentive on adolescent engagement with a smoking cessation program.

Setting/Participants:

Setting: Primary care sites within CHOP's Pediatric Research Consortium along with other non-clinical community settings.

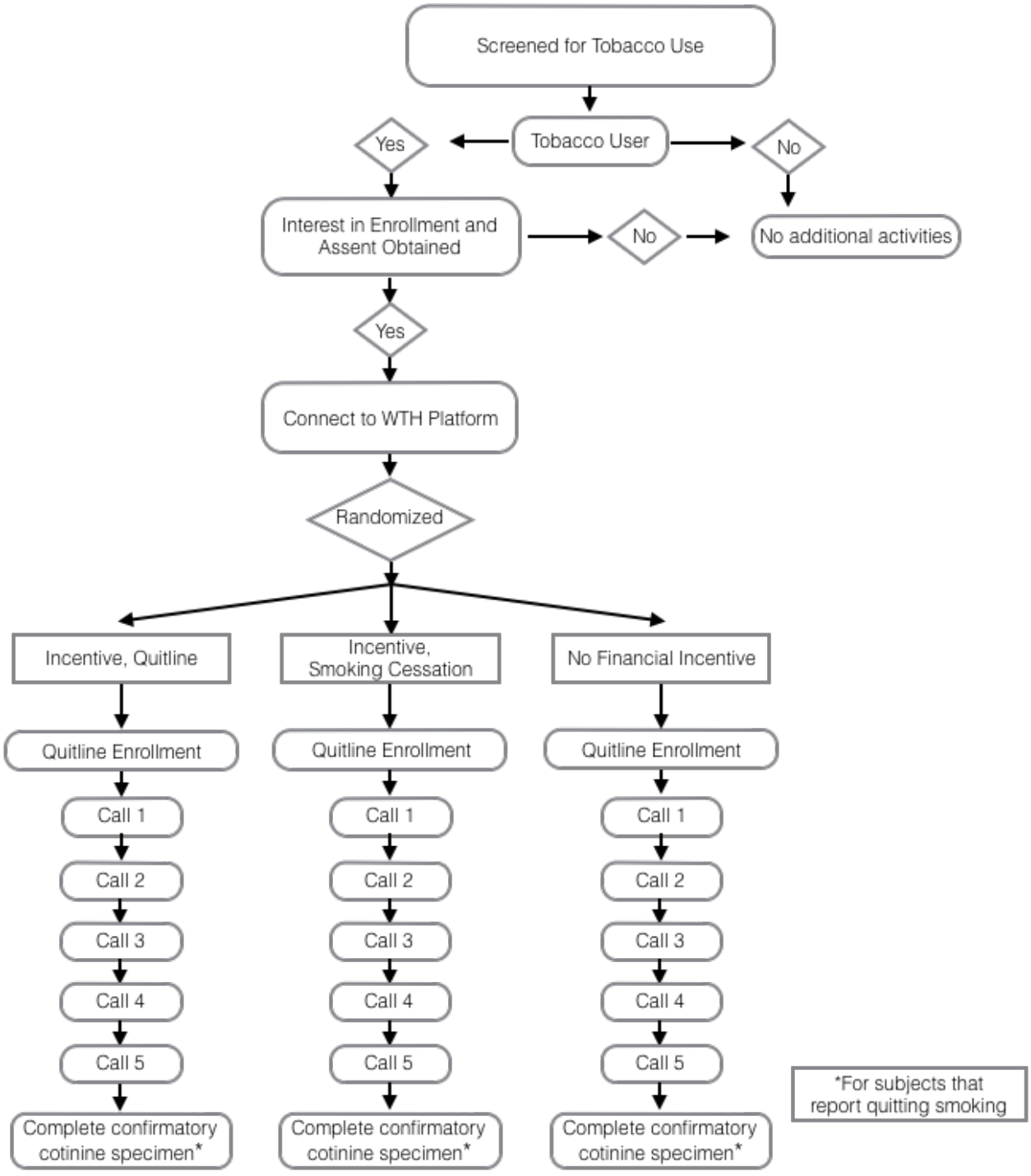
60 adolescent smokers will be recruited. Eligibility criteria include adolescents (aged 14-21 years), who speak English, live in Pennsylvania, screen positive for tobacco use, are interested in quitting, and have a smart phone.

Study Interventions and Measures:

Adolescents will be randomized to 1 of 3 financial incentive groups: (1) Quitline Incentive: the payment structure emphasizes engaging with the quitline, with an additional smaller payment for smoking cessation; (2) Smoking Cessation Incentive: the payment structure emphasizes quitting regardless of engagement with the quitline (though the quitline will be presented as a helpful tool); and (3) no financial incentive. The Quitline is funded by the Pennsylvania Department of Health and staffed by trained cessation counselors available 24 hours a day, 7 days a week.

Outcomes Measures: Objective 1: The main outcome of interest is adolescent smoker completion of the smoking cessation program, defined as the proportion of smokers identified in the clinic that enroll, use, and complete the Quitline program compared across the 3 groups. Objective 2: The secondary outcome is to confirm abstinence, via salivary cotinine concentration of <30 ng per milliliter at 10 weeks after the start of the study.

FIGURE 1: STUDY DIAGRAM



1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Cigarette smoking remains a leading preventable cause of death in the US with substantial morbidity, mortality, and financial costs each year.[1] Nearly 20% of US adolescents smoke cigarettes or use other tobacco products like e-cigarettes,[2] 80% of youth who initiate smoking transition to regular use by young adulthood,[3,4] and more than 90% of adult smokers initiate tobacco use before age 18, making prevention and treatment of adolescent smoking a critical health priority.[1] Further, e-cigarettes are now the most common tobacco product used by teenagers, and adolescent use of e-cigarettes is strongly associated with transition to cigarette use.[5] Pediatricians see the majority of the US child and adolescent population,[6] and adolescents view pediatricians as trusted sources for credible health information.[7] Consequently, pediatricians are uniquely positioned to screen for tobacco use in their patients, initiate treatment, and connect adolescents to smoking cessation services.[8,9]

While evidence-based smoking cessation programs for adolescent tobacco use are available, including the quitline, text messaging, mobile phone apps and web-based programs, they are underutilized by teenagers.[10-14] Although most youth smokers want and attempt to quit, few seek assistance to do so.[8,15] Consensus guidelines and the US Preventive Service Task force emphasize that clinician counseling can initiate behavior change in adolescent tobacco users and effectively educate them about available smoking cessation resources.[16,17] A critical knowledge gap is how to best to translate screening into effective service receipt and quitting.[8,17]

Behavioral economics applies economic, marketing and psychological principles, such as framing, present bias, and loss aversion, to overcome barriers to behavior change. Behavioral economic interventions utilizing financial incentives have been used to promote smoking cessation in adult populations.[18,20,22,23,24] Among adolescents, a systematic review of financial incentives for smoking cessation suggests potential for promoting abstinence.[22] To our knowledge, no studies have evaluated use of financial incentives among adolescents to promote engagement in effective smoking cessation programs through pediatric healthcare settings.[25]

1.2 Name and Description of Intervention

Way to Health (WTH) Platform: Way to Health is a web-based platform that automates many of the research functions necessary for conducting randomized controlled trials of healthy behavior interventions. This was designed by faculty and staff at the LDI Center for Health Incentives and Behavioral Economics (CHIBE) at the University of Pennsylvania to create an efficient, scalable, and low-cost way to test behavioral interventions using a platform that can be deployed anywhere in the United States. The WTH platform uses secure, high-performance servers that have the necessary security protections to permit storage and analysis of data containing protected health information. Further, the WTH platform has secure financial tracking and processing systems to manage participant payments, including the ability to track earnings and pay participants via a non-integrated payment system (ClinCard) ideally suited for adolescent subjects.

2 STUDY OBJECTIVES

The purpose of the study is to determine if financial incentives for adolescent smokers compared to no financial incentive increases engagement in a smoking cessation program.

2.1 Primary Objective (or Aim)

The primary objective of this study is to compare, through a pilot, randomized controlled trial, an incentive for Quitline engagement, an incentive for smoking cessation, or no financial incentive intervention on adolescent smoker enrollment and depth of engagement in a smoking cessation program (Free Smoker Quitline, hereafter referred to as the Quitline).

2.2 Secondary Objectives (or Aim)

The secondary objective is to compare cotinine-confirmed 2-month quit rates across the 3 groups, among users who report abstinence at the 10-week follow-up call.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a randomized controlled trial of financial incentives on adolescent engagement with a smoking cessation program (Quitline).

3.1.1 Screening Phase

Potential adolescent subjects will be screened using the protocol inclusion and exclusion criteria. Adolescent smokers may be identified at their primary care visit through standard screening approaches embedded within the electronic health record (EHR) (Epic®) at PeRC study sites. Adolescent smokers may also be identified through outreach facilitated by the CHOP Research Enhancement Core (REC).

Adolescents will be recruited in one of three ways:

1. Adolescents who screen positive for tobacco use at their primary care visit (defined as having smoked cigarette(s) and/or used an e-cigarette on at least 1 day during the 30 days before the clinical encounter) and are interested in treatment will be approached over the phone (with a potential introductory text message) by the study team to gauge interest in participating and obtain consent either electronically or over the phone and confirm participant eligibility.
2. Adolescents who contact the study team as a result of outreach facilitated by the REC will be screened by the study team. The team will describe the study, inform prospective participants of the eligibility requirements, and ask the prospective participants if they are still interested in participating. If interested, the study team will obtain consent either electronically or over the phone and confirm participant eligibility.
3. Facilitated by REC, advertisements with study information, including eligibility requirements and an embedded REDCap link, will be distributed at schools, CHOP

primary care clinics, and other non-clinical community settings (for example, a commercial entity like convenience stores). Adolescents who are interested in learning more can go to the REDCap link where they will provide consent electronically and then be screened for eligibility. Permission will be obtained from the school principle or non-clinical community setting building owner/proprietor before any recruitment materials are distributed. The research presents minimal risk to participants and involves no procedures for which written consent is normally required outside of the research context.

3.1.2 Study Treatment Phase

Following adolescent consent, subject information (name and smart phone number) will be sent to the intervention delivery platform, called the Way to Health (WTH) platform, using secure, HIPAA-compliant methods for the transmission of protected health information.

The WTH platform will help with management of the financial incentive interventions.

Adolescent subjects will enroll in the smoking cessation program – the Quitline. Adolescents will continue in the program for 10 weeks, depending upon their individual needs. See Section 7 description for full details on Quitline delivered treatment.

3.1.3 Follow-up Phase

To be eligible for the follow-up phase, adolescents must self-report tobacco cessation. All study subjects will be contacted by the study team 10 weeks after study enrollment to inquire about smoking cessation (defined as no tobacco use in the last 30 days). For subjects that report quitting, to confirm cessation, subjects will complete a salivary cotinine specimen. The result will either be collected at the clinic or collected remotely, in the latter case performed in front of a live video-conference with a study staff member to confirm adherence. The result can be reported immediately.

3.2 Allocation to Treatment Groups and Blinding

Randomization to the 3 groups will be based on an automatically generated randomization sequence (block randomization stratified by cigarette or e-cigarette use), managed through the Way to Health (WTH) Platform.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration per subject will be up to 12 weeks, with 1 day for screening, up to 10 weeks for the treatment phase, and 1 day for follow-up. 2 additional weeks are allotted to coordinate both initial enrollment in the quitline and remote follow-up with the adolescent.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at primary care sites within CHOP's Pediatric Research Consortium (PeRC). Subjects may also be recruited through study materials distributed at up to 2 schools and posted in up to 10 other non-clinical community settings (for example, a commercial entity like convenience stores). Permission will be obtained from the school

principle or non-clinical community setting building owner/proprietor before any recruitment materials are distributed.

Recruitment will stop when approximately 60 subjects are enrolled. It is expected that approximately 70 subjects will be enrolled to produce 60 evaluable subjects.

3.4 Study Population

3.4.1 Inclusion Criteria

Inclusion criteria include adolescents (aged 14-21 years), male or female, who speak English, live in Pennsylvania, screen positive for tobacco use (defined as having smoked cigarette(s) and/or used an e-cigarette on at least 1 day during the past 30 days), are interested in quitting smoking, have a smart phone, and provide consent to participate.

3.4.2 Exclusion Criteria

Subjects that do not meet all of the inclusion criteria will not be enrolled.

4 STUDY PROCEDURES

4.1 Screening Phase

4.1.1 Screening at Primary Care Visit

Adolescent cigarette or e-cigarette users may be identified at their primary care visit through standard screening approaches embedded within the electronic health record (EHR) (Epic®) at PeRC study sites. The screening procedure will also include an option to receive text messages about the study (with notice that standard text messaging charges may apply). Adolescents who screen positive for tobacco use and are interested in treatment will be approached by the study team (after the clinic visit via phone call or via text message if the individual opted in to receiving text messages about the study) to gauge interest in participating and obtain consent. Adolescents who have given permission to receive a text may be sent the following introductory message:

"Hi this is [NAME] from CHOP contacting you about a paid research study you might be eligible for. Click here to learn more: [insert REDCap link]

REDCap will be used to track attempts to contact prospective participants in an organized, secure way. The information abstracted from the EHR will be entered into REDCap. The study team will use this information to contact eligible adolescents and to document the date, time, and outcome of all contact attempts. This database will be separate from the main study database and will not be used for any purposes other than managing contact attempts.

- Primary Care Visit: Screening for Tobacco Use (using standard approaches)
- Medical Record Review
- Adolescent Consent (either electronically or over the phone)

4.1.2 Screening by the Study Team

Adolescent smokers may also be identified through outreach facilitated by the CHOP Research Enhancement Core (REC). REC communications will contain information about the study, an embedded link to electronic consent and screening questions, and the study team contact information (name, e-mail, phone number). This provides the option for those interested in the study to reach out to the study team directly or complete consent and study screening electronically.

Adolescents who contact the study team as a result of outreach facilitated by the REC will be screened in one of two ways:

1) Screening by the study team: the team will describe the study, inform prospective participants of the eligibility requirements (listed in section 3.4.1), and ask the prospective participants if they are still interested in participating. If interested, the study team will obtain verbal consent. After providing verbal consent, they will be asked to verbally answer screening questions to ascertain eligibility.
2) Screening electronically: the adolescents will receive an electronic consent form, which will inform the prospective participants of the eligibility requirements (listed in section 3.4.1), and ask the prospective participants if they are still interested in participating. If interested, they will provide electronic consent. After providing electronic consent, they will be asked to answer electronic screening questions to ascertain eligibility.

REDCap will also be used to track contacts by the study team with this group of adolescents. This database will be separate from the main study database and will not be used for any purpose other than managing contact attempts.

4.2 Study Treatment Phase

Adolescents who screen positive for tobacco use and are interested in treatment will be referred to the WTH platform. Following consent, subject information (name and mobile phone number) will be sent to WTH using secure, HIPAA- compliant methods to transmit protected health information.

- Connect to WTH Platform, randomized to 1 of 3 groups (incentive for Quitline engagement, incentive for smoking cessation, or no financial incentive)
- Enroll in smoking cessation program (the Quitline)
- Participate in the Quitline program (up to 5 coaching calls with the Quitline, every 1-2 weeks, depending upon individual subject needs)

4.3 Follow-up Phase

To confirm cessation, adolescents will complete a salivary cotinine specimen either collected in the clinic with a study team member or collected remotely. In the latter case, performed in front of study team member via a live-video conference.

4.4 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. It will be documented whether or not each subject completes the clinical study.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Medical Record Review

Adolescent smokers will be identified through standard screening approaches embedded within the electronic health record (EHR) (Epic®) at PeRC study sites or through outreach facilitated by the REC. Variables abstracted from the EHR may include the following, some of which will be used solely for contact/recruitment purposes and some of which may also be stored in the main study data base (as noted below):

- Patient name (stored in main study data base)
- Patient date of birth and age (stored in main study data base)
- Patient MRN (contact/recruitment only)
- Patient sex (stored in main study data base)
- Patient insurance status (as a proxy for Socioeconomic Status) (contact/recruitment only)
- Patient race/ethnicity (stored in main study data base)
- Patient tobacco use (stored in main study data base)
- Patient email address (stored in main study data base)
- Adolescent mobile/smart phone number (stored in main study data base)
- Parent name (contact/recruitment only)
- Parent mailing address (contact/recruitment only)
- Parent email address (contact/recruitment only)
- Parent phone number (contact/recruitment only)

If non-CHOP patients are enrolled in this study, their medical records will not be accessed. Any participant information needed for the study will be collected by directly asking the participant.

5.1.2 Laboratory Evaluations

- Salivary cotinine measurement
    - Smoking cessation abstinence will be biologically confirmed by a salivary cotinine measurement at 10 weeks after study initiation, with a concentration of <30 ng per milliliter as a threshold.[26,27]

- Subjects will use a salivary swab measurement that they are able to perform on their own that immediately reports the measurement.
- This will be performed either in front of a study team member at the primary care clinic or in front of a study team member via a video-conferencing session.
- No videos will be recorded. The specimen will be thrown away by the subject immediately after the result is noted.

5.2 Efficacy Evaluations

The main outcome of interest is adolescent smoker completion of the smoking cessation program, defined as the proportion of smokers identified in the clinic that enroll, use, and complete the Quitline program compared across the 3 groups.

The secondary outcome is to confirm abstinence, via salivary cotinine concentration of <30 ng per milliliter at 10 weeks after study initiation.

5.3 Safety Evaluation

This study presents no more than minimal risk to study participants, as this is a study aimed to improve adolescent cigarette or e-cigarette user engagement in a smoking cessation program. Adolescents smokers can already access the particular program – the Quitline – free-of-charge.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The main outcome of interest is adolescent cigarette or e-cigarette user completion of the smoking cessation program, defined as the proportion of smokers identified in the clinic that enroll, use, and complete the Quitline program compared across the 3 study arms.

6.2 Secondary Endpoints

The secondary outcome is to confirm abstinence, via salivary cotinine concentration of <30 ng per milliliter at 10 weeks after study initiation.

6.3 Statistical Methods

6.3.1 Baseline Data

Characteristics of subjects in all 3 groups of the study will be described with proportions for categorical variables and means and standard deviations for continuous variables.

6.3.2 Efficacy Analysis

We will calculate proportions for the clinical outcomes (enrollment, use, and completion of the Quitline program) and evaluate the magnitude and statistical significance of differences between the 3 groups. Intention-to-treat analysis will be used so that subjects will be analyzed according to the group to which they were initially randomized. Secondary analyses will describe results for participants as-treated. Categorical variables will be compared between groups using chi-square tests. Multivariable logistic regression models (that potentially include confounding variables) will be used to compare quit rate between groups. These models will include indicator variables for each of the financial incentive groups; the no financial incentive group will be the reference. The treatment groups will differ significantly from usual care if its indicator variable differs significantly from zero (p-value < 0.05 as criterion for statistical significance in a likelihood ratio or Wald's test). A Wald's test of the hypothesis that the two indicator variables are equal will also be performed (hypothesis that the probability of a subject quitting is the same for both financial incentive groups). We will explore for potential confounding by referral bonuses in the models and adjust if necessary.

6.3.3 Safety Analysis

As this study presents no more than minimal risk to study participants, a safety analysis will not be performed. If any safety risks are realized, see section 8.2 for adverse event reporting.

6.4 Sample Size and Power

The goals of this pilot project are feasibility and estimation of effect size and, therefore, no formal sample size calculations are performed. We anticipate 20 participants per group (60 total) will provide sufficient data to determine effect sizes to power a future larger grant.

7 STUDY INTERVENTION

7.1 Description

Intervention: Subjects will be randomized within the WTH platform to 1 of 3 financial incentive groups:

1) Quitline Incentive: the payment structure emphasizes engaging with the quitline, with an additional smaller payment for smoking cessation. Each adolescent can receive $15 payments for enrolling in the quitline, for maintaining involvement in the quitline program ($15 per call for up to 5 calls), and, for those reporting abstinence, $20 for submitting the cotinine swab and $25 for confirmed quitting (negative cotinine swab);
2) Smoking Cessation Incentive: the payment structure emphasizes quitting regardless of engagement with the quitline (though the quitline will be presented as a helpful tool). Each adolescent will receive $15 for enrolling in the quitline and, for those reporting abstinence, $20 for submitting the cotinine swab and $100 for confirmed quitting (negative cotinine swab); and
3) No financial incentive.

The WTH platform has secure financial tracking and processing systems to manage participant payments, including the ability to track earnings and pay participants via a non-integrated payment system (ClinCard) ideally suited for adolescent subjects. ClinCards are reloadable, prepaid cards managed by Greenphire. Subjects will be able to access the payments during the study duration. Payments are based off the following:

- **Enrolling in the Quitline Program**, defined as the subject connecting with a Quitline counselor, providing basic information about smoking history, and discussing program details (see "Quitline Delivered Treatment" section below). To receive this payment, subjects must enroll in the Quitline within 2 weeks of start of the study;
- **Maintaining involvement in the program**, defined as the subject engaging in 5 proactive counseling calls with the Quitline counselors. Calls are scheduled every 1-2 weeks, depending upon the needs of the subject, and the Quitline counselor reaches out to the subject to initiate the call. Subjects eligible to receive payments for quitline calls must complete each call within a 2-week designated window;
- **Submitting the Cotinine Swab,** defined as, for those subjects who self-report quitting smoking (defined as no tobacco use in past 30 days) at the 10-week follow-up call, successfully completing the cotinine-specimen within 2 weeks of the call.
- **Quit Confirmed**, defined as a salivary cotinine measurement concentration of <30 ng per milliliter.

Subject engagement with the Quitline will be reported back to the WTH platform in real time using secure, password-protected methods. This allows subjects, through their interactions with the WTH platform, to see regular progress reports of their payments. See Table 1 for payment structure.

All subjects across the 3 groups, regardless of their level of engagement with the Quitline, will be contacted by the study team at 10 weeks after study enrollment to assess their smoking status. For those reporting quitting smoking, they will be asked to complete the salivary cotinine measurement.

Table 1: Payment Structure

	Connect to Way to Health	Quitline Enrollment	Quitline Counseling Calls					Submit Cotinine Swab*	Quit Confirmed^
Incentive, Quitline	$15	$15	$15	$15	$15	$15	$15	$20	$25
Incentive, Smoking Cessation	$15	$15	0	0	0	0	0	$20	$100
No Incentive	$15	0	0	0	0	0	0	$20	0

*For subjects that report quitting smoking (defined as no tobacco use in past 30 days) at the 10-week follow-up call. All subjects will receive $20 for submitting the salivary cotinine swab, regardless of the result.
^Payment received for negative result, meaning cotinine level <30 ng per milliliter

Quitline Delivered Treatment

The PA Free quitline is funded by the Pennsylvania Department of Health and staffed by trained cessation counselors available 24 hours a day, 7 days a week, and most holidays. Counseling is available in English, Spanish, Arabic and can be provided in more than 15 additional languages through a third party. All cigarette or e-cigarette users who enroll in smoking cessation treatment will receive counseling and support consistent with accepted clinical practice guidelines.[28] This treatment includes 5 proactive counseling calls, each designed to help develop problem-solving and coping skills, secure social support, and plan for long-term abstinence. Participants can also call an 800 telephone number as needed for additional support between proactive calls. The timing of counseling calls will be relapse sensitive and include a call 1 or 2 days after the quit date, another telephone call a week after the first call, and additional calls generally occurring at 1- to 2-week intervals thereafter. The call timing will be flexible and adjusted as needed. Completing the program involves completing at least of the 5 proactive counseling calls and reporting no tobacco use in the last 30 days.

8 SAFETY MANAGEMENT

8.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

8.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

9 STUDY ADMINISTRATION

9.1 Treatment Assignment Methods

9.1.1 Randomization

Randomization to the 3 groups will be performed via a random number generator used by the Way to Health platform and employ block randomization. Block randomization with stratification by cigarette and/or e-cigarette use will be used over simple randomization to ensure an equal number of participants among groups, considering the relatively small sample size.

9.1.2 Blinding

Subjects will not be blinded to their study treatment group. The statistician will be blinded to individual subject group allocation. The WTH platform team, not part of the study team, will not be blinded to group allocation.

9.2 Data Collection and Management

To minimize the risk of loss of confidentiality, adolescent subjects will have a unique study ID number. The generated report that contains adolescent name and contact information will be stored within PeRC databases managed by DBHi. Data from this generated report will be sent, via secure-password protected methods, to the WTH platform and the Quitline team to facilitate interactions with individual adolescent subjects, via their mobile phone. Data will also be sent to Greenphire ClinCard via secure password-protected methods so that subjects can receive payments. The WTH platform, Quitline, and Greenphire ClinCard use secure, high-performance servers that have the necessary security protections to permit storage and analysis of data containing protected health information. Interactions with the WTH platform and the Quitline – to assess benchmark complete and trouble-shoot any potential issues in these interactions – will be reported back to the study team via these same secure methods.

Further, the study team will use additional procedures to minimize risk to confidentiality, including unintentional disclosure by the adolescent to their parent/guardian regarding their tobacco use. In telephone-based interactions, the study team will begin any phone discussions with questions that assess level of privacy (e.g. “Can anyone overhear our conversation?”). To obtain the salivary cotinine measurement, subjects will be given the choice to either return to the clinic to perform the specimen in front of a study team member at a mutually agreed upon time or have the salivary swab mailed to their home, with the specimen collection performed remotely. If needed, the research team may also meet subjects at a mutually agreed upon location.

After data cleaning and quality assurance procedures are completed, the de-identified data will be converted into SAS format or Stata format (or equivalent software) for analysis.

We will keep a master list containing PHI and subject study ID numbers separate from data forms that will only have the study ID number. All files will be stored on one of the Hospital’s password-protected secure servers, specifically REDCap. All consent documents will either be obtained via REDCap or obtained via paper then scanned and stored within

REDCap, with the original paper versions destroyed. These servers are secure with planned redundancies in place to prevent the loss of data.

PHI data will be stored on password-protected, secure systems until 6 years after study closure. After those 6 years, all PHI identifiers will be deleted from the stored data.

9.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. No PHI, managed by DBHi, will be retained for future research, as it will be destroyed after data collection.

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

The study PI will monitor and review the study progress, the accuracy and security of the emerging data, and will maintain oversight over data integrity. Identifying information collected for study or recruitment purposes will be stored securely. No PHI will be retained for future research, as it will be destroyed upon closure of the study protocol. No other PHI identifiers will be collected at any time, and no other PHI identifiers will be stored.

9.4.2 Risk Assessment

Risks are not greater than minimal. Current national guidelines recommend that pediatricians and pediatric clinicians screen adolescents for tobacco use (both at routine preventive visits and at visits for diseases that may be caused or exacerbated by tobacco use) and offer tobacco dependence treatment and/or referral to adolescents who want to stop smoking.[9] For adolescent subjects, because the procedures herein involve discussion and connect to a smoking cessation program that they could already access as part of routine clinical care, we foresee no special risks. The main risk, therefore, to subjects is breach of confidentiality.

While this study involves treatment for tobacco use, there is the potential for adolescent subjects to report additional substance use to the study team. In those rare situations, the study team will review and consult with site clinicians about the case and determine if further evaluation or treatment is necessary.

9.4.3 Potential Benefits of Trial Participation

Although the proposed research poses minimal risks to participants, there are both potential direct benefits to study participants and contributions to scientific knowledge. The objectives of the study involve increasing adolescent engagement in an evidence-based program that helps smokers quit. Helping adolescent smokers quit provides direct benefit. Further, this trial may contribute to scientific knowledge by examining how to best translate routine tobacco use screening into effective service receipt and quitting.

9.4.4 Risk-Benefit Assessment

From a risk-benefit assessment perspective, the potential benefits outweigh the minimal risk posed by the study, justifying proceeding with the trial.

9.5 Recruitment Strategy

Identification of adolescent smokers will be achieved through the clinical care encounter, as described in protocol section 4.1.1, or through outreach facilitated by the CHOP Research Enhancement Core (REC), or through a referral program. The REC aids with recruitment plan development and may assist in identifying and contacting potential participants using the CRU, the CHOP Recruitment Registry, social media and internal communication resources. For social media postings, the study team will use the main CHOP social media pages and will work in conjunction with the REC and CHOP Social Media group. The REC also engages community partners and facilitates outreach on behalf of the research Institute and CHOP research studies. REC-facilitated recruitment strategies may include deploying recruitment emails and paper letters, tear pad and flyer advertising around CHOP's campus, schools, and commercial entities, public facing short ads posted on CHOP's public website, and This Week at CHOP and Clinical Trial Finder advertisement. All recruitment materials circulated by the REC will be first be submitted for review and approval by the IRB before use. In addition, permission will be obtained from the school principle or non-clinical community setting building owner/proprietor before any recruitment materials are distributed.

Subjects who are enrolled in the study after AM13 will also have the opportunity to receive a referral bonus, with a cap of 5 referrals per enrolled individual. The investigators will track referrals through a REDCap contact tracking database. This database will be separate from the main study database and will not be used for any purposes other than managing contact attempts.

9.6 Informed Consent and HIPAA Authorization

Prior to the completion of any study materials, verbal or electronic informed consent from all subjects, including minors who can consent for themselves, will be obtained. Consent will be obtained over the phone or electronically, either after the clinic visit or after the REC-facilitated recruitment. Subjects will be emailed (from a CHOP study email account) an electronic version of the consent form for their records. In current clinical practice, adolescent tobacco use is screened for by pediatric practitioners at confidential adolescent visits. Parents are not present in the exam room during this part of the visit, though they may be present with the adolescent at the clinic for other portions of the visit. Thus, to project privacy of subjects, adolescent consent will be obtained after the visit, over the phone or electronically. Adolescents who screen positive for tobacco use and are interested in further treatment will be asked, by the pediatric practitioner, if they can be contacted by a member of the study team. After verbal or electronic consent is obtained, current tobacco use will be confirmed electronically or by a study team member.

9.6.1 Waiver of Parental Permission

This study is minimal risk, and conducting the research involves treatment for adolescent tobacco use. Studies of adolescent tobacco and substance use identify systematic biases, including lower responses rates overall and lower enrollment rates of males, African-Americans, and self-reported tobacco use, when parental permission is required.[29] In this situation, parental permission may be a barrier to identification and treatment for adolescent tobacco use. Further, all subjects who enroll in this study are either adults or minors who can consent for themselves (14-17 years) under the alcohol or drug abuse provision, since they want to quit smoking. Minors who can consent for themselves will be providing consent rather than assent and we will not need to request a waiver of parental permission.

9.6.2 Re-consent of Subjects Turning 18

Per IRB protocols, documentation of verbal or electronic consent will be obtained at time on enrollment into the study. Participants turning 18-years-old during the follow-up period will not be asked to re-consent before continuing with the study because they are minors who can consent for themselves, and thus are providing consent at their time of enrollment into the study.

9.7 Payment to Subjects/Families

Subjects will receive $15 for their participation in the study. The intervention involves comparing 3 financial incentive structures on adolescent engagement in a smoking cessation program, with participants eligible for payments depending on completion of certain requirements. All study subjects will receive $20 for completing the confirmatory saliva specimen. All payments will be distributed through the virtual accounts, managed through the WTH platform.

Subjects who are enrolled in the study after AM13 will also have the opportunity to receive an additional $5 per potentially eligible person they refer, with a cap of 5 referrals per enrolled individual. Referral fees will be paid independent of whether or not the referred individual enrolls in the study.

10 PUBLICATION

Results from this study will be submitted for publication in peer-reviewed journals. Results may also be used for presentation at relevant professional seminars and meetings. No identifiable information will be disclosed in any publication.

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