Disseminating and Implementing a Smoking Cessation Program for Pregnant and Postpartum Women

Study Protocol

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Project Summary:

There is a compelling need to disseminate and implement effective programs that help pregnant women quit smoking and stay quit postpartum. Smoking during pregnancy results in unequalled risks to the mother and newborn, (placental abruption, preterm birth, SIDS) and markedly increased healthcare costs (NICU admissions). While prenatal smoking cessation interventions do help women quit, postpartum relapse rates can be as high as 85%. This proposal will test whether a smoking cessation intervention for pregnant women that extends postpartum (*Striving to Quit*) can be implemented and disseminated outside of the research environment that established its effectiveness (40% biochemically verified 6-month postpartum quit rates). Research aims include:

1. Can *Striving to Quit,* a cessation program for pregnant women who smoke, be implemented effectively to low-income pregnant and postpartum women in Northeast and Southwest Wisconsin communities (including Milwaukee) outside of a rigorous research protocol?

2. Is *Striving to Quit* more effective in achieving postpartum smoking cessation than "*First Breath,"* the current standard of care for pregnant women in Wisconsin who smoke?

3. What barriers exist to dissemination of *Striving to Quit* throughout Wisconsin, and how can these barriers be addressed?

The study applies the Consolidated Framework for Implementation Research (CFIR) and the design is an innovative Type II hybrid that combines both comparative effectiveness research and dissemination and implementation research to speed the translation of research findings into clinical practice. 250 women will be randomized into one of two study groups. Pregnant women in Group A ("FB", n=125) will receive the existing First Breath prenatal intervention. Those in Group B ("*STQ*", n=125) will receive all Group A interventions, plus 1 additional prenatal home visit, 3 postpartum in-home smoking cessation counseling visits, 3 postpartum phone calls, and up to an additional $100 in gift cards. The primary outcome will be biochemically confirmed smoking cessation at 6-months postpartum. This dissemination and implementation research will include three stakeholder groups: First Breath prenatal care providers, In-home counselors (Health Educators), and Policymaker/Purchasers. Stakeholders will be engaged via focus/discussion groups, stakeholder advisory committees, and online surveys. The RE-AIM framework will be used to analyze participant interviews, surveys, and case record reviews that measure program adherence, adoption of smoke-free strategies, acceptance of the intervention and perceived social support. The dissemination and implementation results will be integrated with the comparative effectiveness results to support full-scale STQ dissemination.

At the conclusion of this project, we will be poised for statewide dissemination of STQ. This will include a viable plan, which may include combining funds from multiple sources to address the anticipated need for system changes. We will seek external funds to support training, technical assistance, and evaluation activities, especially measures of fidelity.

Background and Significance:

There is a compelling need to disseminate and implement effective programs that help pregnant women quit smoking and stay quit postpartum. Smoking is the leading preventable cause of adverse pregnancy outcomes. Smoking one pack of cigarettes/day during pregnancy increases the risk of placental abruption by 40%[1]. Mothers who smoke during pregnancy have a 23% greater risk for preterm births than nonsmokers[2]. Preterm birth is a leading risk factor for infant mortality, a tremendous problem in Milwaukee County where the infant mortality rate (11.3 deaths per 1,000 live births) is the 3rd highest in the nation[3]. Smoking during pregnancy causes between 20% and 29% of deaths due to Sudden Infant Death Syndrome (SIDS)[4], and increases the risk of admission to an NICU by almost 20%[5]. In sum, smoking during pregnancy results in unequalled risks to the fetus and newborn, as well as markedly increased healthcare costs.

First Breath, managed by Wisconsin Women's Health Foundation (WWHF) on behalf of the State of Wisconsin, is a well-established prenatal smoking cessation intervention that uses evidence-based practices and has served over 17,000 women since 2000. First Breath is delivered by health care providers at prenatal care locations where women already receive services. Approximately 85% of First Breath participants are Medicaid members. First Breath typically consists of 2 *prenatal* and on postpartum cessation counseling sessions, each lasting 2-5 minutes, a fax-to-quit connection to the Wisconsin Tobacco Quit Line, and non-financial incentive gifts for the mom and expected baby.

The opportunity for cessation interventions during pregnancy is high; many pregnant smokers quit, at least short-term. At least 30% of First Breath participants self-report quitting smoking by their third trimester[6]. Unfortunately, postpartum relapse rates are very high – approaching 85%[7].

Stakeholders at First Breath sites (local public health officials, prenatal care providers, and WIC providers) have long identified the need *to expand prenatal cessation services and extend smoking cessation services into the postpartum period*. UW-CTRI addressed this need, with its partner WWHF, by conducting the 5-year *Striving to Quit (STQ)* study funded by Center for Medicare and Medicaid Services (CMS) (Preliminary STQ study). STQ was designed to address the high risk of postpartum relapse by providing in-home counseling sessions, phone call check-ins, and financial incentives for abstinence. Women enrolled in First Breath (N=1,052) were recruited to participate in STQ. A 40% smoke free rate (biochemically verified) was observed at six months postpartum.

Striving to Quit was an experimental study. Unknown is whether this intervention can be implemented effectively outside the confines of a rigorous research protocol. In addition, we must present a compelling case for the superiority of *STQ* over the existing First Breath (FB) prenatal program before stakeholders will invest in the system changes required to extend smoking cessation interventions into the postpartum period.

Specific Aims/Study Objectives

A. Specific Aims

1. Can *Striving to Quit,* a cessation program for pregnant women who smoke, be disseminated and implemented effectively to low-income pregnant and postpartum women in Northeast and Southeast Wisconsin communities (including Milwaukee) outside of a rigorous research protocol?

2. Is *Striving to Quit* more effective in achieving postpartum smoking cessation than "*First Breath,"* the current standard of care for pregnant women in Wisconsin who smoke? We hypothesize that *Striving to Quit* will be more effective than *First Breath*

3. What barriers exist for the wide scale dissemination of *Striving to Quit* throughout Wisconsin, and how can these barriers be addressed?

B. Study Duration

18 months

Research Design and Methods

A. Study Overview

This proposal will test whether a smoking cessation intervention for pregnant women that extends into the postpartum period (*Striving to Quit* [STQ]) can be implemented outside of the research environment that established its effectiveness. We will be using the Consolidated Framework for Implementation Research (CFIR)[8,9], to conduct this implementation study and identify barriers and solutions to dissemination. Our preliminary work with stakeholders identified the CFIR construct of Relative Advantage[10] as a key construct. It determined that our approach needs to compare the existing First Breath's prenatal-only program to an alternative solution, STQ, which expands services during pregnancy and includes postpartum home visits. This comparison is a key goal because STQ requires more clinical resources than First Breath and because First Breath providers currently have limited ability to seek reimbursement for postpartum services. Because of the need for compelling evidence of the superiority of STQ over the existing First Breath program, this project includes an effectiveness research component. Thus, the overall study design is an innovative Type II hybrid design that will efficiently test both clinical interventions and evaluate implementation strategies, speeding the translation of research findings into clinical practice[11]. We will use RE-AIM as our measurement framework[12,13]. Specifically, the comparative effectiveness aspect of the project focuses on real-world effectiveness while the implementation aspect focuses on adoption of the intervention.

Implementation Evaluation (Aims 1 and 3) We will address aims 1 and 3 by structured interactions with three specific Stakeholder groups. Our interactions will be facilitated and evaluated using CFIR principles. Based on prior WWHF experience and preliminary stakeholder data, we hypothesize the following CFIR constructs to be highly relevant to implementing STQ:

- Intervention characteristics of Relative Advantage;
- Adaptability, Complexity, and Cost;
- Outer setting characteristic of External Policy & Incentives;
- Inner setting characteristics of Implementation Climate (Compatibility and Relative Priority) and Readiness (Available Resources);
- Individual characteristics of Self-efficacy and Individual Stage of Change; and
- Process characteristic of Engaging (External Change agents).

Representatives from these stakeholder groups will only be asked about relevant aspects of implementing STQ statewide such as barriers to statewide implementation and resources needed for statewide implementation. There will be no personal information collected. Stakeholder participants, are, therefore, not participating in research. The outcome for both aims 1 and 3 will be a Statewide Implementation Plan document. This document will describe a strategy for statewide implementation, an associated time line, the barriers to statewide implementation and sustainability, listed in order of perceived importance, and recommendations about how to address the identified barriers and challenges.

1) *First Breath Providers* – We will hold four discussion groups with Prenatal care providers currently providing First Breath (6-8 per group) using questions suggested by CFIR[14] to identify implemnatation barriers, challenges, and needed resources. Since information obtained from these discussion groups is intended to inform the statewide expansion (Aim 3), these discussion groups will not be limited to the geographic area of this project (northeast and southeast). Rather, these discussion groups will take place throughout the entire state. Recruitment for the discussion group will be purposive so that the diversity of First Breath providers is represented.

These groups will take place the first 6 months of the project. Discussion questions will be developed by WWHF staff and will come from the pool of recommended questions from the Consolidated Framework for Implementation Research (CFIR). WWHF staff will conduct the discussion groups. The discussion groups will begin with a description of STQ as First Breath providers may not be familiar with it. Participants will be paid $30. The discussion groups will be recorded. Recordings are transcribed verbatim and entered into SurveyGizmo (SG). Results will be coded using the text analysis tool in SurveyGizmo.

Discussion group findings will be used to create an e-survey for all First Breath providers in the state. Survey results will further clarify key implementation challenges and barriers for our eventual statewide dissemination plan. The purpose of this survey is to collect information from all First Breath providers about barriers to statewide implementation of STQ and possible ways to address these concerns and barriers. SurveyGizmo, the same software used in the preliminary STQ study, will be used to create the survey. It will be sent electronically to First Breath providers by WWHF staff using its database of these providers. Two electronic reminders to complete the survey will be sent.

2) Health Educators providing STQ – Staff providing the STQ intervention will be interviewed about the materials employed in the intervention and the intervention procedures by Krissy Alaniz, WWHF's Perinatal Programs Manager, as part of their monthly quality assurance/quality improvement (QA/QI) meetings. Ms. Alaniz will develop questions designed to gather information about the challenges when delivering STQ, suggestions for improvement, and anticipated barriers to statewide implementation. Questions about this latter topic will be informed by the characteristics noted in the CFIR framework. Responses will be recorded and integrated into a report. This report will be used with the other qualitative information (aim 1) to improve the STQ program in the real world and to prepare for state wide implementation/expansion.

3) Sustainability Planning Committee - This group will be made up of First Breath site providers, representatives of the Wisconsin Department of Health services (Division of Public Health), Prenatal Care providers, and representatives of the BadgerCare Plus HMOs. The advisory group will meet four times with check-in calls or emails in between the in-person meetings: *at baseline*, before enrollment if the comparative effectiveness study begins to provide feedback on study feasibility, initial plans, and likely challenges that can be anticipated; *at three months* and *at six months* after enrollment into the effectiveness study has begun to provide feedback on early successes and challenges and advise on potential project modifications that could improve implementation; and *after the interventions* included in the effectiveness study have been completed to review preliminary data and to discuss the statewide implementation strategy.

Comparative Effectiveness Study (Aim 2) In this comparative effectiveness study we will compare the effectiveness of STQ to First Breath (FB) in real world settings. We will recruit low-income pregnant women who smoke in Northeastern and Southeastern WI (including Milwaukee) and invite them to participate in the study. Invitations will continue until 250 women agree to participate. These 250 women will be randomized into one of two study groups, stratified by race/ethnicity and county as was done in the STQ preliminary study. Pregnant women randomized to Group A ("*First Breath/FB"*, n=125) will receive the existing First Breath prenatal intervention. Pregnant women randomized to Group B ("*Striving to Quit/STQ*", n=125) will receive all Group A interventions, plus 1 additional prenatal home visit, 3 postpartum in-

home smoking cessation counseling visits, 3 postpartum phone calls, and up to an additional $100 in gift card payments to increase program adherence and abstinence, similar to the preliminary STQ study (see table 1). The primary outcome measures will be women's biochemically confirmed smoking cessation (i.e., breath carbon monoxide [CO] level of < 6) at six months postpartum during an in-home counseling session.

Table 1. Study Conditions and Treatment Components

Conditions	Components
Group A: First Breath ***(Prenatal)***	▪ Health care provider-delivered First Breath cessation counseling at prenatal visits ▪ Link to WI Tobacco Quit Line ▪ One 6-month postpartum in-home abstinence evaluation visit (WWHF staff) ▪ Up to $40 total incentives for participation including $20 for enrollment and $20 for completing the six-month biochemical confirmation of abstinence
Group B: Striving to Quit ***(Prenatal & Postpartum)***	**All First Breath Components PLUS:** ▪ 1 prenatal and 3 postpartum in-home counseling visits ▪ 3 postpartum counseling phone calls ▪ Up to $100 additional incentives for participation & abstinence (up to $140 total)

B. Study Population (recruitment, inclusion/exclusion criteria, selection, informed consent procedures)

Population description and inclusion/exclusion criteria The participant pool for this study is pregnant women who have enrolled in the existing First Breath program in northeast and southeast Wisconsin, including Milwaukee (counties of Brown, Door, Kenosha, Manitowoc, Milwaukee, Outagamie, Racine, Waukesha and Waupaca). Inclusion criteria includes: age 18 or older; English speaking; willingness to quit or reduce smoking in the next 30 days (if not already quit) or if already quit, desire to remain quit after delivery; daily smoking (at least one cigarette per day for at least a week sometime in the past 6 months); and willing to provide updates in contact information. Exclusion criteria include not being pregnant, not smoking in the past six months, not residing in one of the target counties or involved in another smoking research study. Based on First Breath enrollment in the target counties, 75% of participants will be low income and 48% of study participants will be African American. Health status will be varied, but will reflect low income women of child bearing ages.

Recruitment and eligibility screening Participant screening and informed consent procedures are the same in this study as were approved for the preliminary STQ study. Potential study participants will be identified from existing First Breath sites located in the target counties. A set of affiliated providers (providers employed by clinics and community agencies) who have an agreement with the Wisconsin Women's Health Foundation (WWHF) provide First Breath program services which includes supportive prenatal services to women who smoke. Such services are designed to encourage smoking cessation during pregnancy and the maintenance of abstinence post-delivery. These organizations are affiliated with, but not part of, the WWHF. These clinics and other providers will provide standard First Breath (FB) prenatal services to all participants in this study. This protocol refers to these organizations as First Breath sites. Staff at these sites will be providing only the existing First Breath services; their care procedures are

unaffected by this study. They are not performing any research activities such as obtaining informed consent, collecting data or information they wouldn't ordinarily collect for First Breath, or administering any of the clinical services/interventions that are part of this study but not part of the standard First Breath Program. Thus, these staffs are not conducting research and these First Breath sites are not research sites. (All staff who are conducting research are employed by either UW-CTRI or the WWHF.)

Participant recruitment will take place among women enrolled in the First Breath program. First Breath program enrollment occurs following an enrollment survey form being sent from a First Breath site to the WWHF. This form includes a wide variety of information including county of residence, information about ability to read/speak English, age, and other program-relevant information. Based upon this First Breath enrollment form completed by the FB provider, WWHF staff will determine if the First Breath enrollee might be eligible to participate in this study using the inclusion/exclusion criteria above. WWHF research staff will contact the enrollee by phone within one week of receiving the FB enrollment forms. If after 5 attempts, WWHF has been unable to reach the FB enrollee, WWHF will send a letter inviting the enrollee to call the WWHF to see if they qualify for the study. If the FB enrollment form is missing a phone number or the listed phone number is non-working, WWHF will send a letter inviting the FB enrollee to call the WWHF to see if they qualify for the study and will follow-up with the FB site. If the enrollee hasn't responded within 2 weeks, WWHF will follow-up with a postcard mailing.

Postcards announcing the availability of the study will also be provided to First Breath sites. Site staff place the postcards in patient folders, in exam rooms and in waiting rooms. In addition, the postcards will be distributed at community events in the target area attended by WWHF.

If the FB participant is screened to be eligible, the WWHF will:

a) Describe the study briefly (including the opportunity to receive incentives), and the need to do screening, answer any questions the participant has, and then ask if she is interested and would be willing to be screened for possible participation
b) Screen interested pregnant women for entry criteria: i.e., not involved in another stop smoking research study, and willingness to quit or cut down on smoking in the next 30 days (if not quit) or, if quit, desire to stay quit after the birth:
c) Ask if she smoked daily (at least one cigarette each day for at least one week) at sometime within the last 6 months
d) Ask about her willingness to complete additional surveys (phone and home) and do a CO breath test.
e) Confirm her willingness to inform the WWHF as to any change in address, phone number, or clinic/site attended
f) Confirm that she wants to quit or remain quit after delivery

If the woman does not pass screening, she will be given standard FB services as appropriate. De-identified data from such encounters will be kept by WWHF in order to determine sample representativeness of those who enter the study.

Informed consent procedures If the participant completed inclusion questions successfully, the WWHF staff member will present the consent information to the participant over the phone and obtain and document the participant's formal (verbal) study consent. This study would not be able to be performed with written consent for participation for the following reasons:

(a) The characteristics of this low income population include low levels of literacy and distrust of written communication requiring signature; a mailed and returned consent process would be unworkable, based on our experience with this population, since few would return the signed consent.
(b) All participants receive standard First Breath interventions at First Breath sites at the outset of study participation; the first in-person contact with study staff does not occur until the first postpartum visit for participants assigned to the STQ condition and not until the 6-month postpartum visit for participants assigned to the FB condition and ate pregnancy for the STQ group. It is impractical and costly to try to perform hundreds of in-person visits for the sole purpose of obtaining consent. If required, valuable resources for the study would be wasted. Moreover, requiring an in-person visit would constitute an additional burden to this at-risk population.
(c) The study poses very low risk—and offers very large benefits—to the target population.
(d) Through the CMS-funded preliminary STQ study, the WWHF obtained verbal consent from 1052 low income pregnant women without incident.
(e) The study is real world translational research. An in-person or mailed signed consent would introduce barriers that would not be present in translation of its findings into a real-world environment. These barriers would interfere with the study's aims, since the study is designed to evaluate a real-world program. The reasons for this are:
    (i) As stated above, it is likely that a substantial portion of participants would not return a mailed consent. One of the study's aims is to determine what the *reach* of such a program would be in the real world setting and this would not be possible to do if people were lost because of the required return of a mailed consent (which would not be present in a real-world program setting).
    (ii) Introducing a study procedure to reach out to every potential participant to complete a signed consent *in person* at the beginning of the study is equally problematic. First, this would have to be done by WWHF (research) personnel (there are too many "affiliated" non-WWHF providers to have them deliver research procedures). Thus, the WWHF personnel would have to contact the women and arrange ad hoc, face-to-face visits for each participant. Without a personal relationship, many women would not want a stranger to come to their home, there would be missed visits, some women would refuse after the work of establishing contact, and so on. Thus, this would impose two hurdles: getting women to take a phone call, and having them agree to a visit with a stranger where no services are being provided. The imposition of two hurdles could affect the nature of the sample ultimately recruited (and generalizability). Plus, the added expense, especially of in-home visit solely to obtain consent, would certainly require a reduction in N's significantly, reducing power and generalizability.
(f) Offering signed consent at the first in-person visit with research staff from WWHF (post-partum Visit 1), was considered but is also problematic. Those women assigned to Group A (First Breath) receive only a single in-person contact with study staff, the 6-month post-partum in-home visit to measure CO, which is the very last study contact. It would make little sense to obtain written informed consent at the last contact.

Based on this, the team is seeking full verbal consent and proposing that, at the first in-person visit with the WWHF research staff, the staff member invite discussion of the study procedures and consent at the beginning of the visit. For the reasons offered above, we believe that this method would provide the best estimate of the effectiveness of this intervention as it would occur in real world use, and very adequately protects individuals in this low-risk, potentially highly beneficial, study.

Following verbal consent, the WWHF staff will then mail a brief letter welcoming the woman to the study, an informed consent information sheet, and an easy-to-understand list of upcoming treatment and research elements (treatment calls, visits, payments to the participant) to the participant. This material will include the UW-CTRI Research coordinator number [608-265-5617] for questions—as well as the UWHC Patient Relations Representative at 608-263-8009 or University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819). The woman's oral consent over the phone will mean that the person is officially registered in the trial and will be included in the denominator of the intent-to-treat analyses.

Also at this initial call:

a) At least 2-3 additional contacts will be obtained for the participant (i.e., friends, family) to try to establish a route to re-contact the participant if she moves or changes phones, etc., along with permission to inform those contacts of the participant's research participation.
b) Because in-home visits are involved, the participant will be informed that the Health Educators are required by law to report suspected cases of abuse and neglect as well as those situations in which they have reason to believe that a person has been threatened with abuse or neglect or that abuse or neglect will occur.
c) Study baseline questions will either be administered via phone at this time, or if the participant does not have time to complete the baseline, WWHF staff may either complete it later or schedule a follow-up appointment to complete the baseline (see F. Collected Information).

Randomization will occur via a preset randomization list developed by UW-CTRI. Participants will be randomized in separate tables based on race (white/non-white) and county, in order to better control for these effects. The First Breath provider will be informed that his/her patient has enrolled in the research study. (Permission for this communication will be addressed during the consent procedure.)

C. Collaborating Sites

The Wisconsin Women's Health Foundation is a collaborating site. All interventions and data collection will take place over the telephone or in the home of study participants and be conducted by WWHF staff who have been approved to conduct this study. Collected data will be maintained at WWHF.

D. Study Activities

Standard of care procedures vs. research procedures All study participants will be offered standard of care smoking cessation counseling by FB providers (prenatal) (both groups A - FB

and B - STQ, see Table 1). These are not study procedures. Rather, they are standard of care cessation services for FB. Additionally, standard care includes prenatal data collection by FB providers (attendance and content of visits). Enrollment in First Breath includes a set of standard data questions regarding smoking and pregnancy. While the study will utilize some of these data, the collection of this information is not a study procedure. Study research procedure (procedures specific to the study and conducted by WWHF research personnel) include the following:

a) screening, consent and randomization (offered after First Breath enrollment).
b) baseline study data collection (completed immediately following verbal consent or at a scheduled telephone follow-up appointment).
c) 1 prenatal and 3 postpartum in-home counseling visits (Group B – STQ) conducted by WWHF research staff using a counseling protocol developed in accord with the US Public Health Service Clinical Practice Guideline. The expected duration of each in-home visit is 45 minutes. The prenatal visit will occur in the third trimester, and the three postpartum visits will occur in months 1, 3 and 6.
d) 3 postpartum counseling phone calls (Group B – STQ) will be conducted by WWHF research staff using a counseling protocol developed in accord with the US Public Health Service Clinical Practice Guideline. The expected duration of each counseling phone call is 20 minutes. These calls will occur during months 2, 5, and 5 postpartum.
e) 6-month postpartum in-home abstinence evaluation visit (Group A - FB and B - STQ) conducted by WWHF research staff
f) postpartum study data collection (collected 6 months postpartum)
g) CO test (completed at 1-month postpartum visit for STQ participants and at 6-month postpartum visit for both FB and STQ participants)
h) provision of incentives: Group A will receive up to $40: $20.00 for enrollment and $20.00 for taking the six-month CO test. Group B will receive $20 for enrollment, $20 for each of the four home visits, and a bonus $20 for passing the CO tests at the delivery (1 month postpartum) and last home visit (6 months postpartum) (Total of $140.00) (It will be specified in the consent that visits where all study procedures are not completed will not be eligible for compensation.)

Attachment 1 presents the study intervention and incentive time line.

Retention Procedures The following procedures are designed to minimize loss of potential enrollees or data from these enrollees:

a) From the point of enrollment, WWHF will track expected due dates and follow-up with the prenatal FB provider for any delivery where they have not received notification of delivery 14 days after the expected due date. This will address the potential loss of enrollees in the transition between the prenatal FB provider counseling and the start of postnatal counseling by the WWHF staff.
b) There will be reminder calls (up to 5 attempts) about 2 days before every in-home visit.
c) For each missed in-person visit, WWHF staff will make proactive calls to the participant to reschedule.
d) For each of the telephone counseling sessions, WWHF staff will make 5 call attempts for each scheduled call, providing participants with encouragement to return the call.
e) If the woman is not home for a scheduled home visit, and does not reschedule it, the WWHF will make an additional effort to track/contact her by phone (with reminders of

the visit payment she will receive for attending) and, if that fails, by letter and contact with people whose names were given as contacts at enrollment.

f) If the appointment is not completed within 4 additional weeks, this visit will be closed and the participant will not be compensated. An additional call will be made letting the person know the window for that visit was passed; if no phone contact can be made in three weeks, other contacts (people listed by the participant who will know her location) will be contacted. If this fails, a letter will be sent confirming that this visit is closed and encouraging the participant to contact the WWHF office.

g) Prompt payment of participants is a key variable in retention. WWHF will disperse the incentive payments; payments will be in the form of a $20.00 Walmart gift card. Enrollment gift cards will be mailed. The will be distributed in-person, at the completion of each home visit/CO test.

Procedures for incarceration While the study does not target incarcerated individuals, incarcerations during the period of study involvement are anticipated within the population being recruited for this study. The study has made the following procedural accommodations for this: If an individual is reported to have been incarcerated, all study involvement during the period of confinement will be suspended. No contact will be made with (and no data will be collected from) the individual during any period when they are incarcerated. The appointments during the incarceration will be recorded as missed. If the length of incarceration is known and the individual becomes available in the community again, scheduled study contacts will re-commence at that time. Follow-up appointments and/or calls that are scheduled subsequent to a period of incarceration may occur. If there is no indication of when the individual will be available again, study contacts will be recorded as missed and attempts to contact will start again at the next scheduled contact. Incarcerations will not be reported to the IRB unless the above protocol has not been followed.

E. Safety Monitoring Plan

Participant risks are minimal. No drugs are used in this study. The pre-natal smoking cessation counseling services (Frist Breath) provided as part of the project have been used with this population throughout Wisconsin for 15 years. No adverse effects have been documented. The services provided postpartum are commonly used cessation/relapse prevention counseling strategies. They were used previously in STQ without any adverse effects. Participants may be experiencing more stress than normal because they are at home with a new born. In this context, smoking relapse may produce some emotional upset. All the health educators are trained to recognize this and are prepared to provide support and/or mobilize community resources as needed. There is a risk for inadvertent breach of confidentiality. This risk will be highlighted in the consent procedures.

F. Collected Information

Some information is provided to WWHF by FB sites when women enroll in FB and again at the end of their standard services to the enrolled women. All other assessment data gathered from participants will be obtained by telephone or in person by WWHF staff. These include:

a) Baseline assessment. This survey takes approximately 10 minutes to complete and is administered by WWHF staff at the time of enrollment and after verbal consent or during a separate call if the study participate cannot complete it during this initial call. Variables collected include: motivation and confidence to quit/reduce smoking; smoking history; current smoking; barriers to cessation; past quit attempts; general health information and goals; and perceived social support (via the Wisconsin Social Support Scale).
b) CO test for STQ participants only at the first postpartum visit
c) CO test at the 6-month postpartum follow-up in-home visit for both STQ and FB (primary outcome)
d) Brief survey (10 minutes) administered at the 6-month postpartum follow-up in-home visit. This survey collects information such as smoking status at delivery and at one-month postpartum as well as re-measures some of the variables collected at the baseline assessment. Also measured will be: adoption of smoke free strategies; self-efficacy to remain smoke free; motivation to remain smoke-free; time to relapse, perceived support from others; and birth putcome.
e) WWHF staff will also record information about pertaining to conducting the study. This information includes: screening/informed consent results; participation in treatment services; counseling delivered information; and ending study prior to completion

Attachment 2 lists all the information that will be contained in the study data set.

G. Data Security

Data collected in the home are entered into SurveyGizomo, (online software). Survey Gizomo is HIPPA compliant and has Safe Harbor certification. Data is encrypted and hyperlinks are secure. The research database will be housed at WWHF. It will be stored on a computer with password access controlled by WWHF. Only WWHF staff approved to work on this study will have access. Following conclusion of the study, all research data will be cleaned and verified and then placed in a de-identified data set for analysis. UW-CTRI will assist WWHF with data analysis. To facilitate this, the de-identified database will be provided to UW-CTRI by secure FTP. Study records will be kept for seven years.

G. Data Analysis Plan

Aim 2: Is Striving to Quit more effective in achieving postpartum smoking cessation than "First Breath," the current standard of care for pregnant women in Wisconsin who smoke?

a) Results from screening and enrollments will be analyzed to assess the representativeness of the study sample to make inferences regarding the reach of the project among the target population.
b) Groups A (FB) and B (STQ) will be compared on the various background and smoking variables to test the assumption that random assignment resulted in equivalent groups. Inferential statistics will be used to compare the two groups, Chi Square for nominal background/demographic data such as health insurance status and race and t-tests for interval data such as age. These variables will also be used to describe the sample using

descriptive statistics. These variables will be used as co-variates in the analysis of the primary outcome, smoking abstinence.

c) The primary outcome is biochemically confirmed reports of abstinence for the past 7 days (i.e., 7-day point-prevalence abstinence) at six months postpartum. Biochemical confirmation will be accomplished with exhaled breath carbon monoxide (CO) testing. Experience with First Breath suggests that about 20% of all women receiving services will be abstinent at 6 months postpartum after receiving prenatal services only (vs. the 30% pregnancy abstinence rates). When tested using research protocols, STQ found that 40% were smoke free at 6 months. Because we anticipate that this rate will be lower when implemented in real world settings, we use an estimated 36% rate for power calculations. With 125 participants in each condition and two tailed alpha set at .05, we have .81 power to detect this hypothesized effect size difference (36% vs. 20%). The intent-to-treat principle will be used so that non-ascertainment (i.e., failure to attend the Follow-up Visit or a lack of a confirming carbon monoxide value) will be treated as a non-abstinent outcome. Logistic regression will be used to analyze the effect of treatment status (FB vs. STQ) on the binary abstinence outcome, and models will be run both with and without covariate adjustment. We predict that STQ will produce higher abstinence rates at 6-months postpartum than FB.

d) Other variables collected at the 6-month postpartum follow-up visit are secondary outcomes. These include time to relapse, motivation to quit/remain quit, confidence about quitting/remain quit, and birth outcomes. Some of the secondary outcomes will be continuous for which linear regression will be used. Demographic variables will be used as co-variates in these analyses. The Benjamini-Hochberg approach will be used to control experiment-wise error for secondary outcomes. Meaningful missingness is likely for variables collected at the 6-month postpartum home visit. For such variables, we assume missingness to be nonignorable. We will model or treat missingness in several ways. For instance, we will conduct sensitivity analyses with different assumptions about the relation of missingness to actual unobserved values, which will provide explicit modeling of the impact of missingness assumptions on results. We will also use multiple imputation methods appropriate for nonignorable missing data (for both continuous and binary data) and will generate imputation models that reflect different assumptions about the missing data mechanism. Missing data, due to drop out or otherwise, it will be recorded and its causes will be noted. Relevant information will include reasons for dropout, who made the decision to drop out, and what type of participation was withdrawn (e.g., termination of intervention, refusal to complete survey, etc.).

Aim 1 and Aim 3

First Breath Providers Discussion Groups. The discussion groups will be recorded. Recordings are transcribed verbatim and entered into SurveyGizmo (SG). Transcriptions are independently reviewed and codes developed by 3 study staff. Staff met to come to a consensus on the final list of codes. Final codes entered into SG and transcriptions are coded in SG using text analysis tool. The data is qualitatively analyzed for trends, themes, and quotes. Results will be used to develop items for the survey to FB providers.

First Breath Providers Survey. Survey responses will be analyzed using descriptive statistics (percent endorsement, measures of central tendencies, standard deviation). This survey will include several questions regarding the First Breath provider characteristics such as location,

length of time as a First Breath site and number of women enrolled annually into the First Breath program. Survey results will be examined as a function of these questions (Do experienced First Breath providers perceive different challenges than inexperienced First Breath providers? Urban vs. rural providers?) via inferential statistics. Finally, this survey will include several open ended questions. Responses will be analyzed for trends and themes.

Heath Educator Interviews. Responses to interview questions will be recorded and integrated into a report. This report will be used along with the two data sources above to develop an implementation plan for state wide expansion and as an assessment of Aims 1 and 3.

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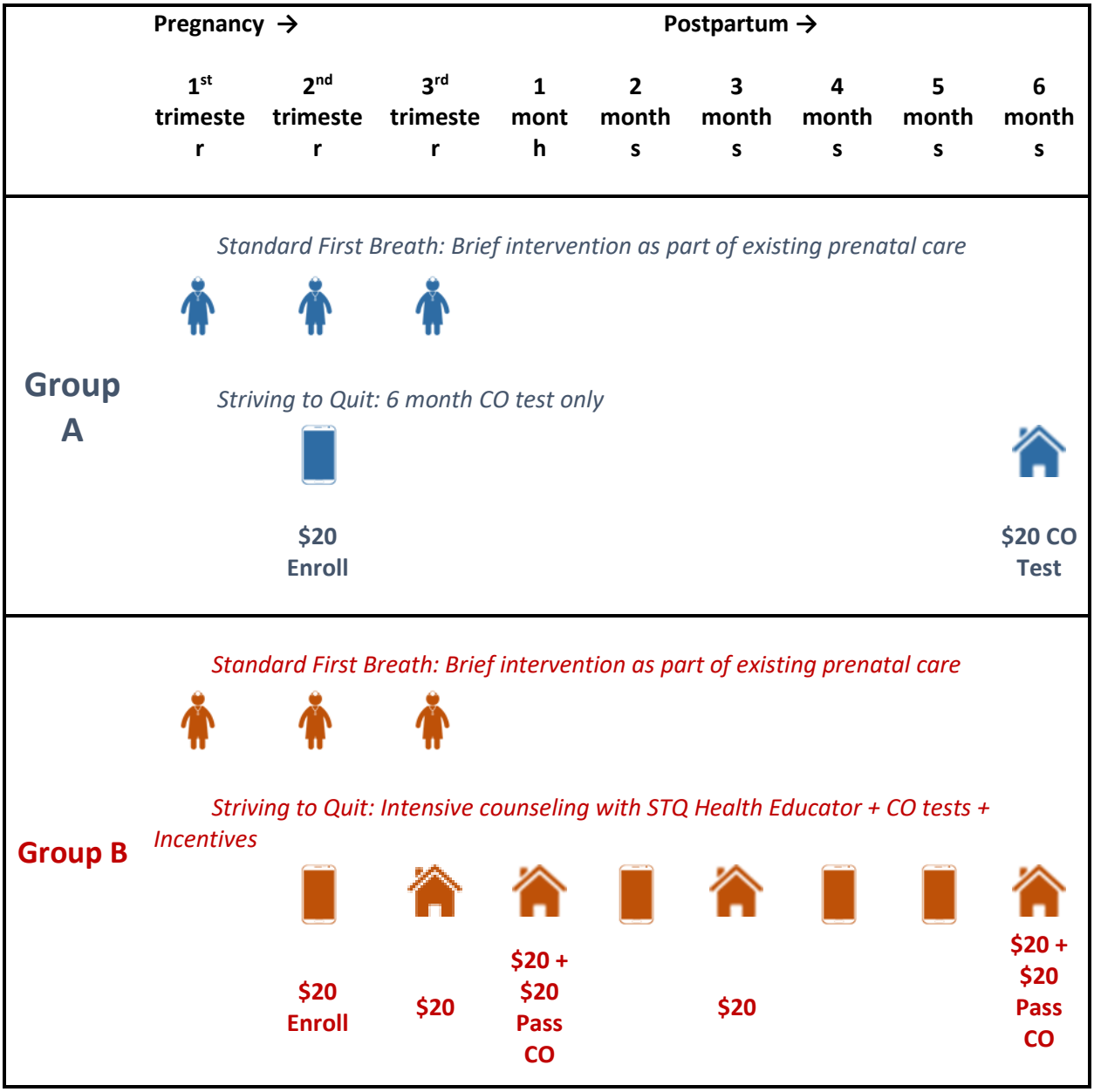
Attachment I
Striving to Quit Schedule – ICTR Grant

Group A: First Breath Only
Group B: First Breath + Striving To Quit



Key

= Brief Counseling with Prenatal Care Provider	= Home Visit with STQ Health Educator	= Phone Call with STQ Health Educator

Attachment 2: Collected Information

Description	Study Group	Source	Purpose	Time	Variable
First Breath Enrollment Information	Both FB and STQ groups	First Breath sites	Identify eligible women	At prenatal visit	• Name • DOB • Expected delivery date • Contact Information • Smoking Status
Screening data	Both FB and STQ groups	WWHF research staff	Establish study eligibility	After First Breath enrollment	• Smoked daily in last 6 months • Willing to quit or stray quit • Willing to meet with FB provider • Willing to have phone calls and home visit • Willing to take CO tests • Willing to inform of changes in contact information • Involved in other smoking study
Screening results	Both FB and STQ groups	WWHF research staff	Results of eligibility screen	After First Breath enrollment	Not willing to be screened; screen fail (reason); not consented; enrolled
Services delivered at First Breath sites	Both FB and STQ groups	Fist Breath sites	Compare groups	At end of services provided at First Breath sites	Number of counseling sessions delivered
Baseline survey (phone)	Both FB and STQ groups	WWHF research staff (Health Educators)	Compare groups	At enrollment	Participant Self-Report: • Race/ethnicity • Income • Education • Employment status • Relationship Status • # in Household

					• # Smokers in Household (smokers/nonsmokers) • Smoking history • Smoking status (Current) • Nicotine dependency • Confidence to quit/remain quit • Motivation to quit/remain quit • Perceived support • Perceived stress • Major stressors • Mental health and SUD status • ETS exposure • Quit goals
CO measurement (Home visit)	STQ group only	WWHF research staff (Health Educators)	Provide feedback regarding quit progress	1 month postpartum	CO value
Session content	STQ group only	WWHF research staff (Health Educators)	Describe services delivered to STQ participants	Every scheduled phone call and home visit, including 6 month follow-up	• Did visit take place • Duration • Topics discussed
6-month Postpartum survey (Home visit)	Both FB and STQ groups	WWHF research staff (Health Educators)	Compare groups, measure primary and secondary outcomes	6-months post-partum	Participant Self-Report • Smoking status (Current) • Confidence to quit/remain quit • Time to relapse (if applicable) • Motivation to quit/remain quit • Quitting/reduction strategies used • Perceived support • Perceived stress • Major stressors

					• Household smoking • ETS exposure • Breastfeeding initiation/duration • Maternal/child health outcomes • Barriers and helpful factors (open-ended) HE Documentation: • CO Result
Case summary (Home visit)	STQ group only	WWHF research staff (Health Educators)	Describe impact on STQ participants	6 months postpartum	• Total minutes of counseling • Level of engagement • Difficulty to reach/complete appointments • Number of times address changed • Referral to Wisconsin Tobacco Quit Line (WTQL) • Education to support people • Support people referred to Texting program • Support people referred to WTQL • Topics covered • Qualitative case summary
Study status	Both FB and STQ groups	WWHF research staff	Track participants through study	End of study	Unable to locate; withdrew by participant; withdrew by experimenter; unknown; completed study