Wisconsin
Department of Health Services

Medicaid Incentives for the Prevention of Chronic Disease
Wisconsin Striving to Quit—
Implementation Report

December 2016

University of Wisconsin – Madison
Center for Tobacco Research and Intervention
Wisconsin Women's Health Foundation

P-01732 (12/2016)

The study described in this report was supported by Funding Opportunity Number 1B1CMS330876 from the Centers for Medicare and Medicaid Services. The contents provided are solely the responsibility of the authors and do not necessarily represent the official views of the United States Department of Health and Human Services (HHS) or any of its agencies. The results presented have not been verified by the independent evaluation contract.

TABLE OF CONTENTS

Section I: Introduction 1
Section II: Background 1
Section III: Organization and Administration 1
Section IV: The Wisconsin Tobacco Quit Line Component 3
Section V: The First Breath/Pregnant Woman Component 28
Section VI: Overall Striving to Quit Program 46
Section VII: Evaluations 59

Wisconsin Medicaid Incentives for the Prevention of Chronic Diseases
Striving to Quit Implementation Report
September 2011 - September 2016

Section I: Introduction

This report provides detailed information about the development and implementation of Wisconsin's Striving to Quit initiative. It highlights the issues and challenges encountered over the course of the five-year initiative and how they were resolved. The report provides a running narrative of the complexity of designing and implementing smoking cessation services targeting a low-income population that is generally hard to engage. It also highlights the necessity of being able to adapt proposed processes and procedures quickly to facility effective implementation on the ground. Lastly, the report provides key lessons learned in operationalizing research studies in real-life settings.

Section II: Background

The Wisconsin Department of Health Services (DHS) was one of 10 states awarded a Medicaid Incentives for the Prevention of Chronic Diseases (MIPCD) grant from the Centers for Medicare and Medicaid Services (CMS) in September 2011. Wisconsin's initiative, Striving to Quit, was designed to test the effects of incentives on engaging Medicaid members in smoking cessation treatment and quitting. The initiative included two evidence-based components. The first focused on linking non-pregnant adult Medicaid members with the Wisconsin Tobacco Quit Line (referred to as Quit Line). The second, referred to as First Breath, targeted pregnant Medicaid members for intensive individual cessation counseling during pregnancy and postpartum.[1]

Striving to Quit was a collaborative effort among a number of organizations, both within DHS and with external partners. Two organizations played key roles:

- The Center for Tobacco Research and Intervention at the University of Wisconsin School of Medicine and Public Health (UW-CTRI) managed the Quit Line approach and conducted the comprehensive evaluation of both components.
- The Wisconsin Women's Health Foundation (WWHF) managed the pregnant woman component.

Section III: Organization and Administration

A. September 2011 – September 2013 (Years 1 and 2): Original Project Design

DHS was designated as the lead agency. The DHS Division of Health Care Access and Accountability (the division that manages Medicaid) was designated as the policy lead. The DHS Office of Policy Initiatives and Budget was charged with program management. The

[1] For complete descriptions of both approaches and findings from the study, see the final evaluation reports at https://www.dhs.wisconsin.gov/opib/index.htm

DHS Division of Public Health's Tobacco Prevention and Control Program was designated as marketing and communication lead.

UW-CTRI was assigned two primary roles: (1) to oversee the development and administration of the Quit Line-delivered arm of the project, including outreach activities to clinics that would make referrals of Medicaid members, and (2) to implement the proposed research design and conduct the comprehensive program evaluation.

WWHF was responsible for the design and operation of the First Breath component for pregnant women, including outreach to Medicaid members and obstetric clinics.

Other collaborators included:

- Health maintenance organizations (HMOs) under contract with DHS to provide health care to Medicaid members across the state. DHS was the lead organization for ensuring participation of the HMOs, with UW-CTRI and WWHF reaching out to provide training to clinics, First Breath sites, and providers.
- Quit Line, under a contract with the State of Wisconsin and managed by UW-CTRI.
- Primary care and obstetric clinics providing health care to Medicaid members.

Beyond these named partners, the proposal committed the lead implementing organization to engage a wide variety of stakeholders involved with both providers and eligible participants.

With the primary program partners listed above, DHS developed an administrative structure that included a policy group (organizational leaders), an operations team, and various working groups with specific project design teams for the two projects as well as functional teams (for example, communications and evaluation). All project teams provided advice and guidance to DHS leadership.

1. Challenges and Solutions

Table A: Administrative Challenges	
Challenges	**Changes made in response to challenge**
1. CMS evaluators (RTI, National Academy for State Health Policy - NASHP) joined the national team following internal program and evaluation design; the national research plans and protocols required DHS and the Striving to Quit team to make several modifications. 1.2 The University of Wisconsin Institutional Review Board (UW-IRB) will need more program definition before the Striving to	1. Continued outreach to RTI for updates on the approval processes, development of research protocols, and data needs.

Quit team can seek approval to grant CMS (and its research partners) access to participant data for the focus groups and satisfaction surveys. This will then require coordination at DHS to pull the data and transmit it to CMS (and its research partners).	
2. More guidance from CMS and the national evaluators on the elements needed for Striving to Quit reports.	2. Continued outreach to RTI. RTI supplied DHS with other evaluative research to help guide report development.
3. To balance rapid cycle evaluation and implementation with multiple partners, intuitional review boards (IRBs), etc.	3. Convened quarterly Striving to Quit leadership meetings; established basic principles and timeline for IRB involvement; determined Quit Line component could not be implemented as a clinical trial.

B. September 2013 – September 2015 (Years 3 and 4): Recruitment, Enrollment, and Engagement

In Year 3, the focus moved to member recruitment, enrollment, and engagement as well as clinic recruitment and engagement for both components.

Section IV: The Wisconsin Tobacco Quit Line Component

A. September 2011 – September 2013 (Years 1 and 2): Initial Project Design

The Quit Line component of Striving to Quit originally targeted all Medicaid members 18 years of age or older who smoke and reside in either south central or northeastern Wisconsin. An initial goal was set to engage at least 20 percent of Medicaid members in the targeted areas in this project. If successful, this would result in more than 4,000 low-income residents gaining access to evidence-based cessation counseling plus incentives; it was anticipated that approximately 35 percent would quit smoking. Another 4,000 Medicaid members would receive counseling without the incentives, with an approximate 25 percent quit rate.

The following outlines key elements of the initial project design, submitted by UW-CTRI to the UW-IRB and the Western IRB as a clinical trial.

1. Recruitment and promotion

- Eligible participants must be Medicaid members 18 years of age or older who smoke.
- Eligible participants must reside in either south central or northeastern Wisconsin.
- Each HMO that partners with Striving to Quit may use a variety of communication and outreach strategies to identify tobacco users and engage them in smoking cessation treatment. The HMO's tobacco cessation program may offer a variety of services, including:

    - Personal telephone calls from care management staff.
    - Personal letters with material about the Quit Line or other quit lines supported by the health plan or other cessation programs.
    - Facts about the impact of smoking on individual and family member's health.
    - Simple steps for creating a quit plan with information about what to expect after quitting.
- Members are also encouraged to contact their primary care provider for direct assistance to stop smoking.
- HMOs work intensely with their provider networks to encourage incorporation of screening for tobacco use into protocols for taking vitals and use of Fax-to-Quit, a referral program that links Wisconsin Medicaid smokers who visit their primary care clinic and enroll in the Quit Line counseling program via a signed fax referral form with the individual's contact information.

2. Original linking participants to the study/project

- Adult, non-pregnant Medicaid members will be identified by the HMO or clinic and referred to the Quit Line using Fax-to-Quit.
- The Quit Line designates a quit coach to proactively contact the smoker to confirm their willingness to participate and then provides an intervention after receiving the faxed consent form.
- Finally, the Quit Line faxes a report back to the health care provider regarding the outcome of efforts to contact the potential quitter, including what treatment the smoker has agreed to engage in.

3. Original enrollment processes and components

- The Medicaid member visits a participating clinic and a clinic staff person—generally the medical assistant—identifies the member as a smoker via an expanded vital signs protocol that includes an assessment of smoking status.
- At this baseline visit, the MA also obtains an expired-air carbon monoxide (CO) measure from the smoker. This test both documents tobacco use and serves as a treatment element in providing physiologic feedback, documenting the burden of one toxin from tobacco smoke.
- The clinic staff member briefly explains the availability of free treatment services and monetary incentives and informs the patient that they will receive a call from the Quit Line within 48 hours.

4. Original informed consent process

- The Quit Line manages the informed consent processes.
- UW-CTRI developed the informed consent protocol and processes; DHS reviewed for compliance.

5. **Original study intervention model**
    - Quit Line randomly assigns Medicaid members to one of the two treatment conditions—usual care and usual care plus incentives.
    - A baseline assessment of the standard Quit Line registration and smoking assessment measures that includes the following:
        - Therapy readiness or content relevant measures
        - Standard smoking history questionnaire
        - Socioeconomic status
        - Contact information
        - Motivation to quit or reduce smoking
        - Barriers to cessation
        - General health information
        - Goals
    - A five-call smoking cessation counseling intervention program consistent with the *2008 Public Health Services (PHS) Guideline on the Treatment of Tobacco Use and Dependence*, focusing on skill training, intra-treatment support, and motivation.
    - Eight weeks of combination nicotine replacement therapy (nicotine patch plus an appropriate acute nicotine replacement therapy product, such as nicotine gum); these medications are covered by Wisconsin Medicaid, and this combination is recommended by the 2008 PHS Clinical Practice Guideline as safe and effective.
    - Carbon monoxide tests at six-month intervals for up to 24 months following initial enrollment in the Quit Line at the referring primary care clinic.
    - Those in the usual care plus incentive group receive incentives in the form of Visa gift cards for program participation and quit outcomes. The incentive is contingent upon treatment participation, visit attendance, and biochemical confirmation of quitting.

6. **Original evaluation model**

    UW-CTRI established a study evaluation and research design consisting of four separate aims bulleted below. Measures, analysis, and data sources were outlined for each aim. The evaluation design was proposed as human subjects research on the primary outcome of participant response to use of incentives. The original objectives were to:
    - Determine the extent to which contingent financial incentives increase rates of smoking cessation among Medicaid members who are given access to the Quit Line via a fax referral program from a primary care clinic.
    - Determine the extent to which contingent financial incentives increase rates of engagement in smoking cessation treatment among Medicaid members who are given access to the Quit Line via a fax referral program.
    - Determine the cost-effectiveness and reach of the incentivized smoking cessation initiative relative to a standard (non-incentivized) smoking cessation program.
    - Identify moderating and mediational effects regarding the clinical benefit of incentivized smoking treatment.

7. Challenges and Solutions

Table B: Recruitment and Promotion (model, aims, projections, and methods)	
Challenges	**Changes made in response to challenge**
1. Recruiting clinics to participate. a. Difficulty navigating multi-clinic systems; varying preferences among clinics/health systems regarding outreach and participation (for example, at the system leadership level, clinic by clinic, through HMO relationships, through existing Quit Line-Fax to Quit relationships). b. Reliance on HMOs for recruitment of clinics. c. Complexity of the program setup and the inability to respond to the needs of the providers, clinics, and health systems in a timely manner due to the clinical trial requirements (refer to Table B, challenge number 1).	1a. Discussions with clinic systems on preferred method of outreach. Biweekly HMO calls and additional coordination between DHS, UW-CTRI, and the HMOs around clinic and health system outreach helped improve outcomes. 1b-c. Clinical trial was closed at UW and Quit Line IRBs, and a new application for exemption as a non-research quality improvement project was submitted and approved. This new classification allows more flexibility in the design to better meet the varying requests from clinics. 1c. A system of clinic support was developed by DHS, with help from UW-CTRI and approval from CMS, to help overcome many of the barriers originally reported by clinics and health systems unable to participate. The support consists of an initial payment of $1,000; the payment is made by DHS after the clinic signed a memorandum of understanding (MOU) and demonstrated its staff are trained, or are being trained, and have a testing protocol in place. Any clinic that signs the MOU is then eligible for ongoing support through payments of $50-75 per member-offered enhanced smoking cessation support (e.g., screened, tested, referred to the Quit Line).

2. Recruiting participants. The original design anticipated Medicaid members could identify their HMO when asked, as eligibility criteria required that members self-identify as a Medicaid member, provide their Medicaid ID number, and identify their HMO as one of the participating HMOs in order to be invited to the study. Most Medicaid members were unable to provide correct information for all three criteria. Additionally, because Quit Line coaches are not based in Wisconsin and calls are scripted, the coaches had limited flexibility interacting with members.	• Adjusted recruitment projections. • Created a second method of entry in the study: Any existing Quit Line callers from the five counties with the highest number of Medicaid members could participate. Those who called the Quit Line and self-identified as a Medicaid member were invited to Striving to Quit and referred back to public testing sites staffed by UW-CTRI. The call-in model included additional public testing sites (county health departments and community health centers) and counties. To date, La Crosse County Health Department and Kenosha Community Health Center have signed on to participate. • Expanded eligibility criteria to include members enrolled in any Medicaid HMO, Medicaid fee-for-service (non-HMO members), Medicaid for Supplemental Security Income (SSI), and dual eligibles (eligible for Medicaid and Medicare). • Invited all members who self-identified as a Medicaid member for Quit Line to learn about Striving to Quit, and implemented a protocol for UW-CTRI staff to verify Medicaid eligibility and HMO enrollment. • Developed www.strivingtoquit.org to promote the program. Developed and distributed promotional materials to HMOs, including posters, information cards, and self-mailers. Promoted through a targeted TV ad buy in the Green Bay, Madison, and Milwaukee designated market areas. Campaign ran June-August 2013 and encouraged Medicaid members to call 1-800-QuitNow.
3. Original plans called for direct-to-member outreach. Some messaging and creative ideas had been tested and preapproved, but outreach was stalled until enough testing sites and clinics were trained and available.	DHS tested five quit smoking ads with 1,200 Wisconsinites with incomes of $35,000 or lower; the top two ranking ads were selected to run in target designated market areas, in addition to a Spanish-language ad. Post-IRB transitions, DHS developed a verbal and

	written tag that promoted the concept that Medicaid members could "get paid." This message was not tested but was very effective at garnering interest and resonating with the target audience.
4. Several HMOs expressed interested in allowing Spanish-speaking Medicaid members into the program.	UW-CTRI worked with the Western and UW IRBs to allow for Spanish-language outreach and services. UW-CTRI worked with Quit Line to build Spanish-speaking services (phone and web). DHS provided translation support.

Table C: Linking Eligible Adults to the Program	
Challenges	**Changes made in response to challenge**
1. UW-CTRI initially submitted the program as a clinical trial, which made it difficult to implement at clinics. a. Carbon monoxide verification procedure required equipment and training and was not Medicaid reimbursable. b. Clinics were unwilling to interrupt patient workflow or divert staff time. c. It was difficult for clinics to identify their Medicaid patients and develop a specific set of procedures just for Medicaid members. d. UW-CTRI and the Quit Line require the use of paper forms for faxing, but the majority of the clinics recruited provide Quit Line referrals using electronic health records (EHRs).	1. Following input from CMS and the Striving to Quit leadership, the clinical trial was closed with the UW and Quit Line IRBs, and a new application for exemption as a non-research quality improvement project was submitted and approved. This allowed more flexibility in the design to better meet the varying needs of clinics and health systems. 1a. Design was modified to allow multiple types of biochemical verification of smoking status (for example, urine cotinine). 1b. DHS developed a model to offset the additional workload required by clinics and clinic staff. With approval from CMS, DHS would provide initial support to get sites trained and modify their processes. Additionally, clinics could earn administrative support for each member's biochemical test. 1c. DHS assembled and consulted a clinical advisory group to address the concerns of clinics and health systems. Among the key issues addressed was the original inflexibility of the fax referral form and fax process. The forms and processes were modified to allow clinics to refer any tobacco-using patient so that clinics

	would not have to apply different procedures for Medicaid patients. The Quit Line modified procedures to handle the referral appropriately based on the patient's insurance status indicated on the form. 1d. DHS and UW-CTRI worked with clinics to address EHR concerns; some clinics that have been trained implemented the scanning of Striving to Quit forms into their EHRs.
2. Changes in work process made as a result of challenge number 1 (above) and the new call-in process were costly to implement at the Quit Line.	Limited the number of changes needed. Negotiated process changes, new entry method cost, and launch timeline with the Quit Line.
3. Members eligible to participate in the incentive study who were calling the Quit Line without an HMO referral were not being included in the study.	Created a second method of entry in the study: Any existing Quit Line callers from the five counties with the highest number of Medicaid members could participate. Members from these counties who called the Quit Line and self-identified as a Medicaid member were invited to Striving to Quit and referred back to public testing sites staffed by UW-CTRI. To date, this method of entry has yielded the majority of referrals.
4. Delays in the start of the program shortened the period of enrollment, which impacted initial enrollment goals.	DHS worked with CMS to drop the 12-month biochemical test to extend the enrollment period from December 2014 to April 2015 and alleviate some of the workload for the clinics (one fewer test to administer and results to submit to the Quit Line).

Table D: Enrollment Process and Components	
Challenges	**Changes made in response to challenge**
1. Recruiting clinics to participate as a referral source.	Created second method of entry so referral from a clinic was not required (refer to Table B, challenge number 3).
2. Selecting a Medicaid-covered test that was amenable to clinics, labs, and payors. Initially, the potential biochemical tests were limited due to restrictions on which provider types are authorized to	DHS worked with CTRI and CMS to make modifications to allow any biochemical test covered by Medicaid. DHS also worked with CTRI and CMS to develop a system to allow public testing sites (staffed either by CTRI

administer and bill for the test under Medicaid. NicCheck1, a urine cotinine test, was selected because it is Centers for Medicare and Medicaid Clinical Laboratory Improvement Amendments (CLIA)-waived, very easy to administer, affordable, and reimbursed by Medicaid. However, many labs and health systems raised concerns over quality controls, including that the test was not already approved and/or regularly used in their system. Similarly, some clinics and health systems encountered difficulties incorporating the urine test into their office protocol.	outreach specialists or clinic/health department staff); some of these sites utilize carbon monoxide machines.
3. Ability of members and Quit Line coaches to identify or recognize a member's Medicaid plan, ID number, and/or Medicaid HMO.	• DHS expanded eligibility criteria to include members enrolled in any Medicaid HMO, Medicaid fee-for-service (non-HMO members), Medicaid for SSI, and dual eligibles. • CTRI staff invited all self-identified Medicaid members who had previously called the Quit Line to learn more about Striving to Quit • DHS and CTRI developed a protocol for UW-CTRI staff to verify Medicaid eligibility and HMO enrollment. CTRI staff will coordinate findings with the Quit Line.

Table E: Informed Consent Process	
Challenges	**Changes made in response to challenge**
1. Maintaining IRB processes (for example, two IRBs, UW and Quit Line, independently reviewed and approved study protocol and changes) and required consent language with the need for rapid-cycle implementation and individual-level data sharing with multiple program partners (including HMOs and CMS contractors).	DHS developed a protocol and received approval from CMS to close the clinical trial at both the UW and Western IRBs. A new application was submitted, and accepted, to exempt the program as a non-research quality improvement project. The changes allow ongoing flexibility in making needed changes and sharing data with program partners.
2. The initial research consent process was cumbersome to administer at both the clinic and Quit Line level; it was an	All Medicaid members in service areas are now informed of the availability of a new program and the opportunity to volunteer. If

unnecessary obstacle once the program shifted to a quality improvement effort.	they express interest, they are given full information about the program and asked for their verbal consent to enroll.
3. Difficulty coordinating consent for an RTI research survey and focus groups for which DHS/UW-CTRI do not have enough information.	Included general information in the program consent so that RTI can do outreach and members can opt out of participating.

Table F: Study Intervention Model	
Challenges	**Changes made in response to challenge**
1. Two different Striving to Quit entry methods (clinician fax referral and inbound callers) created difficulty for standardizing a method of medication distribution. The Quit Line was unable to provide nicotine replacement therapy to inbound callers because it was not a Medicaid-certified provider and medications were not reimbursable.	Eliminated medication as a standard element of the program, and encouraged participants to talk to their health care provider about Medicaid-covered smoking cessation medications.
2. The original study design planned for biochemical tests and follow-up for up to two years post enrollment. Some of the anticipated challenges to this long-term window of study included: • Potentially high rates of Medicaid members losing and/or regaining coverage. • Transient population for whom contact information may change throughout the two-year period. • A two-year window of study requires an earlier deadline for enrollment.	UW-CTRI initially shortened the program to only capture biochemical verification of smoking at six months and 12 months, eliminating the final two-year test. This shortened participation will help overcome the challenges related to launch delays and implementation difficulties and will extend the window of enrollment and services.

Table G: Evaluation Model	
Challenges	**Changes made in response to challenge**
1a. Anticipated variability in the Medicaid population (losing and/or regaining coverage) presented problems for the program's initial two-year follow-up design.	1a. Initially shortened the period of participant biological test follow-up for the evaluation to one year in order to increase the ascertainment rate at follow-up. Due to launch delays/difficulties, the window of enrollment and services

1b. The delayed start, IRB challenges, and lack of trained clinics meant either an impact to enrollment goals or the need to extend the enrollment period. 1c. 2014 Medicaid coverage changes. The Affordable Care Act (ACA)/Marketplace and Medicaid eligibility may result in up to 40 percent of current Medicaid Striving to Quit enrollees losing their eligibility before their six-month follow-up test (no impact on services). The coverage changes may result in a 500 percent increase in potentially eligible Medicaid members beginning April 1, 2014.	decreased impacting enrollment goals, so the follow-up period was further shortened to six months to extend the enrollment period. 1b. UW-CTRI and DHS worked to develop a shortened protocol—members would receive all of their services and only conduct one follow-up biochemical test at six months. CMS approved this plan. 1c. UW-CTRI worked with the Quit Line and DHS to establish an updated protocol for screening members for eligibility at six months and coordinating the final test. UW-CTRI and DHS coordinated with HMOs and others to ensure testing sites and clinics are equipped to handle a 500 percent increase in eligible enrollees.
3. Multiplicity of methods of smoking verification designed in response to enrollment/clinic engagement challenge creates analysis challenges.	If and when data is presented for publication, a statement about the data's limitation will be included. Flexibility in testing was necessary to get any testing sites or clinics involved.
4. Because of the nature of the program and the administration of the Quit Line by a third party located out of state, medication could not be distributed by the Striving to Quit program. The inability to distribute medication as a standard element of the program may lower anticipated quit rates.	This affects both arms of the program (usual care and usual care plus incentives) relatively equally. New effect size calculations were done to determine the minimum recruitment level necessary to assess an effect from counseling without medication. Striving to Quit will still collect medication data and assess whether medication use varies among the two groups and whether this mediates outcomes.
5. Reduced recruitment projections could affect the ability to assess the effect of incentives.	The recruitment goal of 8,000 members was more than enough to detect an effect, so a reduction in recruitment projections did not affect the study.
6. Continuous barriers to program development and implementation require flexibility and ongoing program changes.	DHS and UW-CTRI worked to ensure that program changes could be made within the original research design. The Striving to Quit had not anticipated the variety and complexity of changes that would be made, nor developed methods to document and assess the programmatic changes. DHS, UW-CTRI, and WWHF are working together to best document challenges and changes so that they

	can be summarized and reviewed annually and upon program completion.
7. Inability to share data with HMOs as a clinical trial and preventing care coordination via HMOs.	As a quality improvement project, Striving to Quit now has the ability to share patient-level data with HMOs. HMOs have always been encouraged to do outreach to members but are not encouraged to do so specifically about the HMOs participation in the study. DHS and UW-CTRI can now also work to capture and review information about the HMO outreach.

8. Quit Line – Summary of Key Events, Changes, and Milestones

2011	
September	MIPCD grant awarded to Wisconsin; planning begins

October	• Quit Line protocol development begins
	• Striving to Quit evaluation working group meeting at UW-CTRI (October 11)
	  ○ Study questions refined
	  ○ Data elements identified

November	• Striving to Quit evaluation working group meeting at UW-CTRI – Quit Line only (November 11) • Striving to Quit project team meeting at DHS (November 15) • Striving to Quit HMO meeting (in-person) • Striving to Quit detailed work plan
December	Striving to Quit project team meeting at DHS (December 20) Striving to Quit contracts developed Striving to Quit operational protocol drafted
2012	
January	Striving to Quit project team meeting at DHS (January 5)
February	Striving to Quit project team meeting at DHS (February 3)
March	• Quit Line initial protocol submitted to UW IRB • Striving to Quit project team meeting at DHS (March 8) • Striving to Quit HMO meeting
April	• Striving to Quit project team meeting at DHS (April 12) • Striving to Quit HMO contacts identified
May	• UW IRB approved Quit Line protocol • HMOs request Striving to Quit enrollment be expanded to include Spanish speakers • First MIPCD all-state grantee meeting (Baltimore, MD) • Striving to Quit high volume clinics identified
June	• UW-CTRI prepares and finalizes Quit Line in-person and online clinic

	training protocol • DHS Striving to Quit project manager hired • In-person HMO meeting • Striving to Quit project team meeting at DHS (June 22)
July	WIRB approved Quit Line study protocol with consent language changes
August	• Striving to Quit project team meeting at DHS (August 23) • Striving to Quit ForwardHealth provider update drafted and released • Striving to Quit Performance Improvement Project (PIP) development
September	• UW IRB approved WIRB changes to consent language • Quit Line completes programming; Striving to Quit ready to launch; no clinics signed on • Bi-weekly HMO calls begin • Striving to Quit PIP development
October	• Protocol change submitted for Spanish language services • Striving to Quit evaluation working group meeting (October 16) • Striving to Quit leadership team convened (October 26) • One-on-one meetings with HMOs • Striving to Quit PIP development
November	• DHS explores financial support for clinics; secures CMS approval • One-on-one meetings with HMOs • Striving to Quit PIP development
December	• IRB approved Spanish language services protocol • DHS launches clinic support program • MIPCD all-state grantee meeting (Baltimore, MD) • Striving to Quit leadership team convened (December 19) • Striving to Quit PIPs due
2013	
January	• DHS/CMS approve plans to develop a call-in method of entry referring callers to five UW-CTRI testing sites • DHS/CMS approve shortening the period of participant follow-up for the evaluation from 12 months to 6 months
February	• UW IRB granted Quit Line project exempt (or not human subjects research); Striving to Quit clinical trial closed at UW IRB • Striving to Quit program procedures re-worked to shorten follow-up period to 6 months and meet varying needs of clinics (allowed multiple types of biochemical verification, modified referral forms to allow clinics to refer any tobacco use to Quit Line)
March	• UW-CTRI testing site procedures developed • Striving to Quit leadership team convened (March 21)

April	• Centers for Disease Control and Prevention (CDC), through the Office on Smoking and Health (OSH),launches TIPS II campaign to run through June 2013 • Quit Line project soft launches call-in method in Dane and Winnebago counties (April 22) • Zero enrolled; one clinic participating in clinic incentive program and trained to submit Striving to Quit referrals
May	• Quit Line fully launched, including Milwaukee, Rock, and Brown counties • Daily caller/screening/invite reports indicated that Medicaid members were not able to identify their Medicaid insurance, Medicaid ID, or HMO, resulting in ineligibility for Striving to Quit and a loss of potential participants • Quit Line launches eligibility logic changes that allow all Medicaid callers to be invited to test for Striving to Quit, contingent upon eligibility verification by UW-CTRI (May 22) • Further expanded eligibility criteria to include enrollment in any Medicaid HMO (not just Striving to Quit HMOs), Medicaid fee-for-service, Medicaid for SSI, and dual eligibles • MIPCD all-state grantee meeting (Baltimore, MD)—program progress in other states, shared challenges • HMOs begin targeted outreach via member mailings • New Quit Line mailers designed to clearly highlight what the program offers, incentives • 18 enrolled; four trained clinics participating in clinic incentive program
June	• Striving to Quit ads encouraging Medicaid members to call 1-800-QUIT-NOW launched on June 3 and ran for two weeks • UW-CTRI issued a Striving to Quit letter-to-the-editor • 82 enrolled; eight trained clinics participating in clinic incentive program
July	• Striving to Quit ads continue to run for four weeks • 161 enrolled; eight trained clinics participating in clinic incentive program
August	• Striving to Quit ads continue to run for three weeks • 245 enrolled; 11 trained clinics participating in clinic incentive program
September	• Striving to Quit ads end; some public service announcements (PSAs) running through September • Infant Mortality Awareness Month outreach promotes need to prevent household smoke; offers Quit Line as resource • 315 enrolled; 15 trained clinics participating in clinic incentive program

9. Quit Line – Key Lessons Learned

1. Recruiting clinics to participate in the Quit Line program was difficult.
    a. The program anticipated that HMO commitment to participate in the project would lead directly to clinic participation, but this did not occur. A team approach among HMOs, UW-CTRI, and DHS was necessary to secure any clinic participation. DHS devised an additional system to provide financial and administrative support to participating clinics. This support, coupled with active outreach from DHS and UW-CTRI and more flexibility for Striving to Quit implementation at the clinic, resulted in a gradual expansion in the number of clinics participating. This process required ongoing troubleshooting, as well as the involvement of senior DHS leadership, individualized outreach, and meetings with health systems and clinics.
    b. The biological testing process for smoking verification required for enrollment was one of the reported stumbling blocks for the clinics. Requiring a test at the point of referral for enrollment requires a workflow change for many clinics, whether administering on-site or ordering a lab test. Additionally, many labs and health systems expressed concerns over quality controls because the CLIA-waived urine cotinine test was not regularly used.
    c. The request to screen only for Medicaid patients and develop a separate set of or modifying existing protocols just for those patients was difficult for clinics. Creating a hybrid referral form that could be used for any tobacco user, regardless of insurance status, helped mitigate this issue.
    d. Engaging health care providers, clinics, and health systems from the program's planning phase may have identified and mitigated some of these issues. Striving to Quit formed a health care professional working group in early 2013 to engage this group of stakeholders and solicit input as needed.

2. Enrollment was both delayed and slower than expected in part because of the lack of clinic engagement. Some efforts to improve enrollment include:
    a. Launching an alternative method of entry. Inbound Quit Line callers are now being invited to the program and, if eligible, sent to public testing sites.
    b. Targeted television advertising has been instrumental in driving higher rates of Medicaid callers to the Quit Line. These individuals are enrolling through the public testing sites' alternative method of entry.
    c. Clinics are not referring or enrolling members at a sustainable rate. UW-CTRI has begun holding monthly calls to troubleshoot and share stories of success among participating clinics.
    d. DHS continues to conduct outreach to other areas of the state to identify interested clinics and potential public testing sites.

3. Medicaid members may lose and/or regain Medicaid, which paired with the delays in implementation, made it difficult to anticipate the eligibility and engagement of program participants at the six-month test. Wisconsin Medicaid is making changes to its eligibility requirements, which places added uncertainty around the long-term

eligibility and participation of members. While up to 40 percent of participants could lose coverage effective April 1, 2014, due to ACA changes, a previous cap on enrollment will be lifted that could result in up to 500 percent more Wisconsin residents to be eligible for Medicaid and Striving to Quit.

B. September 2013 – September 2014 (Year 3): Summary of Design

The Wisconsin Tobacco Quit Line program design was not modified during the third year of the grant.

The Quit Line component links adult Medicaid and SSI members to the Quit Line to receive up to five proactive counseling calls from highly trained quit coaches. Coaching calls generally occur over a period of 8-12 weeks. Coaches help participants develop a personalized quit plan, offer proven strategies for overcoming nicotine withdrawal and cravings, provide support on use of quit-smoking medications, and assist participants in dealing with slips and avoiding relapse. Participants can initiate additional calls to the Quit Line if more support is needed. Participants are encouraged to talk to their health care provider to discuss a prescription for Medicaid-covered quit-smoking medications to assist in the quit attempt. All participants receive a smoking test attendance incentive for completing a smoking test at enrollment ($40) and at the six-month end-of-program visit ($40) for a possible incentive total of $80. The treatment group additionally receives financial incentives for participating in counseling services ($30 per call; up to five calls) and for a nonsmoking test result at the six-month visit ($40) for a possible additional incentive total of $190.

The Quit Line component will serve a minimum of 2,000 members who smoke. Members can enroll via a Quit Line referral from one of more than 60 participating clinics in South Central, Southeast, and Northeastern Wisconsin participating in Striving to Quit. Additionally, members who reside in 13 counties across Wisconsin with public testing sites can also call the Quit Line to enroll.

1. Challenges and Solutions

a. Participant enrollment

Meeting the Quit Line enrollment goal of at least 2,000 members continued to be a challenge. This was addressed by efforts to: (1) increase the number of Medicaid callers to the Quit Line, (2) recruit more clinics to participate as Striving to Quit testing and referral sites, and (3) increase clinic utilization of Fax to Quit referrals. The next three sections address aspects of the recruitment challenge.

i. Increasing Enrollment via Inbound Quit Line Callers

Promotion of the Quit Line and Striving to Quit in counties with public test sites was critical to sustaining enrollment in Grant Year 3. DHS and the UW-CTRI employed a number of methods to increase call volume to the Quit Line, including TV ad buys and expansion of public testing locations to non-UW-CTRI

sites. As in the previous grant year, Striving to Quit again benefited from the CDC's National Tobacco Education Campaign, Tips from Former Smokers (TIPS 3) campaign in Grant Year 3. The following promotional activities helped with enrollment:

- Quit Line TV ads targeting Medicaid members – DHS's targeted TV ad buy in the Green Bay, Madison, Milwaukee, and La Crosse designated market areas ran two weeks in October 2013 and three weeks in January 2014. The ads encouraged Medicaid members to call 1-800-QUIT-NOW. Calls increased as a result of the ads and varied from week to week, ranging from 35-100 percent increases.
- CDC's TIPS 3 campaign – The TIPS 3 campaign encouraged smokers to call 1-800-QUIT-NOW, ran for nine weeks starting in February 2014, and followed with a nine-week summer campaign that started in July 2014. Quit Line calls increased on average by 65 percent.
- Facebook, YouTube, and Google ads – In March and April 2014, DHS launched a Striving to Quit social marketing campaign, promoting the Quit Line component through Facebook, YouTube, and Google Ad Words advertising. Users had the option of clicking the ads to complete a prescreening survey to learn about their eligibility for Striving to Quit. In all, 66 users completed the survey, 36 of them were Medicaid-eligible and were subsequently invited to a CTRI testing site, five attended testing, and three enrolled in Striving to Quit.
- Expansion of public test sites – DHS recruited non-UW-CTRI public testing sites in new counties in a variety of different settings, including a local health department, a community health center, and several pharmacies. Aided by DHS's system to provide financial and administrative support to potential clinical test sites, DHS recruited eight total additional testing sites, including six pharmacies. By the end of Grant Year 3, the number of public testing sites increased from the original five UW-CTRI public test sites to 13. Additionally, in February 2014, UW-CTRI closed one of their low-yielding public test sites in southern Wisconsin, relocating to a new county in southeastern Wisconsin with a large Medicaid population, which enrolled more than twice the number of members. By expanding the number of public test sites, this program became more accessible for Medicaid members.
- Expansion of Fax to Quit – The DHS clinical support system also extended to clinical sites willing to participate in the Quit Line standard fax referral program, called Fax to Quit. Engaging more clinics in the Fax to Quit program in counties where Striving to Quit public testing was available potentially increases Medicaid member referral to the Quit Line and, thus, enrollment in the study. As a result, 37 clinical sites, including 17 clinics, 17 pharmacies, and three community health centers, registered as Fax to Quit sites. These Fax to Quit sites referred a combined total of 100 tobacco users to the Quit Line; of those, four were eligible for and enrolled in Striving to Quit.

- Outbound recruitment of past Quit Line callers – UW-CTRI accessed the records of thousands of past Quit Line callers from counties with public testing sites and screened them for Medicaid eligibility and other factors (hundreds of participants had self-identified the wrong insurance, making themselves initially ineligible for the study). Callers who were Medicaid-eligible were invited by letter to learn more about Striving to Quit if they were still smoking. Those who responded to the mailing and were interested in Striving to Quit were invited to a public testing site. As a result, over 100 members enrolled in Striving to Quit.
- Direct recruitment in the community – UW-CTRI conducted outreach to a variety of community organizations, such as YWCA, low-income public housing, and housing authority facilities, where Medicaid members likely reside or seek services. Staff and clients were educated about smoking cessation resources and Striving to Quit. UW-CTRI checked eligibility and conducted the biochemical test on-site to assist interested clients in enrolling in the study. As a result, 15 clients were Medicaid-eligible and referred to Quit Line, resulting in 14 enrollments.

ii. Clinic Recruitment

There were fewer clinic recruitment challenges in Grant Year 3 due to steps taken in the prior year to remove barriers to participation, including closing Striving to Quit as a clinical trial (to respond to the needs of providers, clinics, and health systems) and DHS's development of a clinic support system (administrative and financial). To further aid recruitment in the third year, DHS expanded the network of possible clinical sites willing to implement the standard Quit Line referral program, Fax to Quit.

It was sometimes challenging to get new sites operating quickly. In some cases, Striving to Quit startup was slowed by the lengthy process of completing an MOU agreement with DHS and conducting the Striving to Quit training. Other delays centered on competing priorities within the clinic or health system, such as a system-wide rollouts and trainings.

Several strategies were used to increase the number of clinics participating in Grant Year 3:

- Obtain leadership buy-in – DHS and UW-CTRI obtained health care system leadership buy-in and recruited and engaged clinics within the system. Once leadership made the decision for their primary care clinics to participate in Striving to Quit, it eliminated recruiting time on individual sites and the possibility of a decision not to participate. In some cases, starting with leadership also improved the efficiency of completing the MOU agreement process.
- Contracting process – Some clinics preferred not to start staff training until the MOU agreement with DHS was completed. This preference sometimes

led to a delayed start by several weeks or months. DHS encouraged trainings to be scheduled and to take place as soon as possible, emphasizing that referrals would be tracked for payments regardless of the status of the MOU.

- Expansion to pharmacies and community health centers – Pharmacies and community health centers often operate more independently than large health systems, making them easier to navigate. DHS worked through the Pharmacy Society of Wisconsin to recruit pharmacies to participate in Striving to Quit. This yielded six pharmacy sites willing to participate as both a referral and public testing site. As a result, the Quit Line began inviting callers in July 2014 from six additional counties in northeastern Wisconsin to Striving to Quit, referring them to the pharmacy-based public testing sites in their counties. Additionally, 17 Shopko pharmacy locations in counties with existing public testing sites agreed to participate in the Quit Line's standard fax referral program, Fax to Quit. DHS and UW-CTRI efforts also led to several federally qualified health centers' participation in Striving to Quit: One community health center was contracted as a referral and public testing site; two health centers signed on as referral-only sites; and three community health centers registered as Fax to Quit sites.
- Expansion of Fax to Quit – Engaging more clinics in the Fax to Quit program in counties where public testing was available potentially increases Medicaid member referral to the Quit Line and, thus, enrollment in Striving to Quit. Thirty-seven clinical sites, including 17 clinics, 17 pharmacies, and three community health centers, registered as Fax to Quit sites.

At the beginning of the third year of the grant, 11 clinics were trained to test and refer their patients to the Quit Line. By the end of the grant year, more than 60 clinical sites were trained as official Striving to Quit sites; an additional 37 sites contracted with DHS to participate in some capacity (i.e., Fax to Quit).

iii. Clinic Engagement and Medicaid Member Referrals

At the end of Grant Year 2, only 33 members had been referred by the clinics, resulting in just seven clinic-referred enrollments in the study. Clinics that were not engaged with the program had a low Medicaid patient population or were experiencing implementation difficulties and were not referring. Most of the clinics were still having difficulty identifying Medicaid-eligible patients. Many sites did not have systems in place, or staff was not familiar with the process of identifying patients' insurance coverage in the EHR. Many clinics reported that patients were not interested in quitting smoking or in Striving to Quit. UW-CTRI increased efforts to engage clinics and help staff work through these challenges, detailed below.

- Monthly clinic coordinator conference calls – During 15- to 30-minute calls, UW-CTRI shared Striving to Quit program updates and clinic referral progress, discussed referral and testing issues, and encouraged clinics to share their successes and challenges. Problem areas discussed included how

to identify Medicaid patients, how to present the program to patients by emphasizing the benefits, and how to employ motivational interviewing techniques with patients who are ambivalent about quitting.

- Monthly testing reports – In advance of the monthly clinic coordinator calls, UW-CTRI emailed two reports. The clinical referral outcome report provided aggregate data for each clinic on the number of submitted Striving to Quit referrals and the outcome of those referrals (enrolled, unreachable, declined/ineligible, etc.). The second was a six-month testing report providing aggregate data for each clinic on the number of enrolled participants who are due for a six-month test and the number of completed tests. Coordinators were able to compare their clinics' referrals and six-month test performance with other participating clinics.
- Monthly electronic newsletter – After each clinic coordinator call, UW-CTRI emailed a newsletter summarizing coordinator call discussion topics, highlighting top clinic performance for the week, and emphasizing certain aspects of successfully implementing Striving to Quit.
- Weekly motivational email – The weekly email shared the number of referrals to the Quit Line by clinic for the prior week, congratulating the top performers. At times, top performing clinic coordinators were interviewed by phone to share how they were successful. Motivational messaging included the importance of referring at least one patient per week.
- Individualized technical assistance – UW-CTRI continued to offer ad hoc training and technical assistance, especially with high staff turnover at participating clinics.

Clinics with staff, such as caseworkers or health educators, who may be able to devote more time to identifying Medicaid-eligible patients and completing the paperwork for the referral tended to have higher referral rates. Other clinics developed strategies/workflow to identify Medicaid-eligible patients, such as utilizing pre-visit planning, prescreening of insurance before the visit, or flagging eligible patients by medical reception. One of the large health systems created a separate SmartSet in their EHR for Striving to Quit. The EPIC-brand EHR is programed to automatically identify patients eligible for Striving to Quit; it prescreens for patients who are documented smokers, 18 years of age and older, with Medicaid insurance, and prompts clinicians to invite the patient to the program. This EHR modification increased the efficiency of making referrals and was an advantage in recruiting the clinics in this system to participate.

The enhanced training, technical assistance, peer-to-peer learning, and performance feedback boosted utilization of Striving to Quit referrals to the Quit Line. By the end of Grant Year 3, Striving to Quit clinics referred 618 members to the Quit Line, resulting in 303 enrollments.

2. **Six-Month Smoking Ascertainment/Test**

Initial efforts to encourage participant attendance at the six-month end-of-program visit yielded a 52 percent ascertainment rate at the beginning of Year 3. Participants received a call and a letter from the Quit Line inviting them to attend their six-month end-of-program visit. For those who had not attended, a second reminder letter was sent two weeks later. Additionally, UW-CTRI staff conducted three more reminder calls to those who had not yet attended, and the participant's HMO was also informed that the member was due for a six-month visit.

Given that the six-month smoking test is the primary outcome measure, a high level of attendance is critical to the analysis. Possible reasons for the initially lower show rate include inaccurate contact information and participants who were uninterested because they were still smoking or relapsed. To boost follow-up ascertainment, UW-CTRI intensified outreach methods in Grant Year 3, described below:

- UW-CTRI staff conducted additional reminder phone calls (up to 15 calls throughout the testing window). An email reminder was also sent to some individuals who provided an email address during registration at the Quit Line. UW-CTRI also began making calls to Striving to Quit participants attending clinic testing sites. These calls ended up being critical because several participants informed UW-CTRI that they had already tested (the clinic had not faxed the test results to the Quit Line). UW-CTRI followed up with the clinics to ensure test results were communicated to the Quit Line.
- The reminder calls emphasized that the data is still valuable to us even if the participant is smoking. The cash incentive for attendance, regardless of smoking status, was also emphasized.
- UW-CTRI exchanged a file with the Quit Line every couple of weeks to obtain updated contact information and the phone numbers for alternate contacts for unreachable participants (when available).
- The importance of conducting the six-month test was emphasized at the clinic coordinator calls. Clinics were reminded of the DHS clinic support system, which provides a $25 incentive for each completed six-month test at the clinic. UW-CTRI also began distributing a monthly clinic six-month testing report highlighting testing rates by clinics and offered to fax a monthly notification to clinics listing their patients due for a six-month test so that the clinics could conduct their own outreach to their patients; 13 clinic sites requested the fax notification.

As a result of these efforts, the six-month visit ascertainment rate increased to 67 percent by the end of Year 3.

3. **Participant Feedback and Concerns**

The main inquiries fielded by staff came from Quit Line participants who had issues receiving their gift cards or difficulties filling smoking cessation prescriptions covered by Medicaid.

A third-party vendor was used to issue gift cards. There were occasions when shipment of gift card orders were delayed either because of technical issues on the vendor's end or lack of communication between the Quit Line and the vendor. There were also times when the participant changed addresses or did not receive the card at the address they provided within the expected time period. The participant often contacted the Quit Line when there was an issue; however, the Quit Line does not have the authority to request replacement cards or make gift card inquiries on the participant's behalf. In order to address those issues, the Quit Line provided the vendor's customer service number and instructed the participant to call them directly. This sometimes led to participant frustration as they felt their issue was being passed from one entity to the next without immediate resolution. To the extent possible, the Quit Line and UW-CTRI attempted to help these participants resolve the issue with their gift cards.

The smoking cessation prescription issues, in most cases, were prescriber or dispenser error (omission of the proper Medicaid codes). Participants would go to the pharmacy to have their prescription filled only to be told it was not covered by Medicaid. One prescriber incorrectly told a member that a prescription was not needed for nicotine replacement therapy because it was available over the counter. In all of these instances, UW-CTRI staff worked with the participant and Medicaid Provider Services to educate the prescriber on Medicaid coverage of quit-smoking medications, and the participants were eventually able to get their medications. To prevent these types of problems from recurring, UW-CTRI began proactively providing a handout explaining Medicaid-covered quit-smoking medicines to members completing the baseline test at UW-CTRI testing sites. It included information that could be shared with the members' provider on how to write the prescription (with the proper Medicaid codes). UW-CTRI also emphasized Medicaid coverage of smoking cessation medications in Striving to Quit provider trainings and monthly clinic coordinator calls.

4. Participants, Service Utilization, and Trends

The Quit Line enrolled 1,159 Medicaid adults in Striving to Quit by September 30, 2014. From this total, 16 participants that were still smoking at the end of their program re-enrolled for a second time. Most of the participants (54 percent) entered the program through the inbound Quit Line method. The remaining entered via a referral from a primary care clinic fax referral (26 percent) or CTRI testing site fax referral (20 percent). There was also an 8 percent increase in clinic fax referral enrollments in Grant Year 3.

Of the 1,159 enrolled, 581 were assigned to the control group, and 578 were assigned to the treatment group. Enrollment skewed toward women (68 percent) and older Medicaid members (63 percent are age 41 or older). Most of the participants were African American (49 percent) and Caucasian (44 percent). Prior to program completion, 69 (6 percent) individuals withdrew from the study, most of them having lost their Medicaid eligibility prior to the six-month follow-up visit (74 percent).

As part of the Quit Line call program, participants have the opportunity to complete five counseling calls. Of the 867 participants that completed the call program, 55 percent completed four or more calls, 29 percent completed two to three calls, and 16 percent completed only one call. On average, participants in the Striving to Quit program are completing more calls (3.39 calls per participant) compared to participants in a Quit Line five-call program (1.90 calls per participant).

The primary outcome is a biochemically confirmed abstinence at the six-month end-of-study visit. While data from the project have not yet been cleaned for final analysis, the raw data indicate that of the participants whose window to test has closed, 67 percent (261/391) who maintained their Medicaid eligibility and active status in the program completed the test. The overall intent-to-treat quit rate, which assumes participants with missing six-month smoking test data are smokers, is 26 percent. The responder-only quit rate, including only the participants who conducted the smoking test at the end point, was 39 percent. In order to maintain the integrity of the research, the participation and quit rates for the attendance incentive and treatment incentive groups have not been separately analyzed.

5. Key Lessons Learned

- Listed below are details that were essential to implementing the study. A variety of methods are needed to reach and recruit Medicaid members.
  - National and state media campaigns are helpful to drive callers to the Quit Line.
  - Many members who called the Quit Line incorrectly identified their insurance. A mechanism is needed to verify insurance.
  - Clinics are a natural fit for the program and are willing to engage with members in some capacity. Reducing the burden of implementing the program is key to securing clinic commitment.
  - Partnerships with other community-based sites that interact with the Medicaid population are promising. Pharmacies were easy to engage and train.
- A significant amount of training and technical assistance is needed ongoing to encourage clinic engagement and referrals. Providing performance feedback and facilitating peer-to-peer learning are helpful.
- In many clinics, Medicaid patients tend to be a minority of the overall patient population, and delivery of a specialized service to a subgroup presents special challenges. It would be helpful to identify clinical sites that either primarily serve the target population or have a mechanism (such as EHR) to automatically identify potentially eligible patients.
- Continued messaging from the program to clinics about which medications are covered and which codes are required on the prescription is essential. Integration of the medication with the program is necessary since medication has a critical role in helping members quit smoking.
- Utilizing a third-party incentive fulfillment vendor requires at least two weeks for participants to receive their gift cards and creates difficulties for participants who have not received their gift cards in the expected time frame. A more streamlined

method is needed so participants receive the incentive immediately after completing the activity.

- It is difficult to do follow-up with Medicaid members because of losing and/or regaining coverage. Short-term coverage and changes in contact information also made follow-up difficult.

C. September 2014 – September 2015 (Year 4)

1. Summary of Design

The Quit Line program design was not modified during the fourth year of the grant.

The Quit Line component recruitment ended in May 2015 with 1,962 members enrolled, 98 percent of the reach goal (2,000). Members enrolled via Quit Line referral from one of 68 participating clinics in south central, southeast, and northeastern Wisconsin. Additionally, members residing in the 16 Striving to Quit public testing counties across Wisconsin called the Quit Line to enroll.

2. Challenges and Solutions

a. Participant Enrollment

Meeting the Quit Line enrollment goal of 2,000 members continued to be a challenge in Grant Year 4. This was addressed by efforts to increase Medicaid member calls to the Quit Line and recruitment via the public test sites and increase clinic utilization of Striving to Quit referrals to the Quit Line. The following sections address aspects of the recruitment challenge.

i. Member Recruitment via Quit Line and Public Test Sites

The following promotional activities helped with enrollment:

- Television advertising – The DHS Tobacco Prevention and Control Program (TPCP) ran a Quit Line television ad buy in the Green Bay, Madison, Milwaukee, Wausau, and La Crosse designated market areas for three weeks in winter 2014/2015. The ads encouraged Wisconsin tobacco users to call 1-800-QUIT-NOW. As a result of the ads, Quit Line calls increased about 50 percent overall. Additionally, Striving to Quit benefited from the Centers for Disease Control and Prevention's National Tobacco Education Campaign, Tips from Former Smokers (TIPS 4). TIPS 4 ran during the spring and summer of 2015. The campaign, which encouraged smokers to call 1-800-QUIT-NOW, resulted in a 30-percent increase in calls to the Quit Line.
- Facebook advertising – In March 2015, UW-CTRI ran a Facebook ad targeting low-income individuals. The ad, which encouraged Medicaid members to call the Quit Line for free help to quit smoking and up to $80 in gift cards, reached over 52,000 residents in Striving to Quit counties.
- Earned media – In mid-March 2015, UW-CTRI developed press releases for the public test site counties to announce the near end of Striving to Quit enrollment. It was picked up by Milwaukee Biz Times, WPR/WPR.org,

news8000.com in La Crosse, KFIZ AM radio in Fond du Lac, and Winneconne News in Winnebago. The following month, UW-CTRI submitted letters to the editor in those same counties, many of which were published in the county newspapers.

- Additional public test sites – By the end of member recruitment, the number of public testing sites and active Striving to Quit counties increased from 13 to 16. The additional sites included a local public health department in Adams County and two additional UW-CTRI public test sites in Sheboygan and Fond du Lac counties.
- Outbound recruitment of past Quit Line callers – UW-CTRI accessed the records of thousands of past Quit Line callers from counties with public testing sites and screened them for Medicaid eligibility and other factors (hundreds of participants had self-identified the wrong insurance, making themselves initially ineligible for Striving to Quit). Callers who were Medicaid-eligible were invited by letter to learn more about Striving to Quit if they were still smoking. Those who responded to the mailing and were interested in Striving to Quit were invited to a public testing site. As a result of this outreach, 171 members total enrolled in Striving to Quit.
- Direct recruitment in the community – UW-CTRI conducted outreach to a variety of community organizations, such as YWCA, low-income public housing, and housing authority facilities, where Medicaid members likely reside or seek services. Staff and clients were educated about smoking cessation resources and Striving to Quit. UW-CTRI checked eligibility and conducted the biochemical test on site to assist interested clients in enrolling in Striving to Quit. In all, 38 clients were Medicaid-eligible and referred to Striving to Quit resulting in 28 enrollments.

ii. Member Recruitment via Striving to Quit Clinic Referrals

By the end of clinic recruitment in December 2014, 68 clinics were trained to conduct the Striving to Quit smoking tests and referral to the Quit Line. Some of the clinic implementation challenges from the prior year persisted in Grant Year 4 (for example, patients not interested in quitting smoking or in Striving to Quit). But additional factors hindering Striving to Quit referral emerged, including lack of staff motivation (to offer Striving to Quit), competing clinic priorities, and staff turnover.

UW-CTRI continued efforts from Grant Year 3 (refer to page 17) in Grant Year 4 to keep clinics engaged and help staff work through these challenges. In addition to these efforts, UW-CTRI ran two pizza party contests (one in February and the other in April) to encourage clinic participation. The clinics with the most enrollments within their assigned groups (high, medium, and low referring sites) received $50 worth of pizza delivered to their clinical site. The contest increased enrollment for February by 47 percent and for April by 30 percent.

3. **Six-Month Smoking Ascertainment Test**

   Participant attendance at the six-month smoking test continued to be a challenge in Grant Year 4. A difference in attendance rates emerged with the UW-CTRI-run public test sites at 65 percent and the Striving to Quit clinic test sites at 52 percent.

   As in the prior grant year, UW-CTRI staff conducted additional outreach (telephone and email) to clinic-enrolled participants to encourage attendance. Messaging (via teleconferences and e-newsletters) to clinic coordinators emphasized the importance of conducting the six-month test and the $25 incentive payment for each completed six-month test at the clinic. UW-CTRI also distributed a monthly clinic six-month testing report highlighting testing rates by clinics and faxed a monthly notification to clinics listing their patients due for a six-month test so that the clinic could conduct their own outreach to their patients.

4. **Participants, Service Utilization, and Trends**

   The Quit Line enrolled 1,962 Medicaid adults in Striving to Quit by May 27, 2015. From this total, 62 participants that were still smoking at the end of their program re-enrolled for a second time. Most of the participants entered the program through the inbound Quit Line method (52 percent). The remaining entered via a referral from a Striving to Quit clinic fax referral (23 percent) or CTRI testing site fax referral (25 percent).

   Of the 1,962 enrolled, 983 were assigned to the control group and 979 were assigned to the treatment group. Enrollment skewed toward women (61 percent) and older Medicaid members (67 percent are 41 or older). Most of the participants were African American (51 percent) and Caucasian (41 percent). Prior to program completion, 148 (8 percent) individuals withdrew from the study; 110 (74 percent) lost their Medicaid eligibility prior to the six-month follow-up visit.

   As part of the Striving to Quit call program, participants have the opportunity to complete five counseling calls. Of the 1,906 participants that completed their call program, 53 percent completed four or more calls, 30 percent completed two to three calls, and 17 percent completed only one or no calls. On average, participants in the Striving to Quit program are completing more calls (3.37 calls per participant) compared to participants in a Quit Line five-call program (1.90 calls per participant).

   The primary outcome is a biochemically confirmed abstinence at the six-month end-of-study visit. While data from the project have not yet been cleaned for final analysis, the raw data indicate that of the participants whose window to test has closed, 61 percent (861/1404) who maintained their Medicaid eligibility and active status in the program completed the test. The overall intent-to-treat quit rate, which assumes participants with missing six-month smoking test data are smokers, is 19 percent. The responder-only quit rate, including only the participants who conducted the smoking test at the end point, was 31 percent. In order to maintain the integrity of the research, the

participation and quit rates for the attendance incentive and treatment incentive groups have not been separately analyzed.

5. **Key Lessons Learned**
   Listed below are details that were essential to implementing the study.
   - A mix of paid, earned, and social media campaigns is necessary to drive callers to contact the Quit Line.
   - Varied and repeated outreach communications are needed to sustain clinic engagement and referrals. Performance feedback, peer-to-peer learning, and clinic motivation contests are helpful interventions.

Section V: The First Breath/Pregnant Woman Component

A. September 2011 – September 2013 (Years 1 and 2)

1. **Original Project Design**
   The First Breath component targeted adult Medicaid members who were pregnant. The program initially focused on Wisconsin counties with the highest Medicaid populations—Dane, Kenosha, Milwaukee, Racine, and Rock counties—with a focus on engaging African American women. At the program's inception, there were an estimated 4,347 pregnant smokers per year in the target counties.

2. **Recruitment and Promotion**
   - Each HMO under contract with DHS uses a variety of communication and outreach strategies to identify tobacco users and engage them in treatment. The Medicaid member will enroll in the HMO's tobacco cessation program and receive a variety of services, including:
     - Personal telephone calls from care management staff.
     - Personal letters with material about cessation programs, including First Breath (the existing prenatal programs), if appropriate.
     - Facts about the impact of smoking on individual and family member's health.
     - Simple steps for creating a quit plan with information about what to expect after quitting.
   - Pregnant members living in the First Breath target areas will be identified and referred to First Breath. Pregnant Medicaid members will be identified as smokers at a clinical visit via an expanded vital signs protocol that includes smoking assessment.
   - Prenatal providers will refer current patients who smoke to First Breath using the same forms as clinics and sharing the information with the OB/GYN or primary care clinic.

3. **Linking Participants to the Study/Project**
   - Identification and recruitment of Medicaid members who are pregnant smokers in the three southeastern counties was done through the medical home pilot clinics in these counties. Working with the HMOs serving these counties and UW-CTRI, DHS

ensures that all medical home clinic staff are trained to identify smokers and how to make referrals to First Breath.

- Induction of pregnant Medicaid members occurs when the member visits a participating clinic or receives a visit from the Prenatal Care Coordination Program and are identified as smokers. At that point, the member is offered free tobacco cessation treatment via First Breath.
- First Breath delivers evidence-based tobacco cessation treatments via face-to-face contact to pregnant Medicaid members who smoke.

4. Enrollment Process and Components

- Smokers will not have to take the first step to call. Instead, a First Breath enrollment specialist proactively contacts the smoker to provide an intervention after receiving a faxed consent form.
- Either at the initial clinic visit or the next visit, the medical assistant (or other clinic staff) obtains an expired-air carbon monoxide measure from the smoker. The information from the test is tracked either via an EHR or the HMO tobacco registry and shared with First Breath if the member agrees to the referral. The medical assistant briefly explains the availability of free smoking cessation treatment services and monetary incentives and informs the member that First Breath will contact them within two days.

5. Informed Consent Process

First Breath obtains informed consent to participate at the initial contact.

6. Study Intervention Model

- First Breath providers are randomly assigned to one of two treatment conditions, usual care or usual care plus incentives. Medicaid members assigned to a First Breath provider offering usual care will receive the traditional treatment services, while the other group receives traditional services plus the incentives.
- A baseline assessment of the standard First Breath enrollment and smoking assessment measures includes therapy readiness or content relevant measures and a standard smoking history questionnaire that assesses smoking history and goals.
- A five-visit smoking cessation counseling intervention program consistent with the *2008 PHS Guideline on the Treatment of Tobacco Use and Dependence* that includes skilled training, intra-treatment support, and motivation prior to delivery. The number of visits will depend on the member's date of entry into First Breath.
- Counseling supplemented by a provision of eight weeks of nicotine replacement therapy, as approved by the member's physician.
- Carbon monoxide tests either immediately prior or following delivery, dependent on the member's date of enrollment in First Breath.
- One face-to-face postpartum counseling session within the first 60 days following delivery.

- A series of monthly counseling sessions via telephone, text, or email plus quarterly face-to-face counseling sessions for up to 12 months following delivery.
- Carbon monoxide tests at six-month intervals for up to 12 months following delivery (two tests).
- Pregnant Medicaid members assigned to the usual care plus incentives group receive all of the above interventions plus incentives. Payment of incentives is contingent upon treatment participation, visit attendance, and biochemical confirmation of quitting.

7. Evaluation Model

The study evaluation proposed was a research design consisting of four separate aims bulleted below. Measures, analysis, and data sources were outlined for each aim. The evaluation design was proposed as human subjects research on the primary outcome of participant response to use of incentives. The objectives are to determine:

- The extent to which contingent financial incentives increase rates of smoking cessation among pregnant Medicaid members in the First Breath program in comparison with a nonfinancial incentive condition.
- The extent to which contingent financial incentives increase rates of engagement in smoking cessation intervention among Medicaid members participating in the First Breath program.
- The cost effectiveness and reach of the incentivized smoking cessation program relative to a standard (non-incentivized) smoking cessation program for pregnant smokers.
- If incentivized First Breath intervention, in comparison to the non-incentivized group, produces a difference with regard to nonsmoking health outcomes, for example, reduced depression, increased levels of breast feeding, and greater perceived support.

8. Challenges and Solutions

Table H: Recruitment and Promotion (model, aims, projections, and methods)	
Challenges	**Changes made in response to challenge**
1. Sites The 36 existing First Breath providers trained in the five counties at the time of the program launch were not sufficient to serve enough women to reach Striving to Quit enrollment goals.	• Identify and train new sites. • Re-engage current sites through annual events, site visits, refresher trainings, and increased technical assistance. • Work with HMO partners to identify high volume clinics and other potential community partners who were interested in becoming First Breath sites. • Reduce enrollment projection from 3,000 to 1,250.

	• As of September 30, 2013, a total of 105 First Breath sites have been recruited, trained, and re-engaged in the five initial target counties; recruitment of additional First Breath providers continues.
2. Members Pregnant Medicaid members often delay entry into prenatal care, and HMOs do not often receive early notification of pregnancies. This made it difficult to identify women early in their pregnancy to engage them in First Breath.	• Identify partners working with pregnant women (for example, sites where women currently get care/services); use First Breath interest forms to collect relevant information and expedite outreach. • HMOs are sharing tools they use to identify pregnant Medicaid members (for example, pregnancy-related codes). • Community groups are now being used as additional referral sites (connecting women with First Breath/First Breath sites).
3. Counties The initial plan to operate in five counties would not generate adequate volume to reach enrollment goals.	• Expanded from five counties to 28. • Twelve expansion counties were added in March 2013 based on Medicaid enrollment and rates of smoking during pregnancy. • Striving to Quit began offering services in an additional 12 counties adjacent to current service areas in September 2013. • As of September 30, 2013, there were a total of 105 First Breath sites in the 28 target counties, an increase from the initial 36 sites when Striving to Quit was launched. Recruitment of additional First Breath program providers continues.
4. Medicaid coverage changes The Affordable Care Act, Marketplace, and changes to Wisconsin Medicaid eligibility (no changes to coverage for pregnant women; reduction from 200 percent federal poverty level to 100 percent federal poverty level for parents and caretakers) may impact up to 35 percent of women currently eligible for or enrolled in Striving to Quit. These women may no longer be able to maintain coverage postpartum, which could create significant	Medicaid – The Striving to Quit team developed a proposal to fund Striving to Quit-First Breath services for women who are eligible (in a participating HMO) during pregnancy but who lose eligibility 60 days postpartum following the April 2014 Medicaid enrollment changes. Without assistance and modifications, these women would be dropped from the Striving to Quit program because the MIPCD legislative language forbids use of grant funds on those not enrolled in Medicaid.

difficulty for the Striving to Quit-First Breath study both in terms of enrollment projections and enrollment procedures.	

Table I: Linking Eligible Women to the Program	
Challenges	**Changes made in response to challenge**
1. Referrals Few women outside of the existing First Breath sites were being referred to Striving to Quit. An unintended consequence of driving up the volume of referrals was getting a large number of referrals for women who were not eligible (not pregnant, not Medicaid, not smokers, etc.).	Community outreach: • The DHS Tobacco Prevention and Control Program provided in-kind support through a partnership with Jump at the Sun (JATS) Consultants, a firm in southeastern Wisconsin that specializes in outreach to high need communities. JATS used street teams and attended community events with the target population. • Developed event materials, such as bibs and quick screens, for street teams to use in the community to generate program recognition and draw participants to reach out to workers at events. • WWHF staff began additional outreach, attending community events and introducing referral forms to a variety of social service agencies in the target counties.
2. Print materials The original outreach materials were developed to be IRB-compliant and study-oriented and distributed by providers. Both the outreach method and the messaging proved too complex to reach and resonate with the target audience.	DHS and WWHF modified the print materials to be more accessible, simpler to use, and more widely available to do outreach.
3. Special needs members The original protocol was broad and designed to reach as many women as possible. However, the broad approach did not account for the special needs of some members.	• Non-English speakers: Developed Spanish resources and hired multiple Spanish speaking staff. • Hearing impaired participants: Identified interpretive services to allow existing health educators to serve the member effectively. • Participants with disabilities: Met with HMOs providing SSI coverage to learn

	more about members' needs and available community resources. Health educators also traveled to a member's chosen location.

Table J: Enrollment Process and Components	
Challenges	**Changes made in response to challenge**
1. HMOs as First Breath sites The participating HMOs are all structured differently. Some have significant contact with and even provide prenatal services to pregnant members, while others are restricted. Still other affiliated entities provide case management. Of the HMOs that have regular interaction with their pregnant members, the method of interaction also varies from in-person to phone.	Training materials were updated to allow for both telephonic and in-person case management by HMOs participating in the First Breath program. The WWHF office began providing additional support for telephonic First Breath sites by mailing all program materials to women at their homes.
2. Carbon monoxide testing The original protocol called for testing at enrollment. In the early stages of program planning, this was deemed not feasible given the variety of settings for First Breath (public health departments, WIC programs, OB/GYN offices, hospitals, community health centers, etc.). Not all First Breath providers had access to carbon monoxide testing machines, and the cost of purchasing enough machines to cover all First Breath sites was significant.	Women will self-report their smoking status upon enrollment. At the first postpartum visit, health educators will administer the first carbon monoxide test. The WWHF health educators provide testing at the baseline, six- and 12-month postpartum home visits.

Table K: Informed Consent Process	
Challenges	**Changes made in response to challenge**
Consent process Consent and enrollment scripting was necessary and detailed because calls to enrollees took 30-45 minutes to complete. Some women were not able to stay on the	In order to decrease the length of the call, an option was created for women to complete the informed consent and initial enrollment process over the phone (this took about 10 minutes) and then complete the baseline smoking and health survey in person at a later

phone this long and did not complete the enrollment process or needed to be called back again later. Because of the way in which the program was initially approved by the IRB, there could not be a combination of in-person and telephonic enrollment; it had to be one or the other.	date with a health educator (this took 20-30 minutes). This also enables the health educator to make a personal connection with participants earlier, strengthening the relationship and for better engagement postpartum.

Table L: Study Intervention Model	
Challenges	**Changes made in response to challenge**
1. Varying Prenatal Care The frequency of prenatal cessation counseling varies by First Breath site and provider. For example, OB/GYN offices see women more frequently than counterparts in public health settings and home visitation services. As the need for more engaged sites grew and the sites grew in diversity of practice and setting, the standard five-visit counseling intervention was not possible.	First Breath provides incentives for up to six prenatal smoking cessation visits for women in the incentives group. The number of visits will vary by site, but First Breath tracks the number of visits completed regardless of provider type. The tracking has also been simplified from the original protocol and is used for all First Breath participants to ensure that First Breath providers are offering the same level of care. Extensive efforts also continue to grow the number of quality providers.
2. Relapse Women are at a high risk of smoking relapse shortly after delivering their baby, and many women need assistance coping with stressors, including breastfeeding, lack of sleep, and lack of social support. The original distribution of services addressed many of these challenges but not necessarily when most were needed.	Rather than conducting once-per-month postpartum contacts, we front-loaded the visits so there are more frequent contacts early in the postpartum period when women need more assistance. Health educators complete one home visit and two phone calls during the first month after delivery. Referrals were also provided to HMO-sponsored services, including mental health referrals, lactation consultants, and pediatric services. Health educators help women plan ahead for stressors that could derail their quit attempt or stay quit effort. Eleven total contacts (home visits and phone calls) take place during the postpartum period.

3. Carbon monoxide tests were planned for enrollment and at six and 12 months postpartum.	Because of the difficulty conducting carbon monoxide tests at enrollment, we changed the testing timeline to offer three tests: after delivery, six months postpartum, and 12 months postpartum.

Table M: Evaluation Model	
Challenges	**Changes made in response to challenge**
1. Lower expected enrollment might affect statistical power needed for the research.	Re-analyzed and statistical power is sufficient with an enrollment of 1,208 based on expected effect size.
2. The random assignment by provider design proved impossible to implement due to inability to project expected enrollments or number of providers who would participate and concerns about involvement in research of clinic staff.	A new design was created to allow an initial contact with WWHF staff to be the point of random assignment. A database and tables were created for this to be completed more easily. This change was accommodated by a new research design.
3. The First Breath component continues to be under the purview of the UW-IRB as a minimal risk study. This requires coordinating and submitting program changes (for example, expansion to new populations, regions).	The protocol was submitted with anticipation of some required changes and modification; this includes approval of language and multiple media through which it might be delivered.

9. First Breath – Summary of Key Events, Changes, and Milestones

2011	
September	MIPCD grant awarded to Wisconsin; planning begins

October	• First Breath protocol development begins
	• Striving to Quit evaluation working group meeting at UW-CTRI (October 11)
	  ○ Study questions refined
	  ○ Data elements identified

November	• Striving to Quit evaluation working group meeting at UW-CTRI – First Breath only (November 10) • Striving to Quit project team meeting at DHS (November 15) • Striving to Quit HMO meeting (in-person) • Striving to Quit detailed work plan
December	• Striving to Quit project team meeting at DHS (December 20) • Finalized protocol for timing of postpartum visits and amount of Visa gift cards for each reimbursed visit

	• Striving to Quit contracts developed • Striving to Quit operational protocol drafted
2012	
January	• First Breath project coordinator hired and trained • First Breath annual statewide meeting held in Wisconsin Dells offering introductory information about Striving to Quit to all First Breath sites • Striving to Quit project team meeting at DHS (January 5)
February	• Finalized survey questions throughout Striving to Quit and data to be extracted from existing First Breath database • Striving to Quit project team meeting at DHS (February 3)
March	• Striving to Quit team meeting at DHS (March 8) • Striving to Quit HMO meeting
April	• First Breath study protocol submitted to UW IRB • Striving to Quit project team meeting at DHS (April 12) • Striving to Quit HMO contacts identified
May	• First MIPCD all-state grantee meeting (Baltimore, MD) • Striving to Quit high volume clinics identified
June	• UW IRB approves First Breath study • DHS Striving to Quit project manager hired • First Breath walk through meeting with all participating HMOs at DHS • Striving to Quit project team meeting at DHS (June 22)
July	Pilot/soft launch begins – Enrolled nine women in Milwaukee County to test procedures, data collection systems, cessation counseling protocols, and data transfers.
August	• Finalized protocol for incoming calls to WWHF from women interested in Striving to Quit annual First Breath regional sharing session events in five locations; updated sites on upcoming Striving to Quit launch and how to get involved • Striving to Quit project team meeting at DHS (August 23) • Striving to Quit ForwardHealth provider update drafted and released • Striving to Quit PIP development
September	• First Breath Study official Launch; began enrolling women in five initial target counties • Bi-weekly HMO calls begin • Striving to Quit PIP development • 16 women enrolled, 52 First Breath sites participating
October	• Striving to Quit evaluation working group meeting at UW-CTRI (October 16) • Striving to Quit leadership team convened (October 26) • Six health educators hired and trained to perform postpartum home visits

	• Meetings with six HMOs to discuss high volume clinics and referrals for members who need additional services • Outreach presentation at Meriter Hospital Perinatology Conference in Madison, WI • Striving to Quit PIP development • 39 women enrolled, 52 First Breath sites participating
November	• Received permission from the national Nurse Family Partnership (NFP) program to include NFP participants in Striving to Quit. Allows WWHF to address hesitation from local NFP providers as we can assure them that women can indeed participate in both programs and their national office (and funding source) has given their stamp of approval • Breaking the Cycle Prematurity Community Event panel presentation to raise awareness about Striving to Quit and First Breath • One-on-one meetings with HMOs • Striving to Quit PIP development • 60 women enrolled, 55 First Breath sites participating
December	• Striving to Quit leadership team convened (December 19) • Striving to Quit PIPs due • 78 women enrolled, 61 First Breath sites participating
2013	
January	• Submitted multiple changes of protocol to UW IRB, including: Individual-level data sharing with HMOs, conducting in-person consent, and changing study eligibility criteria to include any Wisconsin county and HMO and expanding Medicaid plan eligibility • Created First Breath interest form for use by referral agencies • 97 women enrolled, 63 First Breath sites participating; two HMOs completed training to become First Breath sites
February	• UW IRB approves changes of protocol from January submission • Commenced in-person baseline surveys to reduce time on the phone during consent and enrollment • Outreach work at the Latino Health Summit • 103 women enrolled, 64 First Breath sites participating
March	• Eligibility expanded to include women receiving SSI and fee-for-service Medicaid • Expansion to a total of 17 counties • Striving to Quit leadership team meeting at DHS (March 21) • Striving to Quit evaluation working group meeting at UW-CTRI (March 30) • Annual First Breath statewide meeting in Stevens Point; offered enhanced training opportunities for First Breath sites • 115 women enrolled, 87 First Breath sites participating

April	• Training event for Jump at the Sun street team members • Outreach exhibit at Wisconsin Association for Perinatal Care conference • 153 women enrolled, 88 First Breath sites participating
May	• Three health educators hired and trained to serve participants in new expansion counties • Jump at the Sun street teams begin referring pregnant smokers for First Breath services • MIPCD all-state grantee meeting (Baltimore, MD) • 176 women enrolled, 86 First Breath sites participating
June	• Interpretive services secured for deaf participants • One health educator hired and trained to serve expansion county participants • 203 women enrolled, 87 First Breath sites participating
July	• Developed protocol for triaging pregnant women who are initially connected with the Striving to Quit-Quit Line component of the study • 234 women enrolled, 90 First Breath sites participating
August	• Revisit initial communications plan and consider new earned media approaches • Annual First Breath regional sharing session events in five cities; update on Striving to Quit progress to date; reminder on how providers can engage • 294 women enrolled, 90 First Breath sites participating
September	• Expansion to 28 counties • Infant Mortality Awareness Month press release (DHS' Division of Public Health) promotes Striving to Quit project participation • 324 women enrolled, 105 First Breath sites participating

10. First Breath – Key Lessons Learned

a. Enrolling individuals in the study was challenging.
   i. Many women are transient and have rapidly changing contact information. Phone engagement and enrollment are sometimes difficult.
   ii. Many pregnant women do not receive prenatal care until several months into their pregnancy, making it difficult to engage them in cessation services prior to delivery.
   iii. Many First Breath participants and women expressed interest at community outreach events but are not eligible to enroll in the study.
   iv. Expansion to additional counties was necessary to generate enough eligible and interested women to reach adjusted enrollment goals.
   v. Enrollment is steady, but more time may be needed to reach enrollment goals.

b. Members losing and/or regaining Medicaid coverage may impact the ability to carry out the study.

i. The First Breath component of the study will lose about 30 percent of current participants with the Affordable Care Act/Marketplace changes occurring in January 2014.
ii. Wisconsin Medicaid tentatively accepted a proposal to support women who may lose Medicaid coverage postpartum.

c. HMOs are not engaged in the same ways as initially envisioned in the grant application.
   i. Identification of potential participants early in pregnancy is difficult for most HMOs given their typical claims/billing data and systems.
   ii. Ongoing recruitment/engagement efforts into 2013 were necessary to secure all participating HMOs.
   iii. HMOs vary in the ways they communicate with members and in the type of case management and outreach that they are able to provide.
   iv. HMO engagement did not lead to an increase in high-volume First Breath sites as was initially hoped.

d. First Breath sites and providers are not engaged in the same ways as initially envisioned in the grant application.
   i. There were not enough First Breath sites and providers in the targeted counties to support the number of women expected to enroll in the program.
   ii. Not every First Breath provider or site was fully engaged and able to help support/promote Striving to Quit.

B. September 2013 – September 2014 (Year 3)

1. Summary of Design

The First Breath program design was modified during Grant Year 3. The modification included expansion to new regions of the state and extending the duration of postpartum services.

First Breath will serve 1,250 pregnant and postpartum Medicaid members who smoke. Members can enroll at one of 120 participating First Breath sites located in 34 counties throughout the state. Members can also complete an interest form at community-based agencies and events, and they will be screened for Striving to Quit eligibility and connected to a First Breath site.

Women enrolled in First Breath receive at least three brief interventions from First Breath providers, local perinatal health care providers who have completed specialized training. First Breath participants who are Medicaid or SSI members and meet other requirements are offered participation in the Striving to Quit study. Women who choose to enroll in the study meet with trained health educators during the postpartum period and receive intensive smoking cessation, relapse prevention counseling, and carbon monoxide breath tests.

Participants who enrolled in First Breath prior to July 1, 2014, received five home visits and six phone calls over the course of 12 months. These participants received an incentive for enrolling in Striving to Quit ($40) plus incentives for completing up to three home-based counseling sessions with biochemical verification tests ($40 each test). Participants in the treatment group received additional incentives for completing counseling sessions with their First Breath providers and Striving to Quit health educators ($20 for up to six prenatal visits, $20 for up to six postpartum phone calls, $25 for up to two home-based counseling session visits, and $40 for passing up to three biochemical breath tests).

Participants who enrolled after July 1, 2014, received four home visits and five phone calls over the course of six months. These participants received an incentive for enrolling ($40) plus incentives for completing up to two home-based counseling sessions with biochemical verification tests ($40 each test). Participants in the treatment group received additional incentives for completing counseling sessions with First Breath providers and Striving to Quit health educators ($20 for up to six prenatal visits, $20 for up to five postpartum phone calls, $25 for up to two home-based counseling sessions, and $40 for passing up to two biochemical breath tests).

2. Challenges and Solutions

a. Participant Enrollment

Reaching enrollment goals has been, and will continue to be, a challenge for Striving to Quit-First Breath.

Resolutions:

- Six-month intervention – As of July 1, 2014, all newly enrolled First Breath participants began engaging in a six-month intervention instead of a 12-month intervention. Shortening the length of the intervention has allowed enrollment staff an additional six months of enrollment time.
- Expansion of First Breath service counties – The First Breath component was initially designed to serve five counties in Wisconsin. This was later expanded to 17 counties. In October 2013, First Breath expanded to an additional 15 counties, and in spring/summer 2014, an additional three counties were included. There are now 34 counties currently participating in First Breath.
- Establishing new First Breath sites – The majority (85 percent) of study participants are enrolled in the study through established First Breath sites. Between October 2013 and September 2014, an additional 33 sites were recruited and trained.
- Increasing enrollment at existing First Breath sites – WWHF worked with each site to set an annual enrollment goal and conducted monthly check-ins regarding progress toward these goals. WWHF also created and promoted a webinar that trained providers on successful strategies to increase enrollment. WWHF also

began publically recognizing high performing sites to increase motivation and share techniques with lower performing sites. Additionally, Striving to Quit was promoted at annual meetings and conferences where First Breath sites were in attendance.

- Increasing percentage of eligible First Breath participants that enroll in Striving to Quit – WWHF developed a plan to reduce the number of women screened out due to being unable to reach them, which accounted for nearly a quarter of potentially eligible participants in previous years. Enrollment staff began using a mix of phone calls and text messages to reach women. Enrollment staff also began varying call times to include occasional evening and weekend hours. When enrollment staff received invalid phone numbers or returned mail, they notified First Breath program coordinators, who in turn notified sites that updated contact information was needed. Enrollment staff members also regularly rechecked past Medicaid ineligibles (unable to reach, age) to see if previously screened out participants became eligible.
- Community-based outreach – WWHF conducted outreach directly to the target audience at health fairs, community events, and social service agencies, such as WIC offices and Planned Parenthoods. From October 2013 to September 2014, a total of 117 women enrolled in Striving to Quit as a result of this outreach.
- Pregnancy and smoking ads on TV, Facebook, and YouTube targeting Medicaid members – The DHS targeted TV ad buy in the Green Bay, Madison, Milwaukee, and La Crosse market areas ran in December 2013 and January 2014. The ads encouraged Medicaid members to call the First Breath program. Eight women were enrolled in Striving to Quit as a result of these ads. A different pregnancy and smoking ad was placed on YouTube and Facebook in the spring of 2014 that did not result in any enrollments.

b. Changes to Medicaid Eligibility

On April 1, 2014, the income requirements for Wisconsin Medicaid eligibility changed. It was estimated that up to one-third of First Breath participants would lose coverage at 60 days postpartum and therefore would be deemed ineligible to participate in Striving to Quit.

Resolutions:

- Continuation of services for study participants who lost Medicaid coverage postpartum – DHS and WWHF developed systems to distinguish between services provided for participants still covered by Medicaid and those who were no longer covered. Those who were no longer covered as a result of Medicaid changes were eligible to remain in Striving to Quit with services paid for by DHS rather than through the CMS grant.
- Updated Portal check procedures – Systems were put in place to rapidly share Striving to Quit participants' Medicaid status between enrollment staff and health educators. Health educators followed up immediately with all study participants who showed a lapse in Medicaid status. Many of these participants

were in fact still eligible for coverage, and the lapses were due to missing paperwork or missed deadlines. This maximized the number of participants who remained eligible for Striving to Quit.

c. Health Educator Workload

Striving to Quit health educators have a high potential for burnout due to large caseloads and traveling long distances to meet with participants. Also, health educators become aware of participants coping with difficult issues outside of smoking cessation, such as family death and illness, substance abuse, mental health, domestic abuse, extreme poverty, and legal challenges.

Resolutions:

- Monthly health educator meetings to debrief and group problem solve
- Regular check-ins from supervisor to walk through participants experiencing difficult challenges/situations and assess workload and caseload
- In-service training and outside training programs on participants coping with difficult issues
- Reflective consultation options

3. Participants, Service Utilization, and Trends

First Breath enrolled 866 pregnant smokers in Striving to Quit by September 30, 2014. Most of the participants were enrolled through a First Breath site (85 percent), and 15 percent were enrolled as a result of outreach. Of the 866 enrolled, 432 were assigned to the non-incentive group, and 434 were assigned to the incentive group. The average age of the participants at the time of enrollment was 27. Most of the participants were Caucasian (46 percent) and African American (39 percent).

First Breath allowed women to enroll at any point during their pregnancy. At the time of enrollment, 42 percent were in their third trimester of pregnancy, 48 percent were in their second trimester, and only 10 percent were in their first trimester. Prior to the completion of the program, 61 participants (7 percent) withdrew from the study. Most of the withdrawals (54 percent) were voluntary with no reason given or because the study seemed too time consuming.

As part of the postpartum intervention, participants can receive up to five home visits and six telephone calls with a Striving to Quit health educator. Of the 185 who completed the postpartum intervention, 61 percent completed four to five home visits, 22 percent completed two to three home visits, and 10 percent completed one home visit. There was also a small percentage who completed no home visits (8 percent). On average, participants completed 3.5 postpartum home visits (out of four offered). Among those completing the postpartum phone calls, 56 percent completed four or more phone calls, 25 percent completed two to three phone calls, and 9 percent completed one phone call. There was also a small percentage who completed no phone

calls (10 percent). On average, participants completed 3.5 phone calls with the Striving to Quit health educator.

The primary outcome is a biochemically confirmed abstinence at the six-month visit. While data from the project have not yet been cleaned for final analysis, the raw data indicate that of the participants whose window to test has closed, 68 percent completed the test (274/403). The overall intent-to-treat quit rate, which assumes participants with missing six-month smoking test data are smokers, is 23 percent. The responder-only quit rate, including only the participants who conducted the smoking test at the end point, was 34 percent. In order to maintain the integrity of the research, the participation and quit rates for the attendance incentive and treatment incentive groups have not been separately analyzed.

4. Key Lessons Learned

a. Recruitment and Enrollment

In Year 3, First Breath produced steady enrollment numbers. The majority (85 percent) of participants were enrolled through established First Breath sites. Using First Breath as a feeder program has been critical to reliable enrollment rates. The First Breath program is respected among health care providers, and the name recognition has been important in recruiting participants. Although the majority of enrollments have come from First Breath, an additional 15 percent of participants reached Striving to Quit through outreach events/efforts. Efforts placed in direct community outreach, TV ads, presentations, and promotion at local community-based agencies helped with enrollment. While community-based outreach tends to be more time and resource intensive, in times of lower First Breath site enrollment (around the holidays, for example), community-based outreach efforts have expanded to keep enrollment numbers steady.

b. Participant Retention

Many First Breath participants tend to lead transient lives; participants' addresses changed several times over the course of the study, making it difficult to locate them. Several others do not have permanent addresses and are in transitional housing, shelters, or live with relatives. This makes intervention difficult because there are periods of no contact, some for a few weeks, and some for several months. Despite these challenges, the six- and 12-month completion rates are high due to the following proactive outreach to remain in contact with participants:

- Enrollment staff members collect multiple pieces of contact information: back-up numbers, alternate contact numbers, and email addresses and also distinguish between mailing address and residential address.
- During enrollment, repeated reminders are given to members to provide notification if contact information changes.
- Revised reporting and tracking systems allow field staff to prioritize visits and plan ahead to make multiple attempts to schedule visits.

- Regular contact by field staff proves to be a key part of ongoing participant engagement.
- Field staff members schedule informal check-ins to take place during periods of study involvement where contact is limited (between enrollment and the first postpartum visit and again after the six-month marker.)

c. Referrals for Nonmedical Services

Major life stress due to housing insecurity, financial issues, and legal issues affects both participation in the study (several missed visits) and motivation to quit. Health educators' scope of work limits them from getting too involved in these issues, and solid referrals are necessary. Health educators do research on non-Medicaid-covered referrals. Health educators have been successful at affirming that these issues are major and integrate them into their quit-smoking action plans.

d. Lack of Social Support

It is common for participants to report that their social networks—friends, partners, household members—are saturated with smokers. Many participants have the desire to quit, high confidence, and high motivation but lack the overall support to quit. Some participants are not the head of the household and are unable to enforce rules about smoking in the house. Health educators spend time helping participants to develop a strong action plan that addresses these issues.

C. September 2014 – September 2015 (Year 4)

1. Summary of Design

The First Breath program design was not modified during Grant Year 4. Pregnant and postpartum Medicaid members who smoked enrolled at one of 127 participating First Breath sites located in 34 counties throughout the state. Members could also complete an interest form at community-based agencies and events, and they were screened for Striving to Quit eligibility and connected to a First Breath site.

2. Challenges and Solutions

a. Participant Enrollment

Although enrollment was steady early in Grant Year 4, reaching the enrollment goal was a challenge. To ensure members received the full six months of postpartum services, an estimated delivery date cutoff was set for May 21, 2015. The pool of eligible women began shrinking toward the end of 2014, and enrollment numbers steadily declined from January through April 2015.

To address this challenge, the WWHF team employed the following tactics:

- To generate local interest in First Breath, two WWHF team members and one former participant were interviewed as part of an investigative report with Fox6 Now in Milwaukee that covered smoking, prematurity, and sudden infant death

syndrome (SIDS). In addition, the WWHF promoted Striving to Quit-First Breath at several tobacco coalition and perinatal health conferences and meetings.

- Team members conducted community-based outreach, including community baby showers, engagement with WIC (women, infants, and children) sites, and many other local events.
- To expand the pool of eligible women, participating Striving to Quit-First Breath sites were encouraged to enroll women early in pregnancy. E-newsletters were sent reminding sites of the estimated delivery date cutoff. Striving to Quit was also promoted heavily at the regional First Breath meetings in October 2014 and the Annual Statewide Meeting in March 2015.
- Aggressive outreach to potential new sites took place early in Year 4, and in total, seven new sites were trained and began enrolling participants.
- In April 2015, a competition was launched to encourage Striving to Quit-First Breath sites to enroll more women and expedite enrollment paperwork. This effort resulted in a slight bump in overall enrollment numbers.
- Enrollment staff experimented with new techniques to reach more women, including calling evenings, weekends, and over the holidays.

3. Participants, Service Utilization, and Trends

Enrollment ended May 21, 2015, with a final enrollment number of 1,041. Most of the participants were enrolled through a First Breath site (85 percent), and 15 percent were enrolled as a result of outreach. Of the 1,041 enrolled, 517 were assigned to the control group, and 524 were assigned to the treatment group (nine were pilot test subjects assigned to the non-incentive group). The average age of the participants at the time of enrollment was 26. Most of the participants were Caucasian (46 percent) and African American (39 percent), and 5 percent identified as Hispanic or Latino.

Women are allowed to enroll in Striving to Quit at any point during their pregnancy. At the time of enrollment, 40 percent were in their third trimester of pregnancy, 54 percent were in their second trimester, and 6 percent were in their first trimester.

a. 12-month Program Utilization

As part of the postpartum intervention, participants can receive up to five home visits and six telephone calls with the Striving to Quit Health Educator. Of the 545 who completed the postpartum intervention, 54 percent completed four to five home visits, 22 percent completed two to three home visits, 11 percent completed one home visit, and 13 percent completed no home visits. On average, participants completed 3.1 postpartum home visits. Among those completing the postpartum phone calls, 51 percent completed four or more phone calls, 23 percent completed two to three phone calls, 10 percent completed one phone call, and 16 percent completed no phone calls. On average, participants completed 3.3 phone calls with the Striving to Quit health educator.

b. Six-month Program Utilization

As part of the postpartum intervention, participants can receive up to four home visits and five telephone calls with the Striving to Quit health educator. Of the 70 who completed the postpartum intervention, 44 percent completed four home visits, 33 percent completed two to three home visits, 10 percent completed one home visit, and 13 percent had no home visits. On average, participants completed 2.7 postpartum home visits. Among those completing the postpartum phone calls, 53 percent completed four or more phone calls, 23 percent completed two to three phone calls, 9 percent completed one phone call, and 14 percent had no postpartum phone calls. On average, participants completed 3.1 phone calls with the Striving to Quit health educator.

c. Six-month Abstinence Outcome

The primary outcome is a biochemically confirmed abstinence at the six-month visit. While data from the project have not yet been cleaned for final analysis, the raw data indicate that of the participants whose window to test has closed, 65 percent completed the test (524/805). The overall intent-to-treat quit rate, which assumes participants with missing six-month smoking test data are smokers, is 25 percent. The responder-only quit rate, including only the participants who conducted the smoking test at the end point, was 38 percent. In order to maintain the integrity of the research, the participation and quit rates for the attendance incentive and treatment incentive groups have not been separately analyzed.

Prior to the completion of the program, 113 participants (11 percent) withdrew from the study. Some either moved out of the study area (25 percent), lost Medicaid coverage (11 percent), or voluntary withdrew (65 percent).

Section VI: Overall Striving to Quit Program

A. September 2013 – September 2014 (Year 3)

1. Communication and Outreach

Throughout Grant Year 3, various methods were used to promote the Striving to Quit initiative, including paid, earned, traditional and social media, as well as the development of new or updated creative print materials.

In late December 2013 and early January 2014, the Wisconsin Tobacco Prevention and Control Program (TPCP) ran statewide television advertisements to promote the Quit Line and First Breath components of Striving to Quit. The ads ran the weeks of December 30, January 13, and January 27, with bonus public service announcements running the weeks of January 6 and 20.

Three ads were used to promote the Quit Line portion, including the “Anthem” and “Tiffany” ads from the CDC’s “Tips from Former Smokers” campaign and the North Carolina ad “Destini,” which features a young girl talking about losing her father to

tobacco-related illness. TPCP also used the Oklahoma-produced ad, "Virtual Echo," to promote the First Breath component of Striving to Quit. The Oklahoma ad featured a pregnant woman putting down a pack of cigarettes after envisioning a small baby dealing with the effects of maternal smoking. More than 25 percent of Quit Line callers said they heard about the Quit Line through the ads that ran in January. Judging by call-in information, the Quit Line ads also found their audience—38 percent of callers were Medicaid enrollees. Results from the First Breath ad were inconclusive, as the "Virtual Echo" ad ran for a shorter time period. A separate television buy for First Breath is planned for late September and early October 2014.

In addition to television advertising, TPCP and Wisconsin Medicaid also promoted Striving to Quit through Facebook, YouTube, and Google Ad Words advertising (Quit Line component only) during the months of March and April 2014. Facebook and Google Ad Words used established Striving to Quit brand elements, while YouTube featured the ads from the January 2014 television campaign. Ads referred viewers to online surveys to take part in the program. The Facebook and YouTube ads resulted in:

Facebook:

- 2,337,439 total impressions for 18 Quit Line ads
  - 18 – Average number of times each user saw the ads
  - Yielded **11,534 clicks** to the Quit Line Striving to Quit interest survey
- 215,550 total impressions for the three First Breath Ads
  - 12 – Average number of times each user saw the ads
  - Yielded **931 clicks** to the First Breath Striving to Quit interest survey

YouTube:

- 20,131 views of the Destini ad with one accompanying banner ad (plus 31 earned views)
  - View rate of 12.79 percent, and 13 percent played to ad's completion
  - 13,683 unique viewers who saw the ad an average of 1.5 times
  - Yielded **981 clicks** to the Quit Line Striving to Quit interest survey
- 4,853 views of the Visual Echo ad with three different accompanying banner ads
  - View rate of 13.77 percent, and 14 percent played to ad's completion
  - 3,082 unique viewers who saw the ad an average of 1.6 times
  - Yielded **210 clicks** to the First Breath Striving to Quit interest survey

Google Ad Words resulted in 17,780 impressions and 318 clicks to the Striving to Quit website located at www.strivingtoquit.com.

Unfortunately, while online advertising generated numerous impressions and clicks, it did not result in significant increases in Striving to Quit enrollment. One contributing factor may have been the length and the content of the survey that prospective participants were asked to complete. The surveys, which were modeled on previous questionnaires for prescreening, asked for a great deal of personal information.

Finally, TPCP and Medicaid teamed up with the WWHF and Flaherty and Associates in July 2014 to promote the participation of a Wisconsin woman and a Striving to Quit First Breath health educator in the new series of the CDC TIPS campaign. In her ad, the woman talks about how smoking during pregnancy contributed to her giving birth to her daughter five weeks early at just 3 pounds. A three-day, six-city press conference tour took place July 14-16 to raise awareness of her participation in the campaign and the First Breath program. The highly successful effort resulted in television coverage in all six markets, as well as major newspaper stories in the *Milwaukee Journal Sentinel*, the *Eau Claire Tribune*, and the *Wausau Daily Herald*, among others. Using commonly accepted media tracking metrics places the value of the media coverage for this story at a minimum of $211,700, but possibly as high as $500,000 and $1 million using conventional measurement tools and by making assumptions about media that carried the stories but could not be tracked or measured. In addition to the large amount of news coverage, the press conference campaign led to two new Striving to Quit counties (Juneau and Adams) and re-engaged existing Striving to Quit partners. A slight increase in enrollment was also recorded in the four to six weeks following the press conferences.

2. **Medicaid Eligibility**
   Wisconsin Medicaid eligibility requirements changed April 1, 2014. While the change had less impact on the population in either program than originally anticipated, each program lost about 10 percent of participants due to loss of Medicaid coverage.

3. **RTI**
   Throughout the spring of 2014, RTI (one of the CMS evaluators) coordinated and conducted site visits with several stakeholders involved in the program. Several of those interviewed were interested in learning more about the outcomes of the visit.

   RTI also worked directly with the WWHF and UW-CTRI to coordinate the satisfaction surveys and focus groups. The biggest challenge to date, given the delay in Office of Management and Budget (OMB) and IRB approval of the survey protocol, is the lack of participants eligible to consent.

4. **Minimum Data Set (MDS) Complexity**
   The MDS calculations required to meet the MDS specifications—essentially creating an analytic data set—is very complex and overly burdensome. It has taken over 500 hours to develop, hundreds of queries, and over several thousand lines of code.

5. **Program Sustainability**
   During this period, both programs began to explore opportunities for sustaining the program—or elements of it—post grant. Wisconsin made a request to CMS for a no-cost extension, which was denied.

Both programs worked to review basic information about service utilization and outcomes, developing best practice outlines and identify potential opportunities for funding and support from the Wisconsin Department of Health Services and additional grants.

Because of limitations in data available on pregnant and postpartum smoking and cessation programs, particularly in the period between 60 days and one year postpartum, the WWHF worked to identify what data could be used and inferences made to demonstrate program success.

The Wisconsin Medicaid and public health divisions will continue to work with Striving to Quit to identify opportunities to incorporate pieces of the program into ongoing smoking cessation and infant mortality reduction efforts.

6. Summary of Key Events, Changes, and Milestones

October 2013		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
Conducted first HMO outreach survey to capture HMO activity related to promoting Striving to Quit enrollment among members; collected all activity through September 2013	• Second run of Striving to Quit ads encouraging Medicaid members to call 1-800-QUIT-NOW launched for two weeks (week of October 14 and 28) • Kenosha Community Health Center launched as a public testing site • Six-month testing (end of program) began • Launched monthly Striving to Quit clinic check-in calls for Striving to Quit referring clinics • Trained federally qualified health center (City on a Hill) to make standard Fax to Quit referrals to Quit line • 19 Striving to Quit sites participating; one Fax to Quit site	• Hired and trained a new health educator to work with study participants and conduct outreach in southeast WI (Racine, Kenosha, and Walworth counties) • Formal presentation of First Breath to the Racine Home Visitation Network meeting • Expansion of First Breath services from 17 to 31 counties; First Breath providers received Striving to Quit training and materials, staffing changes made, and internal systems were updated to include additional counties • 114 First Breath sites participating

November 2013		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
Striving to Quit leadership team convened (November 22)	• Quit Line began conducting the six-month telephone survey to participants collecting self-reported smoking information • CTRI testing staff began making calls to participants due for their six-month tests • La Crosse County Health Department launched as a public testing site • Trained local health department (West Allis) to make standard Fax to Quit referrals to Quit line • 21 Striving to Quit sites participating; two Fax to Quit sites	• Developed an internal Increased Enrollment Action Plan for 2014; team will focus on recruiting additional First Breath sites, increasing eligible First Breath enrollees, and reducing number of women screened out of study due to being unable to reach them • Postpartum Medicaid eligibility check procedures updated in response to upcoming Medicaid changes in 2014. • 115 First Breath sites participating
December 2013		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• Striving to Quit ads targeting Medicaid members back on the air for two weeks (December 30-January 5) • Completed work with Dean Health System to build an EHR SmartSet for Striving to Quit (cues clinician to offer the referral and populates fields on the referral form) • Trained federally qualified health center (Gerald Ignace) to make standard Fax to Quit referrals to Quit line	• Expansion of First Breath services to one additional county (32 counties total) • Planned Parenthood staff received training on the use of First Breath referral forms • Tested "Smoking and Pregnancy" TV ads with target audience • First round of "Smoking and Pregnancy" TV ads ran week of December 30 • 117 First Breath sites participating

	• 21 clinic sites participating; three Fax to Quit sites	
January 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
Conducted quarterly HMO outreach survey for the period of October-December 2013	• Striving to Quit ads back on the air (week of January 13 and 27) • 24 Striving to Quit sites participating; three Fax to Quit sites	• Two additional rounds of "Smoking and Pregnancy" TV ads ran week of January 13 and 27 • 117 First Breath sites participating
February 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• The CDC "Tips from Former Smokers" ads encouraging calls to 1-800-QUIT-NOW began airing February 3 for nine weeks • Launched new CTRI testing site in Racine county; closed the CTRI testing site in Rock county • CTRI staff intensifies efforts to reach participants due for their six-month tests • 32 Striving to Quit sites participating; three Fax to Quit sites	• Facilitated Striving to Quit and First Breath presentation at "Fulfilling the Promise" conference for home visitors and supervisors • 119 First Breath sites participating

March 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
• DHS launches Facebook, YouTube, and Google Striving to Quit ads • Striving to Quit evaluation team meeting (March 17) • Strategic communications and outreach meeting (March 31)	• The CDC TIPS ads continued to run • Direct recruitment at a Green Bay housing authority facility resulting in six Striving to Quit enrollments • 32 Striving to Quit sites participating; three Fax to Quit sites	• First Breath annual statewide meeting held; 104 providers from 65 sites attended; Striving to Quit information was presented • Striving to Quit promoted at the Wisconsin Alliance on Women's Health Policy Conference • Piloted new billing and postpartum eligibility check procedures in anticipation of the April 1 Medicaid changes • 120 First Breath sites participating
April 2014		
Striving to Quit Program-Wide	**Quit Line**	**First Breath**
• April 1 changes to Medicaid eligibility went into effect • Conducted quarterly HMO outreach survey for the period pf January-March 2014 • MIPCD stakeholder interviews with RTI	• The CDC TIPS three ads ended April 6 • Promoted Striving to Quit to the Wisconsin Tobacco Prevention and Poverty Network members in Milwaukee • 43 Striving to Quit sites participating; three Fax to Quit sites	• April 1 changes to Medicaid went into effect; new billing and postpartum eligibility check procedures fully implemented • "Smoking and Pregnancy" YouTube and Facebook ads ran • Hired and trained a new health educator to work with study participants and conduct local outreach in northeast Wisconsin • 118 First Breath sites participating

May 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• Began training ShopKo pharmacies to make standard Fax to Quit referrals to Quit line • 49 Striving to Quit sites participating; five Fax to Quit sites	• First Breath promoted at the Wisconsin Association for Perinatal Care and Wisconsin Public Health Association conferences • 119 First Breath sites engaged
June 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• Trained six pharmacy sites to conduct Striving to Quit testing and referrals to the Quit Line • 57 Striving to Quit sites participating; seven Fax to Quit sites	• One HMO (iCare) became a Striving to Quit-First Breath site and began enrolling members into First Breath • Procedures put in place for July 1 intervention changes (shift from 12-month to six-month intervention) • 119 First Breath sites participating
July 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
• Conducted quarterly HMO Outreach survey for the period of April-June 2014 • Striving to Quit evaluation team meeting (July 24)	• New CDC "Tips from Former Smokers" ads encouraging calls to 1-800-QUIT-NOW start July 7 for nine weeks • Launched new pharmacy-based public testing sites in six counties: Oneida, Vilas, Marathon, Portage, Oconto, and Forest • Trained 17 clinics in one health system (Gundersen Health) to make standard Fax to Quit referrals to Quit Line	• Procedure changes for six-month intervention fully implemented • Press tour of CDC TIPS campaign completed to promote Striving to Quit and First Breath • 120 First Breath sites participating

	• Direct recruitment at ARC Community Services in Madison resulting in two Striving to Quit enrollments • 60 Striving to Quit sites participating; 25 Fax to Quit sites	
August 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• Finalized plans with RTI to conduct Striving to Quit participant focus groups at Milwaukee and Madison UW-CTRI testing sites in October 2014 • 61 Striving to Quit sites participating; 35 Fax to Quit sites	• Expansion of First Breath at two additional counties (34 total) • 120 First Breath sites participating
September 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• CDC's run of the new TIPS 3 ads ends the first week of September • Striving to Quit promoted at clinician "Days of Learning" in Eau Claire, Outagamie, and Milwaukee counties; about 120 clinicians attended • Direct recruitment at low-income housing in Milwaukee resulting in six Striving to Quit enrollments • 63 Striving to Quit sites participating; 35 Fax to Quit sites	• 120 First Breath sites participating • 866 participants enrolled • TV spot "Echo" began airing last week of September • First Breath regional practice sessions held in five locations, providing technical assistance to sites, opportunities to practice cessation counseling skills, and information about the science of addiction

B. September 2014 – September 2015 (Year 4)

1. Communication and Outreach

Communication and outreach strategies highlighted in Year 3 continued through the first quarter of Grant Year 4, September through December 2014. Enrollment for both the Quit Line and First Breath ceased on May 31, 2015.

2. RTI and MDS

Work with RTI and MDS also continued during Year 4 to ensure they had the data necessary to fulfill contractual requirements with CMS.

3. Program Sustainability

Efforts also continued to identify potential resources to sustain either all or portions of Striving to Quit. There is some interest in First Breath and how information from the findings might be used by DHS and HMOs to help reduce low birth weight babies and preterm infants.

4. Summary of Key Events, Changes, and Milestones

October 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
Conducted quarterly HMO outreach survey for the period of July-September 2014	• UW-CTRI assisted in RTI focus groups (two in Milwaukee; one in Madison) and participated in stakeholder interviews • Trained three ShopKo pharmacies to make standard Fax to Quit referrals to Quit Line • 67 Striving to Quit sites participating; 38 Fax to Quit sites	• Conducted First Breath regional meetings; 74 First Breath sites received Striving to Quit information and updates • Collected three participant video testimonials • Striving to Quit promoted at community baby showers in Racine and Rock Counties • 120 First Breath sites participating • 45 new participants enrolled • 911 total enrollment

November 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• New CTRI public testing site launched in Sheboygan County • Trained one Shopko pharmacy to make standard Fax to Quit referrals to Quit Line • Trained Kenosha Community Health Department to make standard Fax to Quit referrals to Quit Line • 68 Striving to Quit sites participating; 40 Fax to Quit sites	• Fox6 Now in Milwaukee ran investigative piece on smoking, prematurity, and SIDS; WWHF staff and a former First Breath participant were featured in the story • Outreach to WIC sites in Northeast Wisconsin • 120 First Breath sites participating • 51 new participants enrolled • 962 total enrollment
December 2014		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• Wisconsin TPCP ran statewide Quit Line ads the weeks of December 15 and 29; calls increased 50 percent • Launched Adams County Public Health as a public testing site • New CTRI-public testing site launched in Fond du Lac County • Press release to Fond du Lac news contacts results in radio interview about Striving to Quit • Ended Striving to Quit clinic recruitment • 68 Striving to Quit sites participating; 40 Fax to Quit sites	• Three new First Breath sites trained • 123 total First Breath sites participating • 37 new participants enrolled • 999 total enrollment

January 2015		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
Conducted quarterly HMO outreach survey for the period of October-December 2014	• Wisconsin TPCP ran statewide Quit Line ads the week of January 19; calls increased 50 percent • Began sending fax notification with a list of patients due for a six-month test to all Striving to Quit clinics	• 123 First Breath sites participating • 26 new participants enrolled • 1,025 total enrollment
February 2015		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• Direct recruitment at ARC Community Services resulting in two Striving to Quit enrollments • Launched February Striving to Quit Clinic enrollment contest; clinic enrollments increased 47 percent over prior month • Limited-term employee (LTE) to CTRI-public test sites published in two county papers	• Facilitated Striving to Quit and First Breath presentation at 'Fulfilling the Promise' conference for home visitors and supervisors • Outreach to HMOs and WIC sites in Milwaukee and Dane County • 123 First Breath sites participating • 14 new participants enrolled • 1, 038 total enrollment
March 2015		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• The CDC "Tips from Former Smokers" ads encouraging calls to 1-800-QUIT-NOW began airing March 30 for 16 weeks • Direct recruitment at a Madison housing authority facility resulted in eight Striving to Quit enrollments	• First Breath annual statewide meeting held; 75 providers from 22 sites attended; Striving to Quit information was presented • Striving to Quit promoted at Hispanic-Latino Tobacco Prevention Network meeting

	• Mass outreach to 370 baseline no-shows invited to CTRI testing sites • Striving to Quit press releases in public testing counties announcing upcoming end of enrollment	• Striving to Quit promoted at community baby shower in northeast Wisconsin • One new First Breath site trained; 124 total First Breath sites participating • 12 new participants enrolled • 1, 050 total enrollment
April 2015		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
Conducted quarterly HMO outreach survey for the period of January-March 2014	• Direct recruitment at a Milwaukee housing authority facility resulting in five Striving to Quit enrollments • Produced Striving to Quit happy quitter video • Launched second Striving to Quit Clinic enrollment contest; clinic enrollments increased 30 percent over the prior month • LTEs sent to public testing site county papers to announce enrollment end is near • April 14 – Last day that Quit Line invited inbound callers to Striving to Quit	• Striving to Quit promoted at Wisconsin African American Tobacco Prevention Network Meeting and Wisconsin Tobacco and Poverty Prevention Network • Striving to Quit materials distributed at Wisconsin Association for Perinatal Care • Collected five new participant testimonials • One new First Breath site trained; 125 total First Breath sites participating • Two new participants enrolled • 1,052 total enrollment
May 2015		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
	• May 8 – Last day to submit baseline tests for enrollment • May 27 – Last day of Striving to Quit enrollment • Enrollment ends at 1,962 participants	• Two new First Breath sites trained; 127 total number of First Breath sites • Zero new participants enrolled • 1, 041 total enrollment • First Breath enrollment ends May 21, 2015

July 2015		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
UW-CTRI submitted Striving to Quit-First Breath sub-study change of protocol to UW-IRB seeking to re-contact Striving to Quit participants to participate in focus groups	• Produced Striving to Quit video featuring two homeless participants who significantly cut down on smoking • UW-CTRI data team met to discuss preparations for creating the analytic data set for the Quit Line and First Breath projects	
August 2015		
Striving to Quit Program-Wide	**Quit Line Component**	**First Breath Component**
Striving to Quit-First Breath sub-study approved by UW-IRB		

Section VII: Evaluations

A. September 2015 – September 2016 (Year 5)

The fifth and final year of the MIPCD grant was dedicated to the three key partners—DHS, UW-CTRI, and WWHF—working together to complete the two comprehensive quantitative evaluations of Striving to Quit. A separate report was prepared for each component. In addition, the WWHF completed a detailed qualitative report based on a review of detailed case notes for each participant, focus groups, and individual interviews for those unable to attend a focus group.

These reports are available at https://www.dhs.wisconsin.gov.