



**Submission ID number:**

2015-0844-CR004

**Title:** Transforming the Treatment of Tobacco Use in Health Care: Seizing the Potential of the Electronic Health Record to Deliver Comprehensive Chronic Care Treatment for Smoking: Study 1: the EHR and Fax Referral Study

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**IRB Staff Reviewer:**

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A designated MR IRB member conducted an expedited review of the above-referenced continuing review progress report form. The study was approved by the IRB member for the period of 12 months with the expiration date of 3/20/2020. The study qualified for expedited review pursuant to 45 CFR 46.110 and, if applicable, 21 CFR 56.110 and 38 CFR 16.110:

**Category 8:** The study was previously approved by the convened IRB and the remaining research activities are limited to data analysis

To access the materials approved by the IRB, including any stamped consent forms and recruitment materials, please log in to your ARROW account and view the documents tab in the submission's workspace.

Please review the Investigator Responsibilities guidance (<https://kb.wisc.edu/hsirbs/page.php?id=18881>) , which includes a description of IRB requirements for submitting continuing review progress reports, personnel changes, changes of protocol and reportable events.

If you have general questions, please contact the Health Sciences IRBs at 608-263-2362. For questions related to this submission, contact the assigned staff reviewer.

# EHR-Based Closed-Loop Telephone Tobacco Quitline eReferral

February 28, 2017

## Principal Investigator

Michael Fiore, MD, MPH, MBA, University of Wisconsin School of Medicine and Public Health Professor of Medicine and University of Wisconsin Center for Tobacco Research and Intervention Director

## Project Summary

This University of Wisconsin Center for Tobacco Research and Intervention (UW-CTRI) study is designed to assess whether completely electronic, HIPAA-compliant, EHR-based, closed-loop referrals for tobacco cessation (eReferral) from primary care clinics to a state telephone tobacco quitline can increase the number/percentage of adult tobacco users receiving evidence-based tobacco dependence treatment when compared to paper-based faxed (Fax to Quit). We will also address the rate that referred smokers quit, whether they were referred via eReferral or Fax to Quit.

### 9/19/2017 Amendment Request

We propose changing three aspects of the currently approved protocol. All proposed changes pertain to the SmokefreeTXT electronic referral pilot substudy. First, we propose expanding the horizon for patient-selected target quit days from 14 to 30 days in the future, to reflect a change made by SmokefreeTXT and to ready SmokefreeTXT eReferral for integration with quitline eReferral in the future. Second, we seek to allow clinics to have greater flexibility in deciding which clinic staff roles/members should offer SmokefreeTXT eReferral. We are proposing this change because clinic leaders and staff have indicated that having staff who conduct vital sign assessment and place patients in clinic rooms be the primary conduit of SmokefreeTXT eReferral would be better for clinic workflow. This change affects one skip pattern in the post-SmokefreeTXT eReferral clinic staff survey, but does not affect the content, risks, or benefits associated with that survey. Finally, we seek permission to expand beyond primary care to specialty care clinics, at the request of specialty care clinics eager to implement SmokefreeTXT eReferral. These administrative changes will not affect study risks and may help to extend the reach of SmokefreeTXT by allowing more patients to engage in this evidence-based treatment to help them stop smoking.

### 2/28/2017 Amendment Request

## Project Summary

We would like to extend the scope of the project to include a pilot examination of the feasibility and effectiveness of eReferral to SmokefreeTXT, a text-messaging service for smokers trying to quit sponsored by the National Cancer Institute that is currently available to all Americans, without fees. Like the telephone tobacco quitline, SmokefreeTXT is an evidence-based smoking cessation support service that can be used to extend treatment provided by healthcare providers via referral. We believe it is important to evaluate eReferral to this text-based service as a potential complement or alternative to the quitline telephone counseling service. Fewer than 50% of those referred to the quitline accept counseling services and scheduling live calls is a challenge. SmokefreeTXT is an automated program that pushes out quitting coaching and support messages multiple times per day that users can access whenever they check their phones. In addition, SmokefreeTXT offers on-demand support regarding urges to smoke, smoking slips (i.e., cigarettes smoked during the quit attempt), and negative moods, in real-time. Although the quitline is also available for additional support, this is typically not in real time and usually requires calls back. As such, we expect that SmokefreeTXT may have a higher rate of

engagement that Quitline services and believe it is important to evaluate SmokefreeTXT independent of Quitline referral.

As in the initial protocol, we seek to evaluate the extent to which electronic, HIPAA-compliant, EHR-based, closed-loop referral for tobacco cessation support (in this case, via text messages rather than live phone calls) from primary care clinics can increase the number/percentage of adult tobacco users receiving evidence-based tobacco dependence treatment. In this amendment, we seek to use up to three clinics in the Gundersen healthcare system as eReferral sites in which to evaluate eReferral to SmokefreeTXT alone (without concomitant eReferral to the quitline). We seek to evaluate the eReferral to SmokefreeTXT by examining uptake rates relative to a baseline period in 1-3 clinics (rather than relative to clinics randomized to a control condition) and by examining continuing engagement and self-reported abstinence rates using deidentified data obtained from the SmokefreeTXT vendor six weeks after referral.

We would also like to note that the name of one of the health care systems in which the eReferral to the Quitline is being compared to fax-to-quit referral to the Quitline has changed due to a merger. The system formerly known as Wheaton Franciscan is now called Ascension Wisconsin. This change has been noted throughout this document.

Finally, we would like to add two survey items to the post-eReferral survey completed by clinic staff at the end of the Quitline eReferral study (see Appendix A) to assess how healthcare providers are introducing the eReferral to patients. We have found considerable heterogeneity across providers and clinics in response to eReferral and we want to assess whether there is similar heterogeneity in the ways providers report introducing the Quitline and link this to rates of eReferral and Quitline service engagement across clinics (not specific providers) in our analyses of Quitline referral methods

## **Research Protocol**

### **Closed-Loop Telephone Tobacco Quitline eReferral**

<b>ABBREVIATIONS</b>	
QL	Quitline
WTQL	Wisconsin Tobacco Quit Line
EHR	Electronic Health Record
F2Q	Paper Fax to Quit Referral to the Quitline
eReferral	EHR-based electronic referral to the Quitline
UW-CTRI	University of Wisconsin Center for Tobacco Research and Intervention
GHS	Gundersen Health System
AW	Ascension Wisconsin Healthcare
Epic	Epic Systems Corporation
Optum	Formerly Alere Wellbeing/Wisconsin Tobacco Quit Line Vendor
MA	Medical Assistant
BPA	Best Practice Advisory
IRB	Institutional Review Board
CDS	Clinical Decision Support
CY	Calendar Year

#### **Specific Aims:**

This UW-CTRI study is designed to assess whether completely electronic, EHR-based, closed-loop referrals for tobacco cessation (eReferral) from primary care clinics to a state telephone tobacco quitline can increase the number/percentage of adult tobacco users receiving evidence-based tobacco dependence treatment when compared to paper-based, manual fax referrals.

2/28/2017 Amendment: The specific aim of this extension of the protocol is to evaluate the extent to which electronic, closed-loop eReferral to SmokefreeTXT in up to 3 primary care clinics engages patients who smoke in the program, retains these individuals in the 6-week duration of the program, and helps them to quit smoking as assessed via self-report at the end of the 6-week program.

**Primary Aim 1:** To evaluate the rates of referral of tobacco users visiting primary care clinics to the WTQL, comparing those who were referred via an EHR-based electronic referral system vs. those referred via a manual paper fax referral system. Analyses will address the change in referrals from pre- to post-intervention and the trajectory of referral post-intervention per clinic.

**Primary Aim 2:** To evaluate the rates of quality referrals of tobacco users visiting primary care clinics to the WTQL, comparing those who were referred via an EHR-based electronic referral system vs. those referred via a manual paper fax referral system (quality referrals are defined as ones that result in individuals who enroll in and receive WTQL counseling and/or medication treatment services). Analyses will address the change in referrals from pre- to post-intervention per clinic.

2/28/2017 Amendment: The primary aim of the SmokefreeTXT eReferral project is to examine uptake (initial enrollment), retention (continuing engagement through the end of the 6-week program), and effectiveness (in terms of abstinence 6-weeks after the target stop-smoking date) of eReferral to SmokefreeTXT among primary care patients referred by clinic staff during clinic visits.

**Secondary Aim 1:** To examine variation in referral rates across clinics to test the hypothesis that the eReferral system will result in greater consistency in referral in addition to higher rates of referral. Nonquantitative methods will be used to understand the sources of variation.

**Secondary Aim 2:** To evaluate smoking abstinence rates of tobacco users who were referred to and accepted services from the WTQL, comparing those who were referred via an EHR-based referral system vs. those referred via a manual paper fax referral system. Analyses will address 7-day point prevalence smoking outcomes at 4-months after participant registration with the WTQL and will reflect per clinic rates.

**Secondary Aim 3:** To assess clinician and staff satisfaction with the eReferral and paper F2Q systems.

2/28/2017 Amendment: A secondary aim of the SmokefreeTXT eReferral project is to gather information about the process of implementing eReferral to SmokefreeTXT in primary care clinics, particularly regarding clinic staff implementation of and satisfaction with the SmokefreeTXT eReferral system.

#### **Background:**

The move from the current system of paper-based fax referrals (F2Q) to telephone tobacco quitlines to fully electronic EHR-based referrals (eReferrals) is progressing at a very slow rate – especially when

compared to the rapid advances of other electronic health record (EHR) tools such as ePrescribing. This research is designed to compare the functionality and effectiveness of electronic versus paper-based faxed referrals of outpatients to a telephone tobacco quitline.

#### The Paper Fax-to-Quit Tobacco Quitline Referral System

A paper *Fax-to-Quit (F2Q)* program for the Wisconsin Tobacco Quit Line (WTQL) was developed in 2003 by UW-CTRI as a mechanism to provide evidence-based tobacco cessation treatment to clinic and hospital patients. This system was developed in response to health system requests to more efficiently link their patients to the WTQL (see Figure 1 for F2Q workflow description). Once a healthcare system requests implementation of a F2Q program, UW-CTRI Outreach staff travel to the clinic or hospital to train staff on using the program and provide necessary materials (e.g., clinic-specific F2Q referral form – Figure 2). Utilizing F2Q is relatively simple but requires a number of steps. First, staff have to query patients regarding their tobacco use status. Staff then describe WTQL services (tobacco cessation counseling and nicotine replacement therapy) to the identified tobacco user and ask if the patient is interested in receiving such services. If the patient agrees and provides written permission, staff then manually complete a paper F2Q form that includes contact information and best times for the WTQL to call the patient. The form is then manually faxed by a clinic staff person to the WTQL; the WTQL then attempts to contact the patient within 48 hours and deliver WTQL treatment services. Depending on the clinic, different staff members assume responsibility for these different tasks. Finally, the WTQL faxes back to the referring clinic/provider (not to the patient's chart) a form describing the outcome of the referral, including whether their patient was reached, if s/he agreed to receive services, and which services were provided. Clinics are encouraged to enter such QL treatment information into the patient's EHR (via scanning or manually), but few clinics report doing so. Since 2003, approximately 1,000 healthcare settings (clinics, hospitals) in Wisconsin have implemented a F2Q program, with 221 active (referred at least one patient to the WTQL) in 2014 (many clinics that implement F2Q don't continue to use it, in part due to the cumbersome operational requirements). In 2014, these 221 active sites referred a total of 2,420 patients to the WTQL, averaging 11 referrals per clinic per year (WTQL data). Of the patients fax referred, 41% enrolled in WTQL services.

2/28/2017 Amendment: No such fax-to-quit referral system currently exists for SmokefreeTXT, although information about the service is provided via handouts or after-visit summaries in some clinics. Indeed, there is no systematic referral mechanism to SmokefreeTXT in the clinics under study or those that might disseminate eReferral to SmokefreeTXT, should it be found to be effective. As such, there is a need for pilot work to determine the feasibility and uptake of a referral process for SmokefreeTXT. In light of the challenges and low enrollment rates observed with a paper-based process in the fax-to-quit program for referral to the Quitline, we are electing to use EHR technology to implement an eReferral process for SmokefreeTXT.

#### The eReferral Quitline Referral System

In an effort to take advantage of the recent wide scale implementation of electronic health record (EHR) technology in healthcare settings in Wisconsin and nationwide, UW-CTRI, in collaboration with Epic Systems Corporation (Epic), health systems, and the Wisconsin Tobacco Quitline vendor (Optum) developed a new electronic quitline referral system (eReferral) (see Figure 3 for eReferral workflow description). This new system is designed to more efficiently and effectively refer patients who smoke and visit a healthcare facility to the WTQL. Specifically, during every patient visit, the EHR already prompts the clinic Medical Assistant (MA) or Roomer (the clinic staff person who typically transports the patient from the waiting area to the examination room and collects key information prior to the clinician seeing the patient, e.g., current medications, vital signs, allergies) to inquire about tobacco use as part of

the standard EHR workflow – a near-universal process as a result of the Federal meaningful use of EHRs incentive program and other regulatory requirements. The MA’s documentation of tobacco use activates a “Best Practice Advisory” (“BPA” - an Epic EHR-tool to guide evidence-based clinical interventions) that electronically prompts the clinician to offer tobacco quitline services (see Figures 3 and 4).

The BPA gives the clinician the choice of selecting a WTQL referral *order* or documenting that the *patient declined* a referral to the WTQL. If the patient indicates an interest in receiving WTQL services, the clinician “accepts” the BPA which takes him/her to the *eReferral order*, which is automatically populated with the patient’s name and contact information, and presents options for the clinician to indicate optimal times for the WTQL to call the patient. The eReferral is then sent to Optum, the WTQL vendor (Figure 4), in real-time when the provider clicks “Place Order.” The exchange of patient information in both directions (closed-loop) between the healthcare system and the WTQL is done via Health Level 7 version 2 (HL7v2) standard messaging. The data sent to the WTQL will be in a general outgoing order message (ORM in HL7v2), and the WTQL will return an unsolicited observation message (ORU in HL7v2) and a pharmacy encoded order (RDE in HL7v2).

Once the WTQL receives an eReferral, they attempt to contact the patient and provide cessation services exactly as occurs with the paper fax referral described above. Once the WTQL completes treatment or exhausts the five attempts to reach the patient, the quitline electronically sends the WTQL treatment data back to the patient’s EHR, which automatically populates the patient’s EHR in two places – data on patient contact, counseling provided, and quit date are saved as a “referral outcome note” (Figure 5), while provision of over-the-counter nicotine replacement medication (including the medication start-and end-dates based on the quit date) is documented in the patient’s medication list (Figure 5).

2/28/2017 Amendment: The workflow for eReferral to SmokefreeTXT will mimic that of eReferral to the Quitline almost exactly. Medical Assistants or Roomers will be responsible for assessing smoking status and recording this in the EHR, in accordance with current clinic practices and standards of care. As with the Quitline eReferral, documentation of current smoking status for a patient will activate a BPA that will alert the clinic staff to the smoking status of the patient and will prompt the clinic staff person to offer referral to SmokefreeTXT to the patient. Clinic staff will record in the BPA whether the patient accepted referral or declined the service. If the patient accepts, that clinic staff member will also need to record a target stop smoking day in the next 30 days. If the patient accepts the service, a SmokefreeTXT eReferral order will be populated and queued for clinician review and confirmation. SmokefreeTXT eReferral orders placed by clinic staff will be sent to ICF International, the vendor that implements SmokefreeTXT, in real-time, using Health Level 7 Version 2 general outgoing order message (ORM in HL7v2). Six weeks after the target stop-smoking date, ICF International will send an unsolicited results message (ORU in HL7v2) that will go to the patient’s providers EHR inbox and the patient’s record. Because SmokefreeTXT does not provide medications to users, it will not be necessary to update the patient’s medication list as it was for eReferral to the Quitline. Clinic staff will be instructed to offer other tobacco dependence treatments in accordance with best practices, as they see fit. This means that clinic staff may refer some patients to the Quitline (via fax, handout, or both), prescribe stop-smoking medications, refer patients to an in-clinic or in-system specialist, and/or provide brief counseling. This is in keeping with the intent of the project, which is to evaluate eReferral to external resources as treatment extenders rather than treatment substitutes.

## **Methods:**

**Methods Overview:** Following UW Institutional Review Board (IRB) approval, the study will take place in primary care clinics (general internal medicine/family practice) that are part of Ascension Wisconsin Healthcare (AW) and Gundersen Health System (GHS). Each is an integrated healthcare delivery system located in southeastern Wisconsin (AW), and western Wisconsin, northeastern Iowa and southeastern Minnesota (GHS) respectively. AW includes approximately 50 primary care clinics with over one million outpatient visits annually. GHS includes 27 primary care clinics with over one million outpatient visits annually. Currently, some of these primary care clinics offer paper F2Q referrals to the WTQL for patients who use tobacco and want to quit. The target population for the study will comprise adult (18 and older) patients who use tobacco, want to quit, and seek primary care clinical services during the study period. In consultation with each system, about 26 clinics will be selected for participation in the study, one pilot clinic per system to test the new eReferral software. The remaining clinics, about 12 clinics from each system, will be randomized to the two study conditions (see below).

2/28/2017 Amendment: Following IRB approval of this amendment, the study will take place in up to 3 clinics in the Gundersen Health System. As in the existing protocol, the target population will be adult (age 18 and older) patients served at these clinics during the study period who smoke combustible cigarettes and are willing to set a target stop-smoking date in the period required by the referral service (in this case, the quit date must be within 30 days). There will be no control clinics and no randomization of clinics to condition in this pilot project.

## I. Methods for Evaluating the eReferral Mechanism

The study will include three phases (see Table 1):

- 1) The Preparation Phase (3 months): 24 clinics (12 clinics/system) are to participate in the randomized clinical trial. Clinics will meet inclusion criteria (see below), and generate baseline rates of manual paper fax referral of adult tobacco users to the WTQL. These will be calculated for the prior 6-12 months, and the 24 clinics that will participate in the clinical trial will be randomized to two different WTQL referral mechanisms (twelve to use the manual F2Q mechanism, and twelve to transition to the eReferral mechanism). Also during this phase, the eReferral procedures and technology will be tested in one clinic within each system for one to three months. The technology will be adapted as needed. These pilot clinics will not be involved in the research.
- 2) The Study Implementation Phase (12 months): Staff in all 24 clinics will receive a baseline 30 minute in-person training, regarding either the paper or electronic referral to the WTQL (based on their randomization). While some of the clinics randomized to the paper referral system will have already received training on this referral mechanism at some time in the past (when the system was implemented in that clinic or refreshed), we will provide a refresher training on F2Q referral for all clinics in this condition consisting of about the same amount of time as used in the eReferral training. An UW-CTRI Outreach Specialist will lead all trainings and a member of the research team will also be present. All Medical Assistants, Nurses, Clinician Providers (physicians, nurse practitioners, and physician assistants), and Clinic Managers will be asked to attend the training. For any staff member who misses the initial training, a second training will be scheduled and data collected on the proportion of all staff who attended either of the trainings.

A UW-CTRI Outreach Specialist will provide additional support to all 24 participating clinics to encourage referrals to the WTQL modeled on typical clinical performance feedback activities. Specifically, this periodic support will include: 1) a one-week post-intervention launch, telephone or email check-in by UW-CTRI staff with both the Clinic Manager and the Physician Leader of each clinic, focusing on early challenges and problem solving as well as emphasizing the importance of systematically identifying tobacco users and referring (either via F2Q or eReferral) all appropriate patients to the tobacco quitline (“quality contacts”), 2) Monthly performance feedback will be shared with all staff and will include rates of F2Q or eReferrals from each clinic as well as data on the quality of the referral - the proportion of referrals that result in tobacco users who engage in quitline counseling (“quality contacts”). Specific performance feedback on the number of referrals and the number who accepted service will be provided for the clinic as a whole. Finally, 3) clinic staff will be provided with e-mail and telephone access to UW-CTRI staff who will be available to respond to questions or concerns about the F2Q or eReferral program.

At about one month after the launch of the intervention, all clinics will receive a refresher training (about 20 min) based on their randomized condition (F2Q vs. eReferral). Attempts will be made to piggy-back all trainings onto existing staff meetings. In total, rates of referral to the WTQL from all 24 clinics will be monitored for 6 months after the initial training. In this way we will compare the number and quality of quitline referrals between the six clinics randomized to the F2Q system and the six randomized to the e-Referral mechanism for receipt of WTQL treatment services.

2/28/2017 Amendment: This pilot SmokefreeTXT eReferral evaluation project will take place in 1-3 clinics (depending on clinic size, patient flow, and smoking prevalence in the clinics) over 12-17 months. This will include 2-4 months to finalize and troubleshoot the eReferral technological specifications with ICF International, Epic Systems, and Gundersen Health System Information Technology staff and then 6-9 months of testing of SmokefreeTXT eReferral engagement, retention, and effectiveness. Effectiveness testing will end 8 weeks after the end of eReferral implementation in each of the clinics, so eReferrals will end 8-11 months post-launch.

Evaluation and dissemination of results will occur over the next 2-4 months. In the host clinics, staff will be surveyed regarding their tobacco dependence treatment practices and attitudes and their knowledge of SmokefreeTXT prior to study launch. As in the existing Quitline referral protocol, an UW-CTRI Outreach Specialist and Gundersen IT trainer will provide training in SmokefreeTXT eReferral in a clinic staff meeting shortly before the EHR-enabled process goes live and will elicit feedback and provide additional training at a scheduled one-month follow-up staff meeting. The UW-CTRI Outreach Specialist will also be available to provide support to eReferral clinics upon clinic request, as needed.

- 1) The Evaluation Phase (6 months): Data will be analyzed, findings will be shared with the health system, and at least one manuscript describing the findings will be prepared and submitted for publication. 2/28/2017 Amendment: In the 2-4 month Evaluation Phase for the SmokefreeTXT eReferral pilot, data will be analyzed and results disseminated to the healthcare system, ICF International, and a peer-reviewed academic journal.

**Table 1. Study Timetable**

Preparation (3 months)	Implementation (12 months)	Evaluation (6 months)
Clinic Selection Baseline Data Collection (a 12 month look-back) Clinic Randomization	Staff Training in All Clinics at baseline and one month. Data collection and monthly Performance Feedback in all 24 Clinics (both Paper F2Q and eReferral Clinics)	Data Analysis Manuscript preparation Health system Feedback and Dissemination

**Table 1A. 2/28/2017 Amendment Pilot Study Timetable**

Preparation (2-4 months)	Implementation (6-9 months)	Evaluation (2-4 months)
Clinic Selection Baseline staff survey	Staff Training in 1-3 Clinics at baseline and one month. Data collection and monthly Performance Feedback in all clinics	Data Analysis Manuscript preparation Health system Feedback and Dissemination

**Clinic Eligibility Requirements:** The following specific inclusion criteria will be used to establish clinic eligibility: the presence of discrete primary care clinical services within the clinic (defined as general internal medicine or family medicine clinical services); at least three primary care clinician providers in the clinic (physicians or nurse practitioners/physician assistants who see patients independently of a physician); a total primary care clinical volume of at least 60 patients each week; an existing EHR requirement for staff to document tobacco use status including smoking status on all adult patients visiting the clinic at every visit; a capacity to enumerate patient visit information including adult patients/month and adult tobacco users/month by clinician and by clinic; a willingness to participate in the proposed research; a lead physician or a clinic manager on site who agrees to serve as a clinic champion for the project; and, a willingness to accept random assignment to either of the two experimental conditions.

2/28/2017 Amendment. The clinic eligibility for the SmokefreeTXT eReferral pilot will be the same as those for the existing protocol, such that clinics must have at least three clinicians serving at least 15 patients per week. The clinics must be using an EHR to document patient smoking status at every visit and must be able to share information about the flow of adult tobacco using patients (i.e., a denominator for analyses of eReferral rates) seen in the clinic in each of the 6-9 months of the active eReferral period. Clinic leaders must agree to participate in this quality assurance evaluation activity. Clinics will not be required to agree to randomization, as that is not part of this pilot study.

**Clinic Selection:** Once WF, GHS, and UW-CTRI identify eligible clinics based on inclusion criteria from the potential clinics in the each system, UW-CTRI staff (Study PI Physician [Fiore] and one other staff person) will meet with both the physician leader and clinic manager. During this brief meeting, inclusion criteria will be confirmed and the study will be described in detail including the two randomization arms and the approximate date of initiation of the intervention. These will continue until 13 clinics from each system meeting inclusion criteria have been identified and agree to participate.

2/28/2017 Amendment: As in the existing protocol, Study PI Fiore and one other research staff person will reach out to the physician leader and clinic manager at 1-3 clinics meeting the eligibility criteria specified above. Inclusion criteria in terms of provider numbers and patient flow will be confirmed and the study timeline, training and assessment activities, and eReferral workflow will be discussed in detail.

**Baseline Data Collection:** Prior to initiating the Intervention Phase of the study, an EHR-based look-back process will be used to collect 12 months of baseline data from the selected clinics that had previously used F2Q. These 12 months of clinic ascertainment baseline data will include: information on adult patients and adult tobacco users seen in the clinic; rates of quitline referrals via existing F2Q programs; and, rates of quitline engagement for those fax-referred for services (the rate of “quality referrals”). Clinic staff will not be informed that baseline data will be collected prior to the start of the intervention in an effort to minimize changes in clinician WTQL referral behavior prior to the intervention.

2/28/2017 Amendment. Prior to eReferral launch, staff in each clinic will be asked to complete a brief, anonymous survey regarding their knowledge of, current practices, and attitudes toward tobacco dependence treatment and SmokefreeTXT. Baseline data collection is not relevant to SmokefreeTXT eReferral, so we will not request aggregate historical EHR records regarding this, as we expect this to be near zero in clinics and because there is no clearly identified field in which such a referral would be recorded.

**Clinic Randomization:** Once each of the 2 sets of 12 clinics are identified and agree to participate, they will be stratified within each health system and randomized into the two study conditions using Urn randomization<sup>1</sup> (NOTE: one clinic from each system will serve as an eReferral pilot clinic to test the eReferral technology). In this methodology, the project MATCH randomization beta program will be used to equate the two clinic groups with respect to three factors: approximate number of primary care providers, approximate smoking prevalence amongst the adult patients seen during the one-year baseline period, and approximate rate of F2Q referral for all tobacco users seen during the baseline period. Each of the 24 identified clinics will be randomized into one of the following two intervention conditions: a) six per health system to continue with the existing F2Q WTQL referral system (Fax to Quit) and b) six per health system to transition to an EHR-based WTQL referral system (eReferral)

2/28/2017 Amendment. The 1-3 clinics for pilot testing of SmokefreeTXT eReferral will not be randomized; all will receive access to the EHR eReferral tools for 6-9 months during the study.

**Implementation Phase:** The following activities (with associated key outcomes) will take place over the twelve months of the Implementation Phase in each of the two study conditions (Table 2):

**Table 2. Intervention Activities and Outcomes**

Intervention	Activities	Key Outcomes
<b>Fax Referral – Fax to Quit Condition</b> (12 clinics)	✓ On site Baseline training (30 minutes) for all clinical staff describing the Wisconsin Tobacco Quitline (WTQL) and its services, which tobacco users are appropriate for a WTQL referral, and workflow for use of that clinic's condition-	✓ Monthly total of adult patient visits to the clinic as well as number and proportion of those adults who report on that clinic visit that they are current tobacco users
<b>eReferral Condition</b> (12 clinics)		
NOTE: apart from their different referral mechanisms, the intervention training,		

feedback, and other activities will be identical for the two intervention conditions	<ul style="list-style-type: none"> <li>✓ specific WTQL referral mechanism (either F2Q or eReferral)</li> <li>✓ One week post-intervention launch meeting with clinic manager and physician champion to assess the launch and program</li> <li>✓ Monthly aggregate reports sent to clinic contact indicating percentage and volume of tobacco user referred by that site; and number of patients referred who engaged in WTQL services</li> <li>✓ Referral refresher trainings at one month</li> </ul>	<ul style="list-style-type: none"> <li>✓ Percentage and number of patients who smoked referred to the WTQL</li> <li>✓ Number of referred patients who engage in tobacco telephone quitline services</li> <li>✓ Baseline and 6 month post-intervention staff satisfaction regarding the WTQL referral</li> <li>✓ 4 month post-quitline registration date quit rate</li> </ul>
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**Table 2A. 2/28/2017 Amendment. Intervention Activities and Outcomes**

Intervention	Activities	Key Outcomes
<p><b>eReferral Condition</b> (1-3 clinics)</p> <p>NOTE: providers in all clinics will be encouraged to continue to address tobacco use with all patients in accordance with best practices. The study intervention will be to turn on an EHR eReferral tool to connect adult patients who smoke and who want to quit in the next 30 days to a fee-free text-message support program, SmokefreeTXT</p>	<ul style="list-style-type: none"> <li>✓ On site Baseline training (30 minutes) for all clinical staff describing SmokefreeTXT services, which tobacco users are appropriate for a SmokefreeTXT referral, and eReferral workflow</li> <li>✓ One week post-intervention launch meeting or call with clinic manager and physician champion to assess the launch and program</li> <li>✓ Monthly aggregate reports sent to clinic contact indicating percentage and volume of tobacco user eReferred to SmokefreeTXT by that site; and number of patients referred who engaged in</li> </ul>	<ul style="list-style-type: none"> <li>✓ Monthly total of adult patient visits to the clinic as well as number and proportion of those adults who report on that clinic visit that they are current tobacco users</li> <li>✓ Percentage and number of patients who smoked and had text-capable phones referred to SmokefreeTXT</li> <li>✓ Number of referred patients who enroll in SmokefreeTXT</li> <li>✓ Baseline and 6-9 month post-intervention staff satisfaction regarding SmokefreeTXT eReferral</li> <li>✓ 6 week post-target quit date quit rate</li> </ul>

	✓ SmokefreeTXT services eReferral refresher trainings at one month	
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**Baseline Training Activities:** The following information will be conveyed to all staff during the 30 minute baseline training. Apart from details regarding use of the F2Q vs the eReferral WTQL referral process, all training activities will be identical for the two intervention conditions:

- Providing an overview of the tobacco telephone cessation services – the WTQL
- Demonstrating how the F2Q or eReferral WTQL referral mechanism can be integrated into clinic workflow
- Emphasizing that the WTQL is a supplement to, and not a substitute for, their clinical tobacco cessation intervention
- Providing a step-by-step approach to using F2Q or eReferral with patients including the use of the necessary technology and EHR documentation
- Providing instructions on how to obtain patient informed consent for either F2Q or eReferral
- Describing which adult patients will be good candidates for a referral for WTQL services (i.e., “a quality referral”)
- Offering resource materials and hand-outs to promote the WTQL
- For the clinic manager only, a telephone number and e-mail address to contact study staff with any problems in the implementation or continuation of F2Q or eReferral at their site.

2/28/2017 Amendment. As in the existing protocol for Quitline referral, SmokefreeTXT pre-launch training will provide an overview of the SmokefreeTXT program as a treatment extender (not substitute) and will review the SmokefreeTXT eReferral workflow and provide step-by-step guidance in the eReferral process, including how to assess readiness to quit and obtain patient consent. At the training, the clinic manager and identified clinic champion (if different from the clinic manager) will be given a study number and e-mail address for support and assistance regarding SmokefreeTXT eReferral.

#### **Additional Training provided at Baseline Training for Clinic Managers including Implementation**

**Manual:** As part of the 30 minute baseline training, each clinic manager will receive a paper and electronic copy of the UW-CTRI manual for implementing either F2Q or eReferral in the clinic. That manual already exists for the F2Q condition, as it has been used over the last decade for Wisconsin clinics that have implemented this WTQL referral option (“Fax to Quit Manual: A Step-by-Step Guide for Healthcare Organizations”). That existing F2Q manual will be adapted for the eReferral condition clinics. The manual is designed to be a self-guided implementation tool for health systems for referring patients who use tobacco to the WTQL. The manual includes all required forms including for the F2Q condition a specific F2Q enrollment form personalized to the clinic that must be faxed to the quitline in order to link an interested patient to the WTQL (Figure 2) for the F2Q sites. For the eReferral condition, there will be an essentially identical EHR –based form for WTQL referrals. Also included in the manual is a “Fax to Quit Flow Chart” (Figure 1). All 24 clinic sites (fax and EHR-based referral clinics) will be urged to follow this flow chart (title will be adapted for eReferral condition) as they integrate tobacco quitline referral into the regular workflow of patient care. Effective use of the WTQL referral programs (both F2Q and eReferral) will be guided via this flowchart and requires two key components: a) a few simple systems-level changes in clinic operations to ensure that the tobacco quitline option is consistently offered to

tobacco users, and, b) a commitment by clinician and support staff to integrate these operational steps into their clinic workflow.

2/28/2017 Amendment. As in the existing protocol, clinic managers will be given paper and electronic copies of a UW-CTRI manual for eReferral. This manual will reflect the nature of the SmokefreeTXT program and the specific workflow for eReferral to this texting service.

In terms of the specific flow chart steps (Figure 1), the foundation of the program is a clinic-wide system to assess tobacco use status as a regular part of the vital signs ascertainment, typically determined and documented by the Medical Assistant (MA) or other clinic staff who “rooms” the patient (the person who brings the patient from the waiting room to the examination room). Once the patient is brought to the examination room, the MA typically collects and documents the vital signs (blood pressure, pulse, temperature, and respiratory rate). With the advent of the Federal Meaningful Use EHR Incentive Program, nearly all EHR vendors, and healthcare systems also collect and document tobacco use status on each patient. At this point, workflow processes diverge based on whether the clinic was randomized to the F2Q or the eReferral condition.

2/28/2017 Amendment. The workflow for SmokefreeTXT eReferral is similar to that of Quitline referral in the existing protocol. The first, foundational step is for “Roomers” who assess vital signs to assess and record smoking status in the EHR. Only clinics in which this is already standard protocol will be eligible for this pilot study. As such, this step in the workflow will reflect current practice rather than a change in the clinics to be studied.

**Tobacco User Referral in F2Q condition:** If a patient is identified as a current tobacco user, the MA will leave a clinic-specific (to allow for ascertainment of clinic-specific referral rates) F2Q form (Figure 2) in the exam room to prompt the clinician to address the topic. Importantly, once tobacco use status is documented, the clinician will be asked to address tobacco dependence only with clinic patients who use tobacco - about 17% (based upon the current smoking prevalence rate among adults in Wisconsin). The F2Q protocol then requires the clinician to advise each tobacco user to quit and assess the patient's willingness to quit within the next 30 days. If unwilling, the clinician ends the tobacco cessation discussion at that point, offering the tobacco user a WTQL card or brochure and motivational counseling to consider quitting in the future. If the patient expresses a willingness to try to quit over the next 30 days, the clinician recommends a prescription for an FDA-approved cessation medication and offers telephone counseling through the WTQL. If the tobacco user is willing to accept counseling from the quitline s/he is asked to sign the simple F2Q form at the end of the clinic visit, consenting to the referral and the exchange of information, providing two telephone numbers and best times to call. The form is then passed to the MA (part of the visit closure workflow procedures) who then faxes the form to the WTQL. The WTQL then makes at least five attempts to proactively contact the patient by telephone over the next three days. If a successful contact is made and the patient agrees to WTQL treatment services, evidence-based counseling and over-the-counter nicotine replacement medication is then provided to the patient (via the telephone and via a mailing with additional self-help quitting materials). Finally, the WTQL faxes back to the clinician the outcome of the telephone contact.

The F2Q program is designed to be of minimal burden to the clinic and staff, requiring about 30 seconds of time by the MA when rooming each patient, and about two to three minutes of clinician time for the approximately 17% of adult patients who use tobacco. Our experience in Wisconsin has demonstrated that clinics are willing to adopt the program because it is viewed as a modest time commitment and a free, value-added service for their patients.

The F2Q form (Figure 2) is an essential document for the successful use of F2Q. This form provides key information on both the patient and the clinician so that the quitline can proactively contact the patient and then give the clinician feedback on efforts to contact the patient and services used. This WTQL feedback for each referred patient is faxed back to the patient's clinic. As shown on Figure 2, F2Q is intended for use only with tobacco users who indicate they want to make a quit attempt within the next 30 days. This criterion is an effort to refer "quality contacts" - tobacco users interested in quitline counseling.

In addition to patient-specific information (primary and secondary telephone number, language preference, type of tobacco used, best time of the day to call, and consent to receive a call from the quitline and share follow-up information with clinician), the F2Q form includes specific contact information for the patient's clinician. The purpose of this contact information is to provide feedback to the clinician regarding whether the quitline was able to contact the patient, and which service options the quitline provided to the tobacco user (self-help materials, over the counter nicotine replacement therapy, referral to a local cessation program, enrollment in the quitline counseling, readiness to quit, and quit date). Finally, F2Q forms are personalized to each clinic and to each clinician so the source of each referral can be adequately tracked and assigned to the appropriate source of the referral.

2/28/2017 Amendment. There is no fax-to-quit enrollment mechanism for SmokefreeTXT.

**Tobacco User Referral in eReferral Condition:** The EHR-based, fully electronic bi-directional referral (eReferral) condition involves all of the procedures and resources used in the F2Q condition above. In addition, the following workflow will be followed for the eReferral clinic site (Figure 3). Once the MA has identified a patient as a tobacco user, the EHR will be programmed to prompt the WTQL eReferral Best Practice Advisory (BPA). A BPA is an EHR-based functionality that prompts clinical interventions and provides clinical decision support (CDS) once certain clinical conditions have been met (in this instance, upon a patient being identified as a current tobacco user, the BPA prompt appears, driving the clinical staff to click on it and consider the recommended clinical activities prior to the completion of that clinic visit). In this instance, the eReferral manual will inform clinic staff of a workflow modification requiring that, in response to a WTQL eReferral BPA, the MD, NP, or PA should assess the patient's willingness to quit, and for those willing, should discuss potential cessation medications, and offer the patient a referral to the WTQL for more in-depth support/counseling. If the patient is interested in support from the WTQL, the clinician records in the EHR the patient's verbal consent for the referral and exchange of information (Yes/No box), selects the best time for the quitline to call the patient (drop-down menu). Upon completion of these minimal EHR actions, the clinician then places "the order", an electronic request to the WTQL to contact the patient for quitline treatment services. This order is electronically transmitted to the WTQL and includes patient demographic information so that the quitline can contact the patient. As with F2Q, the quitline will make five attempts to contact the patient. Once the WTQL completes treatment or exhausts the call attempts, they electronically send the eReferral service data back to the patient's EHR, which automatically populates the patient's EHR in two places – data on patient contact, counseling provided, and quit date are saved as a "referral outcome note" (Figure 5), while provision of over-the counter nicotine replacement medication mailed to the patient (including the medication start and end dates based on the quit date) is documented in patient's EHR as part of the patient's medication list (Figure 5).

2/28/2017 Amendment. As with eReferral to the telephone Quitline, eReferral to SmokefreeTXT will be a fully electronic, "closed-loop" referral in which the outcome of the referral is automatically fed back

into the patient's EHR 6 weeks after the target stop-smoking date. When a "Roomer" documents that a patient is currently a smoker, this will cue a Best Practice Advisory (BPA) to appear for clinic staff during the encounter. This BPA will guide clinic staff in the offer of SmokefreeTXT and allow them to document the patient response (acceptance or decline). If a patient consents to setting a quit day in the next 30 days, indicates that they have a text-capable phone, and accepts the referral, the provider will place an order for the text-capable phone to receive SmokefreeTXT messages. SmokefreeTXT will send terms of use (including a notice that text messaging fee rates may apply) and privacy practice information to the identified phone upon receipt of the eReferral. Patients have the option to stop receiving SmokefreeTXT messages at any time by texting "STOP" to SmokefreeTXT. Text messages may use patient cell-phone service plan minutes. Patients will be advised of this by SmokefreeTXT upon enrollment. Patient records in the EHR will be automatically update with the result of the eReferral 6 weeks after the target stop-smoking date (set at enrollment). This may be up to 10 weeks post-referral (as the target stop-smoking date could be set up to 30 days after eReferral) and will indicate whether the patient stayed enrolled, dropped out (by texting "STOP"), and reported any smoking in the past 7 days at the 6-week post-quit follow-up. No medications will be provided by SmokefreeTXT, so there will be no need to update the patient medication list in the EHR.

## **II. Methods to address Secondary Aim 3: To assess clinician and staff satisfaction with the eReferral and paper F2Q systems.**

In addition to our systematic testing of the impact of eReferral relative to F2Q in terms of rates of smokers to the WTQL as well as cessation rates of those enrolling in WTQL services, we will conduct brief pre- and post-electronic questionnaire surveys of all clinic staff regarding their experience with the two methods of referring patients who smoke to the WTQL. The pre-survey will be sent electronically to all staff members during the three-month Preparation Phase and the post-survey will be sent at six months post-initiation of the study in each clinic. Staff to be surveyed include the Medical Assistants, nurses, clinic manager, and provider staff (physicians, nurse practitioners, and physician assistants). The surveys will be designated by clinical role and will not be further identified. The survey will be designed to target constructs (both "facilitators of" and "obstacles to" adoption of EHR and workflow enhancements) that are implicated by prior research on adoption and maintenance of system changes:

- Task/job training and understanding
- Personal attitudes about smoking
- Appropriateness of activity for role
- Perceived importance to patient and to clinic
- Self-efficacy for task
- Feeling of team membership

Finally, open-ended items on the survey will help ensure that information is gathered on unanticipated or unusual issues that affect referring patients to the Wisconsin Tobacco Quit Line. These surveys are similar to those used extensively in our earlier research on smoking intervention in clinic settings. They were designed to meet high standards with regards to item writing and psychometrics (e.g., Devellis, 2012). The survey to be used for this pre- and post-survey is provided as Appendix A.

2/28/2017 Amendment. The staff survey developed for eReferral to the Quitline has been adapted slightly to assess familiarity with and beliefs about text support programs prior to and after eReferral launch and to assess use of and attitudes toward SmokefreeTXT at the end of the eReferral evaluation period in each clinic. The adapted version of the staff survey is shown in Appendix B. Items I-X and XIX-XX are identical to those used in the existing protocol for Quitline referral. Items XI-XVIII, XXI, and XXIIC

are specific to SmokefreeTXT. We are only asking about experience referring patients to SmokefreeTXT after study launch because we expect very few clinical staff to have knowledge of or experience with SmokefreeTXT prior to eReferral training and launch. Clinics in the existing protocol had experience with fax-to-quit programs for Quitline referrals, but have no such history with SmokefreeTXT or other text-message-support programs for smoking cessation.

9/19/2019. The items in the survey have not been changed, but items that previously only applied to clinicians now apply to rooming staff who will make the SmokefreeTXT referral offer to patients.

Dependent Variables for Intervention Phase: Acquisition & Appraisal: The tobacco quitline vendor (Optum) will derive summary data on an ongoing basis from both the F2Q and the EHR-based referrals with patient specific identifiers removed and provide such summary data to study staff. These summary data forms will allow us to compute the following monthly outcomes linked to clinic: (1) number of referrals to the quitline, (2) number of successful WTQL contacts with patients, and (3) number of quality WTQL contacts with the patient (where the patient enrolls in and receives tobacco quitline services). This quitline information will supplement information provided by the clinic's EHR system (both F2Q and eReferral clinics have identical Epic EHR systems) That is, the number of quitline referrals can be divided by the total number of tobacco users since participating clinics must have accurate estimates of tobacco users seen in each clinic/month to compute a clinic smoker referral rate. Thus, these outcomes will address how many patient tobacco users are *referred* to the quitline each month (via the fax or EHR-based referral mechanism), the number of these referred patients whom the quitline successfully contacts/month, and the number of these patients who enroll in a quitline counseling program/month (quality contacts). We can also determine the proportion of quality contacts by dividing the number of quality contacts by the total contacts. These measures will also be computed on a per month basis by clinic so as to capture such outcomes as contacts/month, quality contacts/month, and referrals/month.

2/28/2017 Amendment. For evaluation of eReferral to SmokefreeTXT, dependent variables will parallel those in the existing protocol for Quitline eReferral. The SmokefreeTXT vendor (ICF International) will send summary data regarding the number of eReferrals received and the number of patients engaged by clinic to study staff no less than monthly. These summary data will indicate how many eReferrals were received, how many were successfully enrolled in the program (i.e., who had a working number), how many of those enrolled dropped out by texting STOP to the program, and, finally, how many texted responses indicating no smoking vs. any smoking in the last 7 days 6 weeks post-target-quit date. Aggregate EHR data will be pulled from the health system at the end of the study to ensure that the number of eReferrals received by ICF International is consistent with the number of eReferrals sent, as recorded in the EHR. These EHR reports will also indicate the total number of patients seen, the total number of visits completed, the total number of patients who smoke seen, and the total number of visits completed by patients who smoke during the active eReferral evaluation period in each clinic, as well. This will be used to determine the rates of referral, engagement, and retention in SmokefreeTXT.

UW-CTRI will evaluate the principal dependent measures on the basis of rate of tobacco users referred to the WTQL/month, showing changes from the baseline to the post-intervention periods on the basis of percentage of tobacco user referral or contact status/tobacco user flow at each clinic. The public health importance of this research will be seen if the EHR-based program results in rates of referrals and contacts (and quality referrals and contacts) that are higher, more uniform, and more sustained across time, than are generated by the F2Q method. It is possible that changes in contact rates from the baseline period to the post-intervention period may reflect correlated secular changes or simply the

passage of time. Therefore, we will keep track of potentially relevant secular events. In addition, because the F2Q control and the EHR referral clinics will enter the study on the same time line, the occurrence of secular changes should not differentially affect the two conditions.

For both the F2Q and eReferral systems, data acquisition to establish WTQL referral rates will be derived from monthly reports to UW-CTRI from the WTQL. Referral rates are based on a denominator reflecting the number of adult tobacco users seen in the study clinics per month during the study time periods; this will be obtained for both referral systems by querying an existing EHR field for all clinic EHR systems that reflect response to an existing vital signs question regarding tobacco use. Such data will be available for both the baseline and post-intervention periods. Thus, the method and presumably the reliability of the data acquisition process will be equivalent across the two study arms.

In order to obtain data for the secondary analysis of smoking abstinence among referred participants, the study will use standard WTQL follow-up evaluation procedures. The standard procedure of the WTQL is to obtain consent to conduct follow up as part of each registration process. The tobacco quitline routinely conducts follow up evaluations of quitline users for QI and self-evaluation purposes four months post registration. Per the study team's request, aggregate follow-up data of four-month 7-day point-prevalence self-reported smoking status, quitting intentions, and other tobacco and tobacco cessation medication use on up to fifty patients completing the follow-up per clinic will be provided to study staff. Cessation rates will be projected separately by the number of tobacco patients visiting each clinic, those referred for quitline services, and those who enroll in WTQL following referral for both the paper faxed-based and EHR-based referral systems. Only patients who register for and agree to be followed up by the quitline will be contacted by the quitline for follow up.

2/28/2017 Amendment. As in the existing protocol, aggregated EHR data will be gathered to determine the number of patients seen per clinic per month in the study, including the number of tobacco using patients seen, and this will be used as the denominator in calculations of the rate of eReferral to SmokefreeTXT. In contrast to the existing protocol evaluating eReferral to the Quitline, there will be no comparison condition in this pilot study. Analyses will focus on the rate of uptake (eReferrals), drop out during the 6-8 week program, and smoking status at six-weeks post-quit. Assessment of smoking status six weeks post-quit is standard practice in the SmokefreeTXT program, along with assessment of smoking status, reset quit dates, craving, mood, and slips throughout the program. As such, there are not additional assessments proposed for the research study; all are standard parts of the SmokefreeTXT program. Data shared for eReferral evaluation purposes will be deidentified and/or aggregated.

**Hypotheses & Analytic Plan for Intervention Phase:** Specific quantitative hypotheses to be tested are-

- The fax referral training and the EHR-based referral training and intervention will both increase tobacco user quitline referrals and contacts, and quality referrals and contacts, during the post-intervention period relative to the baseline period. This pattern will be seen when examining monthly and aggregate /clinic data.
- The EHR-based referral intervention will be more effective than the fax referral intervention in increasing tobacco user quitline referrals and contacts, and quality referrals and contacts, in the post-intervention period relative to the baseline period. This superiority will be seen in /clinic data. Thus, while both interventions will increase contacts relative to baseline, the EHR-based referral will be especially effective in this regard.

Note that this second hypothesis implies the presence of an interaction between intervention condition and the two experimental periods (baseline and post-intervention).

- The EHR-based referral intervention process will increase smoking cessation outcomes more than does the fax referral mechanisms during the post-intervention phase. This will be seen when examining quit rate/clinic data.

The analysis of the primary outcome is designed to show differences in the rate at which patients are referred to the Wisconsin Tobacco Quitline by the 12 control (F2Q) versus the 12 experimental (EHR referral) clinics during the post-intervention period. We will use a mixed effects logistic regression model via Generalized Estimating Equations (via SAS PROC GENMOD; for a population based model) with coding for the baseline and post-intervention phases, and with coding for each post-intervention monthly time point with the models centered at the 6-month post-intervention mark. Based on data from the healthcare systems, we anticipate that on average, each clinic will see about 120 smokers/month, and based upon the urn randomization procedure we expect similar smoker flow rates across the two experimental conditions. The binary dependent variable will be measured at the smoker level, i.e., whether or not a smoker seen at a clinic is referred to the quitline, and aggregated to the clinic level to constitute clinic referral rate. Thus, while clinic is the unit of analysis, our sample is the smoker, each one being one Level 1 unit. Experimental condition will be coded with a single dummy variable. The baseline WTQL referral rate data for each clinic will serve as a covariate (only one covariate will be used to preserve degrees of freedom). We will specify a logit link function and assume a first-order autoregressive structure (to address dependence across measurement occasions). We will test the main effects of experimental conditions. Further, we have an a priori plan to test for post-intervention change over time within each experimental condition and will test for interaction between experimental condition and measurement occasion. Similar analyses will be used for the quality referral outcome.

In a subsequent model we will analyze cessation rates of tobacco patients identified as smokers during a clinic visit. Abstinence will be measured at the smoker level and aggregated to the clinic level by the WTQL to determine a clinic quit rate. We anticipate that there will be no overlap in rates of abstainers/clinic (abstainers from a clinic/smokers presenting to clinics within the relevant time period) for the two experimental conditions, permitting use of a non-parametric analysis of outcome (e.g., Mann-Whitney U).

2/28/2017 Amendment. Given that the objective of the SmokefreeTXT eReferral pilot study is to assess the feasibility, uptake, retention, and quit rates of this program, there are no specific quantitative hypotheses to test or comparisons to be conducted. Instead, analyses will be descriptive and will focus on uptake, retention, and quit rates by clinic. We will also assess staff knowledge of smoking cessation treatments and SmokefreeTXT-specific knowledge, practices, and attitudes prior to and after six months of SmokefreeTXT eReferral, with the expectation that knowledge, positive attitudes, and treatment practices among clinic personnel will improve from pre- to post-launch. In addition, we will document implementation challenges and solutions to inform future evaluation or dissemination efforts.

**Power Analyses for Intervention Phase:** Power was calculated for a two-group cluster-randomized design with clinic as the unit of randomization (n=6 clinics per group for each health system) with a conservative estimate of approximately 90 smokers seen in each clinic per month. The dependent variable for the power analysis is the proportion of smokers referred/month. We based our estimates of

the mean number of monthly referrals in each group on pilot data from an eReferral demonstration project (Adsit et al., 2014) which found a rate of 14% for an eReferral system versus 0.3% for a paper fax referral system<sup>4</sup>. To achieve a more conservative power analysis, we calculated power to detect a smaller difference between the groups. More specifically, we estimated power to detect a group difference on proportion referred per month with values of 2% for the Fax to Quit group versus 7% for the eReferral group. As shown in Table 3, the groups are not expected to differ at baseline (mean of 1% referrals per month for each group). As such, the power analysis was based on a test of the difference between groups for the post-intervention proportion of referrals per month (2 vs 7%). The following power analysis therefore should be conservative since it does not take advantage of baseline referral rate to index change and its projected effect size is considerably less than might be expected based on prior research. For purposes of power analysis, we assumed that the standard deviation for the mean proportion of referrals per month will be 2.5%; we also set alpha at .05 for a two-tailed test. The power analysis was computed via an online program, GLIMMMPSE<sup>5</sup>, that permits power estimation for cluster-randomized designs. Results of the power analysis showed that there is >90% power to detect a mean difference of 1 versus 7% of smokers referred per month. The demonstration of this effect within two health systems will allow even greater confidence in these primary outcomes.

**Table 3. Predicted Mean Rates of Quitline Contacts/Clinic/Month as Proportions of Smokers Seen, Two Arms Across Baseline and Intervention Phases**

Intervention Arm	Baseline	Intervention
Fax Referral (Fax to Quit)	1%	2%
EHR-based Referral (eReferral)	1%	7%

2/28/2017 Amendment. Formal power analyses were not conducted for the pilot test of the feasibility of eReferral to SmokefreeTXT that will be conducted in 1-3 clinics.

**Staff Survey Analysis.** Most items on the survey are Likert scale items so their scoring and synthesis will be straightforward. We will compute standard psychometric indices such as item means, variance/standard deviation, and range. We will not subject items to factor analyses or determine coefficient alpha since the items were not designed to index latent dimensions. However, reliability/generalizability analyses will be conducted to determine if level of endorsement varies with type of staff member (this will be done across clinics, within each experimental condition). In formal analyses, we will use GEE (see above) to perform item-specific analyses since respondents will be nested within clinics. Thus, clinic will be treated as a Level 2 variable while staff member will be treated as a Level 1 unit. Because surveys will not carry personal identifiers we will conduct separate analyses on baseline and post-intervention data. The main analyses will test for differences in post-intervention endorsement levels as a function of experimental condition. In a subanalysis we will separately analyze data from the MA's, the only staff group large enough to permit dedicated analysis. These analyses will be repeated for the baseline data. Open ended items will be nonquantitatively synthesized and common or significant themes will be extracted and used to guide interpretation of the survey data<sup>6</sup>.

2/28/2017 Amendment. As in the existing quit line eReferral protocol, staff survey analyses will focus on item means, variance/standard deviation, and range prior to and six months after the SmokefreeTXT eReferral launch. Given that only 1-3 clinics will be involved in the SmokefreeTXT eReferral pilot, however, we will not treat data as nested in clinic and will not examine results by staff role within clinics, and the numbers of particular staff types will be too low to support such an analysis. Survey data will be assessed and coded in the same way in the existing protocol and the SmokefreeTXT pilot.



Figure 1. Manual Fax to Quit: Clinic, Patient, and Data Workflow

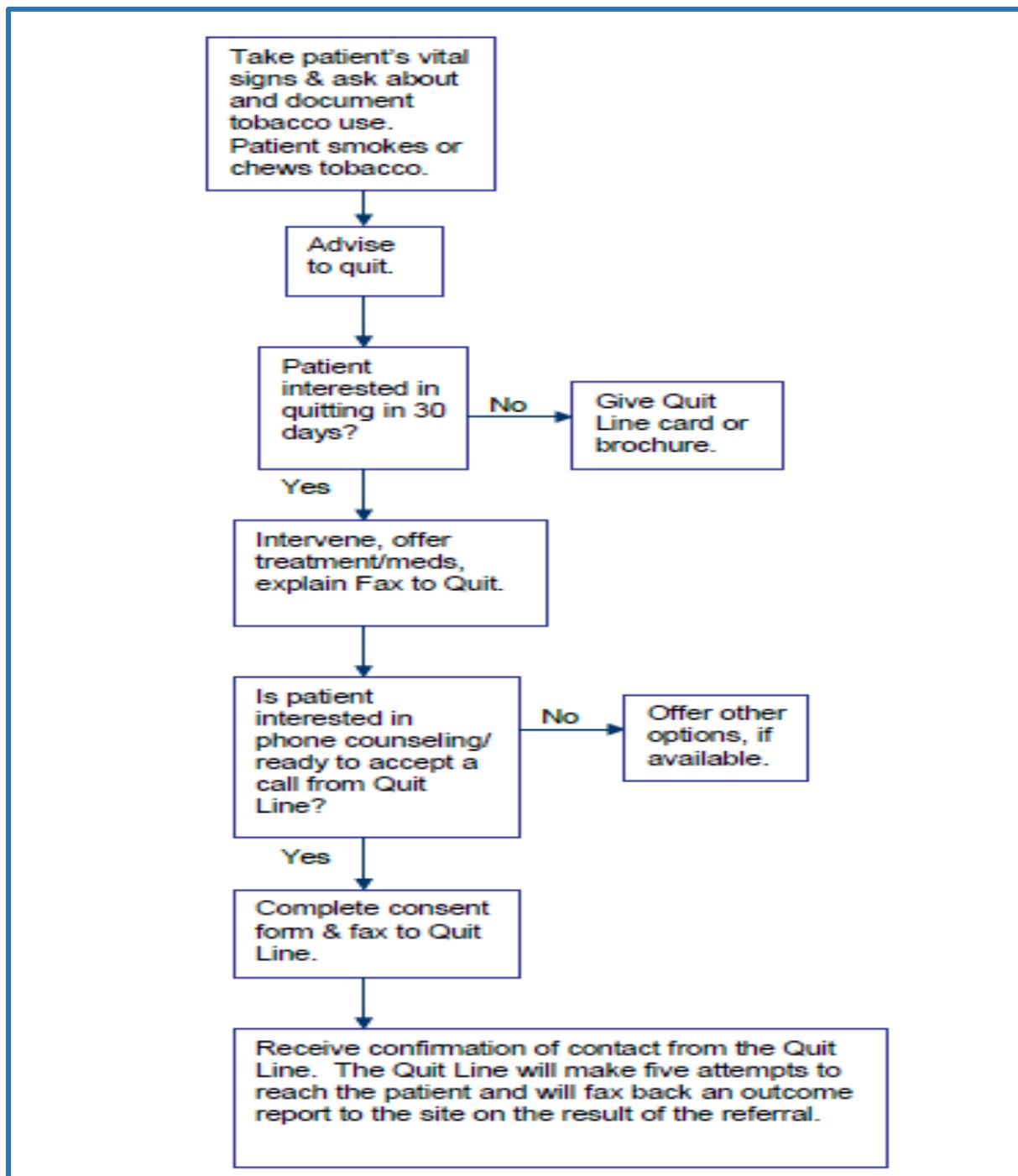


Figure 2. Fax to Quit Consent Form Used in Clinics

**WISCONSIN TOBACCO**  
**QuitLine**  
**800-QUIT-NOW**

When complete, please fax to: 1-800-xxx-xxxx

**Wisconsin Tobacco Quit Line Fax to Quit Consent Form**

Fax to Quit is for patients who are **ready to quit in the next 30 days AND willing to accept a call from the Quit Line**. If neither of these conditions is met, Fax to Quit is not appropriate at this time. Instead, provide patient with Quit Line or other tobacco resource information.

**Provider Information:**

Facility Name: ABC Healthcare Clinic  
HIPAA-Covered Entity (Please check one):  Yes  No  I don't know  
Healthcare Provider: Dr. Francis Smith  
Address: 123 Main Street  
City: Any City Zip: 99999 County: Any County  
Contact Name: Abby Lockhart  
Fax: (999) 999 - 9999 Phone: (999) 999 - 9999  
Email: abby.lockhart@abchealth.org  
Comments: (e.g. Patient has COPD, diabetes, any information that might be helpful to the Quit Line)  
Patient has asthma.

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**Patient Information: (please print)**

Patient Name: Celia Cruz Pregnant?  Yes  No  
Address: 14301 Pine Street City: Any City DOB: 6/18/65  
Zip: 55555  
Phone Number: (555) 555 - 5555 Alternate Phone Number: (333) 333 - 3333  
Language Preference (check one):  English  Other - Spanish  
Tobacco Type (check primary use):  Cigarettes  Chew/Spit  Cigar  Pipe  
CC I am ready to quit tobacco and request the Wisconsin Tobacco Quit Line contact me to help me with my quit plans.  
(Initial):

The Wisconsin Tobacco Quit Line will call you. Caller ID may indicate 1-866-784-8454 (1-866-QUIT-4-LIFE). Please check the best times for the Quit Line to reach you in the next 3 DAYS. The Quit Line is open 7 days a week:

7am - 11am  11am - 2pm  2pm - 5pm  5pm - 8pm  8pm - 11pm

Comments: (e.g. I'm not available weekends, prefer Tues or Thurs, after 9pm, etc.)  
Please call on the weekend when I have free cell phone minutes

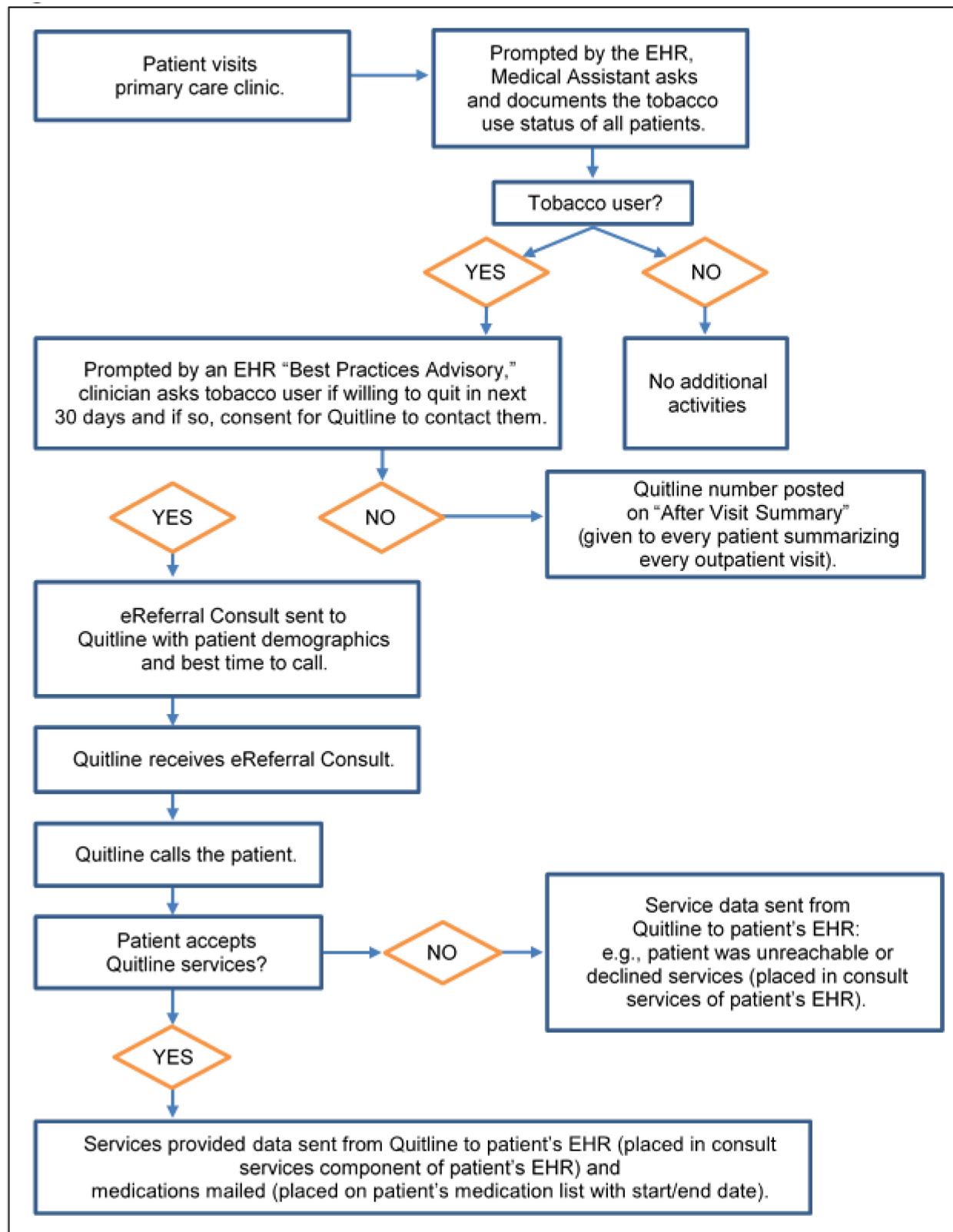
Patient Signature: Celia Cruz Date: 09/09/09

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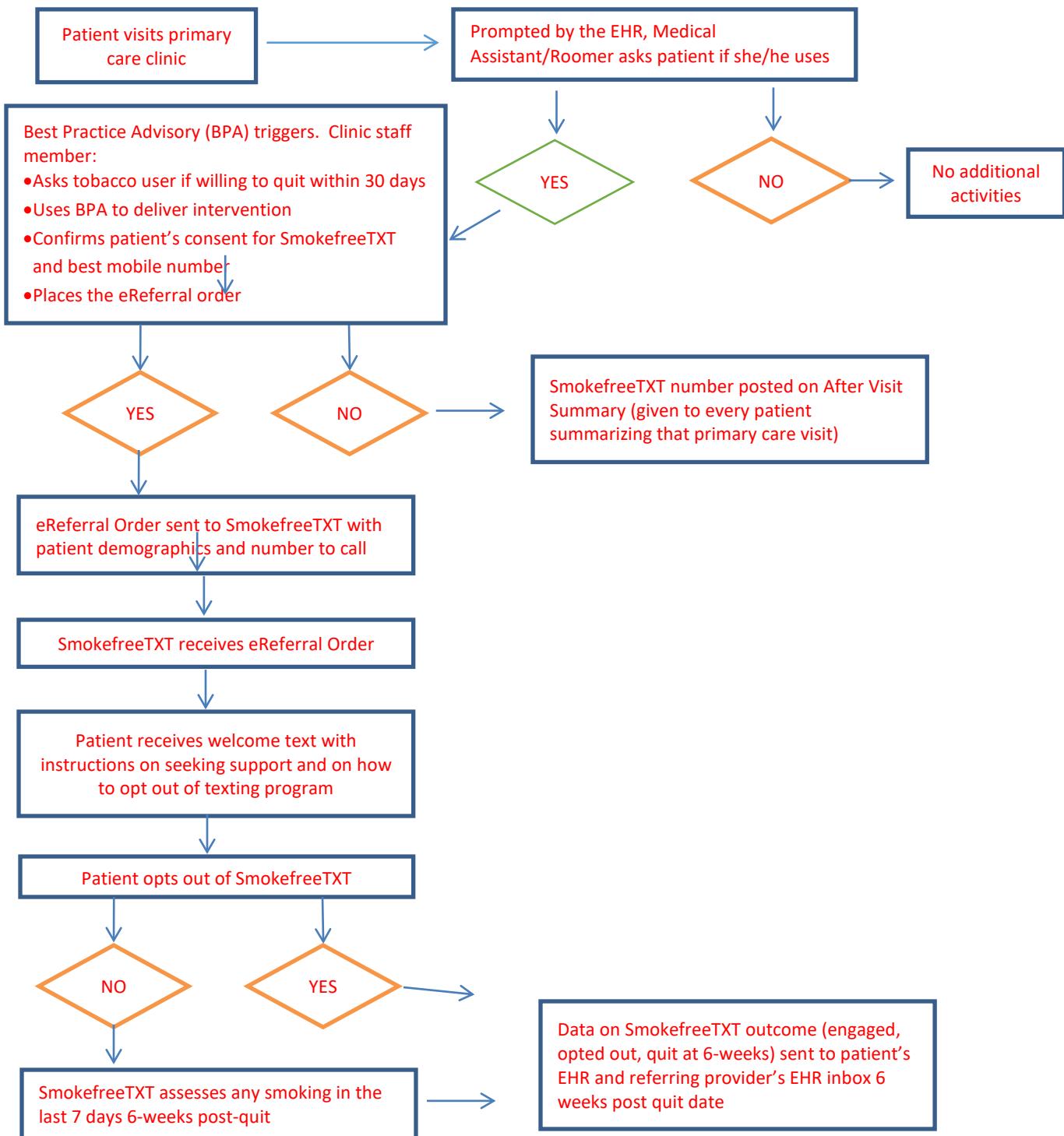
Confidentiality Notice: This facsimile contains confidential information. If you have received this facsimile in error, please notify the sender immediately by telephone and confidentially dispose of the material. Do not review, disclose, copy, or distribute.

Last Update: November 2014

**Figure 3. eReferral to Wisconsin Tobacco Quit Line: Clinic, Patient, and Data Work Flow**



## 2/28/17 Amendment Workflow: Electronic Health Record (EHR)-based Referral (eReferral) to the SmokefreeTXT with Result Feedback to Referring Clinician via Patient EHR



**SmokefreeTXT** is a **treatment extender** that provides ongoing, tailored text-message coaching and support to patients who want to quit using tobacco.

All services are **FREE** and available **24/7**.

**Clinician prescribes** a full course of an FDA-approved tobacco cessation medication(s).

**smokefreeTXT**

**Figure 4. Screen Shots of the eReferral of Tobacco Users to Wisconsin Tobacco Quit Line – Roomer and Clinician Responsibilities**

The image displays three screenshots of a medical software interface, likely from a program like Epic or a similar electronic health record system, illustrating the process of referring a tobacco user to the Wisconsin Tobacco Quit Line.

**Screenshot 1: Vital Signs**

This screenshot shows the 'Vitals' section of the software. It includes fields for 'Taken on' (05/04/2012), 'BP', 'Pulse', 'Resp', 'Temp', 'Source', and 'Pain Information'. A 'Tobacco Use' section indicates the patient is a 'Current Everyday Smoker (Quit: 11/2005)' who 'Uses Cigarettes'. The 'Packs/Day' is 1, 'Years: 10', and 'Smokeless: Unknown'. A 'Review / Edit' button is present. A 'Last reviewed: 4/17/2012' note is also visible.

**Screenshot 2: Best Practice Advisory**

This screenshot shows a 'Best Practice Advisory' window. It contains a message: 'The patient is a tobacco user. Consider offering quit line services which could include both counseling and over the counter nicotine replacement. Select the order below to send a referral to the tobacco quit line, or indicate the patient's refusal.' Below this message are buttons for 'Acknowledge Reason' (with an arrow icon), 'Patient Declines' (highlighted in yellow), and 'Open order: Wisconsin Tobacco Quit Line referral' (with a blue icon). A 'Refresh' button is also present. A 'click to open' link is located in the top right corner.

**Screenshot 3: Acquiring Patient Consent**

This screenshot shows the 'Wisconsin Tobacco Quit Line referral' section. It includes fields for 'Status' (Normal), 'Priority' (Routine), 'Class' (Outside Ref), and 'Questions'. The 'Questions' section contains two prompts: '1. I have discussed tobacco cessation counseling with the patient. Patient agrees to referral to the Wisconsin Tobacco Quit Line, and agrees to information exchange between the quit line and health plan, including patient contact and outcomes information.' and '2. What is the best time for the Wisconsin Tobacco Quit Line to call the patient?'. A 'Yes' or 'No' button is next to the first question. A 'Dx Assoc' table is also visible. A 'Comments (F6): Click to add text' field is at the bottom. Buttons for 'Accept', 'Cancel', and 'Remove' are located at the bottom right.

**Figure 5. Screen Shots Depicting Treatment Services Provided by Wisconsin Tobacco Quit Line that Populate the Patient's EHR – Counseling Notes and Medication List**

Results				REF TO WISCONSIN TOBACCO QUIT LINE																				
<b>Patient Information</b> Zztest, Bullwinkel M [40720611] DOB 06/23/1956 Female 8889 se Home Phone MINERAL POINT, WI 53565 Work Phone 608-256-3333																								
<b>Contact Information</b> Date 3/20/2012 Provider Meetul V. Shah, MD Department Dc Fish Hatch Fm Encounter # 65711142																								
<b>Result Information</b> Status Final result (3/23/2012 12:30 PM) Provider Status Ordered																								
<b>Entry Date</b> 3/23/2012																								
<b>Result Narrative</b> Free and Clear contact date: March 21, 2012 Free and Clear call disposition: One-Call Free and Clear status: Accepted Services																								
Treatment plan: Planned quit date: March 30, 2012 Nicotine Gum 4 mg - 4 weeks																								
<b>Lab and Collection</b> REF TO WISCONSIN TOBACCO QUIT LINE (Order #77067265) on 3/20/2012 - Lab and Collection Information																								
<b>Order Providers</b> Authorizing Provider Shah, Meetul V., MD Encounter Provider Shah, Meetul V., MD																								
<b>Order</b> <b>NICOTINE 21 MG/24HR TD PT24 [32349] (Order 77068137)</b> <table border="1"> <thead> <tr> <th colspan="2">Provider Information</th> <th colspan="3">NICOTINE 21 MG/24HR TD PT24 [32349] (Order 77068137)</th> </tr> <tr> <th>Ordering User</th> <th>Interface, Aleredispense</th> <th colspan="3">Authorizing Provider Services, Tobacco Cessation</th> </tr> </thead> <tbody> <tr> <td colspan="2"></td> <td>Quantity 1</td> <td>Refills 0</td> <td>Start 4/5/2012 End 4/18/2012</td> </tr> <tr> <td colspan="2"> <b>NICOTINE 21 MG/24HR TD PT24</b>            Sig: Apply 1 patch once daily.            Route: (none)         </td> <td colspan="3"></td> </tr> </tbody> </table>					Provider Information		NICOTINE 21 MG/24HR TD PT24 [32349] (Order 77068137)			Ordering User	Interface, Aleredispense	Authorizing Provider Services, Tobacco Cessation					Quantity 1	Refills 0	Start 4/5/2012 End 4/18/2012	<b>NICOTINE 21 MG/24HR TD PT24</b> Sig: Apply 1 patch once daily. Route: (none)				
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<b>Medication List</b>																								

**2/28/2017 Amendment.** The eReferral to SmokefreeTXT EHR tools are still in development and so are not yet available in screen shots. The content will be similar to the material above, except that the Best Practice Advisory text will prompt clinic staff to offer referral to SmokefreeTXT, a text-message program that offers support in quitting smoking, rather than the quit line, for patients willing to quit smoking within 30 days. The clinician will then ask the patient to confirm that the mobile number in the EHR, or record a preferred number, as appropriate. The clinician will then place the order and will review and accept it with other visit-related orders. When the clinician accepts the order, this will trigger secure communication with SmokefreeTXT. Communication will involve the mobile number, clinic, patient identifier (medical record number), name, zip code and city, and age of participants (all of these fields are required for tailoring of text messages and/or for feedback to the EHR to work). All communications will take place via HIPAA-compliant means.

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## Appendix A

### Clinical Staff Survey: Wisconsin Tobacco Quit Line eReferral Study

- I. Addressing tobacco use with patients is a very important use of my time.
- II. Very few patients will stop using tobacco even with treatment.
- III. My clinic supports me in my attempts to address my patients' tobacco use.
- IV. I have enough time to address my patients' tobacco use well.
- V. I know what to do to address my patients' tobacco use well.
- VI. I feel that I am part of a good healthcare team that is working well together.
- VII. Patients seem to welcome my efforts to address their tobacco use with them.
- VIII. The steps I need to take to address my patients' tobacco use are efficient and well designed.
- IX. The EHR helps me address my patients' tobacco use.
- X. I often get feedback on whether my patients got tobacco treatment if they wanted it.
- XI. The Wisconsin Tobacco Quit Line is an effective aid to my patients who want to quit.
- XII. I understand how to refer my patients to the Wisconsin Tobacco Quit Line
- XIII. The method to refer patients to the Wisconsin Tobacco Quit Line is easy
- XIV. The method to refer patients to the Wisconsin Tobacco Quit Line is effective
- XV. I regularly receive feedback regarding the outcome of the patients I refer to the Wisconsin Tobacco Quit Line

Response format for above items 1 = Strongly disagree; 2 = Disagree; 3 = Mildly disagree; 4 = Feel neutral; 5 = Mildly agree; 6 = Agree; 7 = Strongly agree

- XVI. Your smoking status: 1 = never smoked regularly; 2 = ex-smoker; 3 = smoker
- XVII. Your clinical role: 1=Medical Assistant; 2=nurse or clinic manager; 3=provider staff (physician, nurse practitioner, physician assistant)
- XVIII. FOR PROVIDER STAFF (CLINIC ROLE=3 ONLY) AT POST-EREFERRAL PERIOD AT EREFERRAL CLINICS ONLY: How often do you read the script provided in the EHR when assessing patient willingness to accept eReferral to the Quitline 1=Never, 2=Rarely, 3=Sometimes, 4=Often, 5=Always
- XIX. Open field questions
  - a. Are there barriers that keep you from addressing your patients' tobacco use well? If so, what are these?
  - b. What could your clinic do to help you address your patients' tobacco use more effectively or more efficiently?
  - c. AT POST EREFERRAL SURVEY ONLY: What do you typically say to patients to introduce the Quitline?

## Appendix B

### Clinical Staff Survey: Smokefree TXT eReferral Study

- I. Addressing tobacco use with patients is a very important use of my time.

- II. Very few patients will stop using tobacco even with treatment.
- III. My clinic supports me in my attempts to address my patients' tobacco use.
- IV. I have enough time to address my patients' tobacco use well.
- V. I know what to do to address my patients' tobacco use well.
- VI. I feel that I am part of a good healthcare team that is working well together.
- VII. Patients seem to welcome my efforts to address their tobacco use with them.
- VIII. The steps I need to take to address my patients' tobacco use are efficient and well designed.
- IX. The EHR helps me address my patients' tobacco use.
- X. I often get feedback on whether my patients got tobacco treatment if they wanted it.
- XI. I am familiar with text-to-quit programs such as SmokefreeTXT.
- XII. I have referred my patients to a text-to-quit program like SmokefreeTXT.
- XIII. I believe mobile interventions like texting programs can help my patients stop using tobacco.

QUESTIONS 14 THROUGH 18 WILL BE ADMINISTERED AT THE END OF THE EREFERRAL TEST PERIOD ONLY

- XIV. The SmokefreeTXT text-message program is an effective aid to my patients who want to quit.
- XV. I understand how to refer my patients to SmokefreeTXT
- XVI. The method to refer patients to SmokefreeTXT is easy
- XVII. The method to refer patients to SmokefreeTXT is effective
- XVIII. I regularly receive feedback regarding the outcome of the patients I refer to SmokefreeTXT

Response format for above items 1 = Strongly disagree; 2 = Disagree; 3 = Mildly disagree; 4 = Feel neutral; 5 = Mildly agree; 6 = Agree; 7 = Strongly agree

- XIX. Your smoking status: 1 = never smoked regularly; 2 = ex-smoker; 3 = smoker
- XX. Your clinical role: 1=Medical Assistant; 2=nurse or clinic manager; 3=provider staff (physician, nurse practitioner, physician assistant)
- XXI. AT POST-REFERRAL ONLY: How often do you read the script provided in the EHR when assessing patient willingness to accept eReferral to SmokefreeTXT 1=Never, 2=Rarely, 3=Sometimes, 4=Often, 5=Always
- XXII. Open field questions
  - a. Are there barriers that keep you from addressing your patients' tobacco use well? If so, what are these?
  - b. What could your clinic do to help you address your patients' tobacco use more effectively or more efficiently?
  - c. AT POST-REFERRAL ONLY: What do you typically say to patients to introduce SmokefreeTXT?