PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

FINAL RESEARCH REPORT

Adding a Teachable Moment Approach to a Team-Based Primary Care Ask-Advise-Connect Approach for Tobacco Cessation

Susan Flocke, PhD[1]; Eileen Seeholzer, MD, MS[2]; Thomas Love, PhD[2]; David Kaelber, MD[2]; Steve Lewis, MS, MBA[2]; Elizabeth Albert Antognoli, PhD, MPH[3]; Jeanmarie Rose, MPA[3]; India Gill, MPH[3]

AFFILIATIONS:

[1]Oregon Health & Science University, Portland
[2]MetroHealth, Cleveland, Ohio
[3]Case Western Reserve University, Cleveland, Ohio

Institution Receiving Award: Oregon Health & Science University
Original Project Title: Using a Teachable Moment Communication Process to Improve Outcomes of Quitline Referrals
PCORI ID: IHS-1503-29879-IC
HSRProj ID: HSRP20162157
ClinicalTrials.gov ID: NCT02764385

To cite this document, please use: Flocke S, Seeholzer E, Love T, et al. (2021). *Adding a Teachable Moment Approach to a Team-Based Primary Care Ask-Advise-Connect Approach for Tobacco Cessation*. Patient-Centered Outcomes Research Institute (PCORI). https://doi.org/10.25302/02.2021.IHS.150329879IC

TABLE OF CONTENTS

ABSTRACT

Background: Guidelines urge primary care practices to provide routine tobacco-cessation care. Implementation of effective and sustainable strategies is lacking, especially for socially and economically disadvantaged populations. We tested a systems-based approach that engages the medical assistant (MA) who records the patient's vital signs at the beginning of a routine visit and the added effect of a clinician-based approach that draws on a relationship-centered communication strategy.

Objectives: This project aimed to (1) improve delivery and documentation of tobacco-cessation care to disadvantaged patients using an Ask-Advise-Connect (AAC) systems-based approach; (2) test the effect of combining the clinician-based Teachable Moment Communication Process (TMCP) intervention with AAC on advice to quit, referrals to cessation counseling, and provision of tobacco-cessation medications; and (3) examine the narratives of patient subgroups to understand and improve the referral experience.

Methods: This study engaged a health care system and 8 primary care clinical sites with 2 interventions. The 3-month period before the AAC intervention represented a pre-AAC control period (baseline). All sites received the AAC strategy throughout the study, and its use was evaluated for a minimum of 6 months (AAC only). Next, using a group-randomized, stepped-wedge design, sites received the TMCP intervention (AAC+TMCP). The patient population consisted of 40% Medicaid, 23.9% Medicare, 6.1% uninsured, and 30% commercially insured individuals. The AAC strategy involved changes to the electronic health record (EHR), a new role for MAs, and a new capacity to send electronic referrals to the quitline (QL) to enroll patients in tobacco-cessation counseling. Next, in accord with their practice's place in the stepped-wedge design, 44 of the 60 eligible clinicians attended training on the TMCP, an approach to counseling patients to quit tobacco that is aligned with patient readiness. Generalized linear models tested the effect of interventions on immediate outcome measures of process, including delivery of advice, offers of assistance and referrals accepted, and QL contact and enrollment rates. Receipt of tobacco-cessation medications and quit attempts were also assessed. The primary outcome was QL contact. In-depth interviews were conducted with 55 patients referred to the QL to explore their experiences and identify opportunities to improve the referral process.

Results: Of the 224 079 visits to 1 of the 8 clinical sites during the study period, 37 909 (25.9%) were made by identified tobacco users.

Effect of AAC: All indicators of AAC use significantly increased post implementation. Compared with the pre-AAC period, the following process measures increased and remained significant 12 months post-AAC: assessing smoking status (26.6% vs 55.7%; odds ratio [OR], 3.7; 95% CI, 3.6-3.9); providing advice (44.8% vs 88.7%; OR, 7.8; 95% CI, 6.6-9.1); assessing readiness to quit (15.8% vs 55.0%; OR, 6.2; 95% CI, 5.4-7.0); and acceptance of referral to tobacco-cessation counseling (0.5% vs 30.9%; OR, 81.0; 95% CI, 11.4-575.8). This process generated 1223 QL referrals; 324 (31.1%) patients were contacted by the QL, 241 (74.4%) were enrolled, and 195 (80.9% of enrollees) completed at least 1 counseling session.

Effect of TMCP: In total, 44 of 60 eligible clinicians received the TMCP training. During the 6-month post-TMCP intervention period, 68% of TMCP-trained clinicians used a TMCP approach (documented by flow sheet use) ≥1 times, with the median number of uses being 15 (interquartile range, 2-33). Overall, the TMCP was used in 661 of 8198 visits by smokers (8%). There was no improvement in any of the outcomes for the AAC+TMCP group vs the AAC-only group. Among visits when clinicians used the TMCP approach, there was a significant increase in the ordering of tobacco-cessation medications (OR, 2.6; 95% CI, 1.9-3.5). Provision of brief advice, assessment of readiness to quit, contact by and enrollment in the QL program, and quit attempts did not improve. Among a subsample of approximately 125 patients per time period, there were no adverse effects on visit satisfaction for either the AAC-only or the AAC+TMCP intervention time periods compared with the pre-AAC time period. Analysis of in-depth interviews with participants initially agreeing to QL contact found that the major barriers preventing patients from completing the QL program included lack of clear expectations for the QL, life stressors preventing enrollment, and difficulty making time for the counseling sessions. Regardless of level of engagement with the QL program, patients encouraged primary care teams to continue asking them about their smoking status and offering tobacco-cessation support.

Conclusions: The AAC system change intervention substantially increased the provision of tobacco-cessation care, with improvements sustained beyond 1 year. Adding TMCP training for clinicians improved ordering of tobacco-cessation medications, but other outcomes did not improve. Future work requires more complete integration of the AAC and TMCP approaches and tools into EHR systems for the combined process to be fully tested.

Limitations: The study was conducted in 1 health care system with a single EHR system. The modest uptake of the TMCP approach after training (8% of smokers' clinic visits) limited the ability to assess the intervention's impact.

BACKGROUND

Smoking is the leading cause of preventable mortality. Smoking rates in the United States have declined but remain particularly high among socially and economically disadvantaged populations, who are also less likely to use support methods for quitting smoking.[1-5] Therefore, implementing and evaluating strategies that work for socially and economically disadvantaged populations is a high priority. Among US smokers, 59% report seeing a primary care clinician at least yearly,[6] making primary care a major avenue for providing tobacco-cessation assistance tailored to each patient's medical history. However, evidence-based interventions that address tobacco cessation are generally underused.[7] New health care policy initiatives that require assessment of tobacco use and offer assistance to quit require the integration of tobacco-cessation interventions into primary care.[8]

Referral to quitlines (QLs) that provide evidence-based, effective, and cost-efficient assistance with smoking cessation[5,9-12] is recommended as an effective strategy for providing tobacco-cessation assistance.[13-17] However, a clinician's recommendation to call a QL typically results in poor calling rates (range, 1.6%-19%).[18] Success rates do increase when QLs proactively call patients after receiving a direct clinician referral (by fax or electronically).[19-23] Still, clinicians underuse direct referrals,[24] potentially because of low rates of integrating the referral system into the office workflow.[24] Research demonstrates the feasibility of closed-loop electronic referrals using electronic health records (EHRs)[25] for connecting with QLs. The advantage of e-referral is that patient information is securely transmitted between the referring clinician and the QL, and QL enrollment and counseling completion records become part of the patient medical record.

Two intervention approaches for providing patients with assistance for smoking cessation have shown promise in the primary care setting. Ask-Advise-Connect (AAC) is a systems-based approach that uses the EHR to remind clinicians to ask about tobacco use and give advice to quit, and then electronically connects interested smokers to tobacco-cessation counseling services, such as the QL. The Teachable Moment Communication Process (TMCP) is a relationship- and communication-focused strategy designed to counsel patients about behavior change by responding in a way both appropriate to and aligned with the patient's

readiness for a change.[26-29] These approaches are feasible and complementary, and they can potentially be integrated into a health system to improve sustainability.

Ask-Advise-Connect

This proactive, direct-messaging EHR-to-QL referral approach has been shown to increase the number of tobacco users receiving QL treatment 13- to 30-fold.[30,31] However, a major drawback of AAC is a low rate of contacting referred patients. Earlier studies found that the QL was able to contact <42% of referred patients. This poor contact rate diminishes the sustainability of the approach and is likely the result of referring patients inappropriately, ignoring cessation readiness.[25,32,33] In this study, we assessed the patient's readiness to quit and willingness to be connected to the QL before making an e-referral, thereby ensuring appropriate referrals. A drawback of some studies of AAC implementation strategies is that they rely on study research staff to carry out a key step[30,31] rather than using a design that is fully integrated and sustainable in clinical practice. In this study, we trained medical assistants (MAs) and nurses to implement the AAC and to modify EHR functionality to facilitate an e-referral, thereby providing a more sustainable approach.

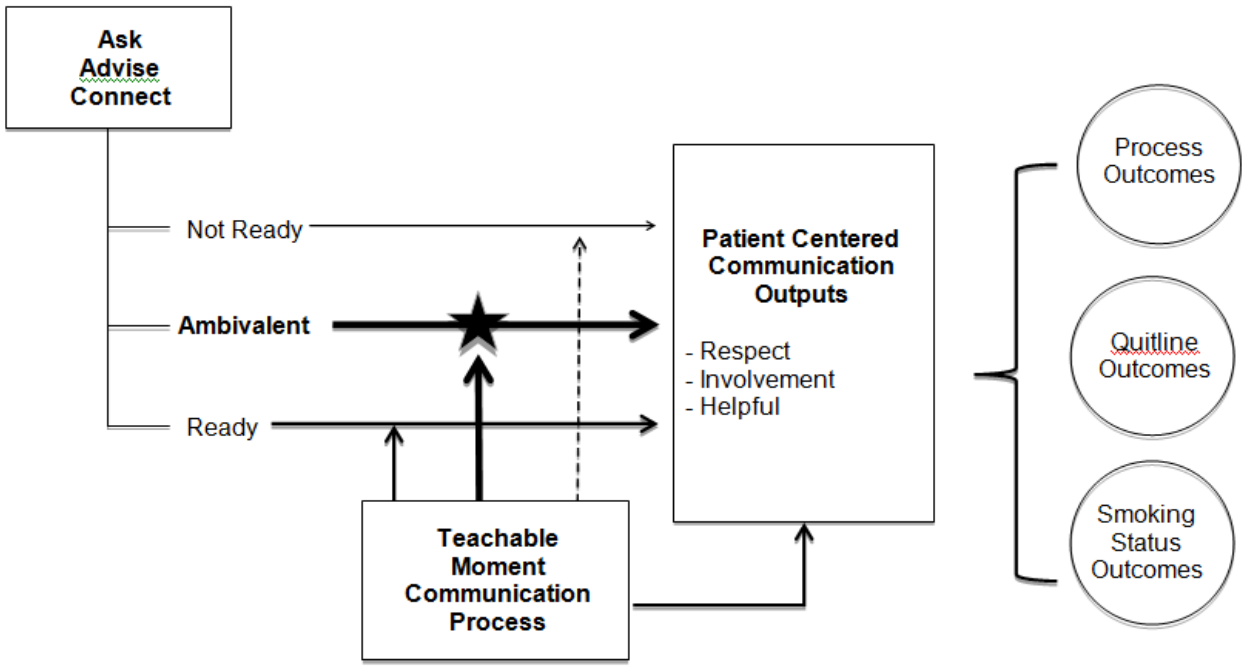
Teachable Moment Communication Process

With the TMCP, the discussion about smoking is initiated in an opportunistic way so that it fits into the flow of addressing concerns during a primary care visit. In providing tobacco-cessation advice, the TMCP calls for clinicians to convey concern, express optimism and partnership, and recommend quitting tobacco. Finally, central to this approach is eliciting an honest assessment of the patient's level of cessation readiness and responding in alignment with this readiness. Research shows that the TMCP approach increases patient motivation to make a quit attempt. Evidence is accumulating that the TMCP intervention is feasible in primary care and acceptable to patients and clinicians, leading to significant increases in clinicians' use of recommended counseling behaviors and activating patients during primary care visits.[27,29,34,35]

We propose that the AAC and TMCP interventions have mutually complementary strengths and that their combined implementation may synergistically boost positive

outcomes.[36] The AAC intervention is designed to be deployed at every visit so that all patients are assessed for smoking status, advised to quit, assessed for their readiness to quit, and offered assistance. Because it is a part of every office visit, the AAC can reach a large percentage of patients. The TMCP intervention, in contrast, is situation specific and driven by identification of and clinician action on a salient concern that arises during the visit. By accounting for concerns salient to the patient, the TMCP can help patients move forward along the readiness-to-quit continuum. It also reinforces the value of quitting by incorporating clinician advice to quit, which has been shown to increase quit rates.[22] If implemented together, these 2 interventions could have a synergistic effect (see Figure 1) whereby the interventions operate at different levels of influence to mutually reinforce each other. Their combined effect has great potential to increase the proportion of appropriate referrals (ie, eligible and ready patients) to the QL, increase the likelihood of successful patient contact and enrollment, positively affect patients' ratings of the experience, and support positive movement toward cessation.

Figure 1. AAC and TMCP Conceptual Model



Abbreviations: AAC, Ask-Advise-Connect; TMCP, Teachable Moment Communication Process.

The study aims were as follows:

- Improve delivery and documentation of tobacco-cessation advice and assistance to socially and economically disadvantaged patients using an AAC approach integrated into the EHR
- Test the effect of combining the TMCP with the AAC on process outcomes, QL referral outcomes, and smoking cessation outcomes
- Examine the narratives of subgroups of individuals to better understand the referral experience and identify ways to improve it

PATIENT AND STAKEHOLDER ENGAGEMENT

Key stakeholders for this project included primary care clinicians and staff; health care system administrators, representing primary care and information systems (IS); tobacco-cessation service providers; Ohio Department of Health Tobacco Use Prevention and Cessation program representatives; Ohio QL operations representatives; and patients who use tobacco.

Identifying Stakeholders

Our project's strong partnership with MetroHealth was critical for designing and implementing both interventions. The MetroHealth System is a safety-net health system in Cuyahoga County, which includes Cleveland, Ohio, and serves the largest portion of Medicaid and uninsured patients in the region. Approximately 75% of outpatient visits are by individuals who are uninsured or have Medicaid or Medicare insurance. Among residents of Cleveland, 35% live below the poverty line.[37] In 2017, 30% of MetroHealth primary care patients reported using tobacco. MetroHealth has exceptional capacity to use EHRs for quality improvement and system change, and it has been recognized since 2014 by the Healthcare Information and Management Systems Society as a stage-7 EHR Ambulatory Adoption Model health care system in all its ambulatory clinical sites and hospitals. Stage 7 represents the highest level of EHR adoption and use and indicates the health system's advanced EHR implementation. MetroHealth's culture of supporting quality improvement efforts facilitated our ability to embed the interventions into existing workflows, thereby improving sustained implementation.

Several stakeholders, including clinicians (n = 2) and representatives from the Ohio Department of Health (n = 1) and Ohio QL (n = 2) were engaged in the project from conception by invitation from the lead investigators. We recruited 2 patient stakeholders from among individuals who had recently quit smoking as well as former smokers identified by MetroHealth staff members who led an in-house tobacco-cessation program. Patient representatives helped shape our approach to primary data collection and measures on the patient survey. Other stakeholders engaged throughout the study included MAs (n = 3), nurses (n = 2), nurse managers (n = 2), informatics representatives (n = 2), IS representatives (n = 1), and Epic software trainers (n = 2). These roles and individuals were identified by team members and other stakeholders as important perspectives for engaging in the study at key junctures in the

study timeline and as we collectively began to understand the practice operations, challenges, and opportunities presented by implementing the study. The study leader worked to foster an appreciation across the group that all stakeholder voices were important to informing and guiding our project.

Engagement Activities

We conducted quarterly in-person stakeholder meetings. The meeting location accommodated the majority of the stakeholder group. Phone and video conferencing options were used for stakeholders who needed to travel significant distances to attend the meetings (eg, QL representatives). To increase time efficiency, meeting agendas and important materials were shared in advance to enable all stakeholders to prepare and fully engage in discussions.

In the beginning, we developed and agreed on guidelines to ensure that all stakeholders felt valued and knew that their ideas mattered regardless of degrees or status. For example, to work with groups in which some members had little research experience, we introduced "jargon-busting" methods of explanation paired with encouraging, clarifying questions. We also provided orientations to the project goals, emphasizing the meaning and importance of the project to each stakeholder. Other examples included encouraging active and respectful listening, embracing differing opinions, and keeping an open mind about new ideas. All participants were equal partners and received the same stipend for participation in the quarterly meetings.

Stakeholder Impact

Input from our stakeholders helped define several key aspects of the project. Specifically, the health system representatives influenced the decision to include patient subgroups for in-depth interviews and recommended inclusion of all clinicians in the TMCP training using the stepped-wedge design. Patient stakeholders' experiences were vital for designing the project's survey and streamlining the process for inviting participants to complete a survey. Further, input from MAs and nurses boosted AAC development, including critical upgrades to training, learning materials (eg, TipSheet), and EHR design. Stakeholder group representatives also helped identify people within organizations whose input at different stages

of the project was crucial to the development and success of the project. Finally, stakeholders' feedback about early findings helped chart the next steps for our inquiry.

In addition to providing impactful input to the project, stakeholders demonstrated significant interest in the outcomes and activities resulting from the study. Specifically, our stakeholders from MetroHealth announced their plans for incorporating AAC into the system wide flow for all clinic specialties. Further, MetroHealth representatives plan to implement the infrastructure developed during the study to send secure e-referrals from the EHR to QL services and to use it as a prototype for providing EHR referrals to external services. Finally, our stakeholders from QL services asked for qualitative findings from in-depth interviews to inform their efforts in making QL processes more user friendly.

METHODS

Study Overview

For this cluster randomized controlled trial (RCT) with a stepped-wedge design, we compared tobacco-cessation support provided during primary care clinic visits between 3 periods: (1) pre-AAC baseline; (2) AAC only; and (3) AAC+TMCP training, in which both AAC and TMCP were implemented. The primary outcome was QL contact rate. Other study outcomes were measures of process, including delivery of advice; offer of assistance and referrals accepted; and QL enrollment rates. The cluster RCT is the best choice for this study because patient visits are the unit of analysis clustered within sites and clinicians; further, the 2 interventions were deployed at the site and clinician levels. Because there was a relatively small number of practice sites to work with and because the health system stipulated that all sites eventually receive the intervention rather than serving only as control sites, we used a stepped-wedge design. In such a design, all sites begin in the control condition and each site is randomly assigned to a time point when it will receive the intervention. This design has greater statistical power over a traditional 2-group RCT.[38]

The intervention phase began with a study site implementing AAC. All sites implemented AAC at the beginning of the intervention phase. After a period of observing the effects of AAC alone, the study team conducted the TMCP training for each site at the beginning of the site's randomly assigned date to implement TMCP. The site was asked to start using the TMCP approach immediately in routine patient care. We examined the impact of the effect of the TMCP approach in 3 ways: intent to treat (by including all clinicians at the site), per protocol (by including those clinicians exposed to the TMCP training), and per documented use in a visit (indicated by the EHR document flow sheet developed for this study; document flow sheets are EHR templates for gathering and documenting information during an encounter). Table 1 outlines the key features of each intervention, the anticipated influences, the possible reach, and the outputs of the intervention. Immediate study outcomes were measures of process, including delivery of advice; offer of assistance and referrals accepted; and QL contact and enrollment rates. Additionally, we evaluated specific patients' clinic experience by surveying them and their QL referral process experience by conducting in-depth interviews.

Study Setting

The study was conducted in 8 primary care community health centers within the MetroHealth System in Cleveland. The rationale for selecting the MetroHealth System was 3-fold: It serves the largest portion of Medicaid and uninsured patients in the region; a high proportion of its patients use tobacco; and it has the capacity to use the Epic EHR system to implement quality improvement initiatives.

Table 1. Interventions, Influences, and Outputs

	Intervention features	Influence	Reach	Outputs
AAC	• System-level intervention • EHR modification for AAC • EHR e-referral functionality • New role for MAs and RNs	Increase structural capacity to do the following: • Document tobacco use and assistance • Prompt tobacco cessation assistance • Cue clinician during visit • Increase use of evidence-based cessation strategy • Increase structural capacity to receive and use QL referral data	• All visits • Best for patients who are either not ready or ready to quit	• Documentation • Meaningful use • Feedback to health care team • Increase patient motivation to change
TMCP	• Clinician-level intervention • TMCP skills for clinician • Development of EHR document flow sheet	• Increase knowledge, self-efficacy, and behavioral capabilities • Increase use of the TMCP approach for tobacco cessation	• Not intended for use at all visits; context specific at the clinician's judgment • Best for patients who are ambivalent about quitting	• Increased patient motivation to change • Preserved continuity of relationship through communication quality • Maintained patient centeredness by respecting patient values

Abbreviations: AAC, Ask-Advise-Connect; EHR, electronic health record; MA, medical assistant; QL, quitline; RN, registered nurse; TMCP, Teachable Moment Communication Process.

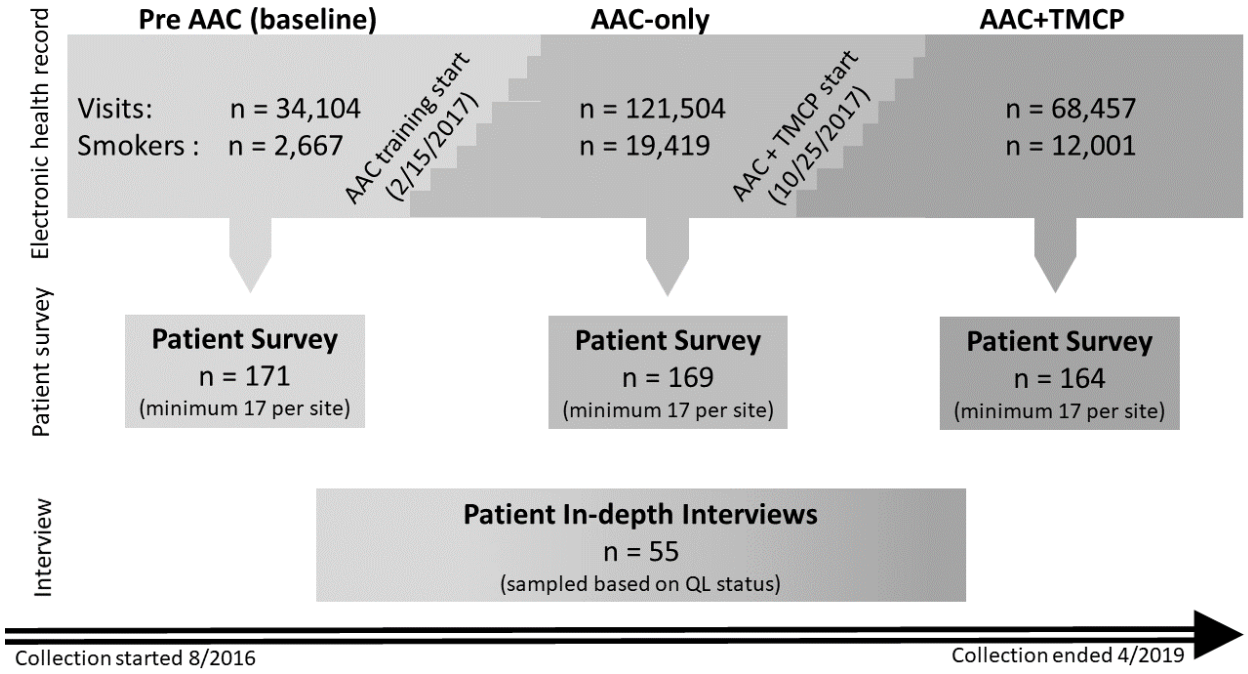
Participants

Patient participants were not specifically recruited for this study. Instead, all adult patients (defined as aged ≥18 years) coming for primary care visits to the study-linked clinics during the study period contributed their EHR data to analyses for aims 1 and 2. The IRB waived patient informed consent for use of the EHR data for 3 reasons: (1) the large number of patients, which made obtaining individual consent impracticable within the time frame of the study; (2) the plan to use deidentified data in the analytic data file; and (3) the overall low-risk nature of study participation. All MAs and registered nurses (RNs) were asked to attend the AAC training. All clinicians at each of the 8 study sites were asked by the health care system to participate in the TMCP training; they were not study volunteers. For the process variables, the unit of analysis is the patient visit. Clustering by clinician and by site is accounted for in our analyses.

Study Design and Timing

This study involved 2 interventions. The AAC intervention was conducted first at the clinic level; the TMCP intervention was conducted second at the clinician level. The study also included qualitative data collection to complement the quantitative evaluations. Figure 2 illustrates the 3 main data collection sources (EHR, patient surveys, and in-depth interviews) and the 3 periods of data collection (pre-AAC, AAC only, and AAC+TMCP). The 3-month period before the AAC intervention represented a pre-AAC control period (baseline). Both interventions were implemented using a stepped-wedge design, as indicated in Figure 2. The start date represents the date of the first clinic's exposure to the interventions. The step graphic between each condition represents the starting points for each clinic's exposure to the interventions. This design enabled us to test the additional impact of the TMCP approach beyond the gains realized with AAC across all the clinics by the end of the stepped-wedge implementation. On a rolling basis, data collection indicated the intervention exposure statuses for each clinic and assessed visit-level process outcomes.

Figure 2. Schema of Data Collection Time Points (for EHRs, Surveys, and In-depth Interviews) Across All Sites



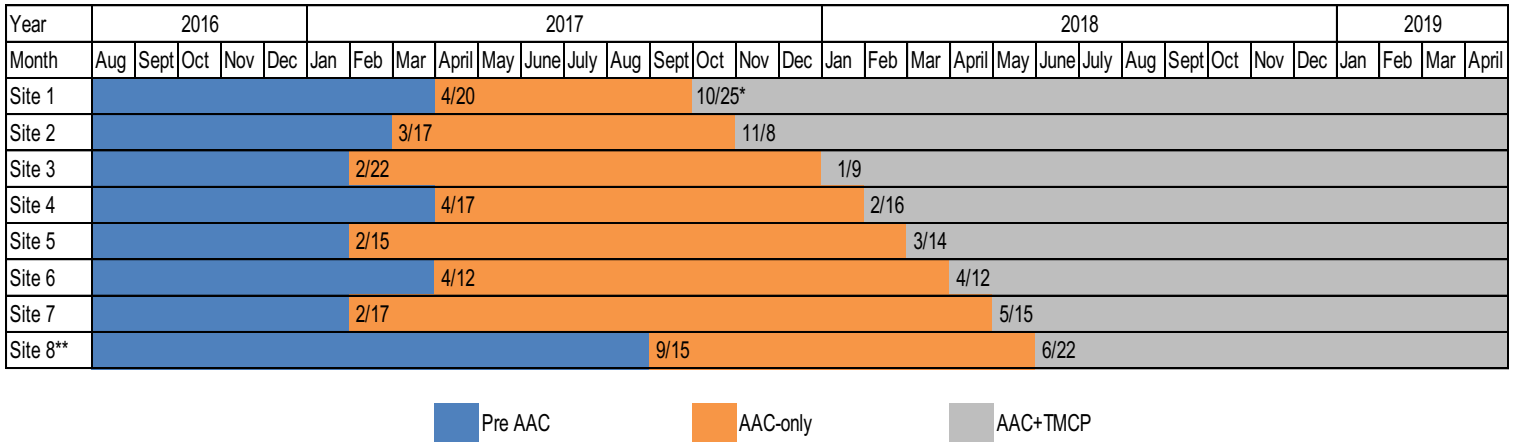
Abbreviations: AAC, Ask-Advise-Connect; EHR, electronic health record; QL, quitline; TMCP, Teachable Moment Communication Process.

Figure 3 provides more detail about the timing of the AAC and the TMCP intervention implementations at each of the 8 sites. AAC was the first intervention implemented, and the AAC training at the first clinic was conducted on February 15, 2017. This training was then conducted at the other 7 clinics at approximately 2-week intervals, but the timing of the training was not randomized. Trainings were scheduled during regularly scheduled monthly staff meetings for each clinic. The training date was noted such that a period of pretraining and a period of posttraining could be defined for each clinic. Approximately 6 months after the implementation of AAC in the last site, the TMCP intervention was implemented, again in a stepped pattern.

For the TMCP intervention, the 8 clinics were randomized to an implementation time point using the following approach. A single-digit number was assigned to each site. A list of 100 random single-digit numbers was generated; using this list, as a site number came up in the random list, it was assigned to the next sequential time point. We encountered 2 anomalies with randomization of the sites. First, after implementing the AAC intervention, the site that

was randomized to receive the TMCP training lost its practice manager. Because of challenges with daily operations at that site, MetroHealth requested that we delay the implementation of TMCP until a new practice manager was effectively in place. This site was moved to be last. Second, also after the implementation of the AAC intervention, 1 of the sites closed. A replacement site was identified to receive the AAC intervention and was included as the last site for training for the TMCP approach. The TMCP implementation time points were scheduled as close to 1-month intervals as possible. The first clinic received the TMCP training on October 25, 2017. The amount of time a clinic was in any 1 of the 3 defined study conditions varied but is accounted for in the analyses.

Figure 3. AAC and TMCP Intervention Implementation Dates and Times Before, Between, and After Interventions for Each Site



Abbreviations: AAC, Ask-Advise-Connect; TMCP, Teachable Moment Communication Process.
*Because of technical problems for some clinicians, a second TMCP implementation was conducted on November 2.
**This site replaced one that had been randomized but that closed shortly after receiving AAC training.

For aims 1 and 2, in addition to collecting EHR data from all patients aged ≥18 years, we drew a random sample to survey patients' experiences with the clinic's process. The sample included at least 17 smokers from each of the 8 sites from each study period (pre-AAC, AAC only, AAC+TMCP). The survey was collected from patient subsamples across the 8 sites during 3 periods: pre-AAC, AAC only, and AAC+TMCP implementation. Patients who attended a primary care visit during specified dates were invited to complete the survey. The survey was completed by web or phone, depending on the participant's preferred contact method. Participation was voluntary.

For aim 3, to conduct in-depth interviews, 3 subgroups provided narratives about QL experience and guidance on process improvement. Groups included patients referred to QL who (1) declined participation in the QL, (2) were determined to be unreachable by the QL, or (3) completed the QL program of 5 counseling sessions.

Interventions: Comparators and Controls

The AAC and TMCP were the 2 comparator interventions. The rationale for comparing the AAC alone with AAC and TMCP combined was to determine whether the patient-centered TMCP approach can boost patient outcomes beyond the benefits of using AAC alone. Appendices 1 and 2 describe the interventions and the implementation strategy for each in detail. Exposure to the interventions was at the clinic level (AAC) and physician level (TMCP). Assessments of effect on process and patient outcome variables began immediately after implementation and continued for a minimum of 12 months for the AAC and 6 months for the TMCP interventions.

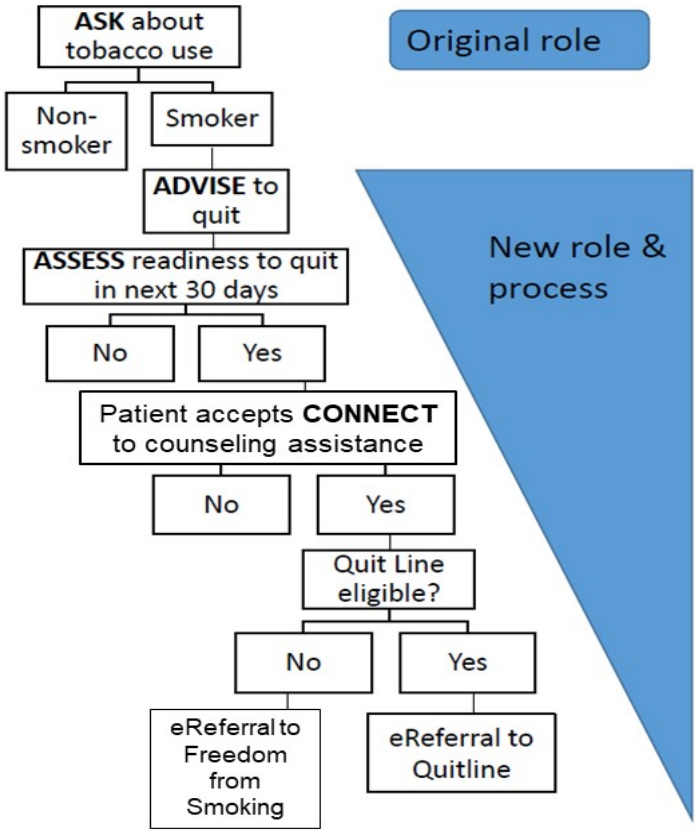
The AAC Process

To implement the AAC intervention, we implemented 3 substantial clinical care process components: (1) establishing e-referral capacity between MetroHealth and the Ohio QL; (2) revising the EHR to prompt and document discussion of tobacco use, readiness to quit, and willingness to receive a referral for tobacco-cessation assistance; and (3) updating clinic staff roles and processes through training and support in using the revised EHR. These components are described in detail in Appendix 1. The role and process changes that were the focus of the

implementation training are highlighted in Figure 4. Table 2 outlines what was in place and assumptions about responsibilities for carrying out the process before and after implementation of the AAC intervention. Patient eligibility for QL services included at least 1 of the following: being aged ≥18 years with Medicaid insurance or no insurance, or being pregnant. The QL services included up to 5 telephone counseling sessions and access to web and online chat support. Individuals who were not eligible for the QL were referred to the in-system Freedom From Smoking (FFS) program, an in-person, 8-session group tobacco-cessation class offered by the health care system. The EHR automatically generated the correct referral order using patient payer data. Therefore, regardless of eligibility, the process was seamless for MAs/RNs and patients.

AAC was implemented through in-person training at each practice site using a presentation of the rationale for the process changes, the specific tasks, the changes to the EHR, and the fact that the role change was to take effect immediately. Hands-on training, with case scenarios to practice using the new EHR display fields and orders, enabled MAs and RNs to experience the process and ask further questions. Audit and feedback provided at the practice level were used to encourage and support uptake.

Figure 4. MA/RN Roles and Process Changes With AAC System Intervention



Abbreviations: AAC, Ask-Advise-Connect; MA, medical assistant; RN, registered nurse.

Table 2. AAC Components, EHR Functionality Changes, and Role Expectations

Component	EHR button	Guiding phrases in EHR	Role expectation before AAC implementation	Role expectation after AAC implementation
Ask	Existing	Existing: Have you used a tobacco product in the past 30 days?	MA	MA
Advise	Existing	NEW: As a member of your health care team, we strongly recommend that you quit using tobacco.	Clinician	MA
Assess readiness	Existing	NEW: Do you want to quit in the next 30 days?	Clinician	MA
Assess interest in referral	NEW	NEW: Would you like us to connect you to a coach who can help you quit?	Clinician	MA
Connect (ie, order referral)	Existing but only for in-house program NEW for QL	NEW: I will place an order for you and someone will call you in the next day or two.	Clinician	MA

Abbreviations: AAC, Ask-Advise-Connect; EHR, electronic health record; MA, medical assistant; QL, quitline.

Teachable Moment Communication Process

Clinicians can use the TMCP approach to initiate discussion about smoking and smoking cessation by incorporating patients' salient concerns into a tailored, partnership-oriented behavior-change discussion integrated into the flow of patient care. Central to this approach is eliciting an honest self-assessment of the patient's level of cessation readiness, and then responding with assistance aligned with the patient's readiness.[34] Unlike AAC, which is designed to be used at all nonurgent clinic visits, the TMCP approach was to be used strategically at the clinician's discretion during visits when the clinician felt that there was an important opportunity and sufficient time to address tobacco cessation.

For the TMCP training, our team adapted in-person training to a web-based training module that consisted of the key learning points; demonstrations of the process, with example patient scenarios; and quiz items throughout the module to promote engagement and assessment of knowledge acquisition. Skill practices, which were included in the intervention as a way to learn behavioral enactment of each skill, took place in the examination rooms at each clinic to provide a realistic setting. The skill practice involved engagement using 6 to 8 case scenarios played by standardized patients (ie, individuals recruited and trained to take on the characteristics of real patients in a simulated clinical environment); a coach observed, and then provided feedback and additional training in technique. The clinician participant had exposure to 6 to 8 scenarios played by standardized patients and up to 4 coaches, all trained in the TMCP approach. Implementation of the TMCP training was conducted at each practice at the random order–assigned intervention date. Appendix 2 provides details of the TMCP intervention.

Development of the Document Flow Sheet

A document flow sheet was developed to serve as a guide for clinicians, with steps and phases for the TMCP, and to document delivery of and patient responses to each TMCP step (see Appendix 2). The TMCP flow sheet eliminated the need for the provider to remember the steps and their order so that they could document the patient responses with minimal effort. In addition, a tobacco-cessation order set in the EHR could be used by providers to order medication and nicotine replacement and to order a referral to the QL or tobacco-cessation classes.

During the skills training, clinicians were shown how to use the TMCP document flow sheet and had it added to their Epic tool shortcuts. Clinicians used the document flow sheet during the skills practice scenarios to gain experience with the different features it allowed. The tobacco-cessation order set was also reviewed and used during skills practice.

Debriefing About the Training

Following completion of the web module and the skills practices, the clinicians regrouped with the research team to debrief about their experiences. Clinicians provided

feedback on format, length of training, processes, and content, and discussed the perceived value overall.

Study Outcomes

Table 3 summarizes the sources of data and key indicators for the study. The population or sample for which the indicators were assessed is noted in the last column. Data were drawn from the EHR, QL data, patient surveys, and in-depth interviews.

Primary Outcome

The primary outcome was QL contact. Other outcomes for the overall study were (1) tobacco-cessation support documentation (eg, documentation of assessment of tobacco use in the past 30 days—namely, "Ask," documentation of provision of brief advice [ie, "Advise"]; (2) QL enrollment; and (3) patients' evaluations of key characteristics of the provision of tobacco-cessation support in the primary care setting.

Smoking cessation support documentation. The AAC approach includes multiple steps. Each was assessed as a process outcome.

Contact and enrollment of referred patients. Outcome variables *for both the QL and FFS* included percentage of referred patients who accepted referral, successful contacts, patient enrollment, and percentage of enrolled patients who completed ≥1 counseling sessions.

Patient evaluation of tobacco-cessation assistance. The AAC and TMCP interventions changed the way clinicians and staff interacted with patients during office visits, and patients' experiences about these changes were evaluated in a survey. We created a measure based on our work with former smokers from our stakeholder team, our previous experience with tobacco-cessation process measures,[39] and cessation literature.[25,40,41] The items were reviewed by a sample of patients who pilot-tested acceptability of the survey to patients. The consent process to participate in the survey and the survey items are reported in Appendices 3 and 4, respectively.

Table 3. Study Outcomes and Data Sources

Data source: EHR	Population
Assessment of the degree to which these functions are happening:	All visits by patients aged ≥18 y to 1 of the 8 clinics during the study period
Ask: smoking status ascertained	
Advise: recommended quitting	
Assess: assessed readiness to quit now	
Connect: offered referral to assistance with quitting (ie, QL or FFS services)	
Patient's smoking status	
Current smoker, previous smoker, nonsmoker	
Patient's readiness to quit in the next 30 d	
Referral accepted or declined	
Data source: referral data returned to EHR	
QL	Patients who accepted a referral to tobacco-cessation counseling
Successfully contacted	
Enrolled	
No. of counseling sessions completed	
FFS	
Successfully contacted	
Enrolled	
No. of counseling sessions completed	
Received NRT	

Data source: patient survey	**Population**
Items measuring patient experience with the primary care team[a]	Random samples of patient aged ≥18 y who smoked were seen during the study period and had a discussion about smoking
Example items:	
Were you treated with respect?	
Did you feel listened to?	
Were you able to honestly speak your mind about quitting?	
Was the advice you received helpful?	
Data source: in-depth interviews	
Patient narratives about experiences with e-referral to the QL	3 groups from the sample of patients who agreed to be referred to the QL and subsequently (1) declined participation in the QL, (2) were unreachable by the QL, (3) completed the QL program
Key covariates	
EHR	
Clinic site	
Provider type: family medicine, internal medicine	
Patient's primary insurance: commercial, Medicare, Medicaid, uninsured	
Patient demographics: age, sex, race/ethnicity	

Abbreviations: EHR, electronic health record; FFS, Freedom From Smoking; NRT, nicotine replacement therapy; QL, quitline.
[a]Item selection informed by patient stakeholders. Items rated on a 5-point scale.

Qualitative interviews. In-depth qualitative interviews were conducted with a subgroup of patients who agreed to be connected to QL counselors. An interview guide contained questions to elicit patient narratives about their experiences with the e-referral and QL processes and obtain their suggestions for improvement. In total, 55 patients from 3 categories participated, all connected through e-referral: (1) those who enrolled in and completed QL counseling, (2) those who declined QL counseling, and (3) those unreachable by QL after multiple unsuccessful contact attempts.

Secondary Outcomes

Two secondary outcomes were also assessed. Orders for tobacco-cessation medications included any form of nicotine replacement therapy (eg, gum, patch), varenicline, or bupropion documented in the EHR. For this study, a quit attempt was defined as a change in smoking status from current smoker to former smoker and documentation of a quit date in the EHR.

Other Variables

Potential covariates included patient sex, race, age, and type of insurance.

Sample Size Calculations and Power

We describe sample size considerations related to the surveys and to the EHR-documented outcomes separately. In each case, we provide an illustrative estimate of available power to detect an important outcome. Our intended survey sample included surveys of 170 patients after a primary care visit at a clinic before the AAC intervention, 170 more patients visiting a clinic with AAC only, and 170 additional patients visiting a clinic after the AAC+TMCP intervention. This sample size could not permit meaningful comparisons between individual clinics on survey items but did enable us to find meaningful changes in rates of satisfaction across clinics from pre-AAC to post-AAC implementation and from AAC-only to AAC+TMCP implementation. If baseline satisfaction is at 75%, for instance, we would have 90% power with this sample size to detect an improvement to 90% with AAC using a 2-sided $\alpha = 5\%$ significance test. A similar gap from 80% to 95% baseline satisfaction after AAC would yield 97% power.

Next, we considered comparisons between AAC only and AAC+TMCP on EHR-documented outcomes—specifically, estimating our power to compare contact rates among patients agreeing to be referred to tobacco-cessation counseling. We selected this outcome because it affects a much smaller group of patients (smokers agreeing to referral) than our documentation outcomes. We assumed that approximately 25% of smokers would agree to referral, yielding at least 240 potential contacts per month referred to the QL across 8 steps (site-specific clusters of primary care providers) in our stepped-wedge design. We assumed that the intraclass correlation coefficient within each cluster would be no larger than 0.10. We also assumed that we could measure QL contact rates monthly, for at least 3 months in the AAC-only period at all sites, and again for at least 3 months after AAC+TMCP implementation at all sites (Figure 3). This design resulted in a stepped-wedge design effect[63] of 0.265, meaning that the study (which accounts for clustering by step and uses repeated measures at each step) might require about a quarter of the participants needed in an individual patient-level RCT with similar goals. We projected that the AAC-only QL contact rate would be approximately 40%. We considered a 10% absolute difference to be a clinically meaningful improvement. Accounting for clustering and repeated measures through the stepped-wedge design effect, with a 2-tailed $\alpha = 5\%$ significance level, we predicted 86% power to detect a change in QL contact rate from 40% to 50% and 99% power for a QL contact rate change from 40% to 55%.

Time Frame for the Study

We used EHR data for a 2-year (retrospective) period to develop and test our methods for data extraction and to establish methods to generate complex variables, such as quit attempts. For the active study period, a 3-month pre-AAC period of the current practice assessment (baseline) was followed by implementing AAC at all 8 practices over 3 months (starting in February 2017). The AAC-only implementation effect was evaluated for approximately 12 months. Next, the TMCP training was implemented (starting in October 2017) using the stepped-wedge design.[38] The combination of AAC and TMCP was evaluated for 6 months after TMCP implementation. Figures 2 and 3 show the timing of the interventions.

Data Collection and Sources

The main data sources collected for the project were (1) EHR data assessed for all visits, (2) patient survey data from random patient subsamples at each study period, and (3) narrative data from the in-depth interviews (Figure 2).

Analytical and Statistical Approaches

Key Analytical Considerations

We compared outcomes across 3 different intervention conditions: usual care before AAC, AAC only, and AAC+TMCP. Data for adult patients with a primary care visit to 1 of the 8 clinic sites were extracted from the EHR to yield the pre-AAC data. (See Figure 3 for the depiction of the time intervals referred to here.)

Aim 1 analyses compared pre-AAC to AAC-only data across patient visits to assess improvement in delivery and documentation of tobacco-cessation advice. Descriptive statistics were reported for the samples during the pre-AAC and AAC-only intervention periods. Process variables representing the proportion of current tobacco users who were asked, advised, assessed about their readiness, and offered a referral were reported by time period. Using the 3 months before implementation as the reference, generalized estimating equations (GEEs) were used to generate odds ratios (ORs) for evaluating the effect of the intervention for each process indicator for 1, 3, 6, and 12 months postintervention relative to the pre-AAC period (ie, baseline). These analyses account for clustering of visits within practice sites. Process variable performance was also graphically displayed for the intervention sites. Our heterogeneity of treatment effect (HTE) analyses were evaluated by modeling the interaction between the intervention status designated by time period and subgroup (eg, 3 categories of race: Black, White, and other).

Our aim 2 analyses compared adjusted rates for the AAC+TMCP intervention with the AAC-only period (ie, the period between rollout of the AAC intervention and the TMCP intervention using a GEE approach, with robust [jackknife] estimation of variances). Specifically, we modeled the log odds of a particular outcome of interest for a particular patient as a function of intervention status (AAC only vs TMCP+AAC), a random practice site effect, and a

random clinician effect in the presence of evidence of substantial clustering at the clinician level within a clinic site. Three analyses were conducted: (1) intention to treat (ITT), (2) per protocol, and (3) per documented use in a visit where the TMCP approach was documented as having been used by completion of the document flow sheet. Outcomes evaluated included referral contact and enrollment rates, provision of tobacco-cessation medications, and quit attempts.

In aim 3 data analysis, we audio-recorded in-depth interviews with 55 primary care patients who agreed to be referred to the QL. These 30-minute interviews included open-ended questions about the patients' experience, with the goal of identifying successes and areas for improvement to address smoking cessation in primary care settings. The interviews, conducted by telephone and audio-recorded, were subsequently transcribed verbatim for analysis. Interviews were based on a semistructured guide designed to explore the experiences of 3 subgroups of patients: those who completed the QL program, those subsequently declining participation in the QL, and those unreachable by the QL. We used a phenomenological approach in our data analysis to understand how people make meaning of their lived experience and to develop a deeper understanding of the common features shared among individuals who agreed to be connected to the QL.[17] Analysis began with careful and repeated reading of several transcripts by 3 trained analysts to identify salient themes of the QL referral process (Appendix 5). Based on this initial round of thematic analysis, an initial set of coding categories was created. As additional transcripts were read, the coding categories were modified as necessary to better fit the themes that emerged.

Next, 2 of the analysts each independently coded all 55 transcripts, meeting regularly to discuss coding and reach consensus on any discrepancies. Additionally, the 2 analysts met with a third analyst to review and discuss emerging themes. Interviews were conducted until the point of data saturation was reached for each QL final disposition category (program completed, declined, and unreachable).

Data Management, Quality, and Missing Data

Evaluation of the data for inconsistencies during the analysis phase included checking the range and distribution of all variables and identifying and resolving potential errors. Missing

data on patient surveys were negligible (<1%). Principles for maximizing participation and survey completion included keeping the survey short, topic focused, and at a grade 6 reading level or less, with clear and acceptable wording of items and response categories and a clear introduction to the relevance of the measure to the potential participant. EHR fields of interest for this study with information *not documented* were noted as such in the tables. Missing data for referral outcomes from the QL and FFS were reported. We adopted multiple-imputation strategies to account for the impact of missingness on these outcomes.

Changes to the Original Study Protocol

We extended the intervention follow-up period from 3 months to 6 months for the TMCP phase of the study. Although not an intentional change to the original study design or protocol, 1 of the 8 clinics closed during the study. That clinic received the AAC training but closed shortly after. A replacement clinic was identified from a similar neighborhood, and the original clinic was excluded from all analyses. The replacement clinic received the AAC training and was assigned to receive the TMCP intervention training 1 month after the TMCP training implementation was conducted at the last clinic that had been randomized. This approach allowed sufficient time for data collection and assessment between implementation of the AAC and implementation of the TMCP intervention.

RESULTS

Aim 1

Improve delivery and documentation of tobacco-cessation advice and assistance to socially and economically disadvantaged patients using an AAC approach integrated into the EHR.

During the study period, among the 176 061 patient visits for the pre- and postintervention periods, 26.1% of these patients were identified as smokers. Patient characteristics for the 2 time periods (pre-AAC and post-AAC implementation) are shown in Table 4. There were no substantial differences in any of the patient characteristics (sex, age, race, ethnicity, insurance type, and smoking status) for the 2 periods. Each of the 8 clinics participating in the study contributed a different percentage of patient visits, as expected.

Table 4. Visit Characteristics for Pre-AAC and Post–AAC-Only Implementation

Description	Overall (N = 176 061 [100.0%]), No. (%)	Pre-AAC implementation (n = 36 677 [20.8%]), No. (%)	Post–AAC-only implementation (n = 139 384 [79.2%]), No. (%)
Sex			
Male	53 518 (30.4)	11 338 (30.9)	42 180 (30.3)
Female	122 542 (69.6)	25 338 (69.1)	97 204 (69.7)
Age, y			
18-34	43 804 (24.9)	9099 (24.8)	34 705 (24.9)
35-64	100 851 (57.3)	21 400 (58.3)	79 451 (57.0)
≥65	31 406 (17.8)	6178 (16.8)	25 228 (18.1)
Race			
White	79 138 (50.0)	15 867 (48.0)	63 271 (50.5)
Black	73 320 (46.3)	16 048 (48.6)	57 272 (45.7)
Other	5802 (3.7)	1108 (3.4)	4694 (3.7)
Ethnicity			
Non-Hispanic	150 782 (87.9)	31 531 (88.2)	119 251 (87.8)
Hispanic	20 840 (12.1)	4209 (11.8)	16 631 (12.2)
Primary insurance class			
Commercial	51 484 (29.9)	10 470 (29.5)	41 014 (30.1)
Medicaid	68 714 (40.0)	14 736 (41.5)	53 978 (39.6)
Medicare	41 014 (23.9)	8285 (23.3)	32 729 (24.0)
Self-pay	10 540 (6.1)	1979 (5.6)	8561 (6.3)

Description	Overall (N = 176 061 [100.0%]), No. (%)	Pre-AAC implementation (n = 36 677 [20.8%]), No. (%)	Post–AAC-only implementation (n = 139 384 [79.2%]), No. (%)
Other	206 (0.1)	34 (0.1)	172 (0.1)
Smoking status			
Current smoker	37 909 (26.1)	8167 (26.7)	29 742 (25.9)
Former smoker	40 732 (28.0)	8525 (27.8)	32 207 (28.0)
Never smoked	66 873 (45.9)	13 953 (45.5)	52 920 (44.3)
Not assessed[a]	30 547 (17.4)	6032 (16.4)	24 515 (17.6)
MetroHealth center			
A	14 299 (8.1)	3003 (8.2)	11 296 (8.1)
B	31 704 (18.0)	5899 (16.1)	25 805 (18.5)
C	22 053 (12.5)	3727 (10.2)	18 326 (13.1)
D	21 348 (12.1)	4521 (12.3)	16 827 (12.1)
E	5434 (3.1)	2573 (7.0)	2861 (2.1)
F	21 757 (12.4)	4680 (12.8)	17 077 (12.3)
G	33 526 (19.0)	6862 (18.7)	26 664 (19.1)
H	20 587 (11.7)	4399 (12.0)	16 188 (11.6)
I	5353 (3.0)	1013 (2.8)	4340 (3.1)

Abbreviation: AAC, Ask-Advise-Connect.

[a]Not included in the denominator for smoking status.

As indicated in Table 5, the pre-AAC implementation period served as the contrast group, and the intervention resulted in a 2-fold increase in asking about smoking status across the 8 sites at the 1-month postintervention time point. This level of impact increased at each subsequent time point and reached OR of 3.7 (95% CI, 3.6-3.9) at 12 months postimplementation. Provision of a brief statement advising patients to quit smoking had a 4-fold increase 1 month after implementation of the AAC intervention. Performance rates increased from 44.8% at baseline to 82.7% at 1 month postimplementation and, with the exception of the 3-month postimplementation time point (78.8%), remained at >80%. For assessing readiness, the baseline rate of 15.8% increased to 74.2% at 1 month after AAC implementation (OR, 14.9; 95% CI, 12.8-17.3). The increase in rates decayed over the 12-month follow-up period to 55% (OR, 6.2; 95% CI, 5.4-7.0). A similar pattern was observed for patient acceptance of an offer for referral to tobacco-cessation counseling (ie, QL or FFS program). The pre-AAC acceptance rate of referrals was 0.5%; after AAC implementation, it was 58.9% (OR, 260.5; 95% CI, 36.9-1840.5). By 12 months after AAC, the rate had decayed to 30.9% but was still dramatically higher than it was during the pre-AAC period (OR, 81.0; 95% CI, 11.4-575.8). Figure 5 shows the effect of the intervention graphically for each of the 8 clinical sites. Six of the sites improved and largely maintained the improvement, while 2 of the sites made marginal improvements, and then declined to baseline levels of performance.

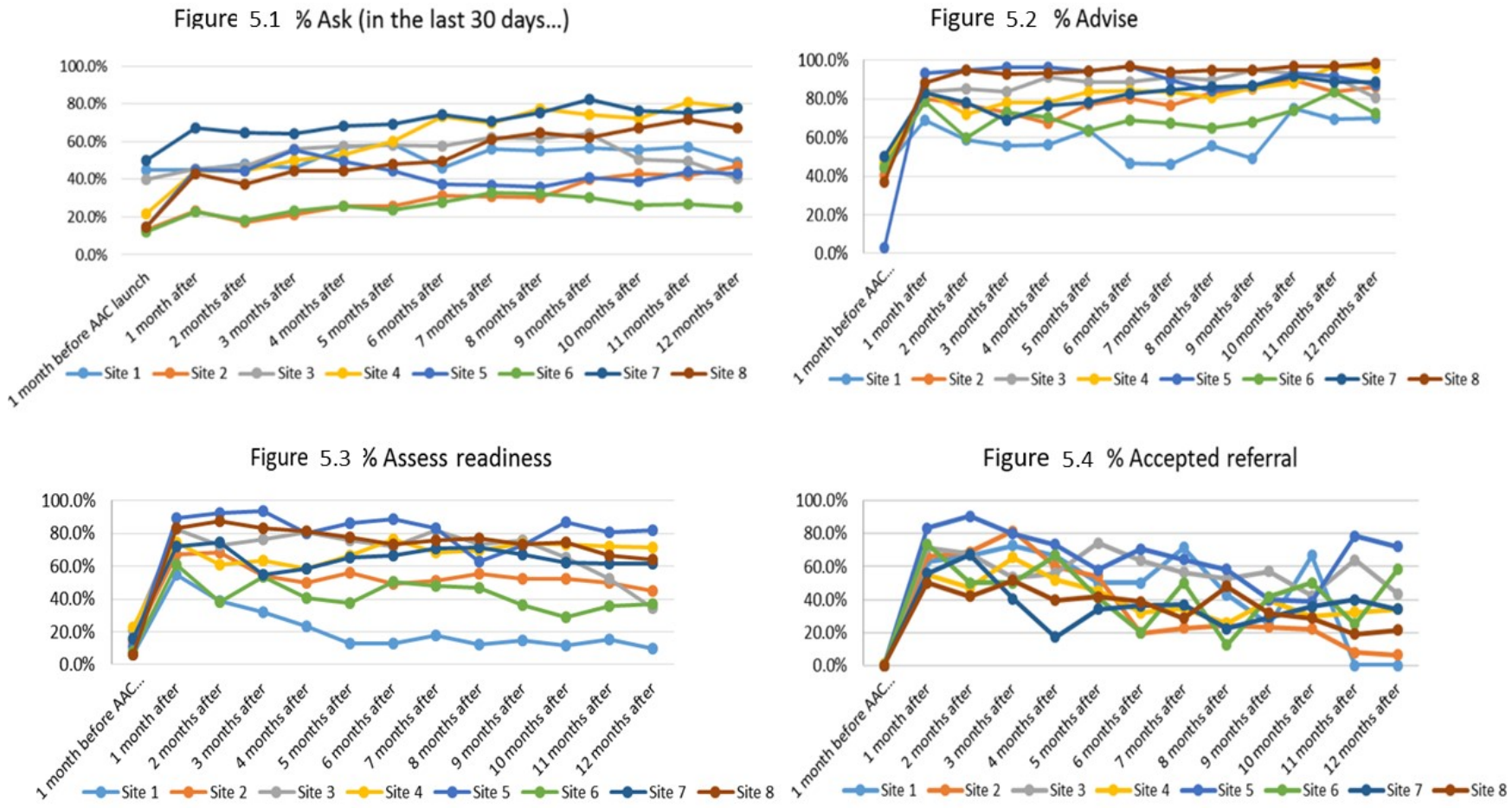
Table 5. Process Variables for the 3 Months Before Implementing AAC and Months 1, 3, 6, and 12 After Implementing AAC

	1-3 mo before AAC (Baseline)			1 mo after starting AAC[a]			3 mo after starting AAC			6 mo after starting AAC			12 mo after starting AAC		
	No.	%	OR (95% CI)	No.	%	OR (95% CI)	No.	%	OR (95% CI)	No.	%	OR (95% CI)	No.	%	OR (95% CI)
Total visits	36 677			12 274			12 012			11 605			11 991		
% of patients asked about smoking	9742	26.6	–	5035	41.0	1.93 (1.85-2.00)	5437	45.3	2.33 (2.24-2.43)	5976	51.5	3.08 (2.95-3.22)	6674	55.7	3.72 (3.56-3.89)
Visits by smoker	2775			1729			1890			1891			2117		
% of patients advised to quit	1243	44.8	–	1430	82.7	4.71 (4.06-5.48)	1490	78.8	3.72 (3.23-4.28)	1589	84.0	5.16 (4.44-6.00)	1877	88.7	7.76 (6.61-9.12)
% of patients assessed for readiness to quit	438	15.8	–	1283	74.2	14.90 (12.80-17.33)	1244	65.8	9.87 (8.56-11.39)	1225	64.8	9.29 (8.08-10.69)	1164	55.0	6.15 (5.37-7.03)
Visits by smoker ready to quit in 30 d	184			484			437			399			301		
% of patients who accepted referral	1	0.5	–	285	58.9	260.51 (36.87-1840.52)	245	56.1	230.97 (32.66-1633.34)	151	37.8	110.17 (15.55-780.34)	93	30.9	80.95 (11.38-575.80)

Abbreviations: AAC, Ask-Advise-Connect; OR, odds ratio.

[a]Each time point represents 30 days of data (eg, the 1 month after starting AAC represents day 1 to day 30 postintervention).

Figure 5. Effect of the AAC Intervention on Separate Components at 8 Clinical Sites



Abbreviation: AAC, Ask-Advise-Connect.

To evaluate the HTE for selected patient visit characteristics, we used a GEE model to examine the pre-AAC and AAC-only periods as well as the intervention effect across subgroups for each process indicator. As shown in Table 6, the percentage of visits for male patients where "Ask" was documented was 24%; this figure increased to 53% after the AAC implementation. For female patients, the percentage was 28%; this figure increased to 50% after the AAC implementation. The sex × time period interaction was significant ($\chi^2 = 80.49$; $P < .001$), which indicates that the intervention had a greater positive impact on documentation of smoking status for visits by male patients vs female patients. For "Ask," each characteristic examined resulted in a statistically significant interaction effect. One indicator, age, was significant for "Advise." Given the sample size and thus the power to detect small and clinically nonsignificant differences for "Ask," we took a conservative approach and interpreted a 10% difference in changes as clinically meaningful. Only 1 variable remained with a significant interaction effect: individuals of "other" race showed a much smaller increase in "Ask" than did White and Black individuals (11.9 vs 23.1 and 27.1, respectively).

With regard to referrals, among the 661 individuals referred to the FFS program, 551 had outcome data (see Figure 6). A total of 133 (24.1%) were contacted by the program, 92 (69.2%) were enrolled, and 16 (16.3%) attended ≥1 classes. Among patients referred to the QL, 31.1% were contacted by the QL; of those contacted, 74.4% enrolled and 80.7% received ≥1 counseling calls. It is notable that 98 of the 241 patients (40.7%) received only 1 of the recommended 5 counseling calls before unenrolling or becoming unreachable by the QL.

Table 6. Frequency of Tobacco Use Assessment; Provision of Advice to Quit; Offer of Referral for Cessation Counseling by AAC Time Period; and Test of HTE for Sex, Age, Race, Ethnicity, and Insurance Type

Description	Pre-AAC implementation (n = 36 676), %	Post–AAC-only implementation (n = 139 384), %	Pre-AAC to post–AAC-only difference	Significant characteristic × time period interaction effect
Ask[a], % yes				
Sex				
Male	24.1	52.6	28.5	<0.001
Female	27.6	49.9	22.3	
Age, y				
18-34	22.6	43.1	20.5	
35-64	27.8	53.1	26.0	
≥65	27.9	53.7	25.8	
Race				
White	33.4	56.5	23.1	<0.001[b]
Black	21.6	48.7	27.1	
Other	22.3	34.2	11.9	
Ethnicity				
Non-Hispanic	27.7	52.7	25.0	
Hispanic	18.4	35.9	17.5	
Primary insurance class				
Commercial	29.8	52.2	22.4	<0.001

Description	Pre-AAC implementation (n = 36 676), %	Post–AAC-only implementation (n = 139 384), %	Pre-AAC to post–AAC-only difference	Significant characteristic × time period interaction effect
Medicaid/self-pay	23.5	47.6	24.1	
Medicare	28.6	55.2	26.6	
Advise, % yes				
Sex				
Male	22.2	40.9	18.7	
Female	12.9	30.4	17.5	
Age, y				
18-34	15.3	30.3	15.0	
35-64	17.4	38.3	20.9	
≥65	9.4	23.1	13.7	
Race				
White	16.1	36.2	20.1	
Black	16.3	32.9	16.6	
Other	5.7	21.4	15.7	
Ethnicity				
Non-Hispanic	15.8	34.7	18.9	
Hispanic	11.8	22.7	10.9	
Primary insurance class				
Commercial	12.2	28.1	15.9	

Description	Pre-AAC implementation (n = 36 676), %	Post–AAC-only implementation (n = 139 384), %	Pre-AAC to post–AAC-only difference	Significant characteristic × time period interaction effect
Medicaid/self-pay	20.7	41.1	20.4	
Medicare	12.5	29.8	17.3	
Assess readiness, % yes				
Sex				
Male	6.4	26.8	20.4	
Female	4.2	18.7	14.5	
Age, y				
18-34	4.8	17.5	12.7	
35-64	5.5	25.4	19.9	
≥65	2.4	12.5	10.1	
Race				
White	4.4	21.1	16.7	
Black	5.9	23.5	17.6	
Other	1.2	7.7	6.5	
Ethnicity				
Non-Hispanic	5.1	22.0	16.9	
Hispanic	2.6	13.7	11.1	
Primary insurance class				
Commercial	2.7	15.3	12.6	

Description	Pre-AAC implementation (n = 36 676), %	Post–AAC-only implementation (n = 139 384), %	Pre-AAC to post–AAC-only difference	Significant characteristic × time period interaction effect
Medicaid/self-pay	7.3	28.3	21.0	
Medicare	4.2	18.2	14.0	
Accept connect, % yes				
Sex				
Male	0	43.7	43.7	
Female	0.8	43.6	42.8	
Age, y				
18-34	0	41.5	41.5	
35-64	0	44.6	44.6	
≥65	12.5	40.0	27.5	
Race				
White	0	40.4	40.4	
Black	0.7	45.8	45.1	
Other	0	48.1	48.1	
Ethnicity				
Non-Hispanic	0.6	42.9	42.3	
Hispanic	0	52.0	52.0	
Primary insurance class				
Commercial	0	41.8	41.8	

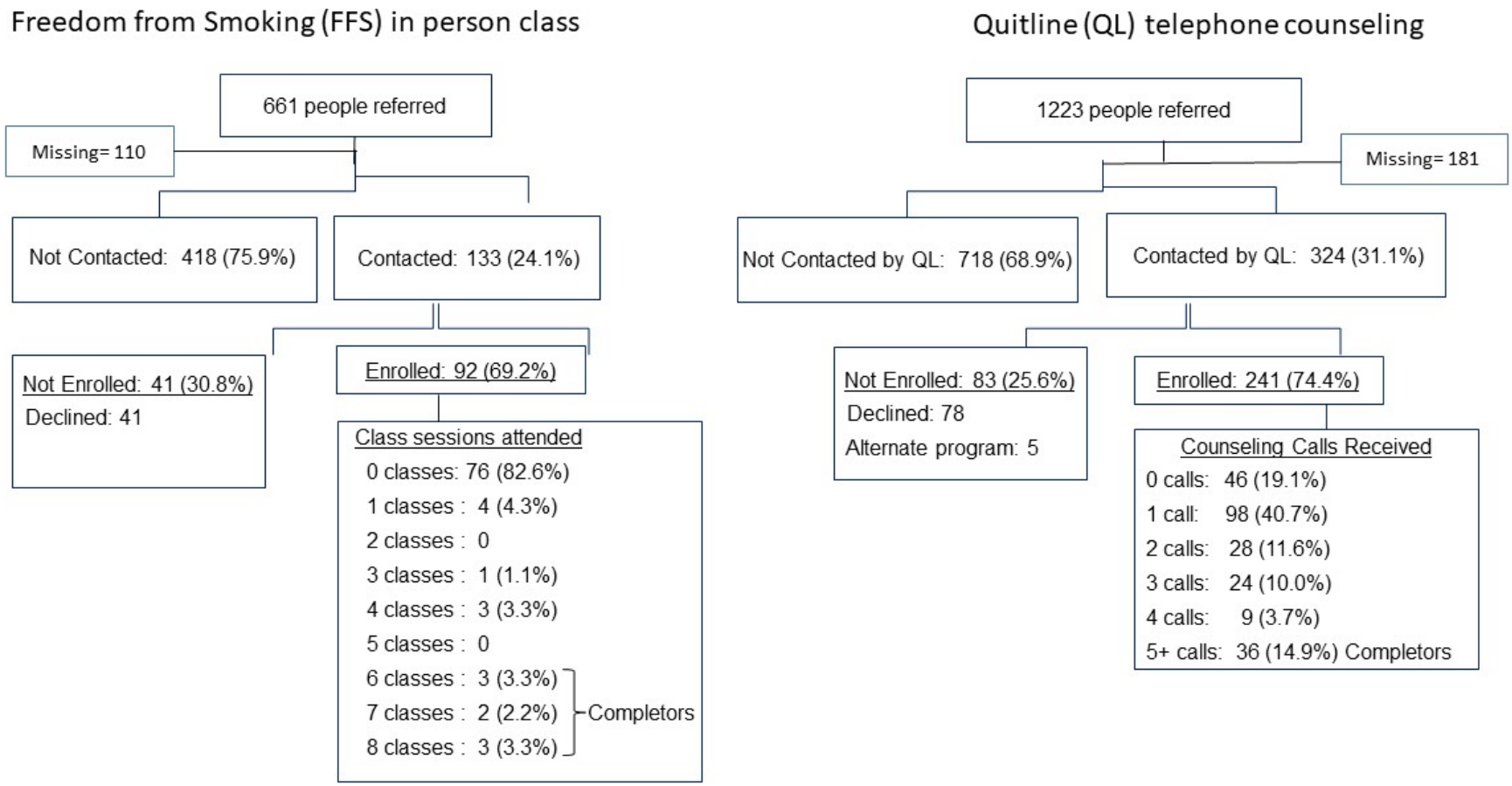
Description	Pre-AAC implementation (n = 36 676), %	Post–AAC-only implementation (n = 139 384), %	Pre-AAC to post–AAC-only difference	Significant characteristic × time period interaction effect
Medicaid/self-pay	0	44.1	44.1	
Medicare	3.0	42.9	39.9	

Abbreviations: AAC, Ask-Advise-Connect; HTE, heterogeneity of treatment effect.

[a]Analyses for "Ask" adjusted for smoking status.

[b]Indicates significant interaction effect at $P < .001$ and >10% difference in differences. Only statistically significant values are indicated in this table.

Figure 6. Flow Diagram of Referrals and Enrollment



Aim 2

Test the effect of combining TMCP with AAC on process outcomes, QL referral outcomes, and smoking outcomes.

Of the 60 clinicians at the 8 study sites, 44 received the TMCP training (see Table 7). Those who received training were similar in number of years since the last clinical degree, degree type, and internal vs family medicine. Women were significantly underrepresented among those receiving TMCP training ($P < .001$). Nurse practitioners (NPs) had lower participation, perhaps because they are more likely to work part time and to provide care at ≥1 clinic than physicians, thus decreasing the likelihood of being at the scheduled clinic training. No other characteristics significantly differed between those with TMCP training vs no TMCP training. Among TMCP training participants, 43% were internal medicine and 57% were family medicine specialists; 68% were doctors of medicine, 12% were doctors of osteopathic medicine, and 20% were certified NPs. The average (SD) time since last clinical degree was 16.3 (11) years.

Table 7. Clinician Characteristics

Characteristic	Received TMCP training (n = 44), No. (%)	No TMCP training (n = 16), No. (%)	*P* value
Sex			
Male	19 (43)	1 (6)	.001
Female	25 (57)	15 (94)	
Training			
MD	30 (68)	7 (44)	
DO	5 (11)	1 (6)	.09
NP	9 (21)	7 (44)	
PA	0 (0)	1 (6)	
Specialty			
Family medicine	25 (57)	7 (44)	
Internal medicine	19 (43)	9 (56)	.37
No. of y since residency, mean (SD)	16.3 (11.0)	11.4 (9.4)	.12

Abbreviations: DO, doctor of osteopathic medicine; MD, doctor of medicine; NP, nurse practitioner; PA, physician assistant; TMCP, Teachable Moment Communication Process.

The characteristics of the patient visits across the 3 time periods (ie, pre-AAC, AAC only, and AAC+TMCP) for the overall study are shown in Table 8. There were no substantial differences between the time periods in the characteristics of the patients making visits. Overall, 69% of visits were by female patients, 50% were by White patients, 45% were by Black patients, and 14% were by Hispanic patients. Most had government insurance (ie, Medicaid [40%] or Medicare [24%]); 29% had commercial insurance. About 26% of visits were by individuals who smoked, and 28% were by former smokers. Most (99.9%) patients had their tobacco status documented. The volume of patients seen at each site varied by site but was relatively stable across each time period.

Table 8. Characteristics of Patient Visits for the Pre-AAC, AAC-Only, and AAC+TMCP Implementation Periods

Description	Overall (N = 224 079), No. (%)	Pre-AAC (n = 34 104), No. (%)	AAC-only (n = 121 518), No. (%)	AAC+TMCP (n = 68 457), No. (%)
Sex				
Male	68 967 (30.8)	10 624 (31.2)	37 768 (31.1)	20 575 (30.1)
Female	155 097 (69.2)	23 479 (68.8)	83 736 (68.9)	47 882 (69.9)
Age, y				
18-34	55 665 (24.8)	8534 (25.0)	29 834 (24.6)	17 297 (25.3)
35-64	127 436 (56.9)	19 872 (58.3)	69 551 (57.2)	38 013 (55.5)
≥65	40 964 (18.3)	5698 (16.7)	22 119 (18.2)	13 147 (19.2)
Race				
White	100 639 (50.2)	15 700 (51.5)	54 089 (50.5)	30 850 (49.2)
Black	90 431 (45.1)	13 707 (44.9)	48 851 (45.6)	27 873 (44.4)
Other	9333 (4.7)	1099 (3.6)	4206 (3.9)	4028 (6.4)
Ethnicity				
Non-Hispanic	188 206 (86.1)	29 065 (87.4)	101 128 (85.3)	58 013 (86.9)
Hispanic	30 340 (13.9)	4177 (12.6)	17 413 (14.7)	8750 (13.1)
Primary insurance class				
Commercial	64 098 (29.2)	9932 (30.1)	34 097 (28.7)	20 069 (29.8)
Medicaid	88 039 (40.2)	13 567 (41.1)	48 064 (40.4)	26 408 (39.2)
Medicare	53 054 (24.2)	7587 (23.0)	28 874 (24.3)	16 593 (24.6)
Self-pay	13 824 (6.3)	1872 (5.7)	7669 (6.5)	4283 (6.4)

Description	Overall (N = 224 079), No. (%)	Pre-AAC (n = 34 104), No. (%)	AAC-only (n = 121 518), No. (%)	AAC+TMCP (n = 68 457), No. (%)
Other	243 (0.1)	32 (0.1)	142 (0.1)	69 (0.1)
Smoking status				
Current smoker	47 533 (25.9)	7600 (26.3)	25 913 (21.3)	14 020 (25.5)
Former smoker	51 416 (28.0)	8003 (27.7)	27 832 (22.9)	15 581 (28.3)
Never smoked	84 536 (46.1)	13 243 (45.9)	45 849 (37.7)	25 444 (46.2)
Not assessed[a]	40 580 (18.1)	5258 (15.4)	21 910 (18.0)	13 412 (19.6)
Readiness to quit assessed				
No	14 966 (43.9)	2242 (84.1)	7082 (36.5)	5642 (47.0)
Yes	19 121 (56.1)	425 (15.9)	12 337 (63.5)	6359 (53.0)
Ready to quit				
No	13 752 (71.9)	246 (57.9)	8607 (69.8)	4899 (77.0)
Yes	5369 (28.1)	179 (42.1)	3730 (30.2)	1460 (23.0)
MetroHealth center				
1	16 410 (7.3)	3003 (8.8)	7665 (6.3)	5742 (8.4)
2	45 620 (20.4)	5899 (17.3)	25697 (21.1)	14024 (20.5)
3	22 481 (10.0)	3727 (10.9)	9224 (7.6)	9530 (13.9)
4	26 980 (12.0)	4521 (13.3)	14777 (12.2)	7682 (11.2)
5	34 217 (15.3)	4680 (13.7)	21073 (17.3)	8464 (12.4)
6	43 023 (19.2)	6862 (20.1)	22855 (18.8)	13306 (19.4)

Description	Overall (N = 224 079), No. (%)	Pre-AAC (n = 34 104), No. (%)	AAC-only (n = 121 518), No. (%)	AAC+TMCP (n = 68 457), No. (%)
7	28 697 (12.8)	4399 (12.9)	17011 (14.0)	7287 (10.6)
8	6637 (3.0)	1013 (3.0)	3202 (2.6)	2422 (3.5)

Abbreviations: AAC, Ask-Advise-Connect; TMCP, Teachable Moment Communication Process.

[a]Not included in the denominator for other smoking status.

The TMCP training web module was fully completed by all who began it except for 1 clinician, who completed 80%. The average score on the module quiz was 80% correct, and 10 clinicians scored ≥90%. Use of the document flow sheet was used as an indication of uptake of the TMCP approach. Among the 44 clinicians trained, 68% used it ≥1 times during the postintervention period. The median number of uses during the 6 months following the training was 15 (interquartile range, 2-33). Seventeen clinicians (39%) used the document flow sheet >10 times, and 4 used it >50 times. Among the 44 clinicians trained, the proportion of visits by smokers with document flow sheet use ranged from 0% to 21%. In all, a document flow sheet was used in 661 of 8198 (8%) visits by smokers during the evaluation period.

The ITT analyses included all 60 clinicians, regardless of whether they received training; there were no significant increases in any of the process or outcome indicators when we compared the post-AAC period with the post-TMCP period. The per-protocol analyses were examined next. The data in Table 9 are limited to the visits in each time period to 1 of the 8 sites and the 44 clinicians who participated in the TMCP training. As noted in Table 9, there was no meaningful increase in the process variables or patient outcomes from the TMCP training. The AAC intervention was designed to be deployed at every visit, whereas the TMCP intervention was situation specific and driven by identification of and clinician action on a salient concern that arose during the visit. The last column presents the tobacco-cessation support indicators for the visits in which the TMCP document flow sheet *was used, indicating that the clinician attempted a teachable moment approach to tobacco cessation*. When we examine those visits in which a TMCP approach was documented using the document flow sheet (see the last column of Table 9), we note that when TMCP was documented, “assessing readiness” was performed at a higher rate, and there was a significant increase in the ordering of medications for tobacco cessation (OR, 2.6; 95% CI, 1.9-3.6). No other outcomes improved.

Table 9. Evaluation of the Added Effect of the TMCP Training on Tobacco-Cessation Support Outcomes

	1-3 mo before AAC			AAC only			AAC+TMCP[a]			AAC+TMCP among clinicians who used the document flow sheet		
	No.	**%**	**OR (95% CI)**	**No.**	**%**	**OR (95% CI)**	**No.**	**%**	**OR (95% CI)**	**No.**	**%**	**OR (95% CI)[b]**
Total visits	**20 469**			**77 500**			**41 774**			**661**		
% of patients asked	5618	27.5	–	38 687	49.9	2.76 (2.67-2.86)	26 452	63.3	1.73 (1.70-1.77)	492	74.4	1.89 (1.62-2.20)
Visits by smokers	**1744**			**13 342**			**8198**			**466**		
% of visits in which patients were advised	778	44.6	–	11 323	84.9	4.35 (3.79-5.00)	7466	91.1	1.97 (1.81-2.14)	443	95.1	3.21 (2.19-4.72)
% of visits in which patients were assessed for readiness to quit	226	13.0	–	8848	66.3	12.34 (10.67-14.27)	4684	57.1	0.66 (0.62-0.69)	347	74.5	1.24 (1.00-1.54)
Ready to quit (No. of visits)	115			2690			1073			93		
Acceptance of referral during visits												
% of visits in which patient accepted a referral	1	0.9	–	1176	43.7	83.20 (12.58-550.36)	369	34.4	0.66 (0.57-0.77)	43	46.2	1.00 (0.66-1.51)
% of visits in which patient accepted QL referral	0	0.0	–	827	30.7	NA	252	23.5	0.68 (0.58-0.80)	22	23.7	0.71 (0.45-1.14)

	1-3 mo before AAC			AAC only			AAC+TMCP[a]			AAC+TMCP among clinicians who used the document flow sheet		
	No.	**%**	**OR (95% CI)**	**No.**	**%**	**OR (95% CI)**	**No.**	**%**	**OR (95% CI)**	**No.**	**%**	**OR (95% CI)[b]**
% of visits in which patient accepted FFS referral	1	0.9	–	349	13.0	14.89 (2.50-88.70)	117	10.9	0.79 (0.64-0.98)	21	22.6	1.45 (0.85-2.49)
Ready to quit (No. of patients)	**112**			**2239**			**1001**			**93**		
Patients who accepted referral	1	0.9	–	1089	48.6	77.67 (13.10-460.61)	357	35.7	0.59 (0.47-0.74)	43	46.2	0.80 (0.50-1.29)
Patients who accepted QL referral	0	0.0	–	765	34.2	NA	247	24.7	0.64 (0.50-0.82)	22	23.7	0.58 (0.38-0.90)
Patients who accepted FFS referral	1	0.9	–	328	14.7	14.47 (2.88-72.66)	112	11.2	0.74 (0.58-0.95)	21	22.6	1.42 (0.86-2.34)
QL referrals received				**649**			**200**			**15**		
Contact rate	NA			211	32.5	NA	44	22.0	0.58 (0.36-0.95)	3	20.0	0.53 (0.18-1.55)
Enrollment rate	NA			158	74.9	NA	29	65.9	0.65 (0.35-1.23)	1	33.3	0.15 (0.01-1.96)
FFS referrals received	**0**		**–**	**276**			**106**			**21**		
Contact rate	NA		–	75	27.2	NA	23	21.7	0.82 (0.53-1.26)	5	23.8	1.00 (0.46-2.18)
Enrollment rate	NA		–	50	66.7	NA	18	78.3	1.74 (0.47-6.40)	3	60.0	0.79 (0.12-5.18)

	1-3 mo before AAC			AAC only			AAC+TMCP[a]			AAC+TMCP among clinicians who used the document flow sheet		
	No.	%	OR (95% CI)	No.	%	OR (95% CI)	No.	%	OR (95% CI)	No.	%	OR (95% CI)[b]
Medications	113	7.9	–	1126	14.9	1.85 (1.53-2.23)	718	12.4	0.81 (0.74-0.88)	139	31.6	2.61 (1.92-3.55)
Quit attempts[c]	51	2.5	–	44	2.1	0.82 (0.54-1.23)	45	2.3	1.09 (0.72-1.67)	8	3.7	1.95 (0.86-4.45)

Abbreviations: AAC, Ask-Advise-Connect; FFS, Freedom From Smoking; NA, not applicable; QL, quitline; TMCP, Teachable Moment Communication Process.

[a]Comparison is the post-TMCP to post-AAC period among clinicians who received training.

[b]Comparison is post-TMCP for visits in which a document flow sheet was used compared with visits during the post-AAC period for clinicians who had ever used the document flow sheet.

[c]Quit attempts are defined based on ≥2 visits in the time period, a change in smoking status from current smoker to former smoker, and documentation of a quit date. Numerator and denominator for quit attempts for each period: 51/1986 (1-3 mo before AAC), 44/2088 (AAC only), 45/1951 (AAC+TMCP), and 8/216 (AAC+TMCP among clinicians who used the document flow sheet).

The patient report indicators from the survey were the last outcomes examined across the 3 time periods: pre-AAC, AAC only, and AAC+TMCP. The mean and standard deviation for each patient report indicator for the MA/RN discussion and the discussion by the doctor are reported in Table 10. Across the time periods, patient reports were in the “very good” to “excellent” range (ie, scores of 4-5). Although there were some modest increases in the scores in the AAC-only and AAC+TMCP periods, using analysis of variance and planned paired comparisons evaluated with Tukey tests, none of the differences were statistically significant or clinically meaningful. We also examined the proportion that selected 5 (“excellent”) and compared the 3 time periods and found no meaningful difference in the groups. The scores on the patient report items were high at baseline and remained high in the 2 subsequent intervention periods.

Table 10. Patient-Reported Outcomes of Being Treated With Respect, Feeling Listened to, and Stating That the Discussion About Smoking Was Helpful

	1-3 mo before AAC (N = 171 surveys)	AAC only (N = 169 surveys)	AAC+TMCP (N = 164 surveys)
Did the nurse talk about smoking?			
% of patients responding "yes"	65	72	70
	Mean (SD)[a]	**Mean (SD)[a]**	**Mean (SD)[a]**
I was treated with respect	4.35 (0.91)	4.53 (0.76)	4.37 (0.92)
I felt listened to	4.17 (1.00)	4.36 (0.84)	4.29 (0.90)
I was able to honestly speak my mind about quitting	4.09 (1.14)	4.28 (0.98)	4.23 (1.04)
My opinion about quitting smoking was treated with respect	4.08 (1.06)	4.36 (0.98)	4.28 (1.00)
Things were explained in a way that I could understand	4.12 (1.07)	4.36 (0.96)	4.27 (0.95)
Did the doctor talk about smoking?			
% of patients responding "yes"	79	74	75
	Mean (SD)[a]	**Mean (SD)[a]**	**Mean (SD)[a]**
I was treated with respect	4.43 (0.86)	4.55 (0.85)	4.58 (0.75)
I felt listened to	4.37 (0.93)	4.45 (0.90)	4.44 (0.87)
I was able to honestly speak my mind about quitting	4.37 (0.92)	4.38 (0.99)	4.48 (0.82)
My opinion about quitting smoking was treated with respect	4.29 (0.92)	4.36 (0.97)	4.36 (0.86)
Things were explained in a way that I could understand	4.32 (0.86)	4.37 (1.03)	4.51 (0.73)
The discussion about smoking was helpful	4.15 (0.99)	4.13 (1.26)	4.33 (0.92)

Abbreviations: AAC, Ask-Advise-Connect; TMCP, Teachable Moment Communication Process.

[a]Items are reported on a 5-point Likert scale (1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = excellent).

Aim 3

Examine the narratives of subgroups of individuals to better understand the referral experience and identify ways to improve it.

We interviewed 55 participants who accepted a referral by the MA at their primary care clinic. Participants had a median age of 53 years, with the majority being female (75%), Black (58%), and non-Hispanic (93%). Overall, those who participated were similar in age, sex, race, and insurance type to those who did not participate (see Table 11). Data collection was conducted on a rolling basis, and participants were contacted at varying points throughout the e-referral to QL counseling process and in various categories.

Table 11. Interviewee Sample Characteristics

Characteristic	Total (N = 229)	Participants (n = 55)	Nonparticipants (n = 115)	Not contacted[a] (n = 59)
Age, y, mean (SD)	51.3 (13.2)	50.6 (12.0)	51.6 (13.8)	51.6 (13.4)
Female, %	65	76	57	71
Black, %	54	58	55	49
Insurance type, %				
Commercial	3	2	3	4
Medicaid	64	57	65	67
Medicare	33	39	32	28
Self-pay	1	2	0	2

[a]These individuals were sampled but were not invited to participate because the target number of interviews was completed before we attempted to contact this group.

Reasons for QL program noncompletion included lack of clarity at the point of referral, changing life circumstances and events making cessation unviable, inconvenient time of phone calls, cell phone difficulties, discomfort with telephone counseling, and having already quit smoking. We also found that some individuals who were no longer receiving QL support– either because they had been classified as program completed, unreachable, or declined – still valued

and wanted additional support from the QL. Example quotes to substantiate these themes are included in Table 12.

Table 12. Themes and Example Quotations From Smokers e-Referred to the QL

Differing expectations regarding the QL referral
"You know, and I just wasn't sure [what to expect]. To be honest with you, I thought it was a program like a friend of mine went through some years ago where he actually went to one of the clinics in the evenings." [ID #08]
"The only thing I got was 'You call them, and they'll call you back.' That's the only thing I got. . . . I wanted to ask, but I was in pain. I couldn't really breathe and stuff like that. I wanted to know about, like, if you go to the hospital and you sit down with somebody. I wanted to ask those questions, but I honestly was not feeling good and I didn't wanna hear anything." [ID #14]
"I wanted patches. So that's what I thought I was gonna get, some patches. Like I was saying, that's not what I wanted to do—them checking on me and this and that and all that. . . . So you know, I told them, 'That's all right.' If I couldn't get the patches, that's all right. That was the end of that conversation." [ID #25].
Changing life circumstances and stressors
"My mother had a stroke, and she wasn't doing too good and wasn't nobody here to take care of her but me. You know how hard that was on me. She was bedridden, and she died like in August of last year. Yeah, and trying to take care of myself and trying to take care of her. It was a lot."
"I just had a lot going on. A lot of issues with family, things going on lately. Our home was just burglarized a couple weeks ago. I've just had a lot going on. . . . I mean it's definitely something I'd like to do eventually. It's just gotta be the right time, and a lot of times when you try to quit something and then you go back to it, becomes, you know it just becomes worse, I guess." [ID #33]
"Well they sent me the brochures and everything. But my mindset wasn't in the right frame of mind at that point, 'cause my dad was in a nursing home. And he just recently passed away, so I wasn't really in the right state of mind back then. It was kind of stressful, and that was like the stress-relief to get out the nursing home and have me a cigarette and go home." [ID #44]
Unable to find time for counseling
"I've been at work so much that I never get a chance to conversate with them, 'cause I'm at work like from morning 'til late evening." [ID #13]
"I actually received a couple calls that I missed because I was at appointments, or I was either at my kids' school or something and didn't answer the phone." [ID #12]
"Usually when they call, sometimes I don't answer because I'm either picking up my kid, or taking him to school . . . and then with Christmas, holidays. Everything is just, you know, and then trying to figure out with the doctor, 'cause well I just had another episode, so I was in the hospital." [ID #22]
Cell phone barriers

"They probably tried to call me, but my phone's been stupid. . . . I cracked it, so sometimes it answers and sometimes it doesn't." [ID #54]
"Yeah, and then the phone I had, I lost it, and I ain't been able to afford me another phone, but I got a birthday soon coming. I guess they'll pitch in and buy me a phone, and I'm using a temporary phone now until I get me another real good phone. I had phones and kept having problems with them." [ID #52]
"The MA asked if I had any interest in stopping and I told her yes, and then she gave me or told me about the quitline was supposed to call me, which I believe they may have, but the number comes up and if it's an 800 number, I usually don't answer it, because you know it doesn't come up under the quitline, you know, ID. It just comes up as an 800 number." [ID #04]
Discomfort with/disbelief in the efficacy of QL counseling
"I did [agree to be connected to the quitline], and we did speak. Someone did call me with the department of the quitline, and I was not comfortable. I'm not gonna lie to you. . . . I think it was just the person that spoke to me over the phone. In reality, I know that it's just your job to try to give information out, or try to help someone, but you need to feel comfortable with somebody when you speak to them over the phone, and I just didn't feel comfortable with the first call I got. So I didn't agree to the over-the-phone line quitting situation because, I don't know. I just didn't feel comfortable." [ID #15]
"You know the first time, the lady was professional and generous. It's just, I don't think it was very helpful to me."[ID #41]
"Cause talking with somebody about quitting doesn't do any good. I feel like talking wouldn't do any good. 'Cause I would go ahead on and say 'Yeah. Um hmm. Yeah. You're right. You're right,' and it'll be going in one ear, coming out the other. [ID #23]
Quitting on their own
"I got a call and they asked me, you know they said 'Are you interested in quitting?' and I said 'Yeah.' I told them I was in the process of trying to quit then, you know, and they told me if I needed help, to get in touch with them." [ID #28]
"They called me, but I didn't really speak with them because I actually stopped, and I didn't need the help. And I've been doing good ever since then. "[ID #03]

Abbreviation: QL, quitline.

A common theme among those who had received any QL counseling, including those who at some point disengaged and did not complete the protocol, was that they benefited from the experience. Although some participants reported quitting or cutting down on their smoking, others reported an increased desire to quit, more awareness of their smoking behavior, or some other form of incremental progress in smoking cessation:

It was helpful. It definitely was. When I do wanna smoke a cigarette, that [counseling advice] *always plays in my ear. So I'll never forget that every time I pick up a cigarette. So that's making it better for me.* [ID 49]

Another finding was that several participants who completed the QL program or were no longer receiving calls because they had been categorized as having declined or being unreachable, desired continued cessation support. Some specifically wanted to re-engage with the QL:

Yes, I would [like to talk to the QL]*, because it was just a misunderstanding and the wrong moment. That's all it was.* [ID 9]

Yeah. I'd still like to talk to them. That way we can still set goals and have the motivation to keep going. [ID 54]

With regard to the larger, primary care context of smoking cessation, the overwhelming majority of patients reported wanting providers' continued engagement and support with smoking cessation. When asked what role they wanted their primary care providers to play in their smoking cessation, participants expressed the desire for ongoing assistance and encouragement:

"If this don't work, let's go to the next level," you know. In other words, let's not give up on me. You know, "Come on—you keep trying until we find the right thing for you." That's what I want. [ID 14]

Just check up to see how I'm doing. Am I still smoking? Am I not smoking? "How are you doing with your smoking?" or "If you are still smoking, is there something else that we can do to help you stop smoking?" Those type of questions. [ID 42]

DISCUSSION

The implementation of the AAC strategy resulted in a large, statistically significant increase in performance and documentation of tobacco-cessation assistance. Although the uptake of all the new tasks was good, the most robust uptake and sustained performance was associated with the provision of brief advice. This finding may be a result of 2 factors. First is the health care system's preference for implementing a routinized approach to addressing tobacco assessment and cessation assistance for every primary care patient at every visit. Second, the study team extensively engaged MAs as representatives of the frontline users of the approach during the development and implementation phase. The MAs were instrumental in developing the wording of the brief advice phrase, which resulted in a phrase that the MAs were comfortable using. In addition, we anticipated that the overall approach would be empowering to the MAs because the AAC strategy enables them to sign the referral order for external tobacco-cessation counseling. Overall, we found that the successful and sustained adoption of AAC was in large part the result of its being embedded within and supported by the health care system and designed and implemented in partnership with the end users.[42] Greenwood et al[43] also found that MA role expansion and empowerment to support tobacco-cessation care improved documentation of smoking status and referrals to telephone-based cessation counseling (ie, QL) significantly. Training various clinical support staff to assess tobacco status, provide brief advice, and assist or refer patients for assistance is reported as efficacious in a variety of health care settings in a growing number of studies,[44-46] although none to our knowledge has measured the sustained effect at 12 months postimplementation. Shifting some of the responsibility for tobacco-cessation support to nonphysicians can be an effective strategy, particularly as a component of larger system change.

Our approach to training and technical assistance for implementation of the AAC strategy had good fidelity across each of the 8 community health centers. However, there was substantial variation in the uptake of assessing readiness and therefore offering referral to the QL for the 8 sites. Several similar studies have documented barriers that can contribute to variability in uptake across practices and individual staff members. Possible explanations offered include high staff turnover combined with no systematic process for training new staff

on the protocol,[45] hesitation or discomfort with asking every patient at every visit about smoking,[43] and varying levels of EHR competency.[45]

It is encouraging that there was minimal HTE of the AAC intervention; this effect was limited to a few visit characteristics for the "Ask" process indicator. Although the performance of the AAC process was sustained at most practices for most indicators for 12 months, patient acceptance of assistance to quit smoking decreased after 6 months. It is likely that individuals who had return visits and who encountered the AAC process at each subsequent visit may have already engaged once but either continued to use tobacco or, as indicated from the qualitative findings, may have already quit.

This is the first study to engage clinicians in the TMCP approach as part of a systems-change intervention. Prior work engaged clinicians as study volunteers.[34,35] The training was conducted at the practice site during a clinical work day and used protected administrative time granted by the health care system. Feedback solicited from the clinicians about the web module, the skill practice section, and the place and timing of the training was positive. The TMCP approach and training were viewed as both important and pragmatic. This study also developed and deployed a document flow sheet, which is a common EHR tool, to both cue and document the TMCP. During the training, coaches observed substantial variability in clinician willingness to use the document flow sheet while learning the new communication process. The overall uptake of the TMCP approach in routine patient care was poor; a document flow sheet indicated use of the TMCP approach in 8% of visits by tobacco users. This low rate of uptake limits the ability to evaluate the impact of its use on patient outcomes. Variation in clinician uptake of tobacco-cessation counseling training has been reported as resulting from variation in clinicians' beliefs regarding the importance of cessation.[47,48] Like other EHR tool implementation efforts, our findings show significant variability in the adoption and use of this EHR tool despite specific training and technical assistance.[45] Unlike the AAC approach, which was built into existing work flows, the TMCP was designed to be used at the clinician's discretion when a salient patient concern made discussion of tobacco cessation relevant to the visit. Further, a technical limitation of the implementation of the TMCP approach was that uniting the AAC activity (ie, patient ready to quit declined referral to tobacco-cessation services)

with the clinician dashboard view of the EHR was not sufficiently achieved. Thus, there was no way to prompt clinicians about potentially activated patients. Nonetheless, when the TMCP approach was used, it substantially increased the orders for tobacco-cessation medications compared with the AAC-only period. This is important in that tobacco-cessation counseling and medications to support a quit attempt together increase the likelihood of a quit attempt.[49,50] To realize the potential of the TMCP approach to augment patient support and the effectiveness of tobacco-cessation attempts, systems change work is needed to better integrate and align the AAC activity with the EHR view for clinicians. Doing this in a way that is technically feasible and acceptable to clinicians by fitting it into the workflow is essential. Clinician EHR alert fatigue is a concern, and continued engagement of frontline clinicians and clinician informatics experts is essential to meaningfully designing an EHR interface that supports the care-delivery process in a nondisruptive way. Other strategies that could be considered in future research to improve clinician uptake include conducting audits and gathering feedback on performance[51] as well as providing booster training.

An important aspect of this study was examining the tobacco-cessation support process from the perspective of patients. We elicited the experiences from QL-referred smokers to understand the overall experience and to identify reasons for and circumstances surrounding their noncompletion of a state QL's 5-session counseling protocol. By interviewing not only participants who completed the program but also those who at some point declined to be involved or were unreachable by the QL, we have expanded understanding of why rates of noncompletion are high. We found that a major reason for noncompletion was having significant life stressors, such as poor living conditions and long and/or unpredictable work hours. Others have also found that stressors related to poor socioeconomic status are a barrier to use of QL counseling.[52,53] Integrating QL interventions with community-based resources that address the sociocontextual mediators of tobacco use could be a promising strategy.[54] Discomfort with telephone-based counseling was found to be another reason for QL disengagement. Some researchers have improved QL engagement by incorporating culturally specific adaptations[55,56] because different ethnic/racial groups can have differing norms and values with regard to smoking and experience unique barriers to cessation.[57,58] The potential

for QLs to reach and support the population of smokers is significant, but addressing some of these barriers in future research is warranted. Finding ways to increase engagement in tobacco-cessation counseling support is important for improving the likelihood of a successful quit attempt. Piñeiro et al found that those who completed ≥3 sessions had the greatest likelihood of achieving abstinence and were approximately 4 times as likely to be abstinent at 6 months compared with those who completed no sessions or only 1 session.[59]

The categories "program complete" and "quit status" are often used by QLs as indicators of the degree of QL engagement and the success of a tobacco-cessation program. Our findings suggest that these categories do not tell the whole story. Many participants who did not complete the program found great value in their engagement with the QL and accomplished goals such as quitting or cutting down on their use of tobacco products. Because smoking cessation is a process that frequently involves several quit attempts as well as a behavior change that needs to be sustained over time, the QL can potentially play an important role regardless of where a patient may be along the tobacco-cessation trajectory. We found that some individuals who were no longer receiving QL support, because they had been classified as program completed, unreachable, or declined, expressed that they would value ongoing or future support from the QL. Other studies have found that many relapsed smokers are interested in re-entering treatment[60,61] and that interventions to encourage past QL participants to return to services and reinitiate QL-assisted quit attempts are effective.[62,63]

Finally, we found that study participants want ongoing communication with their primary care providers about smoking and smoking cessation. Regardless of their quit status, patients appreciate their providers checking in with them, offering encouragement, and working with them to solve problems with cessation strategies. Closed-loop EHR referral systems that include delivery of treatment information from the QL back to the primary care team may help facilitate ongoing patient-provider communication.[25]

Subpopulation Considerations

This study was conducted in a setting with a high proportion of socially and economically disadvantaged patients. Those with low income and lower levels of education are

more likely to use tobacco and thus are an important group to reach with interventions designed to improve tobacco-cessation support in the context of the primary care setting. As noted previously, the AAC intervention appeared to work equally well for all subgroups.

Study Limitations

The study sample was drawn from a health care system (MetroHealth) that serves patients who tend to have very low income. Thus, socioeconomic barriers to engaging with the QL were prevalent. The smoking rate in the primary care practices at this system is about 30%; the approach to a routinized, "every patient, every visit" strategy may be less efficient where smoking rates are lower. The calculation of a quit attempt assumes documentation of a quit date in the EHR. However, in some instances, a quit attempt may have been made by a patient without supportive documentation in their record. Consequently, our quit attempt estimate serves as a lower bound for the actual quit attempt rate. Although we observed variation in uptake across the 8 clinical sites of the AAC process, data collection did not include practice-level variables that may explain some of this variation. Finally, uptake of the TMCP approach by clinicians (as recorded by the document flow sheet) was poor and severely limited our ability to evaluate the impact of the TMCP approach. Low TMCP use across most clinicians and the small number of TMCP uses overall resulted in poor statistical power to evaluate the effect of the TMCP approach on outcomes. Despite these limitations, the findings and the utility of the intervention components tested in this study (ie, using EHR e-referral to a state QL, routine training methods supported by audit and feedback on performance) are relevant and applicable to other primary care settings.

CONCLUSIONS

The AAC system change intervention substantially increased the provision of tobacco-cessation care, with improvements sustained beyond 1 year. Adding TMCP training for clinicians improved ordering of tobacco cessation medications, but other outcomes did not improve. However, low uptake limited our ability to test the impact of the TMCP approach on patient outcomes. This pragmatic cluster RCT indicated the value of a system-based approach and the importance of structures that fully support the integration of simultaneously implemented interventions by the primary health care team. Future work will require more complete integration of the AAC and TMCP approaches and tools into the EHR systems for the combined process to be fully tested.

REFERENCES

1. Cokkinides VE, Halpern MT, Barbeau EM, Ward E, Thun MJ. Racial and ethnic disparities in smoking-cessation interventions: analysis of the 2005 National Health Interview Survey. *Am J Prev Med.* 2008;34(5):404-412.

2. Fix BV, Hyland A, Rivard C, et al. Usage patterns of stop smoking medications in Australia, Canada, the United Kingdom, and the United States: findings from the 2006-2008 International Tobacco Control (ITC) Four Country Survey. *Int J Environ Res Public Health.* 2011;8(1):222-233.

3. Fu SS, Sherman SE, Yano EM, van Ryn M, Lanto AB, Joseph AM. Ethnic disparities in the use of nicotine replacement therapy for smoking cessation in an equal access health care system. *Am J Health Promot.* 2005;20(2):108-116.

4. Trinidad DR, Perez-Stable EJ, White MM, Emery SL, Messer K. A nationwide analysis of US racial/ethnic disparities in smoking behaviors, smoking cessation, and cessation-related factors. *Am J Public Health.* 2011;101(4):699-706.

5. US Department of Health and Human Services. Quitting smoking among adults—United States, 2001-2010. *MMWR Morb Mortal Wkly Rep.* 2011;60(44):1513-1519.

6. Centers for Disease Control and Prevention/National Center for Health Statistics. *National Health Interview Survey, 2011 Data Release*. Accessed February 3, 2021. https://www.cdc.gov/nchs/nhis/nhis_2011_data_release.htm

7. Thorndike AN, Regan S, Rigotti NA. The treatment of smoking by US physicians during ambulatory visits: 1994 2003. *Am J Public Health.* 2007;97(10):1878-1883.

8. National Prevention Council. *National Prevention Strategy*. Published June 2011. Accessed August 8, 2020. https://www.hhs.gov/sites/default/files/disease-prevention-wellness-report.pdf

9. Tobacco Use and Dependence Guideline Panel. *Treating Tobacco Use and Dependence: 2008 Update*. US Department of Health and Human Services; 2008. Accessed February 3, 2021. https://www.ncbi.nlm.nih.gov/books/NBK63952/

10. North American Quitline Consortium. *Quality Improvement Initiative Issue Paper: Quitline Referral Systems. NAQC Issue Paper*. 2013. Accessed August 8, 2020. https://cdn.ymaws.com/sites/naquitline.site-ym.com/resource/resmgr/Issue_Papers/QuitlineReferralSystemsQuali.pdf

11. Ossip-Klein DJ, McIntosh S. Quitlines in North America: evidence base and applications. *Am J Med Sci.* 2003;326(4):201-205.

12. Matkin W, Ordóñez-Mena JM, Hartmann-Boyce J. Telephone counselling for smoking cessation. *Cochrane Database Syst Rev.* 2019 May 2;5(5):CD002850. doi:10.1002/14651858.CD002850.pub4

13. Fiore MC. Treating tobacco use and dependence: an introduction to the US Public Health Service Clinical Practice Guideline. *Respir Care.* 2000;45(10):1196-1199.

14. Riley WT, Glasgow RE, Etheredge L, Abernethy AP. Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise. *Clin Transl Med.* 2013;2(1):10.

15. Simons VA, Flynn SP, Flocke SA. Practical behavior change counseling in primary care. *Prim Care.* 2007;34(3):611-622, vii.

16. US Preventive Services Task Force. *The Guide to Clinical Preventive Services 2010-2011: Recommendations of the US Preventive Services Task Force.* Report No. 10-05145. Agency for Healthcare Research and Quality; 2010. Accessed August 8, 2020. https://www.ncbi.nlm.nih.gov/books/NBK56707

17. Wasserman MP. Guide to community preventive services: state and local opportunities for tobacco use reduction. *Am J Prev Med.* 2001;20(2 Suppl):8-9.

18. North American Quitline Consortium. *The Use of Quitlines Among Priority Populations in the U.S.: Lessons From the Scientific Evidence. NAQC Issue Paper*. 2011. Accessed August 8, 2020. https://cdn.ymaws.com/www.naquitline.org/resource/resmgr/Issue_Papers/IssuePaperTheUseofQuitlinesA.pdf

19. Bentz CJ, Bayley KB, Bonin KE, et al. Provider feedback to improve 5A's tobacco cessation in primary care: a cluster randomized clinical trial. *Nicotine Tob Res.* 2007;9(3):341-349.

20. Redmond LA, Adsit R, Kobinsky KH, Theobald W, Fiore MC. A decade of experience promoting the clinical treatment of tobacco dependence in Wisconsin. *WMJ.* 2010;109(2):71-78.

21. Rothemich SF, Woolf SH, Johnson RE, et al. Promoting primary care smoking-cessation support with quitlines: the QuitLink Randomized Controlled Trial. *Am J Prev Med.* 2010;38(4):367-374.

22. Stead LF, Buitrago D, Preciado N, Sanchez G, Hartmann-Boyce J, Lancaster T. Physician advice for smoking cessation. *Cochrane Database Syst Rev.* 2013;(5):CD000165. doi:10.1002/14651858.CD000165.pub4

23. Warner DD, Land TG, Rodgers AB, Keithly L. Integrating tobacco cessation quitlines into health care: Massachusetts, 2002-2011. *Prev Chronic Dis.* 2012;9:110343. doi:10.5888/pcd9.110343

24. Mathew M, Goldstein AO, Kramer KD, Ripley-Moffitt C, Mage C. Evaluation of a direct mailing campaign to increase physician awareness and utilization of a quitline fax referral service. *J Health Commun.* 2010;15(8):840-845.

25. Adsit RT, Fox BM, Tsiolis T, et al. Using the electronic health record to connect primary care patients to evidence-based telephonic tobacco quitline services: a closed-loop demonstration project. *Transl Behav Med.* 2014;4(3):324-332.

26. Cohen DJ, Clark EC, Lawson PJ, Casucci BA, Flocke SA. Identifying teachable moments for health behavior counseling in primary care. *Patient Educ Couns.* 2011;85(2):e8-e15. doi:10.1016/j.pec.2010.11.009

27. Flocke SA, Clark E, Antognoli E, et al. Teachable moments for health behavior change and intermediate patient outcomes. *Patient Educ Couns.* 2014;96(1):43-49.

28. Flocke SA, Stange KC. Direct observation and patient recall of health behavior advice. *Prev Med.* 2004;38(3):343-349.

29. Lawson PJ, Flocke SA. Teachable moments for health behavior change: a concept analysis. *Patient Educ Couns.* 2009;76(1):25-30.

30. Vidrine JI, Shete S, Cao Y, et al. Ask-Advise-Connect: a new approach to smoking treatment delivery in health care settings. *JAMA Intern Med.* 2013;173(6):458-464.

31. Vidrine JI, Shete S, Li Y, et al. The Ask-Advise-Connect approach for smokers in a safety net healthcare system: a group-randomized trial. *Am J Prev Med.* 2013;45(6):737-741.

32. Sadasivam RS, Hogan TP, Volkman JE, et al. Implementing point of care “e-referrals” in 137 clinics to increase access to a quit smoking internet system: the Quit-Primo and National Dental PBRN HI-QUIT studies. *Transl Behav Med.* 2013;3(4):370-378.

33. Willett JG, Hood NE, Burns EK, et al. Clinical faxed referrals to a tobacco quitline: reach, enrollment, and participant characteristics. *Am J Prev Med.* 2009;36(4):337-340.

34. Flocke SA, Antognoli E, Step MM, Marsh S, Parran T, Mason MJ. A Teachable Moment Communication Process for smoking cessation talk: description of a group randomized clinician-focused intervention. *BMC Health Serv Res.* 2012;12:109. doi:10.1186/1472-6963-12-109

35. Flocke SA, Step MM, Antognoli E, et al. A randomized trial to evaluate primary care clinician training to use the Teachable Moment Communication Process for smoking cessation counseling. *Prev Med.* 2014;69:267-273.

36. Weiner BJ, Lewis MA, Clauser SB, Stitzenberg KB. In search of synergy: strategies for combining interventions at multiple levels. *J Natl Cancer Inst Monogr.* 2012;2012(44):34-41.

37. Adams B, Allan T, Cheatham C, et al. *2018 Cuyahoga County Community Health Assessment: A Community Health Needs Assessment*. 2018. Accessed August 8, 2020. https://hipcuyahoga.org/wp-content/uploads/2018/11/2018CuyahogaCountyAssessmentFinal.pdf

38. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials.* 2007;28(2):182-191.

39. Lawson PJ, Flocke SA, Casucci B. Development of an instrument to document the 5A's for smoking cessation. *Am J Prev Med.* 2009;37(3):248-254.

40. Makoul G, Krupat E, Chang CH. Measuring patient views of physician communication skills: development and testing of the Communication Assessment Tool. *Patient Educ Couns.* 2007;67(3):333-342.

41. Halladay JR, Vu M, Ripley-Moffitt C, Gupta SK, O'Meara C, Goldstein AO. Patient perspectives on tobacco use treatment in primary care. *Prev Chronic Dis.* 2015;12:140408. doi:10.5888/pcd12.140408

42. Flocke SA, Seeholzer E, Lewis SA, et al. Designing for sustainability: an approach to integrating staff role changes and electronic health record functionality within safety-net clinics to address provision of tobacco cessation care. *Jt Comm J Qual Patient Saf.* 2019;45(21):798-807.

43. Greenwood DA, Parise CA, MacAller TA, et al. Utilizing clinical support staff and electronic health records to increase tobacco use documentation and referrals to a state quitline. *J Vasc Nurs.* 2012;30(4):107-111.

44. Chavarria J, Liu M, Kast L, Salem E, King AC. A pilot study of Counsel to Quit: evaluating an Ask Advise Refer (AAR)-based tobacco cessation training for medical and mental healthcare providers. *J Subst Abuse Treat.* 2019;99:163-170.

45. Karn S, Fernandez A, Grossberg LA, et al. Systematically improving tobacco cessation patient services through electronic medical record integration. *Health Promot Pract.* 2016;17(4):482-489.

46. Wye PM, Stockings EA, Bowman JA, Oldmeadow C, Wiggers JH. Effectiveness of a clinical practice change intervention in increasing the provision of nicotine dependence treatment in inpatient psychiatric facilities: an implementation trial. *BMC Psychiatry.* 2017;17(1):56. doi:10.1186/s12888-017-1220-7

47. Papadakis S, Cole AG, Reid RD, et al. From good to great: the role of performance coaching in enhancing tobacco-dependence treatment rates. *Ann Fam Med.* 2018;16(6):498-506.

48. Papadakis S, Cole AG, Reid RD, et al. Increasing rates of tobacco treatment delivery in primary care practice: evaluation of the Ottawa Model for Smoking Cessation. *Ann Fam Med.* 2016;14(3):235-243.

49. Silfen SL, Cha J, Wang JJ, Land TG, Shih SC. Patient characteristics associated with smoking cessation interventions and quit attempt rates across 10 community health centers with electronic health records. *Am J Public Health.* 2015;105(10):2143-2149.

50. Stead LF, Koilpillai P, Fanshawe TR, Lancaster T. Combined pharmacotherapy and behavioural interventions for smoking cessation. *Cochrane Database Syst Rev.* 2016;(3):CD008286. doi:10.1002/14651858.CD008286.pub3

51. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev.* 2012;(6):CD000259. doi:10.1002/14651858.CD000259.pub3

52. Sheffer CE, Brackman SL, Cottoms N, Olsen M. Understanding the barriers to use of free, proactive telephone counseling for tobacco dependence. *Qual Health Res.* 2011;21(8):1075-1085.

53. Varghese M, Sheffer C, Stitzer M, Landes R, Brackman SL, Munn T. Socioeconomic disparities in telephone-based treatment of tobacco dependence. *Am J Public Health.* 2014;104(8):e76-e84. doi:10.2105/AJPH.2014.301951

54. Haas JS, Linder JA, Park ER, et al. Proactive tobacco cessation outreach to smokers of low socioeconomic status: a randomized clinical trial. *JAMA Intern Med.* 2015;175(2):218-226.

55. Butler KM, Begley K, Riker C, et al. Smoke-free coalition cohesiveness in rural tobacco-growing communities. *J Community Health.* 2014;39(3):592-598.

56. Webb Hooper M, Carpenter K, Salmon EE. Web-based tobacco cessation interventions and digital inequality across U.S. racial/ethnic groups. *Ethn Dis.* 2019;29(3):495-504.

57. Daoud N, Jung YE, Sheikh Muhammad A, et al. Facilitators and barriers to smoking cessation among minority men using the behavioral-ecological model and Behavior Change Wheel: a concept mapping study. *PLoS One.* 2018;13(10):e0204657. doi:10.1317/journal.pone.0204657

58. Nierkens V, Hartman MA, Nicolaou M, et al. Effectiveness of cultural adaptations of interventions aimed at smoking cessation, diet, and/or physical activity in ethnic

minorities. a systematic review. *PLoS One.* 2013;8(10):e73373. doi:10.1371/journal.pone.0073373

59. Piñeiro B, Wetter DW, Vidrine DJ, et al. Quitline treatment dose predicts cessation outcomes among safety net patients linked with treatment via Ask-Advise-Connect. *Prev Med Rep.* 2019;13:262-267.

60. Fu SS, Partin MR, Snyder A, et al. Promoting repeat tobacco dependence treatment: are relapsed smokers interested? *Am J Manag Care.* 2006;12(4):235-243.

61. Partin MR, An LC, Nelson DB, et al. Randomized trial of an intervention to facilitate recycling for relapsed smokers. *Am J Prev Med.* 2006;31(4):293-299.

62. Carlini B, Miles L, Doyle S, Celestino P, Koutsky J. Using diverse communication strategies to re-engage relapsed tobacco quitline users in treatment, New York State, 2014. *Prev Chronic Dis.* 2015;12:E179. doi:10.5888/pcd12.150191

63. Carlini BH, McDaniel AM, Weaver MT, et al. Reaching out, inviting back: using interactive voice response (IVR) technology to recycle relapsed smokers back to quitline treatment—a randomized controlled trial. *BMC Public Health.* 2012;12:507. doi:10.1186/1471-2458-12-507

RELATED PUBLICATIONS

Flocke SA, Lewis S, Seeholzer E, et al. Electronic medical record documentation of tobacco cessation support at eight community safety-net clinics with a high prevalence of tobacco use. *J Eval Clin Pract.* 2019;25(3):507-513.

Flocke SA, Seeholzer E, Lewis S, et al. Designing for sustainability: an approach to integrating staff role changes and electronic health record functionality within safety-net clinics to address provision of tobacco cessation care. *Jt Comm J Qual Patient Saf.* 2019;45(12):798-807.

Flocke SA, Seeholzer E, Lewis SA, Gill IJ, Rose JC, Albert EL, Love TE, Kaelber D. 12 month evaluation of an EHR-supported staff role change for provision of tobacco cessation care in 8 primary care safety-net clinics. *J Gen Intern Med.* 2020 Nov;35(11):3234-3242.

Albert EL, Rose JC, Gill IJ, Flocke SA. Quitting the quitline: a qualitative study of patient experience of electronic referrals to quitlines. *BMC Public Health.* 2020 Jul 9;20(1):1080.

ACKNOWLEDGMENTS

This research was funded through PCORI Award IHS-1503-29879. The statements in this report are solely the responsibility of the authors and do not necessarily represent the views of PCORI, its Board of Governors, or its Methodology Committee. We acknowledge the support of all our project partners, including MetroHealth System, the Ohio Department of Health, and the Ohio Quitline provider National Jewish Health. We thank all MetroHealth care providers, staff, and patients who made this research possible. We wish to thank Georgene Bosich, RN; Jay Koren, RN; Versie Owens, MPA; and Teodoro Rosati for their outstanding contributions to this project.

APPENDICES

Appendix 1. AAC Process Description

AAC Rationale

Ask-Advise-Connect (AAC) is an approach to smoking cessation delivery in a primary care setting that has a great potential to reduce morbidity and mortality associated with tobacco use. Specifically, AAC is designed to serve as a process for routinely asking about smoking status, providing brief quit recommendations, and assessing the patients' willingness to quit. Among those expressing interest in taking action to quit, an offer to connect to cessation services is made, and acceptance (or decline) is recorded. Prior research has documented that an Ask-Advise-Connect approach increases the proportion of tobacco users who receive treatment from a Quit Line (QL, an evidence-based and cost-effective smoking cessation assistance service) by 13- to 30-fold, compared to the recommended standard of care.

AAC Process

At non-urgent primary care medical visits, when a patient's vital signs and screening questions occur, AAC engages the medical assistant (MA) or nurse to ask about smoking status and provide brief advice to quit in a manner consistent with the Clinical Practice Guidelines for Treating Tobacco Use and Dependence. Level of readiness is assessed, and for patients who express interest in taking action to quit, a referral to smoking cessation assistance is offered. A direct connection to the QL is made by clicking an EHR link that securely sends the patient's name and phone number; the QL staff then contact the patient within 24 hours. Patients contacted by the QL are invited to enroll for up to 5 telephone counseling sessions to prepare for a cessation attempt. Counseling is designed to develop problem solving and coping skills, secure social support, and plan for long term abstinence. Nicotine replacement therapy, if indicated, is offered, and with approval from the referring clinician, the NRT is mailed to the patient.

AAC intervention

The AAC intervention designed for this study consisted of 3 components: 1) establishing eReferral capacity to the Ohio Quitline, 2) revising EHR to facilitate discussion of tobacco use,

readiness to quit, and willingness to receive Quitline counseling, and 3) updating clinic staff roles and process through training and support in using the revised EHR.

eReferral capacity to exchange data between clinic and QL providers was established in the initial project phase.

Revising EHR: This work was done over the course of a year with substantial engagement from stakeholders to address the proposed fields for the project, existing fields and anticipated changes, new fields, location and nature of the buttons, wording of guiding information and the development of supporting / training documents reflective of the final EHR changes. The changes involved multiple iterations of development and testing before the pilot evaluation in the two clinical sites. Additional fields for smoking cessation readiness assessment were added to the EHR.

Role and process changes for medical assistants and nurses. Next, the clinical support stuff received training to expand their role to ask patients at each visit about smoking status, provide brief advice to quit, assess readiness, and (for patients interested in quitting) make an eReferral to smoking cessation counselors. Individuals who assess vital signs prior to the patient being seen by the clinicians were the focus of this intervention. Prior to the intervention, the MAs/nurses role involved asking about smoking status and documenting smoking history for those that smoke. The new role involved 4 steps: The first was asking the patient about their smoking status. The second step was, for smokers, providing brief advice using a phrase that was collaboratively written with the study team and medical assistant/nurse representatives. The phrase was: 'As a member of your health care team, I strongly recommend that you quit using tobacco'. The third step was to ask about the patient's level of readiness to quit in the next 30 days, and for those that indicated that they were interested in quitting now, the medical assistant/nurse offered to connect the patient to a coach or counselor that could assist them with quitting. If the patient indicated readiness to quit smoking now, the medical assistant placed an order that triggered a referral to either the quitline or to the Freedom from Smoking Program offered by the health system. At the time of this study, eligibility for free quitline services included being aged 18 or older with Medicaid insurance or no insurance, or a pregnant woman.

The features of the services provided by the Quitline for Ohio and for the Freedom from Smoking program offered at Metrohealth are detailed in the chart below.

Features of Quitline and Freedom from Smoking programs

	Ohio Quitline	MetroHealth Freedom from Smoking
Program Entry		
Methods of entry	eReferral Self enroll Website	eReferral Self enroll
Eligibility		
Insurance	Medicaid Uninsured	No restrictions
Diagnoses	Pregnant	No inclusion criteria
Call attempt protocol		
Contact timeline	First call attempt made within 24 hours	First call attempt within 5 days
Contact attempts	2 more call attempts made after 3 and 7 days	2-3 more call attempts within two weeks
Intake protocol		
Process	Asked intake questions (tobacco history, etc.) Offer to enroll in texting option Offer to enroll in web based program	Asked about preferred location
Counseling Program Plan		
Type Counseling	Motivational Interviewing	Motivational interviewing/Behavior change
Setting	Individual, over the phone	Group setting, in person
Frequency	Once a week (about 30 minutes)	Once a week, 90 minutes
Materials	Welcome packet (email or mail)	Workbook
Program completion	5 completed counseling calls	

		Must attend at least 6 out of 8 class sessions to be considered complete. (8 sessions over 7 weeks)
Nicotine Replacement Therapy (NRT)		
NRT type offered	Patch, gum, lozenge	Patch, gum, lozenge
When it is offered	Sent NTR sent after enrolling during first call	At session 4 (goal is to be smoke free by session 4, CO test session 5,6,7)
Quantity	Up to 8 weeks worth, 2 weeks at a time	Up to 4 boxes, 2 weeks at a time
Other programs offered		
Text	Text program: 2-3 motivational texts per day	
Web	Web-based program: tools and support in a personalized profile	
Follow-up		
After completion	Text program lasts 12 months after program completion	Participant is called 30 days, 90 days, 6 months and 1 year after program completion

AAC implementation

The AAC training used the model developed by Dr. Vidrine, who worked with the study team to adapt the training materials to align with the proposed changes to processes and systems. The ACC was implemented through training and feedback.

Training materials also included a 'Tip sheet' that was designed using the standard format for informing staff about EHR change or change in process that required documentation in the EHR. Approximately two weeks after the implementation, a research associate stopped by the practice to talk with individuals to learn how the process was going and to gather feedback about the EHR changes, the changes in role, and information about patient engagement.

Formal feedback provided by the study team consisted of a 1-page document showing clinic rates on each of the process variables for the month prior and for each of 3 months post AAC implementation. Information was shared in both tabular and graphic formats. Informal feedback from the clinic members was solicited to better inform the implementation process and to guide the refinement of documents, EHR functions and guidance, and additional training or informational needs. Field jottings were gathered and reported back to the larger study team. The team continued to provide feedback reports to the practice manager up to 6 months post implementation.

Launch Presentation: The AAC intervention launch sessions were comprised of three parts; a presentation, interactive training session, and introduction of a new Tip sheet. To make it convenient for the practices, each AAC intervention was scheduled during one of the practice's regular meetings times. Each launch began with a presentation that introduced clinical staff to the goals and rational of this systems change. The 20-minute presentation outlined the goal of the initiative, changes to the EHR interface and workflow and demonstrated how the MAs were to complete the new sections with a detailed description with screen shots of the new features in the EHR and the eReferral capacity, a description of the new role / steps for accomplishing the Ask-Advise-Connect strategy, and a period for questions.

New role for MAs/Nurses: This new AAC process also expanded the role of the clinical support staff. With this new system's change the MAs and Nurses were able to sign the order in the EHR, completing the eReferral process without depending on a physician. The original tobacco navigator section of the EMR required MAs to only ask about patient's tobacco use. The new AAC additions to the EMR furthered the role of the MAs by setting up a process allowing the MA to advise patients to quit using a "quit statement," assess patient readiness to quit in the next 30 days, and offer a connection to quit counselors via eReferral through the EMR.

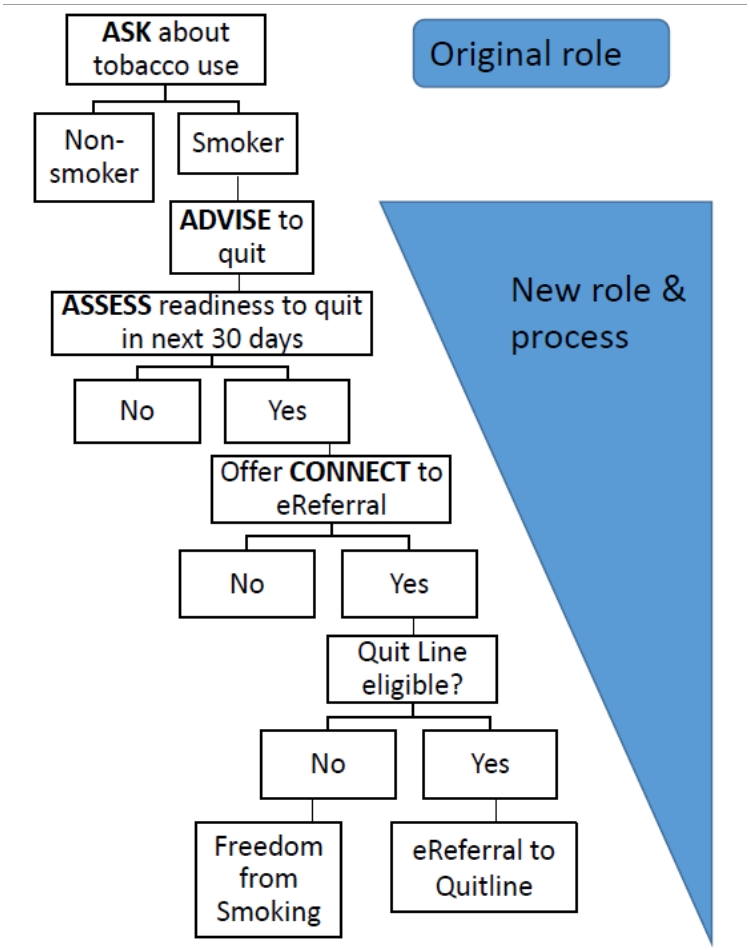
Following the presentation was a hands-on training session where the medical staff tried out the new sections and features of the EHR at computer workstations. Workstations were logged into the EHR test environment and staff worked with 6 patient scenarios designed to expose learners to different features. Each MA was given the opportunity to click through the intervention process with a virtual test patient in the EHR test environment. Patient cases included different levels of readiness to quit smoking and willingness to be connected to quitline counseling services. This was an opportunity for the medical assistants/nurses to see the exact EHR changes, what happened when different entries were clicked, how the order for the referral to the quitline appeared, and how to sign the order. This process generated questions, suggestions from the medical staff, and the opportunity for the study team to refine the instructions for the process and the process itself. After the launch session, the changes to the EHR were officially turned on at the Health Center and available for use immediately.

Strategy for implementation, Development of Tip Sheet: After the presentation MAs were provided with a Tip sheet, modeled after other EHR training documents, which showed step-by-step screen shots of the new sections in the EHR and how to properly complete each step. In this health system, it is a standard practice to distribute "Tip sheets" to clinical staff when changes are made in the EHR that will impact usability. The Tip sheet is a step-by-step guide that illustrates the exact changes to the flow and appearance of the EHR interface. To keep consistent with hospital practices, the study team developed a Tip sheet for the new tobacco navigator with the assistance of the EHR (Epic) Navigators, the team who typically designs Tip sheets for the hospital. The final draft of the Tip sheet was pilot tested for usability and evaluated by clinical staff before being used in the intervention.

Pilot: Before launching the AAC in the 8 community health centers, a pilot test was conducted at two additional practices within the same health system.

Follow-up sessions: Informal feedback for the AAC was assessed about 3 weeks after the initial launch. A member of the study team visited each practice to follow-up individually with MAs to collect feedback about the helpfulness, practicality, and ease of use of the new tobacco navigator. This time was also used to address questions and any user errors effecting the performance of the tobacco navigator.

Booster Sessions: Formal booster sessions took place at each community health center about 3 months after the initial launch. Each booster visit was scheduled for the first 5 minutes of a regularly scheduled staff meeting at the convenience of the practices. Study staff provided each practice with a feedback report with their clinic's data compared side by side to the other clinics in the intervention. Feedback was provided for areas that needed improvement, reminders were given, and new MAs who were not present at the initial launch training were invited to go through the EMR changes with a member of the study team to ensure understanding. This was also a convenient time to talk again one on one with MAs to address any questions or suggestions they may have had and to understand their feelings towards this system's change. MAs were also given new Tip sheets that illustrated any changes made to the tobacco navigator since the launch and new flyers with helpful reminders were posted around the clinic area.


ASK about tobacco use
Original role
Non-smoker
Smoker
ADVISE to quit
New role & process
ASSESS readiness to quit in next 30 days
No
Yes
Offer CONNECT to eReferral
No
Yes
Quit Line eligible?
No
Yes
Freedom from Smoking
eReferral to Quitline

Appendix 2. TMCP Description

TMCP Rationale

The Teachable Moment Communication Process (TMCP) is a communication strategy designed to engage patients in efficient discussions with their providers about quitting smoking. Grounded in primary care research and communication theory, the TMCP enables clinicians to attend to their patient's concerns while guiding the discussion to focus on assessing, and being responsive to, the patients' readiness to quit smoking. This strategy both identifies and refines the process through which teachable moments unfold naturally. The TMCP provides pragmatic, feasible methods for eliciting a patient's readiness to quit using tobacco, and for responding in a way that is appropriate and aligned with that readiness. TMCP enables clinicians to leverage patients' own concerns in a tailored, partnership-oriented, and efficient health behavior change discussion that is integrated into the flow of patient care.

TMCP process

TMCP has 5 main communication elements in which a clinician: 1) identifies a patient's salient concern, 2) links the concern to tobacco use, 3) provides brief cessation advice, 4) assesses the patient's readiness to quit, and 5) responds in alignment with the patient's readiness. In providing brief cessation advice, TMCP calls for clinicians to convey concern, express optimism and partnership, and recommend quitting tobacco. The goal of this approach is to improve the likelihood of positive patient behavior change while also maintaining the clinical relationship between provider and patient.

A central aspect of this teachable moment approach is eliciting an honest assessment of the level of readiness for cessation from the patient, and responding with assistance that is aligned with the patient's readiness. The approach draws on other health behavior change strategies including solutions focused therapy and motivational interviewing. The TMCP is distinct in that it is very brief and is designed for a context where discussing smoking is not the primary reason bringing the clinician and the patient together. Further, with the TMCP, the way in which the smoking talk is initiated is opportunistic and fits the flow of addressing multiple problems during a primary care visit.

TMCP intervention

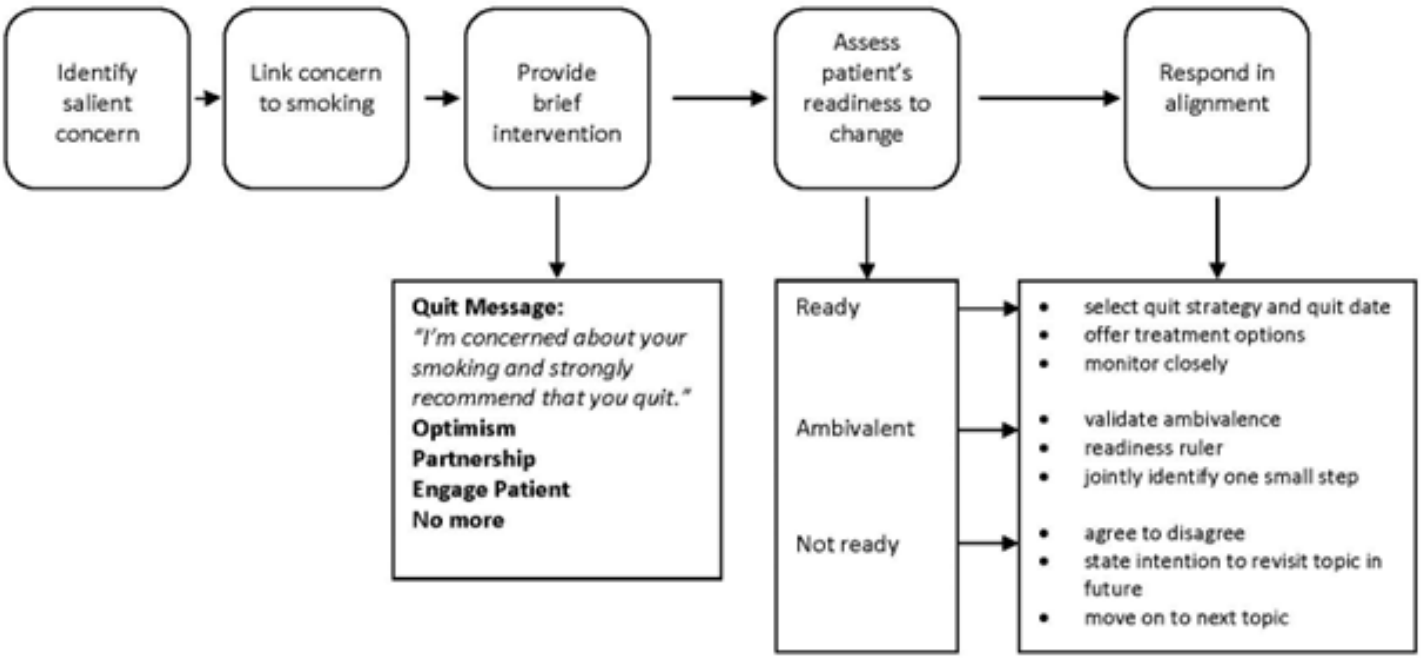
The TMCP intervention format consisted of a 50-minute web-based training module, which clinicians completed in their offices at computer terminals, followed by 90 minutes of skills practices with Standardized Patients (SPs), which took place in the practices' exam rooms.

Web-Module: The research team developed the script for the training and worked with a production company to create a video module consisting of didactic content, actor-portrayed examples of provider-patient interactions, and self-assessments of learning. The content of the module was based on previous research in which the TMCP intervention was implemented in person over two, 3-hour sessions. A standardized teaching guide had been developed to ensure fidelity over multiple interventions, and this guidebook provided the template for the training module content.

The TMCP consists of five elements. It begins with identifying a patient's salient concern, and then linking this concern to smoking behavior. Smoking is portrayed as germane to the patient's salient concern and as problematic. Next, the clinician provides a brief quit message that conveys concern for the patient: 'I'm concerned about your smoking and strongly recommend that you quit'. This is followed by OPEN, a mnemonic representing Optimism, Partnership, Engage, and No more (i.e., stop and listen to what the patient has to say). OPEN information is presented in a sentence or two that includes an expression of optimism that the patient is able to quit and offers the clinician's partnership towards this end. Engaging the patient involves asking an open-ended question about the patient's thoughts about quitting smoking, and encourages the patient to reveal their level of readiness in the patient's own words. Finally, responding in alignment with the patient's expressed readiness to change increases the likelihood that the clinician's response and proposed plan are acceptable to the patient, and reinforces a positive partnership. The goals of responding in alignment for someone who is ready to change included jointly identifying a quit strategy and a quit date, and monitoring closely through phone calls or office visits. For the patient who is ambivalent about change, the goals are to validate the ambivalence that the patient feels about changing behavior and jointly identify one next small step. For the patient who is not ready to quit, the goal is simply to maintain a relationship that facilitates future discussion about smoking. The overall approach

promotes a brief yet effective technique for discussing smoking cessation that both protects and takes strategic advantage of a positive clinician-patient relationship.

Schematic of the Teachable Moment Communication Process.



Training standardized patients: The study team recruited and trained standardized patients (SPs), all of whom had prior SP experience. SP training involved an overview of the TMPC intervention objectives and format, and focused training on the concepts of a salient concern and levels of readiness to change. The bulk of instruction centered on enactment of patient scenario scripts where the SPs were required to convey a salient concern and a specific level of readiness to change. Scripts for the key elements of the cases were developed, read out loud, refined and then rehearsed using role play with a trainer.

Development of cases: Scenarios were based on actual primary care cases from a previous study conducted by the primary investigator. Scenarios were designed to highlight a reason for the visit, a salient concern (which could be different from the main reason for the visit), and a

level of readiness to change smoking. More than 25 cases were developed and 14 were ultimately selected and used for the intervention.

TMCP implementation

The web module taught clinicians: (1) the skills necessary to recognize and foster teachable moments in clinical encounters, (2) strategies to effectively elicit the patients' perspective on health behavior change, and express their alignment with that perspective, and (3) the ability to respond to the patient in a non-confrontational manner while providing brief advice appropriate to the patient's expressed level of readiness to change.

Skills Practice: Following the completion of the web-module, the providers re-grouped with the research team to 1) debrief about the training module 2) introduce the skills practices. Skill practices were included in the intervention as a way to learn behavioral enactment of each skill. Skill practices took place in the exam rooms at the intervention clinic, and involved the provider, a training coach, and an SP working together. The SP had been trained to present a specific, realistic scenario to the participant that highlighted each TMCP component in order of presentation. The participant was provided information about the SP's character, such as age, sex, and smoking history. Both participant and SP were instructed as to the objective of the reenactment. The training coach's role was to observe, keep the task was on track, and provide feedback to the participants. Trainers used a checklist of TMCP skills as a guide for providing additional insight. After each skill practice, the training coach and SP rotated to the next room to work with the next clinician. This process repeated, rotating through 6-8 new scenarios.

EHR with Test Patients: As part of the skills practices, in an effort to create a more realistic experience, 'test patients' were created within the EMR for each SP visit.

Appendix 3. Participant Consent Process

eReferral and Teachable Moment Project

Tobacco Cessation Patient Survey Consent Process

Q1a. You are being asked to participate in a research study at MetroHealth about using primary care teams to assess tobacco use. Your involvement will include completing a short survey, which will take about 5 minutes. It will include questions about the way tobacco use was assessed by the medical technical assistant, nurse or doctor from your most recent visit.

This is a research study and participation is completely voluntary. You have the right to skip any questions that you do not wish to answer, or to stop your participation at any time.

All information collected on the survey is confidential and will not be shared or reported in a way that it would be possible to identify a participant. Your responses will not be shared with your doctor or nurse. Although strategies to protect the data are in place, a rare risk of breach of confidentiality exists.

Participating in the study will help researchers improve the effectiveness and patient-centeredness of tobacco cessation assistance to patients who smoke. Upon completion of this survey you will receive a $10 gift card to Target or Amazon.

A decision to not participate in this study will not affect your medical care or result in any loss of benefits to which you are otherwise entitled. If you are an employee or student, your decision to participate or not will not impact your employment or scholarly standing.

If you have questions about any part of the study now or in the future or if you wish to communicate concerns or a complaint, you should contact the Study Coordinator who may be reached at 216-368-8908. If you have any questions about your rights as a research participant, or if you wish to express any concerns or complaints please contact the MetroHealth Medical Center's Institutional Review Board (which is a group of people who review the research to protect your rights) at 216-778-2021.

By completing this survey, you are agreeing to participate in the study. If you do not wish to participate in the study, then simply do not complete the survey. If you have already participated, we thank you. You may only participate once.

Accept / Do Not Accept

(Each participant is required to select Accept or Do Not Accept. If Do Not Accept is selected, then the following question will be displayed)

Q1b. Are you sure you do NOT want to participate in the study?
I do NOT want to participate / I would like to participate

If I would NOT like to participate is selected, the following message will be shown: We thank you for your time spent reviewing the guidelines of our study. You selected not to be included and have not been entered in our research study. Thank you.)

Appendix 4. Tobacco Cessation Patient Survey

MetroHealth

eReferral and Teachable Moment Project

Tobacco Cessation Patient Survey

Note: Q1. was regarding participating in the study (See Participant Consent Process Document)

Nurse Communication:

Q2. Thinking about your recent visit to [NAME OF CLINIC], did the nurse talk with you about smoking?
Yes / No

(If no, skip to question Q5)

Q3. Thinking of that discussion about smoking with the nurse:

1.) Were you asked whether or not you smoked now or in the past?

Yes / No

2.) Were you asked by the nurse about your interest in quitting?

Yes / No

3.) Were you advised to quit smoking?

Yes / No

4.) Were you offered help to quit smoking?

Yes / No

Q4. Thinking of that discussion about smoking with the nurse, how would you rate the nurse on the following qualities?

	Poor	Fair	Good	Very Good	Excellent
1.) I was treated with respect.	1	2	3	4	5
2.) I felt listened to.	1	2	3	4	5
3.) I was able to honestly speak my mind about quitting.	1	2	3	4	5
4.) My opinion about quitting smoking was treated with respect.	1	2	3	4	5
5.) Things were explained in a way that I could understand.	1	2	3	4	5

Doctor OR Provider Communication:

Q5. Thinking about your recent visit to [NAME OF CLINIC], did your doctor talk with you about smoking?
Yes / No

(If no, skip to question Q7)

Q6. Thinking of that discussion about smoking with the doctor, how would you rate the doctor on the following qualities?

	Poor	Fair	Good	Very Good	Excellent
1.) I was treated with respect.	1	2	3	4	5
2.) I felt listened to.	1	2	3	4	5
3.) I was able to honestly speak my mind about quitting.	1	2	3	4	5
4.) My opinion about quitting smoking was treated with respect.	1	2	3	4	5
5.) The discussion about smoking was helpful.	1	2	3	4	5
6.) Things were explained in a way that I could understand.	1	2	3	4	5
7.) I am open to discussing smoking with this doctor in the future.	1	2	3	4	5

Tobacco Cessation Resources:

Q7. At your recent visit to [NAME OF CLINIC], were you referred to a resource or program to help you quit smoking?

Yes / No

(If no, stop the survey is complete)

Q8. Did you accept the referral for help to quit smoking?
Yes / No

(If no, skip to Question Q11)

Q9. Do you intend to talk with the tobacco specialist when he or she calls?
Yes / No / Not sure

Q10. Are you clear about what is going to happen next in regard to helping you quit?
Yes / No / Not sure

Q11. Did this referral make you feel like your primary care team is leaving you behind? Yes / No / Not sure

Q12. Did this referral make you feel supported by your primary care team?

Yes / No / Not sure

Thank You / Automatic Redirection to Incentive Survey:

Thank you for taking the time to participate in our survey; it is now complete.

When you click next, you will be redirected to a page to gather contact information so we can send your gift card. Any contact information you provide will only be used for the purpose of sending the gift card.

Back / Next

Appendix 5. In-depth Interview Approach

Overall study frame

The in-depth interviews were Aim 3 part of the project and they addressed the experiences of patients referred to Quitlines. Briefly, the study intervention included making changes to the electronic health record (EHR) and expanding medical assistants' (MA) roles to facilitate the documentation of the patient's tobacco use, readiness to quit, and willingness to be connected to a QL counselor. If the patient was interested in being connected to a QL counselor, the MA placed a EHR referral order which sent a secure message to the QL provider, prompting a proactive call to the patient to invite them to enroll in counseling sessions.

Quitline e-referral process

The procedures of the QL e-referral process are detailed in the main document and study protocol. Briefly, The QL e-referral process begins with the identification of all smokers seeing their primary care provider for a routine visit. The MA is the individual who rooms the patient and goes through a preliminary set of questions, including whether the patient is still smoking. If the patient answers affirmatively, the MA was instructed to provide brief advice to quit, and to assess whether the patient was interested in receiving assistance for smoking cessation. If the patient answered 'yes', the MA electronically sent a referral to the Ohio Quitline. Once an electronic referral was sent to the QL, the QL attempted call the participant within 24 hours. Counselors at the QL make 5 attempts to contact referred patients over the course of 2 weeks. If no contact is made, that participant is considered 'unreachable'. If contact is made, the participant can choose to 'decline' or 'enroll' in the program.

During the first QL call, the participant goes through a short intake process before the counseling begins. The intake portion of the call involves gathering demographic information about the participant and their history of smoking, including asking questions about which tobacco products they use, how often they use tobacco, past use of medications and nicotine replacement therapy (NRT), and any past quit attempts. Participants are also given the opportunity to enroll in receiving self-help text messages, mailed information, and other tools to help them quit. In order to receive NRT the participant must be willing to enroll in the QL and make a quit attempt in the next 30 days. They must also be 18 years of age or older, must not be pregnant, and must not have medical issues that would interact with the NRT.

Once enrolled, the QL provides five counseling session calls (the first one can be during the enrollment call if the patient agrees). The QL makes three attempts to reach the patient for each counseling call, and leave messages if the patient does not answer his or her phone. Participants are able to provide the QL with best times to call. After enrollment, participants can choose to disenroll either by formally declining further participation or becoming unreachable, and may do so either initially or after one or more counseling sessions. Participants who complete all five counseling calls are considered to have completed the program. The interviews conducted for this study could occur at any point along the engagement timeline.

Sampling

Monthly QL data was requested from National Jewish Health and included variables pertaining to the patients' progress through the QL program, such as QL enrollment status and reason, number of coaching calls, and nicotine replacement therapy orders. This data was then linked using a unique study identifier with data from the MetroHealth EHR to get patient characteristics including age, gender, race/ethnicity, and insurance type. From this combined data, patients were then divided into three QL outcome categories: enrolled participants had completed the enrollment process had had some counseling; dis-enrolled patients had previously been enrolled but subsequently completed the program, declined further participation, or were unreachable; not enrolled participants were those who had never been enrolled due to either declining when the QL called, or being unreachable. In order to reduce recall bias, patients with the most recent office visits were selected from each of the three categories for recruitment. This resulted in a sample of patients who were at varying stages of the e-referral to QL process. (need to better convey/clarify this)

Recruitment

Patients selected for recruitment were first sent an email or postal letter notifying them that they may be eligible to participate in a study and that a study team member would contact them by phone. The study team made multiple attempts to reach participants to invite them to participate. If there was no answer a brief message with a return number was left and study team attempted calling participants back at their preferred time.

Data collection

Patients who agreed to participate were interviewed by one of two study team members, both of whom were trained in conducting in-depth interviews. The interviews were conducted using a semi-structured interview guide. The first iteration of the interview guide consisted of questions written to elicit participants' thoughts on the electronic referral process and interactions with clinical staff and QL counselors. The participants were asked specifically about their experience with the MA during the referral process, why they decided to accept or decline the referral, their experience interacting with the QL, and their thoughts about using nicotine replacement therapy and medications to help them quit. After several interviews, the interview guide was modified to include additional probing questions to try and understand what was most helpful in their interactions with the QL, why some participants remained unreachable by the QL, or why some participants declined contact with the QL. During the interview, the individual's current smoking status and their current engagement with the QL were noted. Additional questions inquired about participants' practice of answering 1-800 phone numbers, their expectations of what would happen after the referral, and if they remembered seeing their after-visit summary showing the phone number for the QL. More questions about the participants' past history of smoking were also added to provide more historical context to participants' current progress or barriers with quitting. Interviews lasted between 9 and 34 minutes, with an average of 18 minutes, and were audio recorded. Data collection took place between September 2017 and August 2018.

Analysis approach

All interviews were transcribed verbatim. We used a phenomenological approach in our data analysis in order to understand how people make meaning of their lived experience and to develop a deeper understanding about the common features that are shared among individuals who agreed to be connected to the QL.[19] Analysis began with careful and repeated reading of several transcripts by three trained analysts to identify salient themes of the QL referral process. Based on this initial round of thematic analysis, an initial set of coding categories was created. As additional transcripts were read, the coding categories were modified as necessary to better fit the themes that emerged.

Next, two of the analysts each independently coded all 55 transcripts, meeting regularly to discuss coding, and reach consensus on any discrepancies. Additionally, the two analysts met with a third analyst to review and discuss emerging themes. Interviews were conducted until the point of data saturation was reached for each of the QL final disposition categories (program complete, declined, and unreachable).

Disclaimer:
The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

Acknowledgment:
Research reported in this report was funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Award (#IHS-1503-29879-IC). Further information available at: https://www.pcori.org/research-results/2015/adding-teachable-moment-approach-team-based-primary-care-ask-advise-connect