Using a teachable moment communication process to improve outcomes of quitline referrals

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Project summary

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 test a systems-based approach that engages the medical assistant that assesses 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 smoking cessation care to disadvantaged patients using an Ask-Advise-Connect (AAC) systems-based approach, 2) Test the effect of combining the clinician-based Teachable Moments 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 healthcare system and eight primary care clinical sites with two 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 is 40% Medicaid, 23.9% Medicare, 6.1% uninsured and 30% commercially insured. The AAC strategy involved changes to the electronic health record (EHR), a new role for medical assistants 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 in the TMCP, an approach to counseling patients to quit tobacco aligned with patient readiness. Generalized linear models tested the effect of interventions on immediate outcome measures of process, including delivery of advice, offer 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.

Rationale & background information

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 supports for quitting smoking.[1-5] Therefore, implementing and evaluating strategies that work for socially and economically disadvantaged populations is a high priority. Among U.S. 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 addressing tobacco cessation are generally underused.[7] New healthcare policy initiatives, requiring assessments of tobacco use and assistance to quit, call for 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 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] Yet, success rates increase when QLs proactively call patients after receiving a direct clinician referral (by fax or electronically).[19-23] Still, clinicians underutilize direct referrals,[24] potentially due to low integration of the referral system into the office workflow.[24] Research demonstrates the feasibility of closed loop electronic referrals using the electronic health record (EHR)[25] for connecting with QLs. The advantage of eReferral 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 patient's readiness for a change.[26-29] These approaches are feasible, complementary and have the potential to be integrated into a health system to improve sustainability.

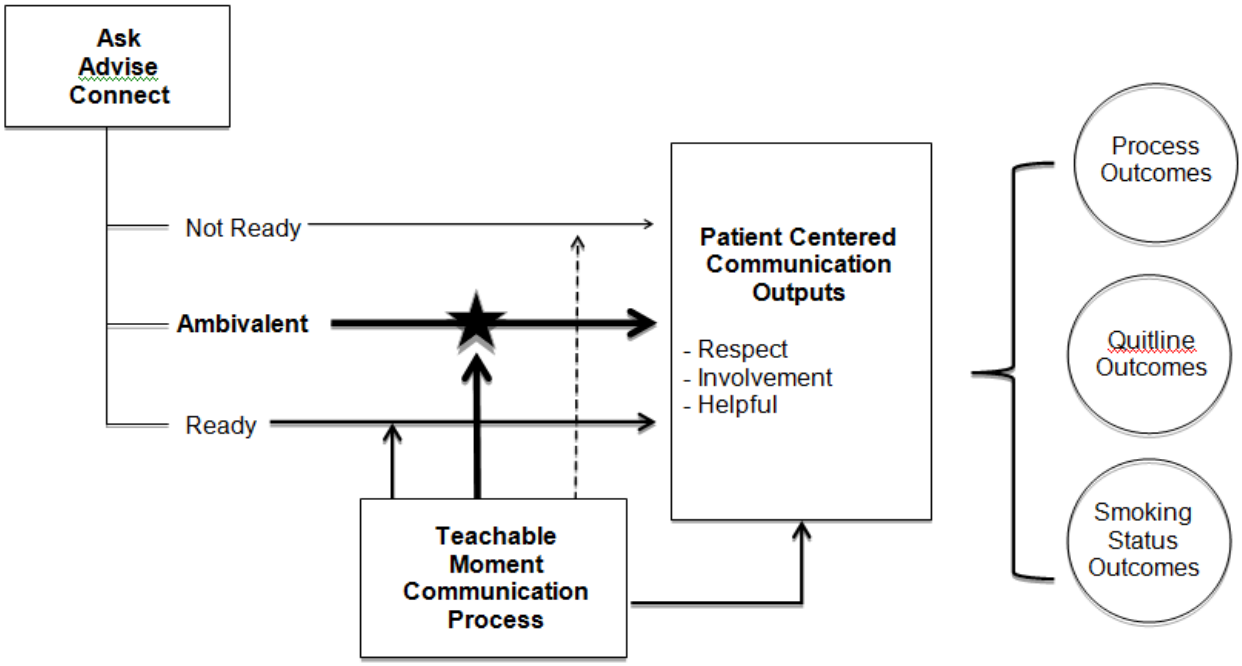
Ask-Advise-Connect (AAC): This proactive, direct messaging EHR-to-QL referral approach has been shown to increase the number of tobacco users receiving QL treatment by 13- to 30-fold.[30,31] However, a major drawback of AAC is a low rate of contacting referred patients. Prior studies found that the QL was able to contact less than 42% of referred patients. This poor contact rate diminishes the sustainability of the approach, and is likely due to referring patients inappropriately, ignoring cessation readiness.[25,32,33]

In this study, we assess the patient's readiness to quit and willingness to be connected to the QL prior to making an eReferral, thereby assuring 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 a design that is fully integrated and sustainable in a clinical practice. In this study, we train MAs/nurses to implement the AAC, and modify EHR functionality to facilitate an eReferral, thereby providing a more sustainable approach.

Teachable Moments Communication Process (TMCP): With the TMCP, smoking talk is initiated in an opportunistic way so that it fits into the flow of addressing problems during a primary care visit. In providing cessation advice, 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 the TMCP interventions have mutually complementing strengths, and their combined implementation might 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 about readiness to quit, and given the opportunity to receive assistance. Since it is a part of every office visit, the AAC can reach a large percentage of patients. The TM intervention, in contrast, is situation-specific and driven by identification of and clinician action on a salient concern that arises during the visit. By leveraging concerns that are salient to the patient, the TMCP can activate patients to move forward along the readiness to quit continuum. It also reinforces the value of quitting by incorporating clinician advise to quit, which has been shown to increase quit rates.[22] If implemented together, these intervention 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 (i.e., 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 towards cessation.

Figure 1. AAC and TMCP conceptual model



Study goals and objectives

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

Study Design and Timing. This study involves two interventions. This report is focused on the TMCP intervention and the AAC information is provided for context. The full report will be publically available on the PCORI website after the 12-month embargo period passes.

The AAC was conducted first at the clinic-level and the TMCP was conducted second at the clinician-level. It also includes qualitative data collection to complement the quantitative evaluations. Figure 2 illustrates the three main data collection sources (EHR, patient surveys, and in-depth interviews) and the three time 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 of the clinics' exposure to the interventions. This design allowed us to test the additional impact of TMCP beyond the gains realized via AAC across all of the clinics by the end of the step-wedge implementation. On a rolling basis, data collection indicated the intervention exposure statuses for each clinic and assessed visit level process outcomes.

Figure 3 provides more detail about the timing of the AAC and the TMCP intervention implementation 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 seven 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 pre- and a period of post-training could be defined for each clinic. Approximately 6 months after the implementation of the AAC in the last site, the TMCP intervention was implemented, again in a stepped pattern.

For the TMCP, the eight 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 and using this list, as a site number came up in the random list it was assigned the next sequential time point. We encountered two anomalies with randomization of the sites. First, after implementing the AAC intervention, the site that was randomized to receive the TMCP training first lost their practice manager. MetroHealth requested that we delay the implementation of the TMCP in that site due to challenges with daily operations 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, one 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. 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 one of the three defined study conditions varied but is accounted for in the analyses.

194 Figure 2. Schema of data collection time points (for EHR, surveys, and in-depth interviews) across all
195 sites.

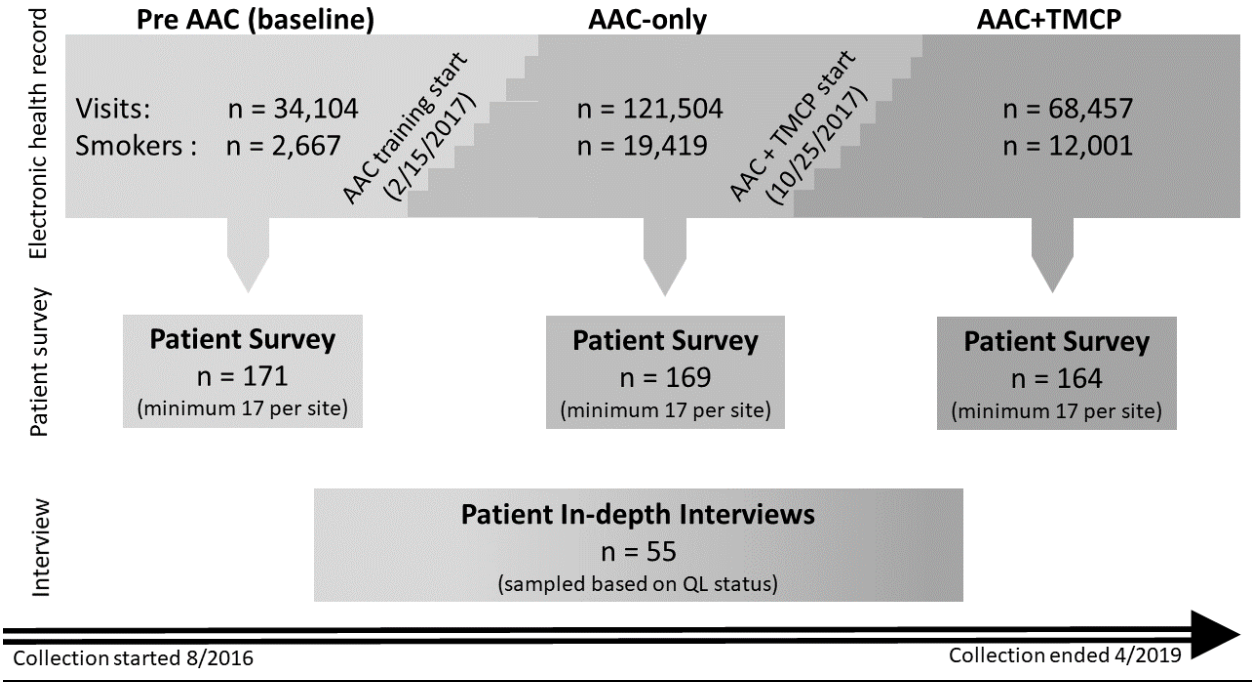


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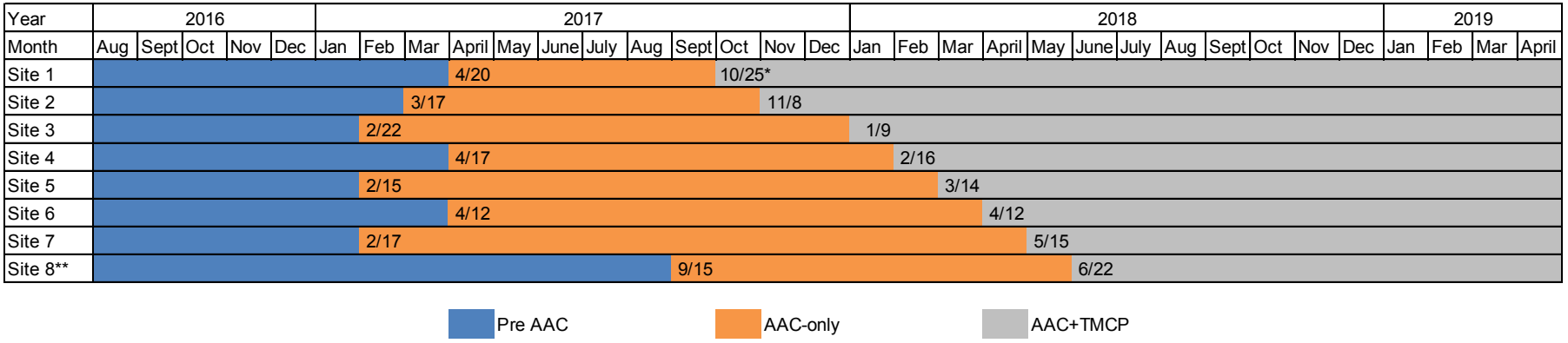
Figure 3. AAC and TMCP intervention implementation dates and periods of time before, between and after interventions for each site.



* Due to technical problems for some clinicians, a second TMCP implementation date was conducted on 11/2

** This site was added to replace a site that had been randomized and received the AAC training, but closed shortly after AAC training.

Research methods

Participating sites and randomization

Eight community-based primary care practices in a large safety-net healthcare system in Cleveland Ohio participated in this stepped wedge comparative effectiveness study. Using a random number list generated by the study analyst, the sites were randomized to separate intervention time points (1-month intervals) in which all clinicians (MD, DO, NPs) who spend 40% or more of the work week providing patient care were scheduled to attend the TMCP training. The health system requested that the intervention be implemented first in one site. The remaining 7 sites followed the randomization procedure. The principal investigator informed each clinical director of the site's assigned time point and scheduled a training date.

Prior to the baseline period for this study, all eight clinics engaged in an AAC system change initiative to improve the provision of tobacco cessation support.[16] The systems change engaged MAs/RNs to use an EHR supported AAC strategy. The MA/RN role, which normally included Asking about tobacco status, expanded to: 1) Using a brief scripted phrase, to Advise those who use tobacco to quit; 2) Assessing interest in quitting tobacco in the next 30 days; 3) for patients interested in quitting now, asking if they would like assistance to quit from a coach or counselor; and 4) for those choosing assistance, Connecting the patient by an electronic referral (e-referral) sent to either the Ohio Quitline (QL) or to the in-house Freedom from Smoking (FFS) program. Eligibility for free QL services included being aged 18 or older with Medicaid or no insurance, or being pregnant. The QL included up to 5 telephonic counseling sessions and access to web and online chat support. The QL offers nicotine replacement therapy (NRT), if indicated, and with approval from the referring clinician, the NRT is mailed to the patient. Individuals not eligible for the QL were referred to the in-system FFS program – an in-person 8-session group tobacco cessation class offered by the healthcare system. The EHR automatically assessed patient eligibility with payer data and generated the correct referral order in a

process that was seamless for both the MA/RN and the patient. The AAC serves as the comparator for the TMCP.

TMCP Training Implementation

The TMCP intervention included a 50-minute web-based module that clinicians completed on office computers, followed by 90 minutes of skills practices with Standardized Patients (SPs) in the practices' exam rooms. Trainings were conducted at the practice sites during a clinical work day with cancellation of 2.5 hours of clinical activity to accommodate the training.

Web Module

The web module, based on our previous work,[14] consists of: 1) didactic content describing the TMCP rationale and process; 2) actor-portrayed examples of provider-patient interactions in each step of the TMCP; and 3) learning self-assessments. During the web module, clinicians were asked to interact with the content by repeating certain phrases aloud and thinking about and then saying aloud how they might respond to a patient with a specific level of readiness. Self-assessments (i.e. quizzes) were integrated after each major learning topic. After each question was answered, the clinician was provided with the reason why the response was either correct or incorrect.

The training included skills practices for clinicians to learn each TMCP skill through enactment. Skills practices took place in the clinic exam rooms, providing a realistic setting. The clinician participants rotated through 6-8 different scenarios played by SPs. The SPs were actors with prior SP experience and received five hours of training specific to this study. Each SP was trained to act out two unique 'case scenarios' that they would routinely play in the skills practices. For each skills practice, the clinician was provided basic SP information, such as age, sex, and smoking history. Skills practices were observed by study team members that served as coaches to provide feedback and additional training in technique. Coaches used a checklist of TMCP skills to insure complete assessment and to guide

feedback. Each SP case was also created as a test patient in the EHR so that clinicians could practice using the TMCP document flowsheet with each SP, as described below.

Development of document flowsheet

Document flowsheets are EHR tools used to document information in a structured manner. The TMCP flowsheet outlines the steps and phrases for the TMCP for clinicians to use as a guide with patients, eliminating the need to memorize each sequential TMCP step. The flowsheet is also a simple standardized tool to record patient responses with minimal clinician effort. With this tool, both the delivery of TMCP and the recording of patient information are done simply and result in retrievable records for future care.

During the skills training each clinician was shown how to use the TMCP flowsheet and had it added to his/her EHR tool shortcuts. Clinicians were asked to use the flowsheet during the skills practice scenarios to gain experience and comfort with its features. As needed, coaches could address any difficulty clinicians had using the flowsheet during the feedback period after a skills practice. An EHR tobacco cessation order set could be used by providers to order tobacco cessation medication and to order QL or FFS classes and was also reviewed during skills practice.

Debriefing about the training and follow-up

Following the completion of the web-module and the skills practices, the providers re-grouped with the research team to debrief about their experiences. Feedback on format, length of training, processes, content etc. were discussed as well as the perceived value overall. Approximately one month after the TMCP training participating clinicians were sent follow-up messages through the EHR that 1) offered reminders about the TMCP, 2) encouraged clinicians to use the TMCP, and 3) provided instruction for using the tobacco cessation flowsheet. Clinicians were invited to respond to messages with questions and or feedback.

Study sample

The study sample consists of eight sites, 60 clinicians from those sites and all adult patient visits during the study period. Figure 3 shows the timing of the training and implementation of the TMCP interventions at each of the eight study sites. Study data collection began August 2016 and concluded April 2019. One of the original eight clinics that received the AAC training closed shortly afterwards. A replacement site (#8) was identified from a similar neighborhood, and the original clinic was excluded from all analyses. The replacement site 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 the implementation of the AAC and the implementation of the TMCP intervention.

Measures

Clinician characteristics gathered from the health system included: sex, degree (MD, DO, NP), specialty and years since last clinical training. Patient characteristics including sex, race, ethnicity, insurance type and smoking status, were drawn from the EHR.

TMCP-specific variables include training participation, online learning module completion and quiz score. Use of the TMCP flowsheet by clinicians during visits was measured for 6-months after training to indicate use of the TMCP. Clinician's documentation of any portion of the TMCP flowsheet was counted as 'use'.

Outcome measures include contact by the QL or FFS among those patients that accepted a referral and provision of brief advice. Secondary outcomes include medication orders (i.e. varenicline, bupropion or nicotine replacement therapy) enrollment among those referred to cessation support (QL or FFS), and quit attempts. For this study, a quit attempt is defined as a change in smoking status from current smoker to former smoker and documentation of a quit date in the EHR. Quit attempts are evaluated for all smokers.

We report the rates of Ask, Advise, Assessment of readiness to quit and acceptance of a referral (Connect) to tobacco cessation assistance for the AAC intervention (AAC only) period and the time period after the TMCP intervention (AAC+TMCP). Each of these indicators is measured from discrete fields in the EHR. As shown in Figure 1, the timing of the AAC and the TMCP intervention implementation and the time periods between the two interventions varied.

We assessed patients' experiences with the clinic's processes. The survey samples included at least 17 smokers from each of the eight sites for the AAC only and the AAC+TMCP study periods. Patients who attended a primary care visit during a specified period were invited to complete the survey by web or phone, depending on the participant's preferred contact method. The survey included 11 items about being treated with respect, feeling listened to, and whether the advice was helpful. Responses were measured using a 5- point Likert scale rating from excellent to poor.

Statistical analyses

We describe clinician characteristics and patient visits during the study period, and participation in the training and uptake of the TMCP as documented by flowsheet usage. Analyses compared adjusted rates for the AAC+TMCP intervention to AAC only period using a generalized estimating equation (GEE) approach, with robust 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) at each time point, incorporating random practice site and clinician effects. Three analyses were conducted: 1) intent to treat, 2) per protocol (i.e. clinicians that participated in the TM training), and 3) per documented use of the TMCP approach in a visit. We report rates of performance, odds ratios (OR) and 95% confidence intervals (95% CI). We used 10% as a minimally important difference. Data analyses were performed April 2019 - August 2020. Because this was an educational intervention for clinicians, all of whom ultimately received the training, neither the clinicians nor the study team could be blinded to the group assignment; this design also made it impossible to blind the analyst to group assignment.

Safety considerations

This is a minimal risk study and involved clinicians participating in an educational intervention to improve communication skills to address tobacco cessation. Maintaining confidentiality of identifiable data for study participants was the primary study consideration.

Follow-up

Follow up for adverse effects of the intervention are not applicable. Performance feedback reports were provided at 1, 2, and 3 months post training and provided an outlet for participating clinicians to contact the study staff with questions or comments.

Quality assurance

Fidelity of the delivery of the Teachable Moment intervention was maximized by using a web-based learning module, extensive training of the standardized patients and the coaches and routine debriefing after each training session. Close monitoring of data allowed us to quickly identify and resolve problems (e.g. systematic data entry omissions). A check for data inconsistencies during the analysis phase included checking the range and distribution of all variables and identifying and resolving potential errors. We expected minimal missing data (less than 2%) on the variables collected from the EHR. Missing data on patient surveys in our preliminary studies was negligible (less than 1%). We followed similar principles to maximize participation and survey completion. Those principles include keeping the survey short, topic-focused, a reading level of 6th grade or less, clear and acceptable wording of items and response categories per cognitive interviewing and pilot testing, and a clear introduction of the relevance of the measure to the potential participant. The anticipated small rates of missing data will be handled through imputation strategies that take missingness patterns into account. Given that this is an educational intervention for clinicians, a data safety monitoring board was not necessary for this clinical trial.

Expected outcomes of the study

This study will contribute to understanding the effectiveness of a health system-wide change in the way discussion about tobacco cessation during a medical encounter is documented, and potential gains from a patient-centered method of delivering tobacco cessation assessment and advice. The potential benefits of improved documentation and patient-centered approaches could improve patient outcomes such as chronic disease maintenance and lower incidences of some cancers and heart disease. Widely implemented, these changes are likely to improve medical practice through more efficient patient counseling and better systematic documentation of tobacco cessation service delivery.

Dissemination of results and publication policy

We will use traditional channels of dissemination including scientific journal publications, presentations at national professional association meetings, and data briefs. These findings will be of particular interest to health services researchers, primary care audiences and tobacco researchers. We also anticipate disseminating other products from this work. Examples of other products that will be prepared for dissemination include training modules, trainer's guide, and workbooks for the TM intervention. The team will use a dissemination tool to facilitate identification of product, audience, priority and modality of dissemination. Authorship will follow OHSU and MetroHealth / Case Western Reserve University guidelines for lead author, co authors and acknowledgements for contribution to the work.

Duration of the project

The duration of the intervention phase of the project is detailed in Figure 3. Prior to the start of the first intervention the study team focused on developing and pilot testing EHR tools and trainings. During the active intervention period activities included data acquisition, analyses and generating findings for each of the study aims. Data analysis and manuscript writing followed the conclusion of data collection and continuing beyond the funded study period.

Problems anticipated

We anticipate encountering technical challenges over the duration of the study as the EHR routine upgrades which are now conducted on a 6-month timeframe have the potential to break links and disrupt new features that are established to support this intervention. Routine checking of functionality and monitoring data will help identify problems so they can be resolved quickly.

Project management

Primary Investigator, Dr. Flocke, (Health Services Research, Implementation and Dissemination Research, Preventive Medicine), will lead all aspects of this initiative, and, in collaboration with the co-investigators and stakeholder team, will facilitate the generation of manuscripts and other materials for dissemination from the project. Eileen Seeholzer, MD, MS, Co-Investigator and MetroHealth Site PI, is currently an Associate Professor of Medicine at the Center for Healthcare Research and Policy, and has training and expertise with system change and quality improvement. She will serve as the key liaison with partners at MetroHealth and will work closely with the Information Systems team and primary care clinics. She will contribute to all aspects of the study and dissemination of findings. Thomas Love, PhD, Co-Investigator is a Professor in the Department of Medicine, Epidemiology and Biostatistics at CWRU and will lead the quantitative analysis. Steven Lewis, MS, MBA will work closely with Dr. Love and is responsible for data management and analyses. Dr Love and Mr. Lewis will contribute to the generation and interpretation findings and dissemination of study products. David Kaelber, MD, MPH, Co-Investigator is an Associate Professor of Internal Medicine, Pediatrics, Epidemiology and Biostatistics. He is the Chief Medical Informatics Officer (CMIO) at MetroHealth, and Director or the Center for Clinical Informatics Research and Education. Dr. Kaelber will contribute to the study design, intervention features specific to the EHR and will contribute to the interpretation and dissemination of findings. Elizabeth Albert, PhD is a medical anthropologist and qualitative expert. She is the lead qualitative analyst, leads the adaptation of the TMCP intervention to a web-based platform, leads the training and

management of the standardized patients and the coaches and will contribute to the interpretation of findings, writing of manuscripts, and dissemination of findings. Jeanmarie Rose, MBA serves as a research assistant who is responsible for contributing to the qualitative and survey data collection and analyses, study regulatory reporting, and will contribute to the interpretation of findings, writing of manuscripts and the dissemination of findings. India Gill, MPH serves as a project manager, organizing team meetings, monitoring grant management and reporting, contributes to the qualitative and survey data collection and analyses, study regulatory reporting, and will contribute to the interpretation of findings, writing of manuscripts and the dissemination of findings.

Ethics

All of the study procedures followed the approved guidelines for the conduct of this intervention and data collection. The study was deemed a minimal risk study by the ethics review board and informed consent was waived.

Informed consent forms

Informed consent was waived for the clinician participants in the Teachable Moment intervention described in this study. For the subset of patients that were surveyed about their visit experience, electronic or verbal consent was obtained prior to completion of the brief survey.

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