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Ask Advise Connect: A New Approach to Smoking Treatment Delivery in Healthcare Settings

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Abstract

Background—Several national healthcare-based smoking cessation initiatives have been recommended to facilitate the delivery of evidence-based treatments such as those delivered by quitlines. The most notable examples are the 5 A's (i.e., Ask, Advise, Assess, Assist, Arrange) and Ask Advise Refer (AAR). Unfortunately, primary care referrals to quitlines are low and the majority of smokers referred fail to call for assistance. This study evaluated a new approach -Ask Advise Connect (AAC) - designed to address barriers to linking smokers with treatment.

Methods—A pair-matched-two-treatment arm group-randomized design in 10 family practice clinics in the Houston, TX metropolitan area was utilized. Five clinics were randomized to AAC (intervention) and five were randomized to AAR (control). In both conditions, clinic staff were trained to assess and record the smoking status of all patients at all visits in the electronic health record (EHR), and smokers were given brief advice to quit. In AAC, the names and phone numbers of smokers who agreed to be connected were sent electronically to the Quitline daily, and patients were proactively called by the Quitline within 48 hours. In AAR, smokers were offered a Quitline referral card and encouraged to call on their own. All data were collected between February and December 2011. The primary outcome – impact – was based on the RE-AIM conceptual framework. Impact was defined as the proportion of all identified smokers that enrolled in treatment.

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Statement of Author Contributions Jennifer Irvin Vidrine and David W. Wetter were equally responsible for the overall conceptualization and design of the study as well as the interpretation of results. Jennifer Irvin Vidrine was the Principal Investigator of the study and was responsible for overseeing data collection and data analysis as well as taking primary responsibility for writing the manuscript. David W. Wetter also played a critical role in writing and editing the manuscript. Sanjay Shete led all data analyses and Yumei Cao assisted with the analyses. Anthony Greisenger, Penny Harmonson, Barry Sharp, Lyndsay Miles and Susan M. Zbikowski contributed substantially conceptualizing the way that the study was implemented in the field and to editing the manuscript.

Results—In AAC, 7.8% of all identified smokers enrolled in treatment versus 0.6% in AAR ($t(4)=9.19$, $p=0.0008$, $OR=11.60$ (95% CI 5.53-24.32), a 13-fold increase in the proportion of smokers enrolling in treatment in AAC compared to AAR.

Conclusions—The system changes implemented in AAC could be adopted broadly by other healthcare systems and AAC has tremendous potential to reduce tobacco-related morbidity and mortality.

Introduction

Tobacco smoking is the leading cause of preventable morbidity and mortality in the United States.[1-4] Fortunately, the health benefits of quitting are substantial[5] and the majority of smokers are motivated to quit, with just over half attempting to quit each year. Unfortunately, only about 6% of all smokers are successful in quitting each year.[6] Quitlines deliver telephone-based tobacco cessation services throughout the United States to help smokers quit (http://www.naquitline.org/), and have demonstrated impressive efficacy and real-world effectiveness,[7-11] yet reach only 1% to 2% of smokers annually.[12,13] Given that 95% of all households in the United States have telephone service,[14] few intervention delivery modalities are likely to have broader reach. Therefore, quitlines could potentially serve a much larger population of smokers than they do currently.[12,13] Cessation treatments such as those delivered by quitlines have generally not been well integrated or institutionalized within healthcare systems,[12] and formalizing partnerships with healthcare providers that include well-defined referral mechanisms has been identified as a key strategy for increasing the impact of quitlines.[13,] Even modest increases in the reach and efficacy of quitlines could dramatically impact smoking prevalence at the population level.[15]

Several national healthcare-based smoking cessation initiatives have been developed and recommended to facilitate the delivery of evidence-based smoking cessation treatment in medical settings. The most notable example is an abbreviated version of the 5 A's (i.e., Ask, Advise, Assess, Assist, Arrange) called Ask Advise Refer (AAR), an approach designed to facilitate the routine assessment of smoking status among all patients, delivery of brief advice to quit smoking, and referral of smokers to evidence-based cessation treatment such as those recommended in the Treating Tobacco Use and Dependence Clinical Practice Guideline (*i.e., the Guideline).*[8] Although assessing smoking status at every patient visit dramatically increases the identification of smokers in healthcare settings,[16,17] referrals to quitlines generated in primary care settings are low[18-20] and the vast majority of smokers passively referred to quitlines fail to call for assistance.[13,18] Thus, there is a critical need to address barriers to the utilization of quitlines.

This study reports the findings of a group randomized trial designed to evaluate a new approach to disseminating quitline-delivered cessation treatment through a healthcare system partnership. "Ask Advise Connect (AAC)" is an approach designed to address clinic- and patient-level barriers to dissemination by linking smokers to treatment through an automated connection system within the electronic health record (EHR).[21] AAC is very similar to the Telephone Care Coordination Program evaluated by Sherman and colleagues within the VA healthcare system,[22] and similar to fax and e-mail referral programs in that patients are proactively contacted by quitlines once referrals are received.[23,24] A relatively unique component of AAC compared to the Telephone Care Coordination Program is that connections to the Quitline are made by Licensed Vocational Nurses (LVNs) and Medical Assistants (MAs), shifting the burden of counseling and referrals away from clinical providers.

Methods

Study Design and Participants

This study utilized a group-randomized design conducted in 10 family practice clinics that were part of Kelsey-Seybold Clinic, a large heath care system located in the greater Houston, TX metropolitan area. Kelsey-Seybold Clinic comprises 20 neighborhood clinic locations with over 370 board-certified physicians representing 56 medical specialties. Their secure EHR system was in place prior to the initiation of the study. Five clinics were randomized to AAC (intervention) and five were randomized to AAR (control). LVNs and MAs were trained to assess and record the smoking status of all patients at all visits in the EHR at the time that the vital signs were collected. All patients who reported current smoking were to be given brief advice to quit consistent with the *Guideline.*[7] LVNs and MAs received an initial 30-minute training session on how to assess smoking status, deliver brief advice to quit, and connect (in AAC) or refer (in AAR) patients to the Quitline at the beginning of the trial. Both approaches were implemented for nine months.

Participants were current smokers ages 18 and older who presented for care at any of the 10 clinics. All participants were insured. Approval was obtained by the Institutional Review Boards (IRBs) of the University of Texas MD Anderson Cancer Center and the Texas Department of State Health Services.

Randomization

Randomization occurred at the level of the clinic. The 10 family practice clinics were paired by the investigators based on the following characteristics: (1) patient volume; (2) smoking prevalence; (3) average age; and (4) gender distribution. Clinics within each pair were then randomized to the two intervention arms (see Table 1).

Procedures

AAC—LVNs and MAs at AAC clinics were trained to ask all patients at every visit about their smoking status at the time that other vital signs were assessed, briefly advise all smokers to quit, offer cessation assistance via the Quitline, and directly connect patients willing to accept assistance with the Quitline." Connections to the Quitline were made by clicking an automated link in the EHR that sent smokers' names and phone numbers to the research team, who then sent the information to the Quitline within 24 hours. Patient information was sent using secure, IRB approved methods to transmit Protected Health Information (PHI). Patients were contacted by the Quitline within 48 hours of receipt of their information. In AAC, counselors at the Quitline made five attempts to contact each participant over a period of up to two weeks, and call attempts were made at different times of the day to increase the likelihood that patients would be reached. After five unsuccessful attempts, participants were classified as unreachable.

AAR—AAR was modeled after a nationally promoted healthcare-based smoking cessation initiative recommended by the American Academy of Family Physicians (www.aafp.org/online/en/home/clinical/publichealth/tobacco.html), the American Society of Anesthesiologists (www.asawebapps.org/docs/SmokeCessation.htm), the American Dental Hygienist Association (www.askadviserefer.org, and other organizations. All procedures implemented in AAR were identical to those in AAC with the exception of providing referral cards (versus connections) to the Quitline. Referral cards were the size of standard business cards and printed on cardstock. As such, LVNs and MAs at AAR clinics were trained to ask all patients at every visit about their smoking status at the time that other vital signs were assessed, briefly advise all smokers to quit, offer cessation assistance via the Quitline, and provide patients willing to accept assistance with a Quitline referral card.

Quitline-Delivered Treatment

The Quitline is funded by the State of Texas and operated by Alere Wellbeing, Inc. It is staffed with trained cessation counselors available 24 hours a day, seven days a week, as well as most holidays. Counseling is available in English and Spanish, and can be provided in at least 15 additional languages through a third party.

All smokers who enrolled in treatment received treatment consistent with the *Guideline*[7,8] along with access to nicotine replacement therapy. This included up to five proactive counseling calls, each designed to help develop problem-solving and coping skills, secure social support, and plan for long-term abstinence. Participants could also call an 800 number as needed for additional support between proactive calls. The timing of follow-up calls was relapse-sensitive, and included a call a day or two after the quit date, a post-quit date call a week later, with additional calls generally occurring at 2- to 3-week intervals thereafter. The call timing was flexible and adjusted as needed.

Data Collection and Management

The EHR was used to record patients' smoking status, the clinics at which patients were seen, and the names and phone numbers of all patients who agreed to be connected (in AAC) or referred (in AAR) to the Quitline.. See Figure 1 for an explanation of data collection and management, and Figure 2 for information concerning participant flow through the study.

Outcomes: Reach, Efficacy and Impact

The RE-AIM conceptual framework[15] was used to evaluate the reach, efficacy, and impact of AAC and AAR. RE-AIM provides a systematic way to evaluate the impact of the dissemination and implementation of public health interventions. RE-AIM includes five criteria: reach, efficacy, adoption, implementation, and maintenance. The focus of the current study was on reach, efficacy, and impact. **Reach** was defined as the number of smokers visiting the clinics that talked with the Quitline / total number of smokers that visited the clinics. **Efficacy** was defined as the total number of smokers visiting the clinics that enrolled in treatment with the Quitline / total number of smokers visiting the clinics that talked with the Quitline. **Impact** was defined as *Reach x Efficacy*. It was hypothesized that AAC would have greater reach than AAR because a much larger proportion of participants in AAC were expected to talk with the Quitline. It was also hypothesized that the efficacy of AAR would exceed that of AAC because smokers who followed up with referrals on their own would be more motivated to enroll in cessation treatment. Finally, it was hypothesized that the impact of AAC would greatly exceed the impact of AAR because of its much broader reach.

Analysis

Proportions for Reach, Efficacy, and Impact were calculated and the magnitude and statistical significance of differences between AAC and AAR were evaluated (Figure 3). Because the data were generated using a pair-matched-two-treatment arm group randomized trial, Donner and Donald's weighted empirical logistic transformation approach was used.[25] This method accounts for the probability of imbalance between treatment groups on participant characteristics, and provides estimated odds ratios (ORs) for assessing significance of the intervention effects over all strata.

Power

Power was originally based on 1,240 smokers at each of the 10 clinics, 2-sided tests, alpha equal to .05, and 80% power. Power estimates were based on a logistic random effects

model that accounted for the fact that observations within clinics would be correlated assuming a compound symmetry correlation structure. Based on other group-randomized trials in primary care settings, the intraclass correlation coefficients (ICCs) were expected to range from 0.05 to 0.15.[26-28] With regard to Reach, the worst case scenario based on an ICC of .15 allowed for the detection of a minimum difference of 9.6% when the proportion of smokers connected to the Quitline in AAR clinics was 10%. With regard to Efficacy, the worst case scenario based on an ICC of .15 allowed for the detection of a minimum difference of 16.6% when the proportion of smokers enrolling in treatment with the Quitline in AAR clinics was 90%. Power for detecting Impact exceeded that for Reach and Efficacy. Although the sample size we achieved was much smaller than projected (3,663 vs. 12,400), our effect sizes were large and highly significant.

Results

During the study, 42,277 smoking status assessments were entered in the EHR. Of these assessments, 9,576 represented repeat visits by unique patients. Thus, the number of unique patients who had their smoking status assessed during the course of the study totaled 32,701, and 3,663 of these unique patients reported current smoking, resulting in an overall smoking prevalence of 11.2%. The observed prevalence of smoking was significantly greater at AAC clinics (2,052 / 17,263 = 11.9%) than at AAR clinics (1,611 / 15,438 = 10.4%), $\chi^2(1) = 18.45$, $p<.0001$. However, the weighted analytic approach of Donner and Donald[22] accounts for such imbalances and yield results that are robust to potential biases due to factors such as this.

Reach

A total of 2,052 smokers were identified at AAC clinics and 1,611 smokers were identified at AAR clinics. At AAC clinics, 11.4% of identified smokers talked with the Quitline (233/2,052). At AAR clinics, 0.6% of identified smokers talked with the Quitline (9/1,611). Using the empirical logistic transformation approach, the reach of AAC was significantly greater than the reach of AAR (11.4% vs. 0.6%), $t(4) = 10.35$, $p = .0005$.[25] The overall estimated odds (OR) for assessing significance of intervention reach over all pair matched clinics was equal to 17.38 (95% CI 8.08-37.36).

Efficacy

At AAC clinics, 160 of the 233 smokers who talked with the Quitline enrolled in treatment, resulting in a 68.7% treatment enrollment rate. At AAR clinics, all 9 smokers who talked with the Quitline enrolled in treatment, resulting in a treatment enrollment rate of 100%. The unconditional test for equivalence of two binomial proportions was used to compare treatment enrollment in AAR versus AAC (i.e., efficacy). As hypothesized, the efficacy of AAR was significantly greater than that of AAC (standardized Z statistic = 2.01, $p=.0445$).

Impact

As described above, impact was defined as reach x efficacy. In AAC, impact (11.4% x 68.7%) was 7.8%. That is, 7.8% of all identified smokers in AAC clinics enrolled in treatment. In AAR, impact (0.6% x 100%) was 0.6%, indicating that less than 1% of all identified smokers in AAR clinics enrolled in treatment. Using the empirical logistic transformation approach, the impact of AAC was significantly greater than the impact of AAR, $t(4) = 9.19$, $p = 0.0008$.[25] The overall estimated OR for assessing significance of the intervention impact over all strata was equal to 11.60 (95% CI 5.53-24.32).

Comment

Directly connecting smokers to the Quitline resulted in a 13-fold increase in cessation treatment enrollment when compared to the nationally recommended method of referring smokers to the Quitline for assistance (7.8% of all identified smokers in AAC vs. 0.6% in AAR). Although relatively high proportions of smokers declined to be connected or were unreachable, the streamlined and automated nature of AAC dramatically enhances the potential public health impact of the approach. In fact, AAC resulted in one of the highest rates of cessation treatment enrollment reported to date.[29] Given that 70% of all smokers in the U.S. see a primary care physician each year,[30] AAC has tremendous potential to increase cessation treatment uptake, and the potential public health impact of AAC is supported by a recent meta-analysis that evaluated the impact of active versus passive recruitment approaches to quitline-delivered treatment. [31,32] Active recruitment resulted in estimates of treatment cessation rates that were equivalent to passive recruitment, which strongly supports the importance of expanding the reach of quitlines through proactive recruitment approaches such as AAC.

Recent policy initiatives have created an environment in which systems-level programs such as AAC could be easily integrated and sustained within healthcare settings. A critically important component of the Patient Protection and Affordable Care Act (i.e., healthcare reform) is that information regarding tobacco use assessment and treatment be systematically tracked and recorded through EHRs.[33] The collection and storage of such information within EHRs is governed by provisions that fall under Health Information Technology for Economic and Clinical Health (HITECH), which allow health care information to be stored, analyzed, and acted upon at a patient and population level. Under HITECH, tobacco-related measures represent one of three core clinical quality measures that primary care practitioners will be required to report. Meaningful use criteria for tobacco require clinicians to screen the smoking status of more than 50% of all unique patients who are 13 years old or older, as well as track the percentage of patients 18 and older who are current tobacco users, seen by a practitioner during the year, and receive advice, cessation treatments, or recommendations to use cessation medications and/or other strategies.[34,35] AAC addresses each of these required areas.

Strengths of this study include the conceptualization, development, and evaluation of AAC based on its potential to make a significant public health impact as guided by the RE-AIM model.[15] Furthermore, the setting in which AAC was tested is representative of real-world health care systems in the U.S. AAC greatly reduces patient barriers to receiving smoking cessation treatment and shifts the burden of counseling and referrals away from clinical providers. Quitline-delivered counseling is convenient, eliminates transportation time and costs, entails no childcare costs, is more acceptable to patients than face-to-face counseling, reduces the burden on physicians and other members of the health care team, and has demonstrated strong efficacy.[7,8,13,36] Importantly, AAC could be implemented in numerous population-based settings for tobacco control (e.g., clinics, hospitals, dentist offices).

Several limitations should be acknowledged. An obvious limitation is that we did not collect smoking outcome data. Therefore, efficacy was defined at the level of the intervention rather than the level of the patient. The study was designed based on an exceedingly large and robust body of literature supporting the efficacy and real world effectiveness of quitline-delivered treatment for smoking cessation,[8-11,36] but smokers who call quitlines on their own may ultimately have better outcomes than smokers contacted proactively following a primary care visit. The possibility of anything more than small differences in cessation rates by method of connection/referral seems unlikely, however, given the recent findings of Tzelepis and colleagues,[32] who found no differences in cessation outcomes associated with

active versus passive recruitment approaches. An additional limitation is that because our goal was to minimally disrupt the clinical encounter, we did not collect information on demographics, nicotine dependence, motivation to quit smoking, previous attempts to quit smoking, medical conditions, or other patient-level data. Collecting such data would have required additional time on the part of the clinic staff and necessitated a more extensive informed consent process that may have reduced the willingness of the clinic leadership and staff to implement AAC and AAR as part of standard clinical practice. In addition, the prevalence of smoking in the clinics was lower than the prevalence of smoking in Houston (11.2% vs. 15.2%;https://sph.uth.edu/content/uploads/2011/12/The_Houston_State_of_Health_2009.pdf), which likely reflects that all patients were insured. Finally, although quitlines are widely available in the United States, current funding for quitlines is subject to political and budget issues at the individual state levels, and many quitlines do not provide nicotine replacement therapy. Thus, the infrastructure for implementing AAC is dependent on state-level issues and would need to be enhanced to be sufficient to support adoption nationally. Fortunately, health care reform provides incentives for enhancing this infrastructure.

In summary, AAC yielded a greater than 13-fold increase in evidence-based cessation treatment enrollment compared to the current recommended standard of care (i.e., AAR) among patients seen in primary care clinics within a large health care system. AAC was designed to streamline and automate the process of linking smokers with evidence-based treatment, and the findings may have important implications for reducing tobacco-related morbidity. .

Acknowledgments

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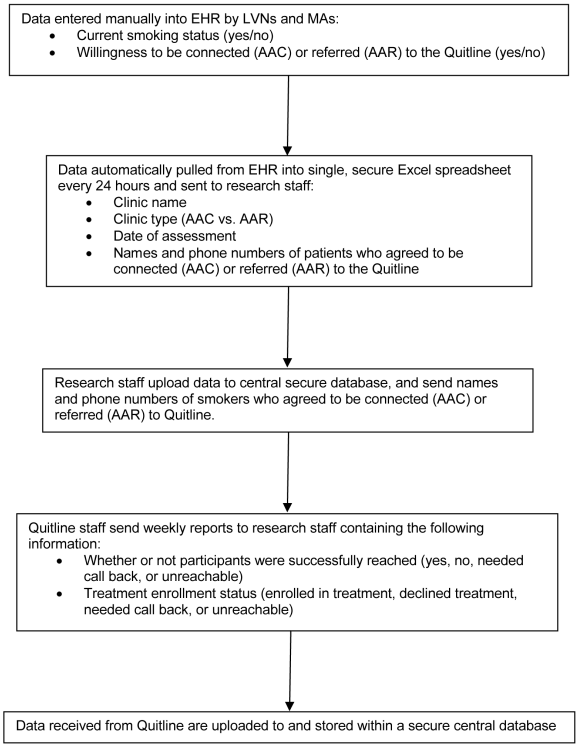

Figure 1.
Data Flow Chart

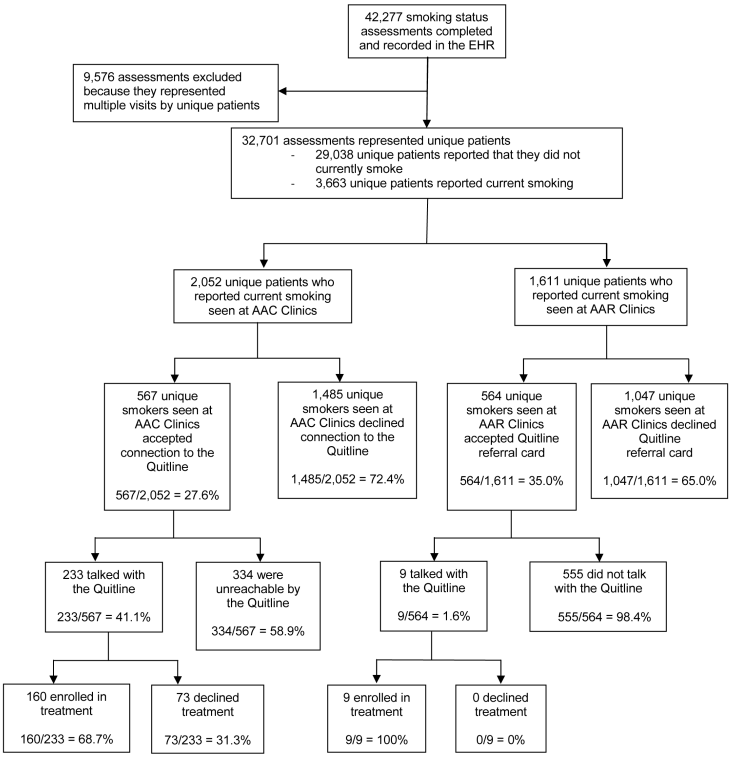

Figure 2.
Participant Flow Through Study

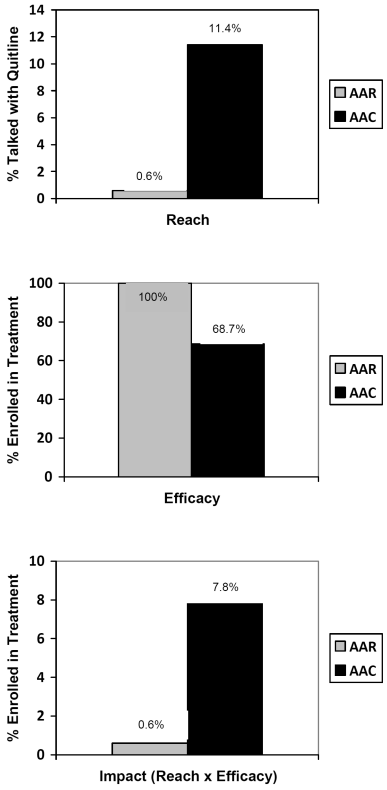

Figure 3.

Reach, Efficacy, and Impact for AAC and AAR

Notes: Reach = proportion of smokers identified who talked with Quitline; Efficacy = proportion of smokers who talked with Quitlline that enrolled in treatment; Impact = Reach x Efficacy

Table 1

Clinic patient characteristics and randomization.

Clinic	Patient Volume	Smoking Prevalence	Age	% Female	Group
A	18,212	10.0%	43.0	57.8%	AAR
B	15,221	7.4%	40.3	64.7%	AAC
C	12,590	9.0%	44.6	58.4%	AAC
D	12,129	11.3%	45.9	63.8%	AAR
E	10,159	8.6%	44.0	58.3%	AAR
F	9,771	10.2%	43.7	58.9%	AAC
G	9,603	11.9%	42.3	32.7%	AAR
H	8,200	11.7%	44.6	52.8%	AAC
I	9,268	12.0%	43.5	53.6%	AAC
J	6,196	8.2%	42.6	60.5%	AAR