

## ONLINE FIRST

## Ask-Advise-Connect

*A New Approach to Smoking Treatment Delivery in Health Care Settings*

Jennifer Irvin Vidrine, PhD; Sanjay Shete, PhD; Yumei Cao, MS; Anthony Greisinger, PhD; Penny Harmonson, BS; Barry Sharp, MS; Lyndsay Miles, MA; Susan M. Zbikowski, PhD; David W. Wetter, PhD

**Importance:** Several national health care–based smoking cessation initiatives have been recommended to facilitate the delivery of evidence-based treatments, such as quitline (telephone-based tobacco cessation services) assistance. The most notable examples are the 5 As (Ask, Advise, Assess, Assist, Arrange) and Ask. Advise. Refer. (AAR) programs. Unfortunately, rates of primary care referrals to quitlines are low, and most referred smokers fail to call for assistance.

**Objective:** To evaluate a new approach—Ask-Advise-Connect (AAC)—designed to address barriers to linking smokers with treatment.

**Design:** A pair-matched, 2-treatment-arm, group-randomized design in 10 family practice clinics in a single metropolitan area. Five clinics were randomized to the AAC (intervention) and 5 to the AAR (control) conditions. 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, and smokers were given brief advice to quit. In the AAC clinics, the names and telephone numbers of smokers who agreed to be connected were sent electronically to the quitline daily, and patients were called proactively by the quitline within 48 hours. In the AAR clinics, smokers were offered a quitline referral card and encouraged to call on their own. All data were collected from February 8 through December 27, 2011.

**Setting:** Ten clinics in Houston, Texas.

**Participants:** Smoking status assessments were completed for 42 277 patients; 2052 unique smokers were identified at AAC clinics, and 1611 smokers were identified at AAR clinics.

**Interventions:** Linking smokers with quitline-delivered treatment.

**Main Outcome Measure:** Impact was based on the RE-AIM (Reach, Efficacy, Adoption, Implementation, and Maintenance) conceptual framework and defined as the proportion of all identified smokers who enrolled in treatment.

**Results:** In the AAC clinics, 7.8% of all identified smokers enrolled in treatment vs 0.6% in the AAR clinics ( $t_4=9.19$  [ $P<.001$ ]; odds ratio, 11.60 [95% CI, 5.53–24.32]), a 13-fold increase in the proportion of smokers enrolling in treatment.

**Conclusions and Relevance:** The system changes implemented in the AAC approach could be adopted broadly by other health care systems and have tremendous potential to reduce tobacco-related morbidity and mortality.

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**Author Affiliations:** Departments of Health Disparities Research (Drs Vidrine and Wetter and Ms Cao) and Biostatistics (Dr Shete), The University of Texas MD Anderson Cancer Center, and Texas Kelsey Research Foundation (Dr Greisinger), Houston; Tobacco Prevention and Control Program, Texas Department of State Health Services, Austin (Ms Harmonson and Mr Sharp); and Alere Wellbeing, Seattle, Washington (Ms Miles and Dr Zbikowski).

**T**OBACCO SMOKING IS THE leading cause of preventable morbidity and mortality in the United States.<sup>1–4</sup> Fortunately, the health benefits of quitting are substantial<sup>5</sup> and most smokers are motivated to quit, with just more than half attempting to quit each year. Unfortunately, only about 6% of all smokers are successful in quitting each year.<sup>6</sup> Quitlines deliver telephone-based tobacco cessation services throughout the United States to help smokers quit (<http://www.naquitline.org/>) and have demonstrated impressive ef-

ficacy and real-world effectiveness,<sup>7–11</sup> yet they reach only 1% to 2% of smokers annually.<sup>12,13</sup> Given that 95% of all households in the United States have telephone

### See Editor's Note

service,<sup>14</sup> few intervention delivery modalities are likely to have a broader reach. Therefore, quitlines could serve a much larger population of smokers than at present.<sup>12,13</sup> Cessation treatments such as those delivered by quitlines generally have not been well integrated or institutionalized

**Table. Clinic Patient Characteristics and Randomization**

Clinic	Patient Volume <sup>a</sup>	Smoking Prevalence, %	Mean Age, y	Female Sex, %	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	9771	10.2	43.7	58.9	AAC
G	9603	11.9	42.3	32.7	AAR
H	8200	11.7	44.6	52.8	AAC
I	9268	12.0	43.5	53.6	AAC
J	6196	8.2	42.6	60.5	AAR

Abbreviations: AAC, Ask-Advise-Connect; AAR, Ask, Advise, Refer.

<sup>a</sup>Indicates average yearly patient volume at each clinic during the year before the study began; patient volume was used to randomize the clinics to condition.

within health care systems,<sup>12</sup> and formalizing partnerships with health care providers that include well-defined referral mechanisms has been identified as a key strategy for increasing the impact of quitlines.<sup>13</sup> Even modest increases in the reach and efficacy of quitlines could affect smoking prevalence dramatically at the population level.<sup>15</sup>

Several national health care–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 As (Ask, Advise, Assess, Assist, Arrange) called Ask, Advise, Refer (AAR), a program designed to facilitate the routine assessment of smoking status among all patients, deliver brief advice to quit smoking, and refer smokers to evidence-based cessation treatments such as those recommended in the guideline by Fiore et al.<sup>8</sup> Although assessing smoking status at every patient visit dramatically increases the identification of smokers in health care settings,<sup>16,17</sup> referrals to quitlines generated in primary care settings are low,<sup>18–20</sup> and most smokers passively referred to quitlines fail to call for assistance.<sup>13,18</sup> Thus, the need to address barriers to the use of quitlines is critical.

This study reports the findings of a group-randomized trial designed to evaluate a new approach to disseminating quitline-delivered cessation treatment through a health care system partnership. The Ask-Advise-Connect (AAC) approach is 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).<sup>21</sup> The AAC approach is very similar to the telephone care coordination program evaluated by Sherman and colleagues<sup>22</sup> within the Veterans Affairs health care system and similar to fax and e-mail referral programs in that patients are contacted proactively by quitlines once referrals are received.<sup>23,24</sup> A relatively unique component of the AAC approach compared with 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 used a group-randomized design conducted in 10 family practice clinics that were part of the Kelsey-Seybold Clinic, a large health care system located in the greater Houston metropolitan area. The Kelsey-Seybold Clinic consists of 20 neighborhood clinic locations with more than 370 board-certified physicians representing 56 medical specialties. Their secure EHR system was in place before the initiation of the study. Five clinics were randomized to the AAC (intervention) and 5 to the AAR (control) conditions. Licensed vocational nurses 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.<sup>7</sup> The LVNs and MAs received an initial 30-minute training session on how to assess smoking status, deliver brief advice to quit, and connect (in the AAC clinics) or refer (in the AAR clinics) patients to the quitline at the beginning of the trial. Both approaches were implemented for 9 months.

Participants were current smokers 18 years or older who presented for care at any of the 10 clinics. All participants had medical insurance coverage. Approval was obtained by the institutional review boards 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 on the basis of the following characteristics: (1) patient volume, (2) smoking prevalence, (3) mean age, and (4) sex distribution. Clinics within each pair were then randomized to the 2 intervention arms (**Table**).

## PROCEDURES

### AAC Approach

The LVNs and MAs at the 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 the smokers' names and telephone numbers to the research team, who then sent the information to the quitline within 24 hours. Patient information was sent using secure, institutional review board–approved methods to transmit protected health information. Patients were contacted by the quitline within 48 hours of receipt of their information. In the AAC approach, counselors at the quitline made 5 attempts to contact each participant during a period of as long as 2 weeks, and call attempts were made at different times of the day to increase the likelihood that patients would be reached. After 5 unsuccessful attempts, participants were classified as unreachable.

## AAR Program

The AAR program was modeled after a nationally promoted health care–based smoking cessation initiative recommended by the American Academy of Family Physicians (<http://www.aafp.org/online/en/home/clinical/publichealth/tobacco.html>), the American Society of Anesthesiologists (<http://surgiprep.wordpress.com/2008/02/01/ask-advise-refer-to-stop-smoking-before-surgery/>), the American Dental Hygienist Association (<http://www.askadviserefer.org>), and other organizations. All procedures implemented in the AAR program were identical to those in the AAC approach with the exception of providing referral cards (rather than connections) to the quitline. Referral cards were the size of standard business cards and printed on card stock. As such, the LVNs and MAs at the 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.

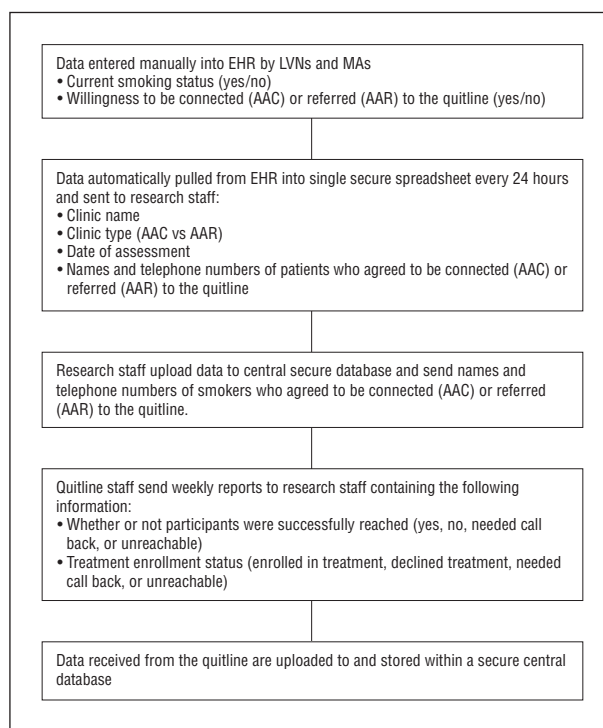
## QUITLINE-DELIVERED TREATMENT

The quitline is funded by the State of Texas and operated by Alere Wellbeing. The quitline is staffed by trained cessation counselors available 24 hours a day, 7 days a week, and 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 smoking cessation treatment received counseling and support consistent with the guideline<sup>7,8</sup> along with access to nicotine replacement therapy. This treatment included as many as 5 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 telephone number as needed for additional support between proactive calls. The timing of counseling calls was relapse sensitive and included a call 1 or 2 days after the quit date, another telephone call a week after the first call, and 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 visited by the patients, and the names and telephone numbers of all patients who agreed to be connected (in the AAC approach) or referred (in the AAR program) to the quitline. **Figure 1** provides an explanation of data collection and management, and **Figure 2** displays information concerning participant flow through the study.



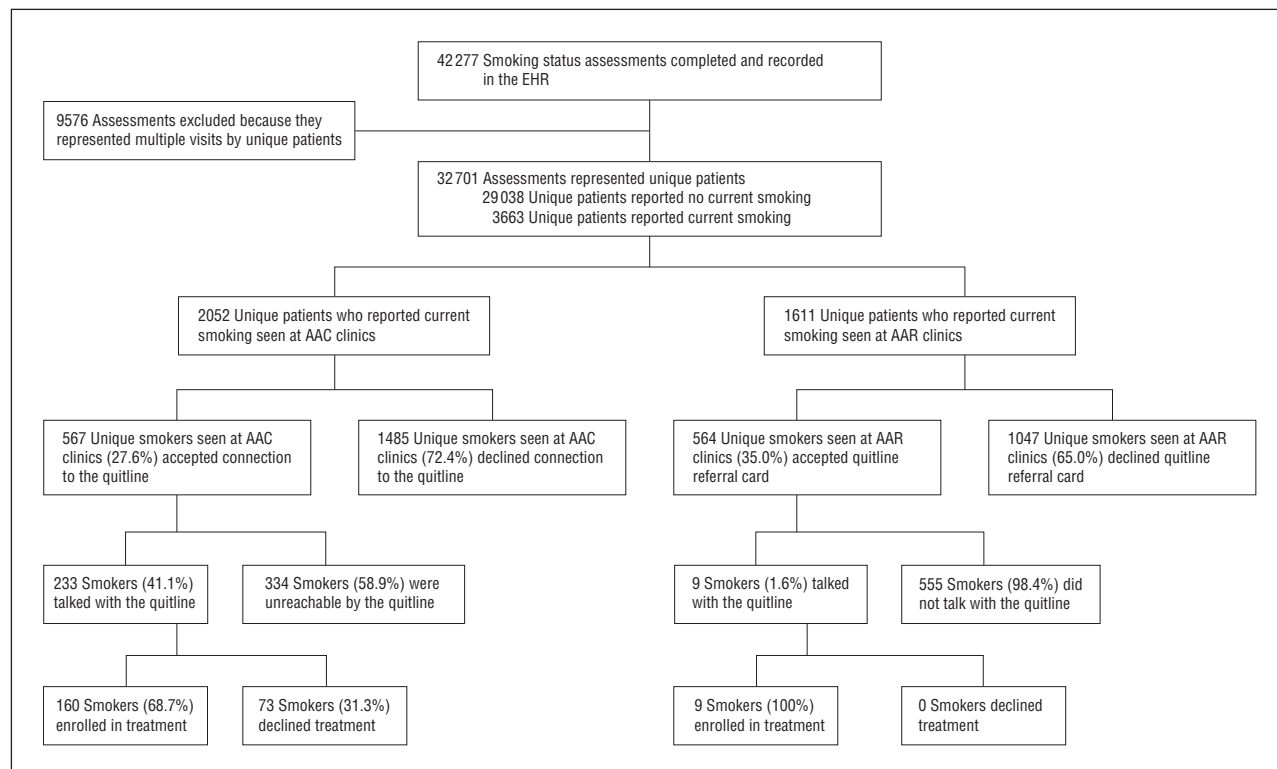
**Figure 1.** Data flowchart. An Excel spreadsheet (Microsoft Corporation) was used to automatically pull participant names and telephone numbers from the EHR and record participants' smoking status so that this information could be sent securely to MD Anderson and to the quitline. AAC indicates Ask-Advise-Connect approach; AAR, Ask. Advise. Refer. program; EHR, electronic health record; LVN, licensed vocational nurse; and MA, medical assistant.

## OUTCOMES: REACH, EFFICACY, AND IMPACT

The RE-AIM conceptual framework<sup>15</sup> was used to evaluate the reach, efficacy, and impact of the AAC and AAR approaches. The RE-AIM model provides a systematic way to evaluate the impact of the dissemination and implementation of public health interventions. The RE-AIM model includes the 5 criteria of reach, efficacy, adoption, implementation, and maintenance. The present study focused on reach, efficacy, and impact. We calculated reach as the number of smokers visiting the clinics who talked with the quitline divided by the total number of smokers visiting the clinics. We calculated efficacy as the total number of smokers visiting the clinics who enrolled in treatment with the quitline divided by the total number of smokers visiting the clinics who talked with the quitline. Finally, we calculated impact as reach  $\times$  efficacy. We hypothesized that the AAC approach would have a greater reach than the AAR program because a much larger proportion of participants in the AAC clinics were expected to talk with the quitline. We also hypothesized that the efficacy of the AAR program would exceed that of the AAC approach because smokers who followed up with referrals on their own would be more motivated to enroll in cessation treatment. Finally, we hypothesized that the impact of the AAC approach would greatly exceed the impact of the AAR program because of its much broader reach.

## ANALYSIS

We calculated proportions for reach, efficacy, and impact and evaluated the magnitude and statistical significance of differences between the AAC and AAR approaches (**Figure 3**). Because the data were generated using a pair-matched, 2-treatment-arm, group-randomized trial, we used the weighted empirical



**Figure 2.** Participant flow through study. AAC indicates Ask-Advise-Connect program; AAR, Ask, Advise, Refer, program; and EHR, electronic health record;

logistic transformation method of Donner and Donald.<sup>25</sup> Their method accounts for the probability of imbalance between treatment groups on participant characteristics and provides estimated odds ratios for assessing the significance of the intervention effects over all strata.

## POWER

Power was originally based on 1240 smokers at each of the 10 clinics, 2-sided tests, and an  $\alpha$  value of .05, with 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 were expected to range from 0.05 to 0.15.<sup>26-28</sup> With regard to reach, the worst-case scenario based on an intraclass correlation coefficient of 0.15 allowed for the detection of a minimum difference of 9.6% when the proportion of smokers connected to the quitline in the AAR clinics was 10%. With regard to efficacy, the worst-case scenario based on an intraclass correlation coefficient of 0.15 allowed for the detection of a minimum difference of 16.6% when the proportion of smokers enrolling in treatment with the quitline in the 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 (3663 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, 9576 represented repeated 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

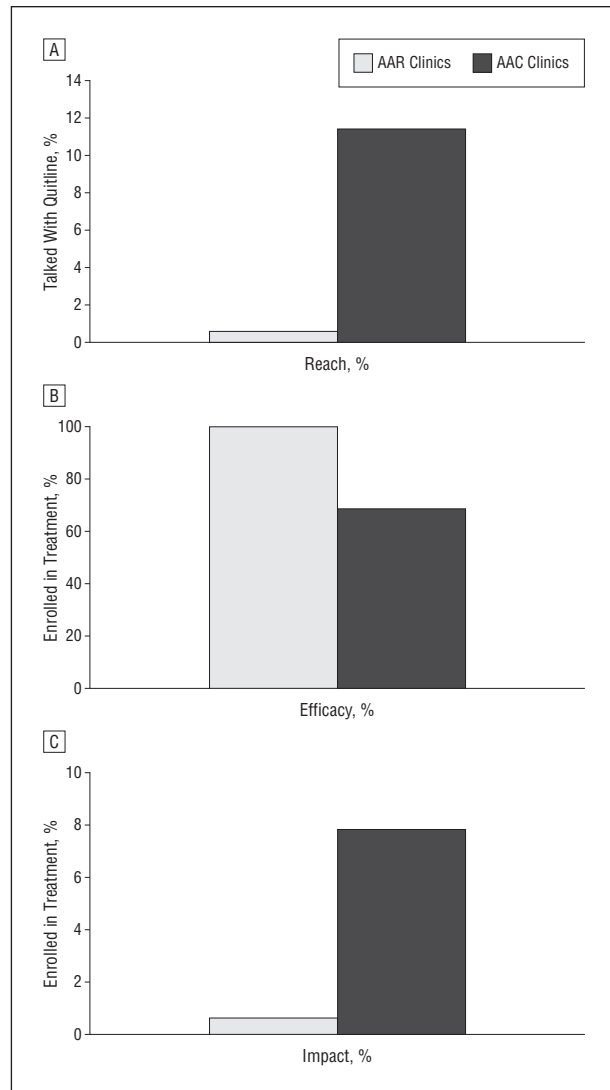
3663 of these unique patients reported current smoking, resulting in an overall smoking prevalence of 11.2%. The observed prevalence of smoking was significantly greater at the AAC clinics (2052 of 17 263 = 11.9%) than at the AAR clinics (1611 of 15 438 = 10.4%;  $\chi^2 = 18.45$  [ $P < .001$ ]). However, the weighted analytic approach of Donner and Donald<sup>25</sup> accounts for such imbalances and yields results that are robust to potential biases owing to factors such as this.

## REACH

A total of 2052 smokers were identified at the AAC clinics, and 1611 smokers were identified at the AAR clinics. At the AAC clinics, 11.4% of identified smokers talked with the quitline (233 of 2052). At the AAR clinics, 0.6% of identified smokers talked with the quitline (9 of 1611). Using the empirical logistic transformation approach, the reach of the AAC approach was significantly greater than that of the AAR program (11.4% vs 0.6%;  $t_4 = 10.35$  [ $P < .001$ ]).<sup>25</sup> The overall estimated odds ratio for assessing the significance of intervention reach over all pair-matched clinics equaled 17.38 (95% CI, 8.08-37.36).

## EFFICACY

At the AAC clinics, 160 of the 233 smokers who talked with the quitline enrolled in treatment, resulting in a 68.7% treatment enrollment rate. At the AAR clinics, all 9 smokers who talked with the quitline enrolled in treatment, resulting in a treatment enrollment rate of 100.0%. We used the unconditional test for equivalence of 2 binomial proportions to compare treatment enrollment in



**Figure 3.** Effects of the Ask-Advise-Connect (AAC) and Ask, Advise, Refer (AAR) approaches. A, Reach, calculated as the proportion of smokers identified who talked with the quitline. B, Efficacy, calculated as the proportion of smokers who talked with the quitline and then enrolled in treatment. C, Impact, calculated as reach  $\times$  efficacy.

the AAR vs AAC clinics (ie, efficacy). As we hypothesized, the efficacy of the AAR program was significantly greater than that of the AAC approach (standardized  $z$  statistic, 2.01 [ $P = .04$ ]).

### IMPACT

As we described in the “Methods” section, we defined impact as reach  $\times$  efficacy. In the AAC approach, impact (11.4%  $\times$  68.7%) was 7.8%. That is, 7.8% of all identified smokers in the AAC clinics enrolled in treatment. In the AAR program, impact (0.6%  $\times$  100%) was 0.6%, indicating that less than 1% of all identified smokers in the AAR clinics enrolled in treatment. Using the empirical logistic transformation approach, the impact of the AAC approach was significantly greater than that of the AAR program ( $t_4 = 9.19$  [ $P < .001$ ]).<sup>25</sup> The overall estimated odds ratio for assessing the significance of the intervention impact over all strata equaled 11.60 (95% CI, 5.53-24.32).

Directly connecting smokers to the quitline resulted in a 13-fold increase in cessation treatment enrollment when compared with the nationally recommended method of referring smokers to the quitline for assistance (7.8% of all identified smokers in the AAC approach vs 0.6% in the AAR approach). Although relatively high proportions of smokers declined to be connected or were unreachable, the streamlined and automated nature of the AAC approach dramatically enhanced its potential public health impact. In fact, the AAC approach resulted in one of the highest rates of cessation treatment enrollment reported to date.<sup>29</sup> Given that 70% of all smokers in the United States visit a primary care physician each year,<sup>30</sup> the AAC approach has tremendous potential to increase cessation treatment uptake, and the potential public health impact of the AAC approach is supported by a recent meta-analysis that evaluated the impact of active vs passive recruitment approaches to quitline-delivered treatment.<sup>31,32</sup> 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 the AAC.

Recent policy initiatives have created an environment in which systems-level programs, such as the AAC, could be easily integrated and sustained within health care settings. A critically important component of the Patient Protection and Affordable Care Act (ie, health care reform) is that information regarding tobacco use assessment and treatment be tracked systematically and recorded through EHRs.<sup>33</sup> The collection and storage of such information within EHRs is governed by provisions that fall under the Health Information Technology for Economic and Clinical Health (HITECH) Act, which allows health care information to be stored, analyzed, and acted on at a patient and population level. Under the HITECH Act, tobacco-related measures represent 1 of 3 core clinical quality measures that primary care practitioners will be required to report. Meaningful use criteria for tobacco cessation require clinicians to screen the smoking status of more than 50% of all unique patients who are 13 years or older and track the percentage of patients 18 years and older who are current tobacco users, who are seen by a practitioner during the year, and who receive advice, cessation treatments, or recommendations to use cessation medications and/or other strategies.<sup>34,35</sup> The AAC approach addresses each of these required areas.

Strengths of this study include the conceptualization, development, and evaluation of the AAC approach based on its potential to have a significant public health impact as guided by the RE-AIM model.<sup>15</sup> Furthermore, the setting in which the AAC approach was tested represents real-world health care systems in the United States. The AAC approach 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.<sup>7,8,13,36</sup> The AAC approach could be implemented in numerous population-based settings for tobacco control (eg, clinics, hospitals, dentist offices).

We should acknowledge several limitations. An obvious limitation is that we did not collect smoking outcome data. Therefore, efficacy was defined at the intervention level rather than the patient level. The study design was based on an exceedingly large and robust body of literature supporting the efficacy and real-world effectiveness of quitline-delivered treatment for smoking cessation,<sup>8-11,36</sup> but smokers who call quitlines on their own may ultimately have better outcomes than smokers contacted proactively after a primary care visit. The possibility of anything more than small differences in cessation rates by method of connection/referral seems unlikely, however, given that Tzelepis and colleagues<sup>32</sup> recently found no differences in cessation outcomes associated with active vs passive recruitment approaches. In addition, because our goal was minimal disruption of 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 by clinic staff and necessitated a more extensive informed consent process that may have reduced the willingness of the clinic leadership and staff to implement the AAC and AAR approaches 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](https://sph.uth.edu/content/uploads/2011/12/The_Houston_State_of_Health_2009.pdf)), which likely reflects that all patients had insurance coverage. 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 the AAC approach depends on state-level issues and needs to be enhanced if it is to be adopted nationally. Fortunately, health care reform provides incentives for enhancing this infrastructure.

In summary, the AAC approach yielded an increase of greater than 13-fold in evidence-based cessation treatment enrollment compared with the current recommended standard of care (ie, the AAR program) among patients visiting primary care clinics within a large health care system. The AAC approach 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.

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**Correspondence:** Jennifer Irvin Vidrine, PhD, Department of Health Disparities Research, The University of Texas MD Anderson Cancer Center, 1400 Pressler St, Unit 1440, Houston, TX 77030 (jirvinvidrine@mdanderson.org).

**Author Contributions:** *Study concept and design:* Vidrine, Harmonson, Sharp, and Wetter. *Acquisition of data:* Vidrine, Greisinger, and Miles. *Analysis and interpretation of data:* Vidrine, Shete, Cao, Zbikowski, and Greisinger. *Drafting of the manuscript:* Vidrine, Harmonson, and Sharp. *Critical revision of the manuscript for important intellectual content:* Vidrine, Shete, Cao, Greisinger, Miles, Zbikowski, and Wetter. *Statistical analysis:* Vidrine, Shete, and Cao. *Obtained funding:* Vidrine and Wetter. *Administrative, technical, and material support:* Vidrine, Greisinger, Harmonson, Sharp, and Miles. *Study supervision:* Vidrine, Greisinger, and Miles.

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