Implementation of Ask-Advise-Connect in a safety net healthcare system: quitline treatment engagement and smoking cessation outcomes

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Abstract
Ask-Advise-Connect (AAC) was designed to link smokers in primary care settings with evidence-based tobacco treatment delivered via state quitlines. AAC involves training medical staff to Ask about smoking status, Advise smokers to quit, and offer to immediately Connect smokers with quitlines through an automated link within the electronic health record. We evaluated the efficacy of AAC in facilitating treatment engagement and smoking abstinence in a 34 month implementation trial conducted in a large, safety-net health care system. AAC was implemented from April 2013 through February 2016 in 13 community clinics that provided care to low-income, predominantly racial/ethnic minority smokers. Licensed vocational nurses were trained to implement AAC as part of standard care. Outcomes included (a) treatment engagement (i.e., proportion of identified smokers that enrolled in treatment) and (b) self-reported and biochemically confirmed abstinence at 6 months. Smoking status was recorded for 218,915 unique patients, and 40,888 reported current smoking. The proportion of all identified smokers who enrolled in treatment was 11.8%. Self-reported abstinence at 6 months was 16.6%, and biochemically confirmed abstinence was 4.5%. AAC was successfully implemented as part of standard care. Treatment engagement was high compared with rates of engagement for more traditional referral-based approaches reported in the literature. Although self-reported abstinence was in line with other quitline-delivered treatment studies, biochemically confirmed abstinence, which is not routinely captured in quitline studies, was dramatically lower. This discrepancy challenges the adequacy of self-report for large, population-based studies. A more detailed and comprehensive investigation is warranted.

Keywords
Implementation, Smoking cessation, Quitline, Phone counseling, Ask-Advise-Connect, Treatment engagement

INTRODUCTION
Tobacco cessation quitlines have become part of the national infrastructure for the provision of population-level tobacco cessation treatment in the USA [1]. Despite strong evidence supporting their effectiveness [2, 3], quitlines reach only a small proportion of smokers each year [4, 5]. Therefore, there is a pressing need to increase the utilization of quitlines nationally [6–8]. Vidrine and colleagues [9, 10] developed an approach called Ask-Advise-Connect (AAC) designed to address both clinic- and patient-level barriers to treatment enrollment by connecting smokers with quitlines through an automated connection system within the electronic health record (EHR). The results of two large group randomized trials indicated that AAC was associated with a 13- to 30-fold increase in treatment enrollment compared with a more traditional referral card-based approach that required smokers to call quitlines on their own (i.e., Ask-Advise-Refer; AAR) [9, 10]. These studies clearly supported the efficacy of AAC in facilitating enrollment in quitline-delivered treatment. However, because the study budgets and timelines did not allow for the collection of post-treatment smoking abstinence data, it was unclear whether cessation outcomes among smokers who enrolled in treatment via AAC would be comparable to outcomes among individuals who enrolled in treatment via more traditional referral card-based approaches such as AAR. The current study sought to address this question through evaluating the real-world effectiveness of AAC in facilitating both treatment engagement and 6 month smoking abstinence rates in the context of a safety net population.

IMPLICATIONS
Practice: Ask-Advise-Connect (AAC) was successfully implemented as part of standard care in a real-world setting and resulted in impressive rates of treatment engagement and smoking abstinence.

Policy: The self-reported abstinence rates observed in this study support the potential public health impact of automated treatment enrollment systems such as AAC.

Research: Future research should carefully investigate factors contributing to discrepancies between self-reported and biochemically confirmed abstinence in population-based studies.
large-scale, 3 year implementation study conducted in the same healthcare system where the original randomized trial that evaluated the efficacy AAC was conducted [10].

METHODS

Participants
Participants were patients at least 18 years of age who reported current smoking at any level and presented for care at any of 13 community clinics that were part of the Harris Health System during the 34 month implementation period (April 2013 through February 2016). Harris Health is a large, safety-net health system that provides care to uninsured and underserved individuals, and approximately 90% of patients are members of racial/ethnic minority groups. The study was approved by the Institutional Review Boards at The University of Texas MD Anderson Cancer Center, the Harris Health System, and the Texas Department of State Health Services. Participants were provided with a written information sheet about the study and provided verbal consent to have their contact information sent to the Quitline.

Procedure

Ask-Advise-Connect
Licensed vocational nurses (LVNs) were trained to implement AAC as a part of standard clinical practice. Specifically, LVNs were trained to assess and record the smoking status of all patients at all visits in the EHR at the time that vital signs were collected, deliver brief advice to quit to all smokers, and to offer to send smokers’ contact information directly to the Texas Quitline via an EHR link so that patients could be contacted proactively and offered treatment. Smokers were called by the Quitline within 48 hr of receipt of their information. Quitline staff made five call attempts over a period of up to 2 weeks before classifying individuals as unreachable. Quitline staff recorded the names of all patients who enrolled in treatment and sent this information to the study team weekly. Booster training sessions were conducted at all clinics every 3 months during the study.

Quitline-delivered treatment
The Quitline is funded by the State of Texas, operated by Optum, and staffed by trained cessation counselors who are available 24 hr 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. Smokers who enrolled in treatment received the Quitline’s standard counseling protocol which comprised up to five proactive counseling calls, each designed to provide practical expert support to help smokers develop problem-solving and coping skills, secure social support, and design a plan for successful cessation and long-term abstinence. Nicotine replacement therapy (NRT) in the form of nicotine patches was provided based on standard operating procedures. That is, NRT was only offered to participants in certain Texas counties, during certain months of the year, and was dependent on the Quitline having adequate funding. The timing of the counseling calls was relapse sensitive and included a quit date call, a call 1 or 2 days after the quit date and a call 1 week later, with additional calls generally occurring at 2 to 3 week intervals.

Outcome measures
Outcomes included (a) treatment engagement, defined as enrollment in treatment, and (b) smoking abstinence assessed 6 months following treatment enrollment among individuals who agreed at the time of enrollment to be contacted for follow-up. Abstinence assessments were conducted via telephone by the research team, and participants who reported being abstinent for the previous 7 days were mailed saliva collection kits within 24 hr that included postage-paid return envelopes. Team members contacted participants by phone to ensure arrival of the packets and to review the instructions for returning the samples. After receipt of samples by the research team, participants were compensated with a US$25 gift card. Participants with saliva samples reflecting cotinine levels of ≥20 ng/mL were classified as smoking [11].

RESULTS

Overall treatment engagement and cessation outcomes
The number of unique patients that visited the clinics during the implementation period was 218,915. Current smoking was reported by 40,888 patients, resulting in a smoking prevalence of 18.7%. Of all identified smokers, 4,806 enrolled in treatment with the Quitline, resulting in a treatment engagement rate of 11.8%. Abstinence was calculated using the subsample of treatment enrollees who agreed to be contacted for follow-up at 6 months (n = 3,704). Both self-report and biochemically confirmed 7 day point prevalence abstinence rates were based on an intent-to-treat (ITT) approach (i.e., missing assessment = smoking). Self-reported abstinence was 16.6% (616/3,704), whereas biochemically confirmed abstinence was 4.5% (166/3,704). Among the 247 individuals who reported abstinence and returned a valid, analyzable saliva cotinine sample, 81 returned samples with cotinine levels of ≥20 ng/mL (81/247 = 32.8%), which were consistent with current smoking.

Self-report and biochemically confirmed abstinence rates by NRT provision
NRT was provided to 56.7% of patients who enrolled in treatment and agreed to be contacted for
follow-up. 20.0% (420/2,095) of patients provided with NRT self-reported being abstinent at 6 months, compared with 12.2% (196/1,609) of those not provided with NRT. Thus, those given NRT were 1.81 times (95% CI: 1.50–2.17) more likely to report abstinence.

Biochemically confirmed abstinence was 5.9% (124/2,095) among participants were provided with NRT, and 2.6% (42/1,609) among participants who were not provided with NRT. Thus, those provided with NRT were 2.35 times as likely to be abstinent (95% CI: 1.64–3.35).

**DISCUSSION**

Directly connecting smokers in a safety-net healthcare system with the Quitline through an automated EHR-based referral system resulted in a treatment engagement rate of 11.8%. This is dramatically higher than the 1 to 2% rates observed nationally without special incentives to facilitate use [4, 5]. Furthermore, the 11.8% treatment engagement rate observed in this study is somewhat lower than the 14.7% rate observed in our group randomized trial that evaluated AAC in the same healthcare system [10]. Therefore, the current results demonstrate that AAC was successfully implemented as part of standard care in a real-world health care system and resulted in an impressive rate of treatment engagement. Thus, streamlined, automated EHR-based approaches such as AAC have great potential to dramatically increase the reach of evidence-based tobacco treatment among low-socioeconomic status smokers.

This study also makes an important contribution to the field through its collection biochemically confirmed, 6 month smoking abstinence data. Self-reported abstinence data are rarely biochemically confirmed in quitline treatment studies, and our study employed scientifically rigorous procedures to attempt to obtain saliva cotinine samples from all smokers who reported abstinence. This contribution is particularly important given that our study comprised a very large sample of low-income, predominantly racial/ethnic minority smokers.

The self-reported smoking abstinence rate of 16.6% was comparable to self-reported abstinence rates for quitline-delivered treatment reported in the Treating Tobacco Use and Dependence Clinical Practice Guideline (i.e., 12.7% without medication and 28.1% with medication) [2], which suggests that the smokers in our study linked with treatment via AAC had cessation outcomes that were similar to those of smokers who enrolled in treatment via more traditional approaches. However, results also indicated that self-reported abstinence was dramatically higher than biochemically confirmed abstinence (i.e., 16.6 vs. 4.5%). One-third of participants who reported abstinence provided saliva cotinine samples with levels that were inconsistent with abstinence.

The discrepancy observed between self-report and biochemically confirmed abstinence in our study could be attributable to numerous factors including continued use of NRT, use of e-cigarettes, exposure to high levels of secondhand smoke, reluctance to disappoint the researchers, or social stigma. These factors, which could have potentially led to cotinine tests that reflected current smoking among participants who were abstinent, were not assessed in the current study. Such factors should be carefully examined in future research. It should, however, be noted that only 57% of participants in our study were provided with NRT, and that those provided with NRT were only given a 2 week supply. Therefore, given that these individuals were predominantly uninsured and of very low SES, it seems unlikely that they would have been using NRT 6 months following treatment enrollment. Furthermore, at the time that our data were collected (i.e., 2013 through 2016), the prevalence of e-cigarette use was low among low-income individuals. Specifically, in 2015, only 4.6 per cent of adults in the USA with annual household incomes less than US$30,000 reported use of e-cigarettes [12]. Therefore, although possible, we believe that it is unlikely that the positive cotinine tests among those who reported abstinence were attributable to continued use of NRT or to e-cigarette use. A more likely possibility is that individuals may have relapsed between their report of abstinence and the time that the saliva samples were provided. It should also be noted that studies have found higher rates of misreporting among individuals in clinical situations where tobacco use is especially stigmatized, such as among pregnant women and those with a significant medical condition [13, 14].

The convention in the field is that self-report is adequate in population-based studies with low participant involvement [15, 16]. Although preliminary, our results call into question the idea that relying on self-report is sufficient for community- and population-based cessation studies. Furthermore, our results are consistent with a recently published review, which found that 40% of recently hospitalized smokers who enrolled in hospital-based smoking cessation trials failed biochemical verification [14]. A much more detailed and comprehensive investigation of this finding is clearly warranted before drawing conclusions.

An important direction for future research is to examine the efficacy of EHR modifications that could potentially boost quit rates among patients who enroll in quitline-delivered treatment via AAC or other similar EHR-driven quitline treatment referral systems. For example, as elucidated by Adsit and colleagues [17], using the EHR to provide closed-loop feedback to directly provide clinicians with information about the outcome of their referrals could have a powerful influence of clinicians’ willingness...
to make future referrals [18, 19]. Similarly, a recent content analysis [20] concluded that EHR modifications that allow tobacco treatment specialists to “pass back” patients to primary care providers along with reports on patients’ progress in quitting smoking has tremendous potential to enhance cessation rates. Additional modifications that could potentially enhance treatment engagement and, ultimately, cessation outcomes include providing EHR-driven prompts to encourage clinicians to check in with patients about their progress and facilitate re-enrollment in treatment following relapse, and providing motivational enhancement scripts for clinicians that could be used during follow-up visits after patients’ motivation to remain engaged in treatment may have declined.

The current findings should be interpreted in light of several strengths and limitations. Strengths include the large sample size, the low socioeconomic status and racial/ethnic diversity of participants, and the real-world setting in which the study was conducted. The collection of biochemically confirmed abstinence data is another major strength, given that quitline studies do not typically collect such data [3]. Limitations include the absence of a control condition, the large proportion of participants who reported being abstinent but did not provide a saliva cotinine sample (59.9%), our inability to collect individual patient-level data that would have allowed us to conduct sensitivity analyses to examine specific variables that may have influenced the results, and our failure to collect data at the follow-up assessment on continued NRT use, e-cigarette use, heavy exposure to secondhand smoke, or other factors which might have contributed to the discrepancy between self-reported and biochemically confirmed abstinence [14].

In summary, AAC was successfully integrated as part of standard clinical practice and resulted in impressive rates of treatment engagement and self-reported smoking abstinence in the context of a large implementation study. Findings are important because the setting where we conducted the work is representative of real-world population-based tobacco control settings, and because participants were low-income and racially/ethnically diverse. Self-reported abstinence rates were in line with other published quitline treatment studies [2, 3], suggesting that proactively connecting smokers with treatment results in cessation rates that are comparable to more traditional referral approaches that are plagued by limited reach. Although we were unable to verify if the discrepancy between self-reported and biochemically confirmed abstinence was due to invalid reporting or to external factors that were not measured, our results challenge the adequacy of self-report for large, population-based studies. Future studies should collect data to allow for more detailed and comprehensive investigations of discrepancies between self-reported and biochemically confirmed cessation outcome data.

Compliance with Ethical Standards

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Conflict of Interest: Dr. Zbikowski was employed by Alere Wellbeing, Inc. at the time that this work was conducted. The other authors declare that they have no conflicts of interest. The authors alone are responsible for the content and writing of this paper.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

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