Quitline treatment dose predicts cessation outcomes among safety net patients linked with treatment via Ask-Advise-Connect

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A R T I C L E   I N F O

A B S T R A C T

The efficacy of tobacco treatment delivered by state quitlines in diverse populations is well-supported, yet little is known about associations between treatment dose and cessation outcomes following the implementation of Ask-Advise-Connect (AAC), an electronic health record-based systematic referral process that generates a high volume of proactive calls from the state quitline to smokers. The current study is a secondary analysis of a 34-month implementation trial evaluating ACC in 13 safety-net clinics in Houston, TX. Treatment was delivered by a quitline and comprised up to five proactive, telephone-delivered multi-component cognitive-behavioral treatment sessions. Associations between treatment dose and abstinence were examined. Abstinence was assessed by phone six months after treatment enrollment, and biochemically confirmed via mailed saliva cotinine. Among smokers who enrolled in treatment and agreed to follow-up (n = 3704), 29.2% completed no treatment sessions, 35.5% completed one session, 16.4% completed two sessions, and 19.0% completed ≥three sessions. Those who completed one (vs. no) sessions were no more likely to report abstinence (OR: 0.98). Those who completed two (vs. no) sessions were nearly twice as likely to report abstinence (OR: 1.83). Those who completed ≥three (vs. no) sessions were nearly four times as likely to report abstinence (OR: 3.70). Biochemically-confirmed cessation outcomes were similar. Most smokers received minimal or no treatment, and treatment dose had a large impact on abstinence. Results highlight the importance of improving engagement in evidence-based treatment protocols following enrollment. Given that motivation to quit fluctuates, systematically offering enrollment to all smokers at all visits is important.

1. Introduction

Tobacco cessation quitlines deliver telephone-based proactive, multi-component cognitive-behavioral treatment for tobacco cessation. This treatment has demonstrated impressive efficacy and real-world effectiveness, and its supportive evidence base has been broadened and strengthened in recent years (Fiore et al., 2008; Stead et al., 2013; Tzelepis et al., 2011). Vidrine et al. (2010, 2013a,b) developed and evaluated an approach called Ask Advise Connect (AAC) designed to link smokers in healthcare settings with state quitlines through an

automated link within the electronic health record (EHR). AAC involves training medical staff to systematically *Ask* all patients at all visits about their smoking status, *Advise* all smokers to quit, and to *Connect* smokers interested in treatment with a quitline using an automated link within the EHR. Following connection, quitlines proactively call smokers within 48 h to facilitate treatment enrollment.

The results of two large group randomized trials that evaluated the efficacy of AAC indicated that AAC was associated with a 13- to 30-fold increase in treatment enrollment compared to Ask Advise Refer (AAR; Schroeder, 2005), a recommended standard of care in the field (Vidrine

et al., 2013a,b). AAR is an approach developed by Schroeder (2005) and is an abbreviated version of the 5 A's (i.e., Ask, Advise, Assess, Assist, Arrange) approach to tobacco cessation (Fiore et al., 2008). AAR involves asking all patients at all visits about their smoking status, advising all smokers to quit, and providing smokers with quitline referral cards and encouraging them to call on their own for assistance. These studies demonstrated that AAC has great potential to enhance rates of enrollment in quitline-delivered treatment in primary care settings, particularly within settings that treat low-income, racially/ethnically diverse smokers. However, follow-up data examining smoking abstinence rates were not collected in these trials.

An important predictor of cessation outcomes in the general tobacco cessation treatment literature is the dose of behavioral treatment that is received, which reflects adherence to evidence-based treatment protocols. Behavioral treatment dose has been defined in multiple ways including number of treatment contacts, number of minutes, and/or amount of content (Brandon et al., 2004; Fiore et al., 2008; Sheffer et al., 2012, 2013, 2009). Although a tremendous amount of evidence supports the efficacy of quitline-delivered treatment within diverse populations of smokers, few studies have carefully examined treatment dose-response associations with abstinence in these populations (Zhu et al., 1996). No studies have examined these associations in the context of healthcare systems-level implementation studies designed to facilitate tobacco treatment enrollment. Furthermore, many of the studies that have evaluated dose-response effects of telephone-delivered tobacco cessation treatment have been tightly controlled randomized clinical trials. It is also notable that a meta-analysis conducted by Tzelepis et al. (2011) included several randomized controlled trials that utilized community-based proactive recruitment methods.

The studies that have examined dose-response associations in the context of behavioral treatments for tobacco cessation include a Cochrane review that evaluated the efficacy of telephone counseling for smoking cessation (including treatment delivered via state quitlines) in an examination of 77 randomized and quasi-randomized trials (Stead et al., 2013). The authors concluded that there was "limited evidence" regarding the optimal number of treatment sessions needed to produce a measurable benefit, but that there was some evidence to support a positive dose-response association. A subsequent study conducted by Bernstein et al. (2016) examined the association between treatment dose and cessation among smokers visiting an urban Emergency Department who were randomized to receive either a quitline brochure (control condition) or a brochure, a motivational interview, a faxed referral to the quitline, and combination nicotine replacement therapy (NRT; enhanced care). Results supported a significant dose-response effect of treatment such that receipt of a larger treatment dose was associated with a higher likelihood of abstinence. However, the vast majority of participants in this study (74.7%) received no quitline services, making it difficult to evaluate the incremental effects of treatment dose. While these previous studies have generally indicated that higher doses of treatment lead to better cessation outcomes, examining this association within the context of a large implementation study is important. That is, in the current study, a much larger number of smokers were proactively approached and offered treatment than is typical in cessation trials. Thus, it is not clear that the results of these previous studies are meaningful within the context of the AAC approach. Thus, the current study is important in that it provides meaningful, real-world data with regard to both the dose of treatment received, and the impact of treatment dose on cessation outcomes within a large sample of low-income, predominantly racial/ethnic minority smokers.

The current study is a secondary analysis of a 34-month implementation trial that evaluated AAC in 13 safety-net community health centers that were part of the Harris Health System (Piñeiro et al., 2018). Harris Health is one of the nation's largest safety-net healthcare systems, and is one of the two healthcare systems where AAC was initially evaluated in a group randomized clinical trial (Vidrine et al.,

2013b). The purpose of the current study was to examine associations between treatment dose received and cessation outcomes at six months among low-income, racially/ethnically diverse, uninsured and under-insured smokers who enrolled in behavioral treatment delivered by a quitline through participating in a systems-level implementation study evaluating AAC. In addition, given that considerable evidence indicates that NRT increases cessation rates for behavioral tobacco cessation treatments delivered via quitlines (Fiore et al., 2008; Hollis et al., 2007), associations between NRT and cessation outcomes were also examined.

2. Methods

2.1. 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). 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 gave verbal consent to have their contact information sent to the quitline. Verbal consent for each participant was documented in the EHR. A waiver of written informed consent and a waiver of authorization were obtained.

2.2. Procedure

2.2.1. Ask-Advise-Connect

Licensed Vocational Nurses were trained to assess and record smoking status in the EHR for all patients at all visits at the time that vital signs were collected, deliver brief advice to all smokers to quit, and to offer to immediately send each smoker's contact information to the Quitline so that they could be contacted proactively and offered enrollment in treatment. Given the nature of the study, it was not possible to collect patient-level sociodemographic information other than name, phone number and language preference, or to collect detailed smoking history information. The names and phone numbers of smokers willing to be contacted were automatically sent to the Quitline every 24 h through an automated connection system within the EHR. Information that was sent to the Quitline was also sent to our research team for tracking purposes. Smokers were proactively called by the Quitline within 48 h of receipt of their information. Quitline staff made five call attempts over a period of up to two weeks before individuals were classified as unreachable. Quitline staff recorded the names of patients who enrolled in treatment and sent this information electronically to our research team monthly. Telephone treatment session completion rates were tracked continuously by Quitline staff.

2.2.2. Proactive behavioral tobacco cessation treatment delivered by a state Quitline

The Quitline was funded by the state of Texas and was operated by Optum and staffed by trained behavioral tobacco cessation counselors who were available 24 h a day, seven days a week, and most holidays. The Texas Quitline is a member of the North American Quitline Consortium (http://www.naquitline.org/) and can be accessed by calling 1-800-QUIT-NOW. Counseling was available in English, Spanish, and in more than 140 additional languages through a third party. Smokers who enrolled in treatment received the standard counseling protocol which consisted of up to five proactive telephone treatment sessions, 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. The counseling session topics included: tobacco history,

setting a quit date, relapse prevention, use of cessation medication, developing a quit plan, withdrawal symptoms, weight gain, and stress. Just over half of all participants (56.6%) who enrolled in treatment were offered a two-week supply of NRT (i.e., patch, lozenge or gum) based on eligibility criteria established by the Quitline which included residing in certain Texas counties, offering NRT during certain months of the year, and having adequate funding to provide NRT. The timing of treatment sessions was relapse sensitive and included a quit day session scheduled to occur one or two days after the initial session, and a post quit day session one week later, with additional sessions generally occurring at two- to three-week intervals. Participants were also provided access to a web-based cessation program which included a quit plan, a Quit Coach, and a private, online community.

2.3. Outcome measures

Treatment dose received (i.e., the number of telephone-delivered treatment sessions completed) was calculated among smokers who enrolled in treatment and agreed to be contacted for follow-up. Smoking abstinence was assessed via telephone at the 6-month follow-up. Participants who reported being abstinent for the previous 7-days were asked to provide mailed saliva cotinine samples to biochemically confirm self-reported abstinence. An envelope was mailed to participants with the following contents: a copy of the informed consent document, instructions on how to provide the saliva sample, a saliva collection kit and a prepaid return envelope. After the saliva samples were received by the research team, participants were compensated with a mailed $25 gift card. Participants with cotinine levels of < 20 ng/ml were classified as abstinent (Jarvis et al., 2008).

2.4. Data analysis

The mean number of treatment sessions completed and the proportions of participants who completed no treatment sessions, one session, two sessions and three or more sessions were calculated. Logistic regression analysis was performed to evaluate the relationship between treatment dose and cessation outcomes six months following treatment enrollment among smokers who enrolled in treatment with the quitline and agreed to be contacted to complete the six-month follow up assessment (n = 3704). Treatment dose was categorized as: 1) no treatment sessions, 2) one session, 3) two sessions, and 4) three or more treatment sessions. We estimated the odds of being abstinent for each level of treatment dose received compared to the referent group of no treatment. Similar analyses explored the relationship between provision of NRT by the quitline (yes vs. no) and cessation outcomes. The odds of being abstinent were estimated for those who were (vs. were not) provided with NRT. Logistic regression outcomes were reported in terms of odds ratios and corresponding 95% confidence intervals. Self-reported and biochemically confirmed 7-day point prevalence abstinence rates were based on an intent-to-treat (ITT) approach (i.e., participants who did not complete the 6-month follow-up were classified as smoking). In addition, participants who reported abstinence but returned saliva samples consistent with current smoking were classified as smoking (see Fig. 1).

3. Results

3.1. Behavioral treatment utilization

Approximately 12% of identified smokers (i.e., 4806/40,888) enrolled in treatment with the quitline, and 77% of these smokers (3704/4806) consented to be contacted to complete the 6-month follow-up assessment. Among smokers who enrolled in treatment and agreed to be contacted for follow-up (n = 3704), 29.2% (n = 1081) completed no treatment sessions, 35.5% (n = 1313) completed one session, 16.4% (n = 606) completed two sessions, and 19.0% (n = 704) completed

three or more treatment sessions. The mean number of proactive sessions completed was 1.21 (SD = 1.40).

3.2. Relationship between number of treatment sessions completed and cessation outcomes

Self-reported abstinence was 16.6% (616/3704), and biochemically confirmed abstinence was markedly lower at 4.5% (166/3704). Self-reported abstinence rates were 11.5% (124/1081; 95% CI: 9.57, 13.37) for those who completed no treatment sessions, 11.3% (148/1313; 95% CI: 9.56, 12.98) for those who completed one session, 19.1% (116/606; 95% CI: 16.00, 22.28) for those who completed two sessions, and 32.4% (228/704; 95% CI: 28.92, 35.85) for those who completed three or more treatment sessions. Biochemically confirmed abstinence rates were 2.4% (26/1081; 95% CI: 1.49, 3.32) for those who completed no treatment sessions, 3.2% (42/11,313; 95% CI: 2.25, 4.15) for those who completed one session, 5.1% (31/606; 95% CI: 3.36, 6.87) for those who completed two sessions, and 9.5% (67/704; 95% CI: 7.34, 11.69) for those who completed three or more treatment sessions (see Fig. 2).

Participants who completed one (vs. no) treatment sessions were no more likely to report abstinence (OR: 0.98; 95% CI: 0.76, 1.26). Those who completed two (vs. no) sessions were 1.83 times more likely to report abstinence (95% CI: 1.39, 2.41). Those who completed three or more (vs. no) sessions were 3.70 times more likely to report abstinence (95% CI: 2.89, 4.72). A similar pattern emerged for biochemically-confirmed outcomes. That is, those who completed one (vs. no) sessions were no more likely to be abstinent (OR: 1.34; 95% CI: 0.82, 2.20). Those who completed two (vs. no) sessions were 2.19 times more likely to be abstinent (95% CI: 1.29, 3.72). Those who completed three (vs. no) sessions were 4.27 times more likely to be abstinent (95% CI: 2.69, 6.78).

3.3. Provision of nicotine replacement therapy (NRT)

Among participants who enrolled in treatment and agreed to be contacted for follow-up, 56.6% were provided with a 2-week supply of NRT along with proactive, telephone-based behavioral tobacco cessation treatment. Participants who were provided with NRT were 1.81 times more likely to self-report abstinence from smoking at the 6-month follow-up assessment than participants who were not provided with NRT (95% CI: 1.50, 2.17). A similar pattern emerged for biochemically confirmed cessation outcomes. That is, smokers who were provided with NRT were 2.35 times more likely to be abstinent than those who did not receive NRT (95% CI: 1.64, 3.35).

4. Discussion

In this real-world implementation study that evaluated the AAC approach to linking smokers in a safety-net healthcare system with treatment, we found that the dose of treatment received had a clear effect on cessation outcomes. Specifically, we found that those who completed three or more treatment sessions had the highest likelihood of achieving abstinence, and were approximately four times as likely to be abstinent at six months compared to those who completed no sessions or only one session. Our findings are in line with other studies that have identified a dose-response relationship between the number of telephone-delivered treatment sessions completed and the likelihood of achieving abstinence (Bernstein et al., 2016; Zbikowski et al., 2008, 2011; Zhu et al., 1996).

Our study adds to the existing literature through demonstrating that completion of at least two telephone-delivered treatment sessions is needed to predict abstinence among low-income, racially/ethnically diverse smokers linked with telephone-delivered behavioral tobacco cessation treatment in the context of a large, real-world implementation study. Furthermore, enhancing treatment engagement is a critically important direction for future research, especially among vulnerable

Fig. 1. Participant flow diagram.

populations of smokers, and as EHR-based treatment referral mechanisms begin to proliferate. This is particularly important given that our results supported a dose-response relationship that predicted cessation outcomes. That is, an important public health challenge is to not only facilitate enrollment in treatment with state quitlines, but to increase *engagement* among smokers who have successfully enrolled to ensure that adequate doses of treatment are successfully delivered. For example, text messaging interventions designed to facilitate treatment engagement may be one promising strategy. Indeed, evidence is emerging to suggest that text messaging is an effective form of supplemental communication for promoting treatment engagement (Hanauer et al., 2009). A recent study supported the efficacy of an optimized text messaging intervention to facilitate adherence to treatment (Graham et al., 2016).

An important caveat is that streamlining and automating the smoking assessment and treatment enrollment processes may have ultimately increased enrollment among smokers with relatively low levels

of motivation to quit. That is, smokers who call quitlines to enroll in treatment on their own may have higher levels of motivation, fewer barriers to quitting, and fewer comorbidities. Therefore, although approaches such as AAC have demonstrated broader reach and dramatically higher levels of treatment enrollment, smokers who ultimately enroll in treatment may have less motivation to engage in treatment, or may be more likely to experience barriers that interfere with treatment engagement. Thus, enhancing the AAC approach with motivational strategies at both the healthcare system and provider levels could potentially lead to increased treatment engagement. Examining how best to deliver such strategies is an important area for future research. For example, improving clinician training in the delivery of brief advice to quit through the use of motivational enhancement techniques could potentially enhance smokers' engagement in treatment and overall motivation to quit. In addition, providing motivationally-based EHR-driven prompts to encourage clinicians to check in with patients about their progress at follow-up visits and facilitate re-enrollment in
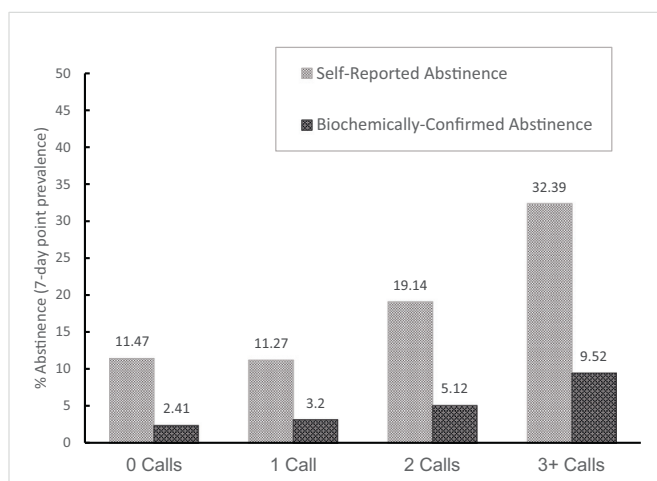
Fig. 2. Self-reported and biochemically confirmed abstinence rates by treatment dose received (i.e., the number of counseling calls completed by individuals enrolled in treatment) six months following treatment enrollment.

treatment could be an important strategy. Finally, motivational text messages focused specifically on adherence could be used to augment counseling call protocols. Nonetheless, following enrollment in treatment, quitline coaches should do all that they can to encourage clients to complete at least two treatment sessions, as Hollis et al. (2007) have elucidated.

A notable finding is that a large discrepancy was observed between self-reported and biochemically confirmed abstinence rates. As described in the main outcome paper (Piñeiro et al., 2018), this discrepancy could be attributable to multiple factors including continued use of NRT, use of e-cigarettes, exposure to high levels of secondhand smoke, or misreporting due to reluctance to disappoint the researchers or social stigma. Future studies should carefully examine such factors.

Several limitations should be noted. First, due to the design of the study, we were unable to collect individual patient-level data (e.g., demographics, dependence, motivation, stress), which restricted our ability to investigate predictors of the dose of treatment received or abstinence. It is possible that motivation to quit may have influenced the number of treatment sessions completed, and that motivation – rather than the dose of counseling received – predicted abstinence. Future research should explore this relationship. Second, more than 20% of smokers who enrolled in treatment did not consent to be contacted for follow-up, and more than one-third of smokers who agreed to be contacted were unreachable. It is possible that these phenomena may have resulted in a pattern of missing data that influenced our results. Third, we did not include the possible influence of NRT in the dose-response analyses. It should be noted that only 57% of participants were provided with NRT by the quitline, and those who were provided with NRT were only given a 2-week supply. Given that these smokers were predominantly uninsured and of very low SES, it seems unlikely that they would have been using NRT six months following treatment enrollment. Therefore, the discrepancy observed between self-reported and biochemically confirmed abstinence rates is not likely attributable to NRT use. Fourth, although the web-based cessation program was made available to all participants by the Quitline, we do not have data on whether or not participants used the program. Therefore, we were unable to control for any possible influence of use of the web-based program on our outcomes.

Despite these limitations, the current study has multiple important strengths. First, we were able to successfully implement a systems-level intervention in a large safety net healthcare system that led to the enrollment of a very large number of smokers in treatment. Second, biochemically-confirmed abstinence rates were assessed six months following treatment enrollment. This is an important strength given that

biochemical confirmation is rarely conducted in studies that evaluate tobacco cessation treatment delivered by quitlines. Third, the setting where we conducted the study is representative of real-world population-based tobacco treatment settings, and findings are likely to be highly generalizable to other settings.

4.1. Conclusion

Our results support a clear dose-response effect of behavioral treatment delivered by a quitline such that the completion of more treatment sessions resulted in better cessation outcomes. All participants were enrolled in treatment via a systematic, EHR-based AAC approach. Given that the majority of smokers who enrolled in treatment completed no treatment sessions or only a single session, elucidating methods of increasing treatment engagement is critically important. Healthcare providers have a powerful influence on smokers' willingness to enroll in and adhere to tobacco cessation treatment, and improving the delivery of brief advice to quit through the use of motivational enhancement techniques could potentially improve smokers' engagement in treatment. This is an important area for future research. Finally, given the broad potential reach of quitlines at the population level, an important public health challenge is not only to facilitate enrollment, but to increase treatment engagement.

Declaration of interest

Dr. Zbikowski was employed by Alere Wellbeing, Inc. at the time that this work was conducted. None of the authors have any conflicts of interest to declare.

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