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A Randomized, Controlled Pilot Study Of Warm Handoff Versus Fax Referral For Hospital-Initiated Smoking Cessation Among People Living With HIV/AIDS

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Abstract

Introduction—The prevalence of smoking among people living with HIV/AIDS (PLWHA) remains higher than the general population. Life expectancy among PLWHA has increased over the past decade, however, PLWHA who smoke will die younger than their non-smoking peers. The primary aim of this pilot study was to examine the effects of warm handoff versus fax referral to the quitline for smoking cessation among hospitalized smokers living with HIV/AIDS.

Methods—25 smokers with a diagnosis of HIV/AIDS hospitalized at a Midwestern academic medical center in 2012–2013 (19 male; mean age = 47.7; 48% African-American) were identified, approached, and randomized to one of two treatment arms. At the bedside for patients in warm handoff, staff telephoned the quitline for on-the-spot enrollment and counseling. Participants randomized to fax were fax-referred to the quitline on the day of discharge. The quitline provided continued outpatient counseling to participants in both conditions. The main outcome was verified tobacco abstinence at 6-months post randomization.

Results—Enrollment and participation in quitline counseling was high among both warm handoff (100%) and fax-referred (71.4%) PLWHA participants. Nearly all (24) completed follow up for outcome data collection at 6 months. Verified abstinence rates were 45.5% in warm handoff versus 14.3% in fax referral at 6 months (not significant).

Conclusions—Hospitalized smokers living with HIV/AIDS were highly engaged in quitline services. Warm handoff seems a promising intervention for hospitalized PLWHA that requires further exploration.

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Contributors

Author Richter and Faseru contributed to the design the study. Author Richer and Mussulman wrote the protocols. Authors Fitzgerald and Patel provided literature reviews. Author Nazir designed and managed the data collection data base and conducted the statistical analysis. Author Mussulman wrote the first draft of the manuscript and all authors contributed to and have approved the final manuscript.

Conflicts of Interest

All authors declare they have no conflicts of interest.

1. Introduction

The prevalence of smoking among people living with HIV/AIDS (PLWHA) is two to three times higher than the general population.^{1,2} Despite achievements gained in antiretroviral therapy (ART), tobacco use disorder continues to lower the lifespan and decrease the quality of life of PLWHA.^{3–5} Studies have demonstrated greater HIV/AIDS-related morbidity and all-cause mortality among PLWHA who smoke cigarettes compared to PLWHA who do not smoke.^{4,6,7} PLWHA who smoke are at greater risk for developing bacterial pneumonia, oral lesions, and increased rates of smoking attributable lung cancer.^{8–10} A number of studies, however, find that most PLWHA are interested in and contemplating quitting smoking.^{2,11,12}

In 2015 an estimated 1.1 million Americans were living with HIV¹³; it is estimated that on average one-third to one-half of PLWHA are hospitalized per year.^{14,15} A majority of these PLWHA patients are hospitalized for reason other than AIDS-related illness, demonstrating the importance of addressing comorbid conditions during their inpatient stay.¹⁶ Promising smoking cessation interventions for PLWHA have been developed, but none focus on initiating treatment during hospitalization.¹⁷ Five randomized-controlled cessation trials have been conducted among outpatient PLWHA^{18–22}; of these, two achieved significant between-group quit rates at 3 months follow up.^{18,21} Hospitalization may serve as a “teachable moment” for smoking cessation. Within the general population, meta-analyses find that initiating cessation treatment during the hospital stay, and providing post-discharge follow-up, is effective for smoking cessation.²³ However, no studies, to date, have examined the potential of hospital-based interventions for helping PLWHA quit smoking.

Providing brief intervention at the bedside and linking patients to tobacco quitlines post-discharge is one way hospitals may provide much needed evidence based care. Many hospitals are currently fax referring patients to quitlines for follow-up care.^{24,25} However, quitline participation appears to vary widely (5% – 53%) among the fax referred.^{25–28}

Warm handoff is commonly used in Screening, Brief Intervention, and Referral to Treatment (SBIRT) - a federal program in medical care settings that has demonstrated improved self-reported drug and heavy alcohol use. During warm handoffs, health care providers walk patients to specialists co-located in the same medical setting for further evaluation and care.

Presently, few published reports of the effectiveness of warm handoffs are available among PLWHA. One pilot study designed to evaluate the acceptability and feasibility of integrating SBIRT for tobacco cessation in a HIV clinic among non-treatment seeking smokers found participants in the SBIRT intervention smoked fewer cigarettes per day, were less nicotine dependent, had fewer urges to smoke, and decreased withdrawal symptoms compared to those not receiving the SBIRT for tobacco intervention.²⁹

The present pilot study was derived from a parent study, EQUIP—Enhancing Quitline Use among Inpatients. EQUIP examined the impact of warm handoff versus fax referral for smoking cessation among a general hospital sample.^{30,31} EQUIP was part of a collaborative agreement between the National Institutes of Health and multiple research sites entitled the

Consortium of Hospitals Advancing Research on Tobacco (CHART). A number of CHART sites received supplements from the National Heart, Lung, and Blood Institute to engage PLWHA in their trials. The purpose of this brief report is to report the implementation and findings of EQUIP for PLWHA.

2. Method

2.1. Participants

PLWHA participants were recruited during hospitalization at a large Midwestern academic medical center between 2011 and 2014. Daily lists of hospitalized patients with a diagnosis of HIV-positive/AIDS were generated. All patients on this list were approached and smoking status and willingness to participate in a clinical trial were assessed. To be eligible participants were required to meet the following inclusion criteria: 18 years of age or older, smoked at least one cigarette in the past 30 days, planning to stay quit post-discharge, spoke English or Spanish, have no other household member enrolled in the trial, not currently pregnant and have no other health issue precluding participation. Non-Kansas residents were initially excluded, however, in order to bolster recruitment the study expanded recruitment to Missouri residents. Study participants were reimbursed \$20 for baseline and month 1 assessments, \$50 for the 6 month follow-up, and \$100 for providing salivary cotinine for cessation verification. The study protocol was approved by the University of Kansas Medical Center institutional review board.

2.2. Study design and procedures

The methods of the parent study are described in more detail in our prior publication.³¹

2.3. Measures

Baseline assessment administered by a research assistant included demographic, psychosocial, health, and tobacco use variables. Unlike tobacco use, hospitals in general do not conduct universal screening of patients' HIV or AIDs (H/A) status on admission. Consequently, there is no one place in the EMR that identifies PLWHA. Moreover, PLWHA are often admitted to the hospital for health issues that are unrelated to their H/A diagnoses, hence their H/A diagnoses are not always included in the primary or secondary diagnoses related to the hospital visit. Therefore, identifying PLWHA in the hospital setting involves screening for a number of H/A related conditions. Fortunately, our hospital screens admissions and provides a list of potential PLWHA to our Ryan White Services unit. Following IRB approval of study procedures, this list was provided to our study staff in order to facilitate recruitment. The list included all patients with one or more of 16 specific ICD-9 codes, including V08 and a number of codes under 042, listed on either their problem list or in their medical history. Where a patients' H/A status was questionable, study staff confirmed H/A status with Ryan White staff. Smoking status was confirmed via patient self-report.

In addition, we collected date of birth, sex, health insurance, primary and secondary diagnoses, procedures, diagnosis related group codes, and length of stay from the electronic medical record. The primary endpoint was 6 month verified abstinence, with missing

outcomes coded as continued smoking. Abstinence was biochemically verified using salivary cotinine (< 15 ng/ml). For those who did not provide saliva, staff contacted participant identified proxies to verify abstinence. Secondary endpoints were self-reported smoking cessation at 1 and 6 months, cigarettes smoked per day, inpatient and post-discharge medication use and adherence to quitline counseling.

2.4. Statistical analysis

Baseline characteristics were summarized using descriptive statistics (i.e., means, *SDs*, and frequencies). To identify potential baseline differences between the two intervention groups we used *t*-tests for continuous and chi-square for categorical variables, respectively. An intent to treat approach was used in which participants lost to follow-up were considered smokers. Fisher's exact test was used to compare the dichotomous cessation outcomes between the two intervention groups. Analyses were completed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

3. Results

3.1. Descriptive statistics

Of 174 PLWHA hospitalized, 135 did not meet inclusion criteria, six refused to participate and eight were unable to be consented. Predominate reasons for ineligibility included being a non-smoker or had not smoked in the past 30 days ($n = 64$), not being a Kansas resident ($n = 35$) and did not plan to quit smoking upon discharge ($n = 21$).

Twenty-five participants were enrolled and randomized into either warm handoff ($n = 11$) or fax ($n = 14$). Mean (SD) age of the participants was 47.7 (8.6) years. The majority of the participants were male (76.0%) and almost half (48.0%) were African American. On average, participants smoked 16.8 (11.4) cigarettes per day. Most (83.3%) smoked within thirty minutes of waking and nearly half (40%) were heavy smokers (heaviness of smoking index > 4).³² Results from *t*-tests and chi-square analyses indicated there were no between-group differences in baseline characteristics.

Verified abstinence from smoking at 6 months was 45.5% among participants in the warm handoff versus 14.3% in the fax condition (Figure 1). All quitters were biochemically verified abstinent except for one who was verified using a proxy. Compared to fax participants, lower proportions of warm handoff participants received inpatient cessation medications and reported using cessation medications post discharge (20.8% and 12.0% among fax referral and 4.2% and 4.0% among warm handoff respectively; these did not differ significantly $p = 0.17$ and $p = 0.60$). All participants in the warm handoff condition and 71.5% in the fax referral condition enrolled in the quitline. Neither of these results were statistically significant ($p = 0.18$ and 0.11 , respectively). Quitline counseling call completion rates were also similar between the two groups, 100%, 50% (call 1); 36.4%, 42.9% (call 2); 27.3%, 21.4% (call 3); 18.2%, 14.3% (call 4); 0%, 14.3% (call 5) for warm handoff and fax referred respectively. Over 90% of the participants were satisfied with the tobacco treatment services they received during their hospitalization.

4. Discussion

The results of this pilot study demonstrate that overall, hospitalized smokers living with HIV/AIDS are willing to enroll, participate and remain in a hospital-initiated smoking cessation intervention and clinical trial. Three quarters enrolled in quitline services and many participated in counseling calls post-discharge. There was a strong trend toward greater abstinence in the warm handoff arm, although the modest sample size precluded our ability to detect significant differences in quit rates. This trend was especially intriguing as the parent study found no differences in verified abstinence at 6-month follow-up between fax referral (25.3%) and warm handoff (25.4%) study arms.³¹ Differences in self-reported and biochemically verified quit rates in hospital-initiated clinical trials often occur, as also shown in this study and our parent study.³³ The greater degree of misreporting in the fax arm may be attributable to the longer bed side contact with our tobacco treatment staff in this arm, compare to warm handoff arm. This may have resulted in a stronger bond between counselors and patients, a reluctance on the part of patients to report that they hadn't quit smoking, higher rates of misreporting and a higher rate of failure to verify smoking cessation in this group. Possibly, the stronger continuity of care provided by warm handoff, in which quitline counseling is initiated during the hospital stay and continued after discharge, is critical to smokers with complex treatment regimens such as PLWHA. It is important to note that a greater portion of warm handoff participants were abstinent even though, as also found in the parent trial, lower proportions in warm handoff used cessation medications.

These findings are consistent with those of Cropsy et al. (2013), who found preliminary support for using a similar treatment modality to treat smokers in an HIV/AIDS outpatient clinical setting;²⁹ it extends those findings to demonstrate the applicability to an inpatient setting as well.

This study has limitations. First, the small sample size may result in a small number of errors in the determination of abstinence rates which could make a large difference in those rates. Thus, the small sample size may prohibit the detection of significant differences in quit rates in warm hand off versus fax referral. Attempts to replicate the current result in a larger sample would be helpful. Second, only those smokers who were willing to quit upon discharge were included in the study. We are unable to determine how appropriate the intervention may be in unmotivated smokers.

5. Conclusions

Findings provide preliminary support for using a warm handoff intervention to treat smoking among hospitalized PLWHA who are willing to quit. Additional research is warranted to explore the potential substantial impact and benefits of a warm handoff to the quitline for this high risk population.

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Highlights

- Life expectancy among PLWHA has increased over the past decade, however, tobacco use disorder continues to lower the lifespan and decrease the quality of life of PLWHA
- All eligible PLWHA accepted enrollment and engaged in treatment in the present study, which suggests that hospitalization is an excellent time to initiate tobacco treatment among PLWHA who are interested in quitting tobacco
- Providing a warm handoff to free tobacco quitlines during hospital stays for PLWH is an extremely promising approach for helping them quit smoking

Fig. 1.
Quitline enrollment and ITT abstinent rates by arm among PLWHA patients.