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Predictors of in-person follow-up among subjects in an ED-based smoking cessation trial

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Introduction

Adequate subject follow-up is integral to the success of clinical trials. Losses to follow-up pose threats to internal and external validity.¹ Emergency department (ED) populations are often highly mobile, with unstable housing and numerous unmet social needs.² ED-based clinical trials that focus on risky health behaviors are at particular risk for loss to follow-up. Often follow-up is completed by telephone, but some studies require in-person assessment, often to collect biological samples for confirmatory testing.

The purpose of this study was to identify predictors of in-person follow-up (IPFU) at three months in a clinical trial of a tobacco dependence treatment intervention in the ED.

Methods

We conducted a secondary analysis of data from a clinical trial conducted from January 2006–September 2007 at a busy, urban ED. Study methodology and main results have been previously reported.³ In brief, 340 smokers, age 18 and older, being discharged from the ED, were randomized to Usual Care (UC) or Enhanced Care (EC), receiving a motivational interview, six weeks of nicotine patches, a telephone call at 3 days post-discharge, a cessation brochure, and a referral to the state smokers' quitline. Usual Care (UC) subjects received the brochure. Subjects were contacted by telephone at three months, and asked to return to the ED for measurement of exhaled carbon monoxide and salivary cotinine, to confirm tobacco abstinence. Subjects who returned received \$25 and a \$4 transportation voucher.

Data analysis

Data were analyzed with SPSS 16.0 (SPSS, Chicago, IL). A logistic regression model was fitted for the endpoint of completed return to ED at three months, with variables selected for inclusion based on clinical criteria. Eleven variables were chosen for inclusion. These were age, sex, race/ethnicity, insurance, self-reported alcohol or drug use, a 2-question depression screen⁴, tobacco-related ICD9 code, subject belief that s/he has a tobacco-related illness, subject belief that s/he is in the ED because of a tobacco-related problem, Fagerstrom Test for Nicotine Dependence score⁵, and study arm. Regression diagnostics were calculated.

The study was approved by the Institutional Review Board of (blinded) Medical Center, and is registered in [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT00297466) (NCT00297466).

Results

Characteristics of study subjects are given in Table 1. There were no important differences between intervention groups in baseline demographic variables. Differences between groups in tobacco behaviors and beliefs are noted.

Results of the logistic regression model are given in Table 2. Three factors were independently associated with IPFU: Medicaid insurance, self-reported use of alcohol or illicit drugs, and subject belief that s/he has a tobacco-related illness. Screening positive for depression was associated with decreased odds of return. Age, sex, race/ethnicity, level of nicotine dependence, ICD9 diagnoses, subject belief that the ED visit was tobacco-related, and study arm were not associated with IPFU.

A Hosmer-Lemeshow test showed reasonable goodness-of-fit, with $P = 0.25$.

Discussion

Losses to follow-up are common in EM research. Although telephone ownership among ED patients is common, cell phones are increasingly used more than land lines. Because of phone loss and turnover, this may result in higher nonresponse rates and refusal rates.⁶ In addition, cell phones may be discarded during the period of follow-up. Subjects are often reluctant to return for IPFU. It may be difficult to take time off from work, for example, or to arrange childcare.

In this study, three factors were associated with increased odds of IPFU: Medicaid insurance, self-reported use of alcohol or drugs, and patient-perceived presence of a smoking-related illness. A positive depression screen was associated with decreased odds of IPFU.

It appears counterintuitive that Medicaid insurance and substance use would be associated with increased odds of in-person follow-up. However, in our region, the hospital runs an extensive ambulatory care network that treats many Medicaid patients. Hence, it may not be surprising that these patients were more likely to return to the ED for follow-up; this reflects patterns and sites of care with which they are already familiar.

Similarly, patients with alcohol use disorders or substance use frequently visit acute care settings, including the ED. They are often engaged in addictions treatment at local alcohol or drug treatment centers. Again, we suspect these subjects are already familiar and comfortable with these settings, including the ED, and hence are amenable to return.

Subjects who believe they have a tobacco-related illness may have a sufficient “cue to action” cue⁷ to seek care and complete IPFU. In this study, subjects believing they had a tobacco-related illness were more likely to be tobacco-abstinent at three months.³ These subjects may have been particularly motivated to comply with the study protocol, as well as to quit smoking.

Subjects screening positive for depression on the PHQ-2 were less likely to return to the ED for follow-up. Depression has been associated with medication nonadherence in a number of conditions.⁸ Given depression’s effects on motivation and activity level, it may not be surprising that these subjects were less likely to return.

The study's findings suggest that additional strategies to augment IPFU may be needed for ED trials. Standard techniques used in other clinical settings include visits by a research assistant to the subject's home, or a public space such as a coffee shop. These methods have not been widely employed in ED-based trials.

Conclusions

Medicaid insurance, co-occurring alcohol or substance use, and self-perceived smoking-related illness were associated with enhanced likelihood of IPFU. A positive depression screen identified subjects at risk for failure of IPFU. Future ED-based trials might enhance IPFU by incorporating visits to home or community settings.

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Table 1
Characteristics of study patients

Variable	Returned to ED, n =145	Didn't return to ED, n = 192	P value
Age, years, mean (SD)	40.7 (11.7)	40.0 (12.3)	0.59
Sex, N (%)			0.10
Male	63 (38.4%)	101 (61.6%)	
Female	82 (47.4%)	91 (52.6%)	
Fagerstrom Test for Nicotine Dependence, median (IQR)	6 (5, 8)	6 (5, 8)	0.27
Race/Ethnicity, N (%)			0.12
Hispanic	89 (42.2%)	122 (57.8%)	
African-American	41 (52.6%)	37 (47.4%)	
White	11 (33.3%)	22 (66.7%)	
Other/Asian	4 (26.7%)	11 (73.3%)	
Insurance, N (%)			0.002
Medicaid	80 (54.8%)	66 (45.2%)	
Medicare	5 (35.7%)	9 (64.3%)	
Third-party	45 (33.8%)	88 (66.2%)	
Self-pay/none	15 (34.1%)	29 (65.9%)	
Alcohol or drug screen, N (%)			0.28
Positive	42 (47.7%)	46 (52.3%)	
Negative	98 (41.0%)	141 (59.0%)	
Depression screen (PHQ-2)			0.08
Positive	93 (39.9%)	140 (60.1%)	
Negative	52 (50.0%)	52 (50.0%)	
Tobacco-related ICD9			0.67
Positive	31 (45.6%)	37 (54.4%)	
Negative	114 (42.7%)	153 (57.3%)	
Self-perceived smoking-related illness			0.001
Positive	89 (51.1%)	85 (48.9%)	
Negative	55 (34.0%)	107 (66.0%)	
Self-perceived smoking-related reason for ED visit			0.18
Positive	59 (47.6%)	65 (52.4%)	
Negative	85 (40.1%)	127 (59.9%)	
Study arm			0.64
Enhanced Care	71 (41.8%)	99 (58.2%)	
Usual Care	74 (44.3%)	93 (55.7%)	

Table 2
Multivariate regression model for predictors of in-person return to ED for three-month follow-up

Variable	OR	95% CI
Age	1.01	0.98, 1.03
Female sex (Male referent)	1.24	0.74, 2.07
Race/Ethnicity (Other or Asian, referent)		
Hispanic	1.54	0.40, 5.96
African-American	2.29	0.56, 9.33
White	0.79	0.17, 3.74
Insurance (Third party referent)		
Self-pay	1.05	0.47, 2.30
Medicaid	2.71	1.58, 4.66
Medicare	1.00	0.27, 3.73
Alcohol or drug positive by self-report (Negative referent)	1.82	1.01, 3.30
Depression screen positive (PHQ-2) (Negative referent)	0.48	0.28, 0.81
Tobacco-related ICD9 (Positive referent)	1.33	0.71, 2.49
Self-perceived smoking-related illness present (Negative referent)	2.38	1.40, 4.05
Self-perceived smoking-related reason for ED visit (Positive referent)	1.14	0.66, 1.98
Fagerstrom Test for Nicotine Dependence	1.04	0.93, 1.16
Usual care study arm (Enhanced care, referent)	1.11	0.69, 1.80