



## Short Communication

## Utility of biochemical verification of tobacco cessation in the Department of Veterans Affairs

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## HIGHLIGHTS

- ▶ The validity of self-report tobacco use varies depending on the population studied.
- ▶ Little is known about the validity of self-report tobacco among Veterans.
- ▶ Sensitivity and specificity of self-report tobacco use was high among veteran smokers.
- ▶ However, the misclassification rate among self-reported quitters was about 1 in 5.
- ▶ Biochemical verification of tobacco use is helpful in determining true quit rates.

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## ABSTRACT

Research on the validity of self-report tobacco use has varied by the population studied and has yet to be examined among smokers serviced by the Department of Veterans Affairs (VA). The purpose of this study was to determine the predictors of returning a biochemical urine test and the specificity and sensitivity of self-reported tobacco use status compared to biochemical verification. This was a sub-analysis of the larger Tobacco Tactics research study, a pre-/post-non-randomized control design study to implement and evaluate a smoking cessation intervention in three large VA hospitals. Inpatient smokers completed baseline demographic, health history and tobacco use measures. Patients were sent a follow-up survey at six-months to assess tobacco use and urine cotinine levels. A total of 645 patients returned six-month surveys of which 578 also returned a urinary cotinine strip at six-months. Multivariate analysis of the predictors of return rate revealed those more likely to return biochemical verification of their smoking status were younger, more likely to be thinking about quitting smoking, have arthritis, and less likely to have heart disease. The sensitivity and specificity of self-report tobacco use were 97% (95% confidence interval = 0.95–0.98) and 93% (95% confidence interval = 0.84–0.98) respectively. The misclassification rate among self-reported quitters was 21%. The misclassification rate among self-reported tobacco users was 1%. The sensitivity and specificity of self-report tobacco use were high among veteran smokers, yet among self-report quitters that misclassification rate was high at 21% suggesting that validating self-report tobacco measures is warranted in future studies especially in populations that are prone to misclassification.

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## 1. Introduction

Tobacco research has relied on both self-reported and biochemical verification of cessation. Biochemical verification, in the form of urine, blood and saliva samples, has been used to validate self-report smoking status to decrease underrepresentation of the actual prevalence of tobacco use (Gorber, Schofield-Hurwitz, Hardt, Lefebvre, & Tremblay, 2009). However, biochemical verification of cessation is expensive (ranging \$7.00 per test strip to \$40.00 for laboratory confirmation not to mention

patient incentives and labor costs) and samples can be difficult to obtain, therefore increasing the response burden for participants.

Various studies examining the validity of self-report tobacco use have yielded conflicting results depending on the population studied (From Attebring, Herlitz, Berndt, Karlsson, & Hjalmarson, 2001; Gorber et al., 2009; Patrick et al., 1994; Sagar, Jain, Sundar, & Balhara, 2011; Shipton et al., 2009; Studts et al., 2006; Wilson, Elborn, Fitzsimons, & McCrum-Gardner, 2011). When self-reported smoking status and biochemical verification were compared among patients from a lung cancer trial, the sensitivity and specificity was 91% and 95% respectively; the misclassification rate was only 7% (Studts et al., 2006). Yet other studies have reported the validity of self-reports smoking to be low among populations such as pregnant woman, patients with heart disease and psychiatric patients (Pell et al., 2008; Shipton et al., 2009; Takeuchi,

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Nakao, Shinozaki, & Yano, 2010) perhaps due to the social stigma surrounding tobacco use in these groups (Gorber et al., 2009).

Patients serviced by the Department of Veterans Affairs (VA) suffer from a disproportionate amount of tobacco-related diseases (McLaughlin, Hrubsec, Blot, & Fraumeni, 1995) and in addition to spending a tremendous amount of money on assisting veterans to quit smoking, the VA also funds a considerable amount of research on smoking cessation including biochemical validation of smoking status. To our knowledge, the utility of biochemical verification among tobacco users serviced by the VA has not been studied. Hence, the specific aims of this study were to: 1) determine the predictors of returning a biochemical urine test; and 2) determine the sensitivity and specificity of self-reported tobacco use status compared to biochemical verification.

## 2. Methods

### 2.1. Design

This study was a sub-analysis of the larger Tobacco Tactics research study conducted from 2006 to 2009 as a pre-/post-non-randomized comparison study to implement and evaluate an inpatient nurse-administered smoking cessation intervention program in three VA hospitals (Duffy, Karvonen-Gutierrez, Ewing & Smith, 2009). The intervention included training of inpatient nurses to provide a pre-designed tobacco cessation program to hospitalized smokers with six-month follow up. Institutional review board approval was received from the VA.

### 2.2. Sample

Inclusion criteria were those who: 1) were admitted as inpatients to intensive care units, general medical, surgical, psychiatric, and extended care units; 2) had used tobacco within one month prior to hospitalization; and 3) had a projected hospital stay of at least 24 h. Exclusion criteria were those who: 1) were too ill to participate, for example they were comatose or terminal; 2) were involved in a concurrent trial that included interventions on smoking; 3) were non-English speaking; and 4) were pregnant. Only participants (N = 645) that returned six month follow-up data as part of the Tobacco Tactics study were eligible for analysis.

### 2.3. Procedures

Veterans were enrolled and completed a baseline health questionnaire during hospitalization. Patients were sent a follow-up survey approximately six-months post-discharge to assess current tobacco use. All participants (including self-reported quitters and continuing smokers) were mailed a urinary cotinine test strip to return by mail at the six-month follow-up. Participants were provided with \$5.00 for returning the survey and \$15.00 for returning the test strip.

### 2.4. Measures

Demographic and health information variables were collected at baseline. Self-rated health was assessed at baseline using a 5-level Likert scale including “Excellent”, “Very good”, “Good”, “Fair”, or “Poor” (Ware, Snow, Kosinski, & Gandek, 1993). Comorbidity information was self-reported by patients and abstracted by research staff from the patient’s electronic medical record (Mukerji et al., 2007). The Alcohol Use Disorders Identification Test (AUDIT) was used to measure alcohol use (Babor, Higgins-Biddle, Saunders, & Monteiro, 2001) and the abbreviated form of the Center for Epidemiologic Studies (CES-D) was used to measure depression (Irwin, Haydari Artin, & Oxman, 1999).

Patients were asked if they thought that quitting tobacco would make them feel nervous; responses were categorized as “extremely unlikely to 50/50 chance” vs. “moderately to extremely likely”. Patients were asked to rate the importance of quitting (“not at all to moderately

vs. “very to extremely important”), difficulty in quitting (“not at all to slightly” vs. “fairly to extremely difficult”) and whether they were thinking about quitting in the next thirty days. Patients were asked about withdrawal symptoms (yes/no) and their interest in receiving cessation services (yes/no). Nicotine addiction was assessed using the Fagerstrom Test for Nicotine Dependence (FTND) (Fagerstrom, Heatherton, & Kozlowski, 1995). Medical records of those participants who reported not using tobacco, but had a positive cotinine test were reviewed to determine if they were prescribed nicotine replacement therapy by the VA within 1 month prior to their six-month survey date.

Outcomes of interest were six-month self-reported tobacco cessation rate and cotinine-verified smoking cessation rate. The patient had to self-report on their six-month follow-up survey that they had not “Used any tobacco products in the past 7 days”. They also had to have a negative urinary cotinine test strip returned with their survey. For the present study NicAlert Semiquantitative test strips, which determine exposure to cigarette use, pipe use and chewing tobacco were used.

### 2.5. Data analysis

Among those that returned the six-month survey, Chi-square or Fisher’s exact tests and Student’s t-tests were used to determine baseline differences in demographics and health information between those who did and did not return a urinary cotinine test. Based on these analyses and clinical judgment, multivariate logistic regression was used to determine the predictors of returning a cotinine test (Yes/No). Binary classification tests were performed to determine the sensitivity and specificity of self-reported tobacco use status compared to biochemical verification. The sample size varied for different results. Data analysis was conducted using SAS version 9.2 (SAS Institute, Cary, NC).

## 3. Results

### 3.1. Univariate and bivariate analyses

In the main Tobacco Tactics study, 2403 patients were approached to participate of which 1207 consented. Of the 1207 consented participants, 1145 completed baseline data, 103 baseline cases had died before six-month follow-up and were excluded from analysis. Of the 1042 participants at baseline, 62% (N = 645) of the total sample returned the six-month follow-up survey. The only difference found between the six-month survey responders (N = 645) and non-responders (N = 397) was that there were slightly more subjects with depression in the responder group (67.6%) than in the non-responder group (60.0%) (P = 0.02). Among subjects with six-month follow up surveys (N = 645), 90% (N = 578) returned biochemical verification of their tobacco use status. Those who returned biochemical verification of their tobacco use status were slightly younger (P = 0.03), more likely to have arthritis (P < .0001), and less likely to have heart disease (P = 0.02) compared to participants who did not return biochemical verification. See Table 1.

### 3.2. Multivariate analyses

Based on the results of the bivariate analysis and considering the sample size, five variables were included in the multivariate analysis. Every 5 year increase in age was associated with a 25% decreased odds of returning a test strip (OR = 0.754, 95% CI = 0.629–0.903, P = 0.002). The odds of returning a test strip among patients who were thinking of quitting using tobacco products in the next 30 days was nearly 2.4 times greater (OR = 2.39, 95% CI = 1.074–5.328, P = 0.033) as compared to people who were not thinking of quitting using tobacco products in the next 30 days. The odds of returning biochemical verification among people with arthritis was nearly three times (OR = 2.9, 95% CI = 1.54–5.39, P = 0.0009) the odds of returning biochemical verification among people without arthritis. The odds of returning biochemical verification among people with heart disease was nearly half (OR = 0.50, 95%

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