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Short Communication

Remote biochemical verification of tobacco use: Reducing costs and improving methodological rigor with mailed oral cotinine swabs

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HIGHLIGHTS

- Participants reported that tests were easy to use, with only minimal prompting.
- Cost per sample including test device and shipping was less than $15.
- There was no difference in the interpretation of mailed versus control samples.
- Oral fluid swabs accurately detected cotinine up to three weeks after testing.

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ABSTRACT

Introduction: Multi-site tobacco cessation trials could benefit from remote biochemical verification for tobacco use without invasive, time-consuming, or expensive collection processes. To the authors' knowledge, there have been no previous studies examining the predictive validity of oral fluid swabs for the detection of cotinine levels with samples collected off-site and mailed for on-site interpretation.

Methods: Tobacco users were recruited through an online survey and participants who met the initial eligibility criteria were invited to take part. Those who elected to enroll provided two positive iScreen Oral Fluid Device (OFD) cotinine test samples during an in-office visit. One sample was used as a control and stored in a temperature-regulated location, while the other was mailed from one of ten surrounding counties. Mailing method and time from collection to mailing were varied, and results were assessed against control samples.

Results: Twenty tobacco users enrolled in the study. Participants ranged in age from 18 to 31 ($M = 16.45$, $SD = 1.54$). Several types of tobacco use were reported, with electronic cigarettes the most commonly reported product. None of the mailed sample interpretations changed from pre- to post-mailing, with up to twenty-one days from sample collection to results confirmation.

Conclusions: Results indicate that the use of mailed oral swabs may be an easy to use, reliable, and low-cost option for the detection of cotinine in tobacco users when in-person collection is not feasible. Test result interpretations were found to be unchanged after mailing, and after extended post-collection time gaps.

1. Introduction

Self-reported tobacco usage data may not be reliable and often results in underestimation of actual usage. Therefore, biochemically verified data are important components of methodologically rigorous tobacco use research (Gorber, Schofield-Hurwitz, Hardt, Levasseur, & Tremblay, 2009; Hughes et al., 2003; Mejia, Braun, Peña, Gregorich, & Pérez-Stable, 2017; Regan, Reid, Kelley, et al., 2016; Scheuermann, Richter, Rigotti, et al., 2017; West, Hajek, Stead, & Stapleton, 2005). Several types of biochemical verification are available, but these collection methods are typically used when researchers have direct contact with research participants. These traditional collection methods are not always feasible for patients without reliable transportation to the study site, or for those located in remote or rural areas. This can present potential problems for researchers who study these populations (Mejia et al., 2017). The detection of cotinine through saliva may be preferable, as it is less invasive than other methods (Gorber et al., 2009). Furthermore, tests that detect cotinine levels may be more sensitive

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than those that assess other factors such as expired air carbon monoxide (CO) (West et al., 2005).

Although the literature indicates that mailed saliva fluid samples may be viable without temperature controls, few studies have evaluated the use of this method (Clements & Parker, 1998; Jones et al., 2005; Mushtaq, Beebe, & Vesely, 2012; Ochnio, Scheifele, Marion, et al., 2007; Sexton, Nowicki, & Hebel, 1986). A PubMed search identified only two studies within the past 20 years as having used mailed mouth swab tests to detect tobacco use, both of which utilized outside lab testing to assess cotinine levels, and such testing may be cost-prohibitive, with expenses of $125 or more per sample reported in previous studies (Cha et al., 2017; Scheuermann et al., 2017). Devices such as the iScreen Oral Fluid Device (OFD) cotinine test present an easy-to-use mouth swab, which can detect cotinine levels with results that can be interpreted by research personnel within ten minutes (iScreen® Oral Fluid Cotinine Test Device [Package Insert], 2013). Despite the availability of such tools, no studies were found to have examined the use of directly interpretable saliva swabs that have been collected remotely and delivered through the mail. Although not intended for mailing or delayed interpretation, the ability to use OFD swabs in this way would be a valuable tool for researchers conducting community-based tobacco studies (iScreen® Oral Fluid Cotinine Test Device [Package Insert], 2013). Thus, our study sought to examine the predictive validity of low-cost cotinine tests for oral fluids, when used for off-site collection with systematic time-gaps between collection and interpretation of the results.

2. Methods

In preparation for a multi-site tobacco cessation trial, we learned that current OFD swab devices are not designed for – and have not been tested with – remote or mailed collection, or for collection with delayed interpretation. Guidelines for the iScreen OFD Cotinine device specify that results should not be interpreted after one hour (iScreen® Oral Fluid Cotinine Test Device [Package Insert], 2013). To evaluate this type of use, tobacco users were recruited from the community surrounding a large southeastern university using an online survey to screen for eligibility. To be eligible, respondents were required to provide initial consent, be a current tobacco user, be at least 18 years of age, speak English, and be willing to attend an in-office visit. Those respondents who were determined to be initially eligible were called for scheduling of the office visit with a research assistant. During the visit, participants provided informed consent, and then provided saliva specimens for two iScreen OFD cotinine tests. Two positive iScreen OFD tests were required for inclusion in the study, and eligible participants were compensated with a $20 Amazon eCode for their time. For each participant, one positive cotinine swab sample was sealed in a clear plastic bag and stored in a temperature-controlled environment within our research lab. The second positive sample was photographed and the results were recorded. This second sample was placed in a small cardboard box and mailed back to the research lab from one of ten different surrounding counties, ranging from 0.8 to 102 miles from the lab. These counties represented a mix of rural and urban locations – an important consideration, given the higher reported incidence of tobacco use among rural populations (Roberts, Doogan, Kurti, et al., 2016). Time from collection to shipping was varied, with samples being mailed from one to seven days after initial collection. This was done to mirror what we would expect in community-based studies, where participants may not adhere to strict mailing protocols. The shipping method was also varied, with samples being mailed by either USPS First Class or USPS Priority mail. Additionally, one known negative test was mailed and one of the known positives was mailed with the sample cover unattached.

Once specimens were returned via United States Postal Service, test results were interpreted. Each mailed test was compared with its corresponding pre-mailing photograph and previously logged interpretation, and the post-mailing results were recorded. Test interpretation results were also compared between those stored in a temperature-controlled environment versus those transported via postal service. Test interpretation results before and after each time gap were examined, and test results were evaluated again at the conclusion of the study. For each sample, results were interpreted at three time points: 1) immediately following the initial office visit, 2) upon receiving the mailed sample, and 3) following the conclusion of the study. Timing of the third interpretation varied from seven to twenty-one days after initial collection. The cost for each test device was $7 and shipping charges ranged from $4 to $8, for a maximum total cost of less than $15 per mailed sample.

Table 1
Enrolled Participant Demographics ($N = 20$).

Variable	*n*	%	Variable	*n*	%
Gender			Number of times used per day		
Female	2	10.0	1 or less	5	25.0
Male	18	90.0	2	2	10.0
			3	4	20.0
Ethnicity			4	1	5.0
White	18	90.0	5	2	10.0
Non-White	2	10.0	> 10	6	30.0
Age ($M = 20.35$, $SD = 2.91$)			Type most commonly used		
18	3	15.0	Cigarettes	6	30.0
19	8	40.0	Little Cigars	1	5.0
20	3	15.0	*E*-Cigarettes	11	55.0
21 to 30	5	25.0	Smokeless Tobacco	2	10.0
> 30	1	5.0			
Type of user			Age of first use ($M = 16.45$, $SD = 1.54$)		
			13 to 16	8	40.0
Single	4	20.0	17	9	45.0
Dual	7	35.0	18	2	10.0
Poly	9	45.0	20	1	5.0

3. Results

Thirty-three potential participants met the initial inclusion criteria, as determined by an online eligibility survey. Twenty-two of those potential participants attended a face-to-face office visit to enroll. Two participants were excluded due to invalid or negative OFD test results, thus twenty participants were enrolled in the study. As shown in Table 1, the sample was largely male (18 of 20) and Caucasian (18 of 20). Participants ranged from 18 to 31 years in age ($M = 20.35$, $SD = 2.91$). Respondents reported using several types of tobacco including cigarettes, cigars, little cigars, water pipes, electronic cigarettes, and smokeless tobacco. The majority of those surveyed reported using e-cigarettes (17 of 20) and cigarettes (14 of 20), with e-cigarettes reported as the primary mechanism for tobacco use (11 of 20). Almost half of participants (9 of 20) were identified as poly-users, meaning that they endorsed the use of three or more types of tobacco products. The remaining participants identified themselves as dual (7 of 20) or single (4 of 20) users. Sixty-five percent (12 of 20) of those in the study were daily users and all participants reported using tobacco three or more times per week.

Twenty-one samples were mailed, including twenty positive swabs from the enrolled participants and one known negative sample. Samples were shipped from 10 surrounding counties, two of which were classified as “urban” and eight of which were identified as “rural”. Time from sample collection to mailing was allowed to vary, with samples sent up to seven days post-collection ($M = 2.67$, $SD = 2.03$). Returned samples were received on average of less than three days from mailing ($M = 2.71$, $SD = 1.42$) and interpreted about five days from sample collection ($M = 5.38$, $SD = 2.13$). Given the overall proximity of the origination mailing facilities to the research office, there was little to no variability in delivery times between samples that were mailed via