



## Full length article

## Comparison of timeline follow-back self-report and oral fluid testing to detect substance use in adult primary care patients



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## ABSTRACT

**Background:** Timeline Follow-back (TLFB) interviews using self-report are often used to assess substance use. Oral fluid testing (OFT) offers an objective measure of substance use. There are limited data on the agreement between TLFB and OFT.

**Methods:** In this secondary analysis from a multisite study in five primary care sites, self-reported TLFB and OFT data collected under confidential conditions were compared to assess concordance ( $N = 1799$ ). OFT samples were analyzed for marijuana, heroin, cocaine, and non-medical use of prescription opioids. Demographic differences in discordance relative to TLFB and OFT concordant results for marijuana, the only substance with an adequate sample size in this analysis, were examined using multinomial logistic regression.

**Results:** Overall concordance rates between TLFB and OFT were 94.9 % or higher for each substance, driven by large subgroups with no use. Among participants with discordant use, marijuana was the only substance with lower detection on OFT than self-report (27.6 % OFT-positive only vs 32.2 % TLFB-positive only), whereas cocaine (65.6 % vs 8.6 %), prescription opioids (90.4 % vs 6.0 %), and heroin (40.7 % vs 26.0 %) all had higher detection via OFT than TLFB. Participants who reported marijuana use but had a negative OFT were more likely to be younger, Hispanic, and White compared to those with TLFB and OFT concordant positive results.

**Conclusions:** TLFB and OFT show disparate detection of different substances. Researchers should consider the implications of using either self-report or oral fluid testing in isolation, depending on the substance and collection setting. Triangulating multiple sources of information may improve detection of drug use.

### 1. Introduction

Self-reported substance use is often a key metric in clinical and epidemiological studies, substance use treatment, and medical care. Such data can be gathered through written surveys, self-administration via computer, or interviews conducted in person or by telephone. In research, a widely used method for collecting self-reported data on the quantity and frequency of substance use is the Timeline Follow-Back (TLFB) Interview technique. TLFB retrospectively collects data on substance use for each day of the reporting period, and thus provides detailed information on use patterns. TLFB is administered by trained staff, using supplemental memory aids such as calendars and anchor dates (e.g., birthdays, holidays, and subject-specific memorable events;

Sobell and Sobell, 1992, 1996). While TLFB is frequently used in research settings, it is not feasible to use in routine clinical practice (e.g., for screening) due to the time required for proper training and administration of the interview (McPherson and Hersch, 2000). However, TLFB represents a rigorous approach to collecting self-report data, offering greater precision than other measures in pinpointing substance use on specific days.

Regardless of the approach to data collection, there are limitations to the validity of any self-report data, particularly for sensitive behaviors such as substance use. Non-disclosure of substance use may occur when an individual perceives that there may be negative consequences from disclosure, or if it could be perceived as socially undesirable. Perhaps for these same reasons, self-report data have been found to be

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less valid for recent substance use (i.e., past 7-days, past 30-days) compared to the validity of self-report data over longer reference periods (e.g., lifetime or past-year; Harrison, 1997).

To improve the accuracy of measuring substance use, both clinicians and researchers have recommended the collection of both self-report data and a urine or oral fluid test (OFT) (Center for Substance Abuse Treatment, 1997; Cone, 1997; Donovan et al., 2012). Oral fluid offers a number of advantages over urine testing, including ease of sample acquisition and lessened risk of falsification or adulteration. Oral fluid compared to urine specimen contains a higher concentration of the parent drug compared to metabolites (Cone, 1993). The window of detection for OFT is generally shorter compared to urine testing, averaging 12–24 hours, but OFT can detect more recent substance use than urine testing (Kidwell et al., 1998).

Research comparing biologic (urine or OFT) screening results with self-reported data have primarily been conducted in substance use treatment settings and have yielded mixed results (Cone, 2012; Neale and Robertson, 2003). Unlike individuals attending substance use treatment programs, patients seen in primary care settings are likely to have lower prevalence and frequency of use, and may have different likelihood of accurately reporting substance use. In comparison to urine drug testing, there have been fewer reports comparing OFT to self-reported substance use. Research comparing OFT with self-reported substance use using measures other than TLFB has been conducted in substance use treatment settings. In one study, 271 newly-admitted patients were administered a structured survey regarding their substance use in the preceding three days (Neale and Robertson, 2003). These reports were compared to OFT results for opiates, benzodiazepines, methadone and cannabis. These authors found that 85.1 % of OFT (both negative and positive results) were consistent with self-report. Of the discordant results, 6.8 % of patients had a positive OFT result but no self-reported use, and 8.0 % self-reported use but had a negative OFT result. Surprisingly, 45.8 % of the participants had a discordant report for at least one substance. Agreement between self-report and OFT was lowest for marijuana (79.7 %) and highest for methadone (94.1 %).

A subsequent study by Cone (2012) compared responses to a brief questionnaire about past seven-day drug use among 400 methadone maintenance patients to cocaine and heroin metabolite OFT results using liquid chromatography coupled with tandem mass spectrometry (LC–MS/MS). Of participants who endorsed drug use, 95 % of results were concordant for cocaine use, and 52.1 % were concordant for heroin use. Of patients who had discordant self-reported drug use, 29.7 % had a cocaine-positive test and 13.8 % had a heroin-positive test.

These studies were conducted mainly in substance use treatment settings and did not collect self-reported data using the TLFB, which captures substance use during a specified window of time. In order to contribute to the literature on identifying substance use in general medical settings and to evaluate the concordance of TLFB compared to OFT results, we report a secondary analysis from a validation study conducted by the National Drug Abuse Treatment Clinical Trials Network of the Tobacco, Alcohol, Prescription Medication, and other Substances (TAPS) Tool (McNeely et al., 2016). Additionally, the present study examines patient demographic predictors of discordance between self-reported use and OFT results for marijuana.

## 2. Methods

The parent study examined the performance of a substance use screening and brief assessment instrument, the TAPS Tool, in a geographically diverse sample of 2000 adult primary care patients CTN-0059: NCT02110693. Methodological details of the parent study have been reported elsewhere (Wu et al., 2016; McNeely et al., 2016) and are summarized below.

### 2.1. Design and setting

Recruitment took place from August 2014 through April 2015 at five primary care clinics in four Eastern US states (Baltimore, MD; Kannapolis, NC; New York, NY; Richmond, VA; Wu et al., 2016). Research assistants (RAs) sequentially approached patients in each clinic's waiting area based on the seating arrangement in that area and asked if the patients would like to participate in an anonymous health survey. Patients who agreed met with RAs in a private room to provide verbal consent. The health survey consisted of the administration of the TAPS Tool, followed by a number of reference measures, including a TLFB Interview (Sobell and Sobell, 1996) collecting data on alcohol, illicit drug use, and non-medical prescription medication use in the 30-days prior to the research interview. RAs emphasized that the study was anonymous and results would not be shared with clinical staff.

Participants were paid \$20 for completing all self-reported assessments, after which they were asked for consent to provide an oral fluid sample for anonymous testing. Participants were paid an additional \$10 for providing the sample. To avoid influencing the self-reported responses, the request for consent for an oral fluid sample occurred after completion of all self-reported measures.

The study was approved by the Friends Research Institute's IRB as well as those of the participating academic institutions with a waiver of written consent. Participants were given IRB-approved information sheets for both the health survey and the oral fluid collection.

### 2.2. Participants

The study had the following inclusion criteria: 1) adult (age 18 or older) primary care patient presenting for a medical visit, and 2) ability to provide informed consent. Individuals were excluded from participation if they: 1) could not comprehend spoken and written English; 2) could not operate an iPad tablet due to physical limitations; and/or, 3) were previously enrolled during an earlier visit.

### 2.3. Measures

#### 2.3.1. Timeline follow-back

TLFB was administered by trained RAs to assess the use of alcohol, cannabis, heroin, cocaine or crack, methamphetamine, non-medical use of prescription sedatives/hypnotics, opioids (including methadone), or stimulants, and other drugs (e.g., inhalants, hallucinogens) in the 30-days prior to the research interview (not including the day of the interview). This method was done in accordance with standard TLFB procedures (Sobell and Sobell, 1996; Sobell et al., 1996). The TLFB recorded only non-medical use of prescription medications. The RA examined the defined 30-day reference period with the participant using a print version of a computer-generated calendar to review anchor dates (such as birthdays, holidays) in order to aid in recall. The RA then guided the participant through each day of the time period and assessed for any use on that day.

#### 2.3.2. Oral fluid collection

Oral fluid swabs (OraSure®) were used to collect oral fluid specimens from participants' inner cheeks. These specimens were tested for recent drug use via enzyme-linked immunosorbent assay (ELISA) with LC–MS/MS confirmation for amphetamines; methamphetamine including ecstasy/MDMA/MDA/MDEA; cocaine/benzoyllecgonine; cannabis (THC); opiates (morphine, heroin metabolite, codeine, hydrocodone); oxycodone; methadone; barbiturates; phencyclidine; and benzodiazepines. Oral fluid specimens were used because of the ease of collection and shipment, and because they have been found to have adequate reliability (Cone and Huestis, 2007; Verstraete, 2004). The OraSure® package insert noted good agreement with gas-chromatography-mass spectrometry (GC/MS) testing (e.g., benzodiazepines-88 %; opiates-90 %; cocaine-93 %; cannabis-94 %; methamphetamine-98

%)

## 2.4. Analytical alignment and classifications of TLFB and OFT

### 2.4.1. Alignment for non-medical use

The TLFB focused on non-medical prescription use and intentionally did not capture use of medications that were used as prescribed. Oral fluid testing does not discriminate between reasons for use, and thus may be positive for prescription medications. For this reason, prior to collecting the oral fluid sample, RAs collected information about any prescription medications that participants reported taking as prescribed in the seven days prior to the interview. For the purposes of the present analysis, OFT results that were positive for medication classes that the participant reported taking as prescribed were re-classified as negative (i.e., not indicative of illicit or non-medical use).

### 2.4.2. OFT classification of illicit vs. non-medical prescription drug use

In regard to the classification of OFT samples, opioids and amphetamines could encompass both illicit substances (e.g., heroin) and non-medical prescription use (e.g., morphine) categories. For the present analyses, positive tests for morphine with the heroin metabolite (6-Monoacetylmorphine) were classified as heroin-positive ( $n = 20$ ); tests positive for other opioids (codeine, oxycodone, hydrocodone, and methadone) were classified as positive for non-medical prescription opioid use ( $n = 79$ ). Morphine-only positive results ( $n = 3$ ) were omitted because they could either be categorized as heroin-positive or prescription-opiate-positive due to similar metabolic processes. Methamphetamine/MDMA/MDA-positive tests were classified as illicit use, while a positive amphetamine test result absent of a positive methamphetamine/MDMA/MDA test result was classified as non-medical prescription stimulant use.

### 2.4.3. Alignment of time frames

While the full TLFB collected self-reported substance use in the 30 days prior to the research interview, in order to compare self-report to OFT results, we limited the TLFB data to the time period that aligned with the OFT detection window, which ranges from 1 to 3 days depending on the substance (Cone and Huestis, 2007; see Table 1). For example, the OFT is able to detect marijuana use in the last 2–24 hours from the time of collection. This detection window of 2–24 hours was matched to the corresponding time period of the TLFB (i.e., one day prior to the research interview). The TLFB did not assess for use on the day of the interview and oral fluid collection, which we identify as a limitation of this analysis.

## 2.5. Statistical analysis

Substances reported on the TLFB were matched with those detected on the OFT. A binary variable was created for any substance use, which combined positive marijuana, cocaine, prescription opioids, heroin, barbiturates, benzodiazepines, methamphetamines, and/or prescription

stimulants, separately for both the TLFB and OFT. Self-reported use on the TLFB and OFT results were compared for overall agreement.

Participants were classified as *concordant (positive)* for each respective substance if the individual endorsed use for the identified substance on the TLFB and had a positive result on the OFT. Likewise, participants were classified as *concordant (negative)* if they reported no recent substance use and had a negative result on the OFT for each respective substance. Discordant participants were categorized into two subtypes for each respective substance: (a) *TLFB positive only* (i.e., self-reported use in combination with a negative oral fluid test); or (b) *OFT positive only* (i.e., no self-reported use in combination with a positive oral fluid test). We report concordance and discordance in lieu of sensitivity and specificity due to a lack of a clear gold standard.

Multinomial logistic regression was used to examine demographic differences in discordance between TLFB self-reported marijuana use and oral fluid test results, using concordant reporting as the reference category and using the independent variables of gender, age (in years), race (White, Black, other), and ethnicity (Hispanic, non-Hispanic). The model also controlled for smoking status as reported by the participant. This approach was used to examine discordant patterns for marijuana only, due to small sample sizes for the remaining substances. We also compared OFT and TLFB for each substance in  $2 \times 2$  tables (see Supplemental Tables 1–5). All data analysis was conducted using SAS/STAT® software version 9.4 [14].

## 3. Results

### 3.1. Participants

The parent study enrolled 2000 participants. Of those, 1831 (91.6 %) provided an oral fluid sample. From the 1831 oral fluid specimens submitted to the laboratory, 24 specimens were rejected by the laboratory and 5 specimens were not sufficient for testing. Additionally, we eliminated three available cases that were positive for morphine only because these results could either be positive for heroin or for prescription opioids, leaving 1799 specimens for this analysis, see Fig. 1. The demographic characteristics of the 1799 participants are shown in Table 2. The mean age was 46.1 years ( $SD = 14.8$ ), 55.5 % were female, 56.0 % were Black, 32.8 % were White, and 12.1 % were Hispanic.

### 3.2. OFT vs. TLFB results

Table 3 shows prevalence of illicit and non-medical prescription drug use based on positive OFT results, as well as endorsement of use on the TLFB (within the detection window as described above; see Table 1). Overall prevalence of positive OFT results and endorsement of use on the TLFB was low for all substances including: marijuana (5.7 % positive OFT, 6.1 % positive TLFB), cocaine (4.7 % positive OFT, 1.7 % positive TLFB), prescription opioids (4.4 % positive OFT, 0.4 % positive TLFB), and heroin (1.1 % positive OFT, 0.9 % positive TLFB).

**Table 1**

Oral fluid test (OFT) detection window in hours, by drug<sup>1</sup>, compared to Timeline Follow-back (TLFB) window.

Drug	Drug detection time in OFT (hours)	TLFB window
Marijuana	2.0–24.0	1 day prior to interview
Cocaine	8.0–72.0	3 days prior to interview
Prescription opioids, including methadone	6.0–24.0	1 day prior to interview
Heroin	2.0–24.0	1 day prior to interview
Barbiturates	50.0	2 days prior to interview
Benzodiazepines	< 5.0–50.0	2 days prior to interview
Methamphetamine	6.0 – 76.0	3 days prior to interview
Prescription stimulants	20.0–50.0	2 days prior to interview

Note. <sup>1</sup>Cone, E. J., & Huestis, M. A. (2007). Interpretation of Oral Fluid Tests for Drugs of Abuse. *Annals of the New York Academy of Sciences*, 1098, 51–103. <http://doi.org/10.1196/annals.1384.037>.

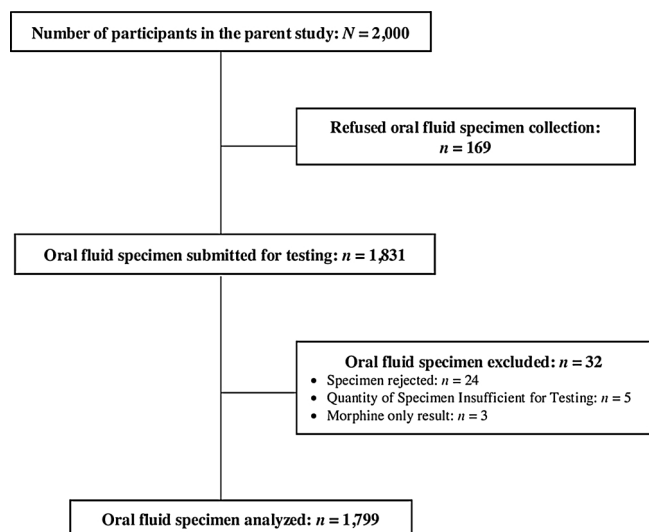


Fig. 1. Study Flow.

Table 2 Demographic characteristics of participants (N = 1799).

Demographic Characteristic	
<b>Age (years)</b>	
Mean (SD)	46.1 (14.8)
	n (%)
<b>Gender</b>	
Male	799 (44.4 %)
Female	999 (55.5 %)
Other/Refused	1 (0.1 %)
<b>Ethnicity</b>	
Hispanic	218 (12.1 %)
Non-Hispanic	1578 (87.7 %)
Other/Refused	3 (0.2 %)
<b>Race</b>	
White	590 (32.8 %)
Black	1007 (56.0 %)
Asian	30 (1.7 %)
Multiracial	63 (3.5 %)
Other/Unknown/American Indian or Alaska Native	103 (5.7 %)
Declined	6 (0.3 %)

Prevalence of use as endorsed on the TLFB compared to OFT results are provided for marijuana, cocaine, heroin, non-prescription opioid use, and any drug (see supplemental Tables 1 through 5). All other substances (barbiturates, benzodiazepines, methamphetamine, and prescription stimulants) had very low prevalence in this sample (< 1%). The agreement between self-reported use on the TLFB and positive OFT results was highest for marijuana (3.4 %) and lowest for non-medical prescription opioid use (0.2 %).

Table 3 Concordance of timeline follow-back (TLFB) self-reported drug use to oral fluid test (OFT) results (N = 1799).

	Positive OFT n (%)	Positive TLFB n (%)	Concordant positive results n (%)	Concordant negative results n (%)	Overall concordance n (%)
Marijuana	103 (5.73)	110 (6.11)	61 (3.39)	1647 (91.55)	1708 (94.94)
Cocaine	85 (4.72)	31 (1.72)	23 (1.28)	1706 (94.83)	1729 (96.11)
Prescription opioids	79 (4.39)	8 (0.44)	3 (0.17)	1715 (95.33)	1718 (95.50)
Heroin	20 (1.11)	16 (0.89)	9 (0.50)	1772 (98.50)	1781 (99.00)
Any drug	278 (15.4)	156 (8.7)	97 (5.39)	1462 (81.27)	1559 (86.66)

Note. Prescription opioids includes non-prescribed methadone use.

Table 4 Discordance between Timeline Follow-back (TLFB) and oral fluid test (OFT) results for marijuana (n = 152), cocaine (n = 93), heroin (n = 27), prescription opioids (n = 84), and any drug (n = 337).

	TLFB positive only	OFT positive only	Total Discordance
	n (%)	n (%)	n (%)
Marijuana	49 (32.2)	42 (27.6)	91 (59.8)
Cocaine	8 (8.6)	62 (66.7)	70 (75.3)
Heroin	7 (25.9)	11 (40.7)	18 (66.6)
Prescription opioids	5 (6.0)	76 (90.4)	81 (96.4)
Any drug	59 (17.5)	181 (53.7)	240 (71.2)

Notes. Discordance is calculated as the proportion of TLFB positive only (TLFB positive, OFT negative) or OFT positive only (TLFB negative, OFT positive) compared to the total rate of positive use (with positive use defined as positive results on either the TLFB Interview and/or OFT).

### 3.3. Patterns of discordance between OFT and TLFB

In the full sample, overall concordance rates (i.e., any agreement between self-reported use on the TLFB and OFT results) for any individual substance were 94.9 % or greater, with the majority of concordance attributable to participants reporting no use (correctly identified non-use ranged from 91.6 % for marijuana use to 99.7 % for non-medical amphetamine use).

In order to examine discordant results on the TLFB and the OFT, individuals were considered positive for each substance if they either reported use on TLFB or had a positive OFT result. As shown in Table 4, among the subsample of participants with any positive marijuana (n = 152), cocaine (n = 93), heroin (n = 27), or non-medical prescription opioid use (n = 84), discordance rates between the two measures were 59.8 %, 75.2 %, 66.6 %, and 96.4 % respectively. TLFB positive only rates for marijuana, cocaine, heroin, and prescription opioids were 32.2 %, 8.6 %, 25.9 %, and 6.0 %, respectively, while OFT positive only rates for these same substances were 27.6 %, 66.7 %, 40.7 %, and 90.4 %, respectively.

Results from the multinomial logistic regression showed that age and race were significant predictors of discordance for marijuana use (see Table 5). Compared to participants who were concordant (positive, for both OFT and TLFB), participants who were TLFB positive only were less likely to be Black (RRR = 0.57; 95 % CI = 0.34, 0.96; p = 0.035), and more likely to be younger (RRR = 0.98; 95 % CI = 0.96, 1.00; p = 0.047). Participants who were OFT positive only were more likely to be older compared to concordant (positive) participants (RRR = 1.02; 95 % CI = 1.004, 1.04; p = 0.016). Hispanic ethnicity was significantly associated with TLFB positive only discordance compared to concordant (positive) participants (RRR = 2.66; 95 % CI = 1.24, 5.71; p = 0.012).

## 4. Discussion

This study investigated the concordance of self-reported substance use using a TLFB Interview compared to oral fluid testing under research-confidential conditions in a diverse sample of primary care patients at five primary care sites in four Eastern US states. TLFB is



**Table 5**  
Relative risk ratio (RRR) estimates of prediction of discordant marijuana use ( $N = 1795$ ).

	<i>TLFB positive only versus Concordance (positive)</i>			<i>OFT positive only versus Concordance (positive)</i>			<i>Concordance (negative) versus Concordance (positive)</i>		
	<i>RRR</i>	<i>95 % CI</i>	<i>p</i>	<i>RRR</i>	<i>95 % CI</i>	<i>p</i>	<i>RRR</i>	<i>95 % CI</i>	<i>p</i>
Age (in years)	<b>0.981</b>	(0.963, 1.000)	<b>0.047</b>	<b>1.023</b>	(1.004, 1.041)	<b>0.016</b>	1.052	(1.039, 1.066)	< <b>0.001</b>
Sex (Reference = Male)	1.534	(0.946, 2.490)	0.083	1.560	(0.941, 2.584)	0.084	2.826	(2.008, 3.977)	< <b>0.001</b>
Race (Reference = White)									
Black	<b>0.569</b>	(0.336, 0.962)	<b>0.035</b>	1.082	(0.612, 1.914)	0.785	<b>0.555</b>	(0.383, 0.806)	<b>0.002</b>
Other	2.240	(0.973, 5.157)	0.058	0.938	(0.336, 2.617)	0.903	1.193	(0.622, 2.287)	0.596
Ethnicity (Reference = non-Hispanic)	<b>2.657</b>	(1.236, 5.713)	<b>0.012</b>	0.957	(0.463, 1.981)	0.907	1.568	(0.966, 2.544)	0.069

Note: RRR = relative risk ratio. 95 % CI = 95 % Confidence Interval. *Concordance (positive)* (both OFT and TLFB positive) is the reference category. Four cases were excluded from this analysis due to missing data for one or more of the predictors. The model above controlled for current smoking status.

commonly used by researchers, but not in clinical care, to gather self-reported substance use data. Oral fluid testing has become an attractive and viable substance use testing option due to the ease of administration, low rate of adulteration, cost-effectiveness, and perceived non-invasiveness compared to urine and hair testing (Bosker and Huestis, 2009; Cone and Huestis, 2007; Langel et al., 2008).

The overall concordance between TLFB and OFT in this study was high. These findings are similar to those of Neale and Robertson (2003), who reported a concordance rate of 85 % across multiple substances, and to Cone (2012) who reported a concordance rate of 94.2 % for cocaine. However, it is important to note that nearly all of the concordance in this study was attributable to participants who indicated non-use on the TLFB and whose OFT results were negative. Among individuals in this primary care sample who had evidence of positive use (based on either the TLFB Interview or OFT results), discordance between the two measures was relatively high (ranging from 59.8%–96.4% of positive results).

The present study found patterns of discordance between self-reported drug use and OFT results that were generally consistent with previous studies (Harrison, 1997; Hjorthøj et al., 2012; Rendon et al., 2017). We found that relying solely on self-report would have missed a number of participants with evidence of cocaine, opioid, and marijuana use as indicated by positive OFT results. Conversely, relying solely on oral fluid testing would also miss considerable evidence of substance use via self-disclosure, which might vary markedly depending on the substance of interest and the conditions in which disclosure is obtained (Fendrich et al., 2004). People may choose not to disclose substance use if they believe negative consequences might result from reporting such use (e.g., perceived legal or treatment consequences). In the present study, this was unlikely because the research was conducted anonymously, and participants were assured that their responses would not be divulged to their medical provider or to non-research staff. Furthermore, the limited time frame of one-to-three days prior to the interview makes recall error an unlikely explanation for potential non-disclosure.

Willingness to disclose substance use can also be influenced by the individual's awareness of confirmatory biological testing. In such cases, individuals may be more likely to provide accurate information if they know their use could be discovered via confirmatory testing. In the present study, RAs conducted the TLFB prior to informing participants of the opportunity to provide an oral fluid specimen for testing. We did so purposefully, in order to obtain responses that were not potentially biased by knowledge of subsequent testing, given the primary purposes of the parent study. Additionally, it is possible that participants would be less willing to provide a specimen for testing when they disclosed substance use, despite the study's privacy protections. In the parent study, 8.5 % declined to provide an oral fluid sample when asked, even

though participants were informed that the process was quick, minimally invasive, and included an additional monetary incentive.

The present study was able to examine the association between participant characteristics and discordance between OFT and TLFB for marijuana use. Compared to participants with OFT-verified self-reported use (i.e., concordant positive), participants with *TLFB positive only* discordance were more likely to be younger, White, and Hispanic, whereas participants with *OFT positive only* discordance tended to be older. Potential non-disclosure could be the result of stigma influenced by social desirability bias, even though there were no additional consequences other than perceived judgment of the interviewer. Participants may have been wary of disclosing substance use while presenting at their doctor's office, despite assurances that their data would not be linked to their identity or medical record, and would not be shared with medical staff. However, this does not explain the number of participants who self-reported recent marijuana use but had a negative OFT.

#### 4.1. Strengths and limitations

This study had a number of strengths including a large diverse sample, collection of data with an assurance of confidentiality and anonymity, use of TLFB Interviews for self-report data, exclusion of positive OFT for medical use of prescription drugs, and laboratory analysis of oral fluid. Additionally, in contrast to previous research (Rendon et al., 2017), the analytical time frame of the TLFB was aligned with the detection window for the OFT, rather than using the entire 30-day TLFB period, thus, providing a more refined examination of potential non-disclosure of use.

Several limitations should be noted. TLFB captured self-reported use for a 30-day period starting one calendar day before the interview date. That is, the TLFB did not capture any substance use on the day the interview was conducted. Given the short detection time of oral fluid testing for some substances such as marijuana (Cone and Huestis, 2007), it is possible that some positive OFTs were the result of substance use on the interview date, which would not have been captured on the TLFB. This limitation would negatively affect the concordance of self-reported use and oral fluid results, if the participant had not reported substance use at any other time in the defined timeframe. Furthermore, data were collected as part of a confidential research study in which data were not shared with providers. This procedure could limit the generalizability of disclosure in the event that patients are more apprehensive about sharing information about drug use with clinicians compared to research staff.

Additionally, the limitations of OFT may result in an underestimation of actual use, thus affecting the concordance estimate. Oral fluid drug concentrations can be contaminated by oral (e.g., smoking)

and intranasal routes of drug administration (Cone, 1997). However, OFT has been accepted as a sensitive measure of recent use and the expected impact of such contamination should be minimal (Allen, 2011; Cone and Huestis, 2007). We are unable to determine the rate of discordant results due to collection error, laboratory error, and other errors associated with ELISA testing. Finally, we note that this study was conducted in primary care clinics in four Eastern US states. Therefore, the extent to which findings can be generalized to substance use treatment or mental health settings, or different geographical areas is limited.

## 5. Conclusions

Self-report has disadvantages when used as a singular measure of substance use due to the potential for underreporting. Oral fluid testing has utility as an objective measure of use, particularly in settings like primary care where recent detection is preferred, and given the limitations of alternative biological measures (e.g., urine and hair). However, biological confirmation testing alone may be a useful – but not error-free – measure of recent substance use, as participants reported recent substance use that oral fluid testing failed to identify. Oral fluid testing and self-report were each able to identify cases of recent substance use that the other missed, but the relative utility of these approaches varied by substance. For example, a sizable proportion of individuals who reported recent marijuana use had a negative oral fluid result. However, the converse was also true, in that a sizable proportion of those who denied use had a positive oral fluid test, suggesting both approaches have an important role for detecting recent marijuana use. In contrast, for cocaine and non-medical prescription opioid use, the balance of detection favored oral fluid testing, such that the majority of individuals with a positive oral fluid test denied recent use, whereas comparatively few reported use but had a negative test. It is possible that confirmatory biological testing such as oral fluid tests may be particularly advantageous for substances perceived as more stigmatized. As noted by Donovan et al. (2012), substance use behavior should ideally be measured by a combination of self-report and biological indicators. Even with the use of both approaches, there may be times when uncertainty will remain (Bell, 1998). Future research should consider factors associated with over- and under-reporting of self-reported substance use in the general population.

## Contributors

CDN contributed to the data collection for the study, assisted in the statistical analysis for this manuscript, and led the writing. JG assisted with the data analyses and contributed to the writing of the manuscript. KEOG led the statistical analysis for the manuscript. KP contributed to the drafting of the manuscript. DS, JM, LW, RPS oversaw data collection for the parent study, provided substantial guidance, and contributed to the writing of the manuscript. All authors contributed to the interpretation of the findings and critically reviewed the final manuscript. All authors approved the final manuscript.

## Disclosures

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## Declaration of Competing Interest

The authors declare that they have no conflict of interest.

## Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.drugalcdep.2020.107939>.

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