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Hair Analysis and its Concordance with Self-report for Drug Users Presenting in Emergency Department*

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Abstract

Background—Secondary analysis using data from the National Drug Abuse Treatment Clinical Trials Network randomized trial (NCT # 01207791), in which 1,285 adult ED patients endorsing moderate to severe problems related to drug use were recruited from 6 US academic hospitals.

Objective—To investigate the utility of hair analysis in drug use disorder trials with infrequent visits, and its concordance with Timeline Follow Back (TLFB).

Methods—This study compared the self-reported drug use on the TLFB instrument with the biological measure of drug use from hair analysis for four major drug classes (Cannabis, Cocaine, Prescribed Opioids and Street Opioids). Both hair analysis and TLFB were conducted at 3, 6 and 12 month follow-up visit and each covered a 90-day recall period prior to the visit.

Results—The concordance between the hair sample results and the TLFB was high for cannabis and street opioids, but was low to moderate for cocaine and prescribed opioids. Under-reporting of drug use given the positive hair sample was always significantly lower for the drug the study participant noted as their primary drug of choice compared with other drugs the participant reported taking, irrespective of whether the drug of choice was cannabis, cocaine, street opioids and prescribed opioids. Over-reporting of drug use given the negative hair sample was always significantly higher for the drug of choice, except for cocaine.

Conclusions—This study extends the literature on hair analysis supporting its use as a secondary outcome measure in clinical trials.

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Contributors: Drs. Sharma, Oden, and VanVeldhuisen designed the secondary analyses for this paper. Dr. Bogenschutz designed and ran the parent study and participated in writing this manuscript. Dr. Sharma conducted the statistical analyses. Dr. Sharma and Dr. VanVeldhuisen wrote the first draft of the manuscript and all authors contributed to have approved the final manuscript.

Keywords

Hair Sample; Drug Abuse; Self-Report; Concordance

1 INTRODUCTION

In clinical trials, a common way to collect illicit drug use information is self-report, yet accuracy of self-reported drug use is highly controversial (Donovan et al., 2012). Some studies have shown good concordance of self-report with biological measures of drug use (Fals-Stewart et al., 2000; Hersh et al., 1999; Napper et al., 2010), while others have shown poor concordance (Ehrman et al., 1994; Winhusen et al., 2003). The reliability and validity of self-report are limited by the veracity and recall ability of research participants.

Often self-report is used in conjunction with a biological measure such as urine drug screen (UDS; Winhusen et al., 2014; Campbell et al., 2014). UDS typically enables the detection of drug use only for a short recent period, usually 1.5 to 4 days. In chronic users, drug use can be detected approximately 1 week after last use (Verstraete, 2004). However, moderate drug use during a longer window of time cannot be detected using urine drug screen. Frequent UDS testing (e.g., 3 times per week in many cocaine treatment trials) is expensive and can affect validity by restricting the study sample to those who will comply with such a regimen, and confound treatment effects with the effects of frequent monitoring. Also, considerable amounts of missing data are inevitable with such designs, complicating the analysis and its interpretation.

Hair testing enables detection of drug use over a significantly longer window of time (Caplan and Goldberger, 2001; Gallardo and Queiroz, 2008) and is increasingly being used as a biological measure to complement self-reported drug use outcomes in clinical trials (Ondersma et al., 2014; Schwartz et al., 2014). Extended detection window of approximately 1 month per half inch of hair allowing 1.5 inch section (3.9 cm) of hair captures a 90-day window of drug use (Gryczynski et al., 2014). A significant benefit of this approach is the non-intrusive nature of collecting a hair sample from the scalp (Kintz et al., 2006). When comparing hair analysis to other methods, Pelander et al. (2008) reported that in 72% of the cases examined, sample compounds that were not present in other matrices were detected in hair, suggesting the increased sensitivity of this approach relative to other biomarkers.

Under-reporting of drug use, defined as a negative self-report when a biological measure indicates drug use, may differ according to drug class. For example, under-reporting for cannabis may be less compared with cocaine, as cannabis is more socially acceptable compared to cocaine and other drugs. Also, there may be factors associated with under-reporting, e.g., pregnant women would tend to under-report drug use due to fear of losing custody or criminal retribution (Kline et al., 1997). Over-reporting of drug use, defined as a positive self-report when a biological measure does not indicate drug use may also occur, but likely less frequent than under-reporting. One possible explanation for over-reporting is inaccuracy of the assay procedure.

This current study compares hair sample results to self-report collected via Time-Line Follow-Back (TLFB; Sobell and Sobell, 1992; Sobell and Sobell, 1996) based on an algorithm developed to map drug classes encountered in hair analyses with drug classes collected on the TLFB. With this algorithm, we investigate concordance between hair sample outcomes and TLFB for the four most prevalent drugs: cannabis, cocaine, street opioids (heroin, opium) and prescribed opioids. We also explore the association between study participant characteristics and under-reporting and over-reporting.

2 METHODS

2.1 Primary Study

This study is a secondary analysis using data from a randomized trial to contrast the effects of a brief intervention with telephone boosters (BI-B) with those of screening, assessment, and referral to treatment (SAR) and minimal screening only (MSO) among patients presenting at an Emergency Department and screened positive for drug use. Both the design of the study and the results of the primary outcome and key secondary outcomes, including the hair sample analysis, are discussed elsewhere (Bogenschutz et al., 2011, 2014).

2.2 Assessments

The Time-Line Follow-Back (TLFB) procedure was used to assess drug use behavior at baseline and follow-up visits. The TLFB is a semi-structured interview that provides estimates of the daily quantity, frequency, and pattern of drug use during a specified time period. This method uses a calendar prompt and a number of other memory aids (e.g., holidays, payday, and other personally relevant dates) to facilitate accurate recall of drug use during the target period. The procedure has been used in numerous clinical and research contexts and has demonstrated adequate levels of reliability and validity when administered as an in-person interview, over the telephone, and by computer (Sobell et al., 1988; Sobell et al., 1996; Sobell and Sobell, 1996). In this study, daily use self-report data were collected for cannabis, cocaine, methamphetamine and prescription stimulants, street opioids (primarily heroin) and prescription opioids, inhalants, sedatives, hallucinogens, alcohol, and other drugs. The TLFB interview was conducted at baseline to assess the past 30 days of drug use, and then at each of the 3, 6 and 12 month follow-up visits to assess drug use over the past 90 days before these visits.

Hair sample analyses were conducted at baseline, 3, 6 and 12 month visits. A standard test of one hundred milligrams of head hair cut close to the scalp provides a several-month window to detect drug ingestion. Hair grows at a rate of 0.6-1.4 cm per month (Saitoh et. al., 1969), thus the first 3.9 cm of hair corresponds to an average of three-month hair growth. Approximately 90-120 strands of hair were required from study participant, and only if head hair was not available, body hair from the leg, chest or underarm was collected as an alternative. Since body hair exhibits longer periods of dormancy than head hair, the timeframe of drug use derived from body hair testing is more difficult to establish than head hair because it spans several months. Head hair and body hair were not mixed in a sample for analysis. Once a hair sample was cut from the participant, the sample was secured in aluminum foil with root ends marked and protruding from the edge of the foil. The sample

was then shipped to the central lab. An extensive wash procedure on test samples was employed to ensure that any potential contamination has been removed or taken into account. The wash procedure minimizes the potential effect of environmental contamination (Gallardo and Queiroz, 2008).

The lab uses a digestion method to liquefy the hair, thereby effectively releasing essentially all the drugs present for analysis, and increasing detection capabilities. Screening cut-off levels followed the laboratory's standard practices for the 5-panel test: 1 ng/gm for marijuana, 5ng/10mg for cocaine and amphetamines and 2 ng/10mg for opioids; GC/MS confirmation cut-offs were: 0.20 pg/10mg for carboxy-tetrahydrocannabinol (THC) metabolite, 0.2ng/10mg for cocaine and its metabolites (benzoylecgonine; norcocaine; cocaethylene), 0.25 ng/10mg for amphetamines, 0.2 ng/10mg for MDA, 1 ng/10mg for MDEA, MDMA and methamphetamines, and 0.2 ng/10mg for hydromorphone, 0.5 ng/10mg for morphine, codeine, oxycodone, hydrocodone, and 6MAM. A sample testing positive during the preliminary screening radioimmunoassay for any of the drug classes were confirmed using gas chromatography tandem mass spectrometry (GC/MS/MS) for marijuana, liquid chromatography tandem mass spectrometry (LC/MS/MS) for opiates, cocaine, and amphetamines, and gas chromatography-mass spectrometry for PCP (Hegstad et al., 2008). If the quantity of hair sample was not sufficient to process and test for the full panel of drugs, only single drug testing was performed until the sample was used up using the following order: Drug of Choice, Opiates, Cocaine, Amphetamines, Marijuana, and PCP.

2.3 Algorithm

The central lab tested the hair sample for 5 drug classes: marijuana, cocaine, PCP, amphetamines and opiates. The TLFB instruments collect daily use for following drug classes: cannabis, cocaine, methamphetamine, prescription stimulants, street opioids, prescription opioids, inhalants, sedatives, and hallucinogens. To investigate the concordance between TLFB and hair sample results, an algorithm was developed to map the 5 drug classes from the hair sample analysis to the drug classes in the TLFB (See supplementary section A[1]).

2.4 Statistical Analysis

The agreement between the hair sample comparator and the TLFB for cannabis, cocaine, prescribed opioids and street opioids was calculated using the percent concordance and Cohen's kappa. In addition, for the discordance, under-reporting and over reporting percentages were calculated for self-report via TLFB compared with the hair. We define TLFB under-reporting to be the probability of self-reporting no drug use in the past 90 days on TLFB, given the hair sample comparator was positive. We define TLFB over-reporting to be the probability of self-reporting any drug use in the past 90 days on TLFB, given the hair sample comparator was negative. (Note that is technically possible for the same person to be both over-reporting at one visit and under-reporting at another.) Sensitivity, specificity, positive predictive value and negative predictive value were also calculated. Except for

[1]Supplementary material can be found by accessing the online version of this paper at http://dx.doi.org and by entering doi:...

concordance and kappa, all analyses implicitly assume that the hair sample results are the "gold standard".

For each of the four most prevalent drug classes (cannabis, cocaine, street opioids, and prescribed opioids), exploratory analyses were conducted to examine predictors of under-reporting using a generalized estimating equation (GEE) approach (Liang and Zeger, 1986 and Zeger and Liang, 1986). To account for the correlated nature of repeated measures data an unstructured working correlation matrix was used under the GEE framework. Similar exploratory analyses were conducted to examine predictors of over-reporting. The following predictors were examined: hair source, drug of choice, site, AUDIT-C score, DAST-10 score, visit, treatment, gender, race, ethnicity and age. All these predictors were included in the model as categorical and were handled multivariately. The responses for the categories used in the statistical model are explained below. For hair source, the hair sample was either collected from head or if the participant did not have enough head hair the sample was collected from the body. For primary drug of choice, during the screening visit, study participants were asked "Excluding alcohol and tobacco, what drug has caused the most difficulties recently? (If no recent difficulties, what drug have you used most often in recent months?)". Due to the low prevalence of some drugs in this sample, the drug of choice was grouped as cannabis, cocaine, prescribed opioids, street opioids and other drugs. Participants were enrolled at 6 sites. AUDIT-C score was grouped as <4 vs ≥ 4 and DAST-10 score as <8 vs ≥ 8, consistent with values used as stratification factors in the randomization. Post-randomization, participant attended three visits, at 3 month, 6 month and 12 months. Participants were randomized to one of the three treatment groups BI-B, SAR and MSO. Gender was grouped male or female. Race was grouped as black, white and other. Ethnicity was grouped as Hispanic or Latino, not Hispanic or Latino, and participant chose not to answer. Participants were categorized into the following age groups 18-<25, 25-<35, 35-<45, 45-<55 and 55+ years old.

3 RESULTS

3.1 Disposition of Hair Sample

A total of 1,285 participants were randomized in this study. Out of these, 1,120 (87%), 875 (68%), 893 (69%) and 832 (65%) participants provided hair sample at baseline, 3, 6 and 12 month visits, respectively (Table 1). At each visit, out of the hair sample collected, 67%-68% of the hair samples were collected from the head and the remaining 32%-33% of the hair samples were collected from the body. The main reasons for hair sample not being collected at baseline visit were "insufficient hair" and "participant refused". At the 3, 6 and 12 month follow-up visit, the main reasons of hair sample not being collected are "participant missed visit", "a phone interview was conducted", "insufficient hair" and "participant refused". GEE-based longitudinal analysis revealed that there were significant demographics differences in the proportion providing a hair sample by race ($p < .0001$, [Odds Ratio Reference group White] Black or African American = 2.16, Other Combined = 1.18) and age ($p < .0001$, [Odds Ratio Reference group 55+] 18-<25=0.48, 25-<35=0.76, 35-<45=0.80, 45-<55=1.34) for percent hair sample collected (data not shown in Table).

3.2 Availability of Hair Sample for Each Drug Class

The quantity of hair was not always sufficient for the lab to perform all the tests corresponding to all drug classes. The availability of hair sample for each drug class is shown in Table 1. Availability of the hair sample was highest for cannabis, ranging from 54%-72% across the four visits, and lowest for prescribed amphetamines, ranging from 45%-54% across the four visits.

3.3 Proportion of Positive Hair Sample Outcome Results for Each Drug Class

At baseline, 73% participants had a hair sample positive for cannabis, 71% for cocaine, 35% for prescription opioids and 23% for street opioids. Methamphetamine, ecstasy, PCP and prescribed amphetamines had lower prevalences of 8%, 1%, 1% and 0%, respectively. Hence, to assess concordance between TLFB and the hair analysis results, analyses were limited to the four most prevalent drugs. The proportion of non-missing hair samples positive for cannabis decreased over the visits, from 73% at baseline to 66%, 66% and 60% at the 3, 6 and 12 month visits, respectively, suggesting a reduction of cannabis use during the course of the study. There was no discernible reduction observed over the visits in use for any of the other drugs.

3.4 Concordance

To evaluate the concordance between hair sample results and TLFB, we excluded the hair samples from the baseline visit, because the TLFB at baseline only assess a 30 day window whereas the hair sample captures a 90 day window of previous drug use.

Concordance for cannabis and street opioids was high (93%-75%), but low to moderate concordance for cocaine and prescribed opioids (61%-71%). For cocaine and prescribed opioids, Cohen’s kappa was very low (<.35). Under-reporting was lowest for cannabis (17%-22%) and highest for prescribed opioids (65%-73%). Over-reporting was less than 11% for all the drugs except cannabis. The positive predictive value was high (> 80%) for all drugs except prescribed opioids (< 71%). Negative predictive value was lowest for cocaine (66%-73%) and highest for street opioids (93%-94%).. The details of these agreement statistics by drug class and visit are provided in Table 2.

3.5 Predictors of Under-reporting

When the hair sample was positive, we predicted the probability of under-reporting and assessed whether the under-reporting differed according to participant characteristics. Table 3 provides the p-value, and the odds ratio (OR) of under-reporting given the positive hair sample, obtained from the GEE analysis. Sample sizes for this longitudinal analysis of under-reporting corresponding to each drug are based on positive hair sample as presented in Table 1.

Consistent across the drugs examined, participants were less likely to under-report a drug if it was their primary drug of choice.

Except for street opioids, site was a significant predictor of under-reporting for the three drug classes. Significant predictors ($p<0.05$) of under-reporting for cannabis were gender

(p=.0085; Female vs Male; OR = 1.33) and age (p=.0076; 45-<55 vs 18-<25; OR = 2.02); for cocaine were AUDIT-C score (p=.0159, <4 vs ≥4 OR = 1.20) and visit (p = .0009; 12month vs 3month; OR = 1.56); for prescribed opioid were DAST-10 score (p=.0277; <8 vs ≥8; OR = 1.30) and race (p = .0031; Black vs White; OR = 4.42); for street opioids were DAST-10 score (p=.0195; <8 vs ≥8; OR = 1.51), visit (p = .0344; 12 month vs 3 month; OR = 1.47) and treatment group (p = .0325; SAR vs BI-B; OR = 2.78).

3.6 Predictors of Over-reporting

When the hair sample was negative, we predicted the probability of over-reporting and assessed whether the over-reporting differed according to participant characteristics. Table 3 provides the p-value and the odds ratio of over-reporting given the negative hair sample, obtained from the GEE analysis. Drug of choice was a significant predictor for over-reporting of all drugs except cocaine. Site was a significant predictor of over-reporting for cannabis and prescribed opioids. AUDIT-C score was significant predictor of over-reporting, except for street opioids. In addition, significant predictor(s) ($p<0.05$) of over-reporting for cocaine was source of hair (p=.0065; Body vs Head; OR = .44); for prescribed opioid was race (p = .0013; Black vs White; OR = .27); for street opioids were visit (p = .0245; 12month vs 3month; OR = .51) and race (p = .0007; Black vs White; OR = .18).

4 DISCUSSION

This study investigated the utility of hair analysis in drug use disorder trials and its concordance with TLFB according to an algorithm developed to construct TLFB comparators for cannabis, cocaine, PCP, street opioids, prescribed opioids, prescribed amphetamine type stimulants, methamphetamine and ecstasy, using a 5-panel hair testing.

4.1 Concordance between Hair Analysis and TLFB

In this sample of adult ED patients indicating moderate to severe problems related to drug use, the concordance between the hair sample results and the TLFB was high for cannabis and street opioids, but the concordance for cocaine and prescribed opioids was low to moderate. For cocaine, only the specificity and the positive predictive values were high, whereas for prescribed opioids only specificity was high. For cannabis, the probability of over-reporting was higher compared to probability of under-reporting; similar results were obtained in previous studies (see Fendrich et al., 2004, Gryczynski et al., 2014). The agreement statistics were fairly similar across the three visits.

4.2 Factors Associated with Under-reporting

Source of hair (body or head) was not a significant predictor of under-reporting for any drug. Drug of choice was associated with a decreased probability of under-reporting, i.e., the under-reporting was least for the primary drug of choice, suggesting that self-reporting drug use by patients may have focused only on the primary drug of choice and not other drugs. Similar findings were reported in Tassiopoulos et al. (2004), where heroin-using participants denied using any cocaine but had positive hair test for cocaine. Site was a significant predictor of under-reporting for all drugs, except street opioids. This could be due to the difference in the population at these sites. At site S1, S2, S3 and S6 participants were

predominantly cannabis users (47%, 50%, 75% and 50%, respectively), at site S4 most (47%) participants endorsed cocaine as their primary drug of choice whereas at site S5 most (44%) participants endorsed street opioids as their primary drug of choice. Female gender and older age were associated with under-reporting of cannabis use which could be attributed to stigma and shame that may be greater for women or older people or the cannabis stays in female hair and older people for longer period of time. Ledgerwood et al. (2008) found a race effect on under-reporting for cocaine, which was not significant in our sample; instead race was significant for under-reporting of prescription opioids. These analyses were conducted assuming 3.9 cm of hair would provide 90-day look back period, but hair grows at a rate of 0.6-1.4 cm per month (Saitoh et. al., 1969). Thus, it is possible that for some of the sub-groups, individual had slower growing hair, and thus came out as significant predictors of under-reporting.

4.3 Factors Associated with Over-reporting

Over-reporting may be due to the inaccuracy of the hair sample assay procedure. Except for the drug of choice, confirmatory tests were performed only if the screen test was positive. A false negative result at screening would remain false negative. However, drug of choice was associated with over-reporting, i.e., the over-reporting was highest for the primary drug of choice, except for cocaine. This finding is not consistent with a false negative effect due to inaccuracies on the testing assay. Another explanation for over-reporting is moderate drug users use at a level that avoids detection when tested in the hair sample (Kintz, 2012). These limitations are also discussed in Ledgerwood et al. (2008) and Gryczynski et al. (2014). Site was a significant predictor of over-reporting for cannabis and prescribed opioids, which may be attributed due to the difference in the population at these sites as discussed in case of under-reporting. Over-reporting for cocaine was higher in head hair compared to body hair which could be due to the differential hair growth in different parts of the body. For both street and prescribed opioids, race was a significant predictor of over-reporting. These analyses were conducted assuming hair analysis as “gold-standard”, which might not be correct as reported by Ledgerwood et al. (2008). Thus, it is possible that for some of the sub-groups the over-reporting was actually due to under detection of drug in the hair.

4.4 Strengths

Strengths of the study include the large sample size at each visit allows us to study various factors associated with under-reporting and over-reporting. The prevalence of the four drug classes is moderate to high which allows us to compare various concordance statistics across the four drug classes. Approximately 33% of the hair samples were obtained from the body allowing for comparisons of head hair to body hair.

4.5 Limitations

One limitation of the study is the availability of hair sample, which ranged from 72%-45%, for the various visits for different drug classes, which limits generalizability of our results to those participants who did not provide the hair sample or provided insufficient sample. Secondly, all the statistical tests conducted for the analysis were not corrected for multiple testing and exploratory in nature, and the results need to be interpreted in that light. Thirdly, the comparison of TLFB and hair analysis assumed hair analysis as “gold-standard”, which

might not be correct as reported by Ledgerwood et al. (2008), and also by our findings of over-reporting.

4.6 Summary

The current study provides information regarding the hair sample analysis in drug use trials with infrequent visits and its concordance with TLFB. It extends the literature on hair analysis (Tassiopoulos et al., 2004; Ledgerwood et al., 2008; Gryczynski et al., 2014) supporting its use as a secondary outcome measure in clinical trials, particularly when assessing long-term abstinence given its extended window of detection compared to typical follow-up sessions, for which urine drug testing may be more appropriate. Reliability varied considerably by drug category and by site, indicating that the target drug and participant characteristics should be considered when weighing the pros and cons of employing hair testing as an objective outcome measure.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- concordance between hair sample and TLFB was high for cannabis and street opioids
- concordance was low to moderate for cocaine and prescribed opioids
- under-reporting of drug use was significantly lower for primary drug of choice
- females and older age were associated with under-reporting of cannabis use

Table 1

Disposition, Availability and Proportion of Positive Hair Sample at each visit

	Baseline	**3-Month Visit**	**6-Month Visit**	**12-Month Visit**
Total Randomized	1285	1285	1285	1285
Disposition of Hair Sample				
	Baseline	3-Month Visit	6-Month Visit	12-Month Visit
Collected	**1120 (87%)**	**875 (68%)**	**893 (69%)**	**832 (65%)**
Hair From Head	759 (68%)	587 (67%)	595 (67%)	557 (67%)
Hair From Body	361 (32%)	288 (33%)	298 (33%)	275 (33%)
Not Collected	**165 (13%)**	**147 (11%)**	**213 (17%)**	**211 (16%)**
Refused	104 (63%)	59 (40%)	63 (30%)	51 (24%)
Insufficient Hair	56 (34%)	18 (12%)	24 (11 %)	27 (13%)
Phone Interview	0 (0%)	60 (41 %)	98 (46%)	103 (49%)
Other	5 (3%)	10 (7%)	28 (13%)	30 (14%)
Participant Missed Visit	**0 (0%)**	**263 (20%)**	**179 (14%)**	**242 (19%)**
Availability of Hair Sample for Each Drug Class				
Cannabis	925 (72%)	766 (60%)	743 (58%)	697 (54%)
Cocaine	879 (68%)	756 (59%)	726 (56%)	665 (52%)
Prescribed Opioids	802 (62%)	706 (55%)	655 (51 %)	591 (46%)
Street Opioids	802 (62%)	706 (55%)	655 (51 %)	591 (46%)
Methamphetamines	777 (60%)	685 (53%)	641 (50%)	578 (45%)
Ecstasy	777 (60%)	685 (53%)	641 (50%)	578 (45%)
PCP	794 (62%)	687 (53%)	643 (50%)	584 (45%)
Prescribed Amphetamines	777 (60%)	685 (53%)	641 (50%)	578 (45%)
Proportion of Positive Hair Sample Outcome Results for Each Drug Class				
Cannabis	673/925 (73%)	506/766 (66%)	487/743 (66%)	418/697 (60%)
Cocaine	620/879 (71%)	532/756 (70%)	526/726 (72%)	472/665 (71%)
Prescribed Opioids	281/802 (35%)	275/706 (39%)	240/655 (37%)	200/591 (34%)
Street Opioids	182/802 (23%)	166/706 (24%)	169/655 (26%)	134/591 (23%)
Methamphetamines	63/777 (8%)	67/685 (10%)	65/641 (10%)	67/578 (12%)
Ecstasy	11/777 (1%)	6/685 (1 %)	4/641 (1%)	2/578 (0%)
PCP	5/794 (1 %)	4/687 (1 %)	2/643 (0%)	1/584 (0%)
Prescribed Amphetamines	1/777 (0%)	0/685 (0%)	0/641 (0%)	0/578 (0%)

Table 2

Concordance, Cohen's kappa, Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value of TLFB Assuming Hair Analysis as Gold Standards

Head and Body Hair Combined	**3-Month Visit**	**6-Month Visit**	**12-Month Visit**
Cannabis			
N	766	743	697
Concordance % (Kappa)	77.81 (.51)	79.14 (.54)	75.32 (.49)
Under-Reporting % (Over-Reporting %)	18.18 (30.00)	17.25 (27.73)	22.01 (28.67)
Sensitivity % (Specificity %)	81.82 (70.00)	82.75 (72.27)	77.99 (71.33)
Positive Predictive Value % (Negative Predictive Value %)	84.15 (66.42)	85.02 (68.77)	80.30 (68.38)
Cocaine			
N	756	726	665
Concordance % (Kappa)	65.21 (.35)	65.01 (.35)	61.20 (.31)
Under-Reporting % (Over-Reporting %)	45.30 (9.82)	45.44 (7.50)	52.12 (6.22)
Sensitivity % (Specificity %)	54.70 (90.18)	54.56 (92.50)	47.88 (93.78)
Positive Predictive Value % (Negative Predictive Value %)	92.97 (45.60)	95.03 (43.63)	94.96 (42.39)
Prescribed Opioids			
N	706	655	591
Concordance % (Kappa)	64.87 (.18)	70.99 (.30)	71.40 (.27)
Under-Reporting % (Over-Reporting %)	72.73 (11.14)	65.00 (8.19)	67.00 (8.95)
Sensitivity % (Specificity %)	27.27 (88.86)	35.00 (91.81)	33.00 (91.05)
Positive Predictive Value % (Negative Predictive Value %)	60.98 (65.69)	71.19 (70.95)	65.35 (72.65)
Street Opioids			
N	706	655	591
Concordance % (Kappa)	90.51 (.73)	92.98 (.81)	91.03 (.73)
Under-Reporting % (Over-Reporting %)	21.69 (5.74)	17.16 (3.50)	25.37 (4.16)
Sensitivity % (Specificity %)	78.31 (94.26)	82.84 (96.50)	74.63 (95.84)
Positive Predictive Value % (Negative Predictive Value %)	80.75 (93.39)	89.17 (94.18)	84.03 (92.80)

Table 3

Generalized Estimating Equation Analysis to test if the participant characteristics were associated with under-reporting given the positive hair sample and over-reporting given the negative hair sample

Predictor	Under-reporting Given Positive Hair Sample		Over-reporting Given Negative Hair Sample	
	Pvalue	Odds-Ratio of Under-reporting	Pvalue	Odds-Ratio of Over-reporting
Cannabis				
Hair Source *[Ref = Head]*	0.8622	Body=0.98	0.8731	Body=0.98
Drug of Choice *[Ref = Cannabis]*	<.0001	Cocaine=3.40, OtherDrugs=4.55, PrescribedOpioids=3.11, StreetOpioids=5.30	0.0029	Cocaine=0.55, OtherDrugs=0.38, PrescribedOpioids=0.27, StreetOpioids=0.25
Site *[Ref = S6]*	<.0001	S1=0.49, S2=1.38, S3=0.33, S4=3.31, S5=1.10	0.0438	S1=1.19, S2=1.22, S3=1.78, S4=0.67, S5=1.08
AUDIT-C Score *[Ref = ≥ 4]*	0.8224	<4=1.02	0.0458	<4=0.81
DAST-10 Score*[Ref = ≥ 8]*	0.9703	<8=1.00	0.0536	<8=0.81
Visit *[Ref = 3M]*	0.1399	12M=1.25, 6M=0.91	0.7294	12M=0.87, 6M=0.90
Treatment *[Ref = BIB]*	0.2671	MSO=0.79, SAR=0.72	0.5648	MSO=1.24, SAR=1.23
Gender *[Ref = Male]*	0.0085	Female=1.33	0.9126	Female=1.01
Race *[Ref = White]*	0.3277	Black=0.79, Other=0.65	0.8673	Black=1.11, Other=1.14
Ethnicity *[Ref = Hispanic]*	0.4810	NoAnswer=0.32, NotHispanic=1.04	0.1251	NotHispanic=1.45
Age *[Ref = ≤ 25]*	0.0076	25-<35=0.78, 35-<45=1.18, 45-<55=2.02, 55+=1.51	0.3281	25-<35=0.99, 35-<45=1.11, 45-<55=0.80, 55+=0.49
Cocaine				
Hair Source *[Ref = Head]*	0.6358	Body=0.96	0.0065	Body=0.44
Drug of Choice *[Ref = Cocaine]*	<.0001	Cannabis=4.14, OtherDrugs=5.01, PrescribedOpioids=6.90, StreetOpioids=2.57	0.1387	Cannabis=0.68, OtherDrugs=1.22, PrescribedOpioids=0.13, StreetOpioids=0.87
Site *[Ref = S6]*	<.0001	S1=0.33, S2=0.73, S3=0.95, S4=2.28, S5=1.20	0.3653	S1=1.16, S2=0.82, S3=1.80, S4=1.54, S5=0.94
AUDIT-C Score *[Ref = ≥ 4]*	0.0159	<4=1.20	<.0001	<4=0.35
DAST-10 Score*[Ref = ≥ 8]*	0.0501	<8=1.18	0.0357	<8=0.61
Visit *[Ref = 3M]*	0.0009	12M=1.56, 6M=1.02	0.6535	12M=0.70, 6M=0.83
Treatment *[Ref = BIB]*	0.7013	MSO=1.04, SAR=0.90	0.5285	MSO=0.67, SAR=0.64
Gender *[Ref = Male]*	0.2090	Female=0.90	0.4301	Female=0.86
Race *[Ref = White]*	0.6248	Black=0.81, Other=0.91	0.7093	Black=1.59, Other=1.12
Ethnicity *[Ref = Hispanic]*	0.5342	NoAnswer=7.96, NotHispanic=1.05	Did Not Converge (Excluded from the Model)	
Age *[Ref = ≤ 25]*	0.2174	25-<35=0.96, 35-<45=0.73, 45-<55=0.67,55+=0.55	Did Not Converge (Excluded from the Model)	
Prescribed Opioids				

Predictor	Under-reporting Given Positive Hair Sample		Over-reporting Given Negative Hair Sample	
Hair Source *[Ref = Head]*	0.6352	Body=0.94	0.6528	Body=1.06
Drug of Choice *[Ref = Presc. Opioids]*	0.0057	Cannabis=1.79, Cocaine=2.96,OtherDrugs=1.39, StreetOpioids=3.30	0.0377	Cannabis=0.48, Cocaine=0.46, OtherDrugs=0.24, StreetOpioids=1.10
Site *[Ref = S6*]	0.0087	S1=0.48, S2=1.17, S3=0.43, S4=3.43, S5=1.05	0.0001	S1=1.47, S2=1.20, S3=1.53, S4=0.28, S5=1.76
AUDIT-C Score *[Ref = ≥ 4]*	0.5960	<4=1.05	<.0001	<4=0.49
DAST-10 *Score[Ref = ≥ 8]*	0.0277	<8=1.30	0.1233	<8=0.76
Visit *[Ref = 3M]*	0.1658	12M=0.80, 6M=0.74	0.1338	12M=0.67, 6M=0.71
Treatment *[Ref = BIB]*	0.2214	MSO=0.87, SAR=0.65	0.9272	MSO=0.95, SAR=0.87
Gender *[Ref = Male]*	0.1063	Female=1.21	0.6640	Female=1.07
Race *[Ref = White]*	0.0031	Black=4.42, Other=0.98	0.0013	Black=0.27, Other=0.48
Ethnicity *[Ref = Hispanic]*	0.7853	NoAnswer=0.46, NotHispanic=1.08	Did Not Converge (Excluded from the Model)	
Age *[Ref = ≤ 25]*	0.8306	25-<35=1.14, 35-<45=0.88, 45-<55=0.84, 55+=0.84	0.0959	25-<35=1.06, 35-<45=0.53, 45-<55=0.69,55+=0.20
Street Opioids				
Hair Source *[Ref = Head]*	0.6013	Body=0.89	0.7327	Body=1.07
Drug of Choice *[Ref = St. Opioids]*	0.0042	Cannabis=9.19, Cocaine=4.08, OtherDrugs=3.36, PrescribedOpioids=1.94	0.0255	Cannabis=0.14, Cocaine=0.25, OtherDrugs=0.33, PrescribedOpioids=0.49
Site *[Ref = S6]*	0.1623	S1=0.51, S2=1.19, S4=3.28, S5=0.64	0.3702	S1=0.61, S2=1.19, S3=0.63, S4=0.87, S5=1.25
AUDIT-C Score *[Ref = ≥ 4]*	0.7500	<4=0.95	0.2629	<4=0.83
DAST-10 Score*[Ref = ≥ 8]*	0.0195	<8=1.51	0.1810	<8=0.78
Visit *[Ref = 3M]*	0.0344	12M=1.47, 6M=0.66	0.0245	12M=0.51, 6M=0.46
Treatment *[Ref = BIB]*	0.0325	MSO=1.67, SAR=2.78	0.2288	MSO=0.87, SAR=1.60
Gender *[Ref = Male]*	0.2310	Female=0.80	0.4155	Female=1.14
Race *[Ref = White]*	0.3010	Black=2.03, Other=1.82	0.0007	Black=0.18, Other=0.91
Ethnicity *[Ref = Hispanic]*	0.3004	NoAnswer=23.32, NotHispanic=0.99	Did Not Converge (Excluded from the Model)	
Age *[Ref = ≤ 25]*	0.2472	25-<35=4.15, 35-<45=2.63, 45-<55=1.81, 55+=1.95	0.7423	25-<35=0.57, 35-<45=0.79, 45-<55=0.51, 55+=0.67