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Witnessed versus Unwitnessed Random Urine Tests in the Treatment of Opioid Dependence

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Abstract

Background and Objectives—Clinics licensed to provide pharmacotherapy for opiate dependence disorder are required to perform random urine drug screen (RUDS) tests. The results provide the empirical basis of individual treatment and programmatic effectiveness, and public health policy. Patients consent to witnessed testing but most tests are unwitnessed. The purpose of the present study was to compare treatment effectiveness estimates derived from witnessed versus unwitnessed urine samples.

Methods—We adopted a policy requiring visually witnessed urine drug screens (WUDS) and studied its impact (a single group, pretest–posttest design) on the RUDS test results in 115 male veterans enrolled in the St. Louis VA Opioid Treatment Program.

Results—The percentage of opioid-positive urine samples increased significantly following implementation of WUDS (25% vs. 41%, $\chi^2 = 66.5$, $p < .001$).

Conclusions and Scientific Significance—Results of this preliminary study suggest that random testing alone does not ensure the integrity of UDS testing. Outcome calculations based on random unwitnessed tests may overestimate the effectiveness of opioid dependence disorder treatment.

INTRODUCTION

Veterans with opioid dependence disorder enrolled in VA Opioid Treatment Programs (OTP) receive substitution pharmacotherapy (methadone or buprenorphine) and submit to at least eight random urine drug screens (RUDSs) annually. RUDS testing provides objective evidence of use of prescribed medications, collateral use of opioids, and other controlled substances (eg, benzodiazepines, cocaine, amphetamines), and yields an ostensibly objective measure of individual progress and programmatic treatment effects.

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Declaration of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this paper.

In 2003, the St. Louis VA Medical Center (VAMC), and many other VAs across the nation, stopped using RUDS data as a basis for discontinuing treatment.[1,2] This new policy was assumed to have eliminated the motive for patients to tamper with or otherwise falsify their urine specimens. However, it is unlikely that the policy would eliminate all motivation to tamper with test results. Confidentiality of testing outcomes cannot be guaranteed and the results may affect other matters of importance to the patient (eg, employment, incarceration, child visitation rights) of which the OTP staff is unaware. Furthermore, a variety of products designed for the "daily user subject to random testing" are commercially available,[3] including penile prostheses, urine substitutes, chemical additives that detoxify the sample or interfere with chemical testing, and warming devices to maintain the sample at body temperature. The federal government has successfully prosecuted the makers of such products but the products continue to proliferate nonetheless.[4]

Due to growing concern about the validity of unwitnessed (albeit random) urine samples, the St. Louis VA instituted a policy that all urine samples be collected under the direct visual oversight of a witness. In this paper, we report an analysis of RUDS data obtained before and after adoption of the witnessed UDS (WUDS) policy.

METHODS

OTP of the St. Louis VAMC has been providing opioid substitution treatment for veterans with opioid dependence disorder since 1972. This report focuses on the 152 veterans who were enrolled in the clinic on March 20, 2007, the date on which the OTP instituted its WUDS policy. The policy required that the production and collection of random urine specimens for toxicology testing be visually witnessed by an OTP staff member. Addiction Management Software (Microsoft® AMS Enterprise 8.4.501, Version 5.1, Copyright© 2007 Microsoft Corporation, Copyright 1990–2006, Netsmart Technologies, New York and Kansas City End User License Agreement to Department of Veterans Affairs) was used to randomly select patients for testing and generate the daily list of patients selected for testing. The AMS random selection algorithm is based in part on the information entered by the addiction therapists, including the frequency of urine testing and minimum time between tests. Of the 152 OTP enrollees, 115 (75.7%) met the only additional study participation requirement, the availability of 10 RUDS test results prior to and another 10 subsequent to the implementation of the WUDS policy.

The chi-square test was used to test the hypothesis that the percentage of positive urine tests post-WUDS would be higher than the percentage before WUDS. All other testing was performed post hoc to provide additional description or elucidate differences observed in the main analysis. Student's *t*-test for paired data was used to compare the mean number of UDS tests that were positive for illicit opiates before and after institution of WUDS. Multiple regression analysis was planned to identify predictors of the number of positive post-WUDS test results, with candidate predictors based on previous studies.[5] Variables included in the model were age, race (African American or Caucasian), the duration of the specimen collection period, number of positive tests pre-WUDS, and substitution treatment modality (ie, methadone or burprenorphine). We anticipated that older participants would be less prone than younger participants to tamper with their specimens.

RESULTS

The sample (n = 115) was composed entirely of men, of whom 71 (61.7%) were African American and 44 (38.3%) were Caucasian. The mean age was 54.6 ± 7.5 years. Their demographic characteristics did not differ significantly from the 37 patients who were enrolled in the OTP at the time of the policy shift but who did not provide enough urine

specimens to be included in the study. Most patients (n = 103, 89.6%) received narcotic substitution in the form of methadone and the others (n = 12, 10.4%) received burprenorphine. The percentage of subjects having no opioid-positive tests decreased significantly with implementation of WUDS (pre-WUDS vs. post-WUDS: 37.4% vs. 30.4%, $p < .01$). The percentage of all random UDS tests that were opiate-positive increased from 25% before to 41% after institution of WUDS ($\chi^2 = 66.5$, $p < .0001$). The interval over which the pre-policy UDS samples were collected was significantly longer than the interval over which the post-policy UDS samples were collected (439.8 vs. 383.5 days, $t = -12.5$, $p < .001$). Subjects with one or more opiate positive test (n = 80) were similar in age to those with no positive tests (54.4 vs. 55.1 years of age). Of the 115 patients, 16 (13.9%) improved subsequent to WUDS implementation (ie, a decrease in the percentage of samples that were opiate-positive), 40 (34.8%) were unchanged, and 59 (51.3%) worsened (ie, had more opiate-positive tests).

The prediction model accounted for 53.4% (adjusted R^2) of the variance in post-WUDS opiate-positive tests ($p < .001$). The number of positive tests pre-WUDS strongly predicted the number of post-WUDS tests (B = .74, SEM = .01, beta = .56, t = 7.6, $p < .001$). African American race also was a significant predictor ($B = -1.7$, SEM = .58, beta = −.22, $t = -2.9$, p = .004), whereas duration of the specimen collection period (p = .07), substitution treatment modality (p = .26), and age (p = .18) were not significantly associated with number of post-WUDS tests.

DISCUSSION

At the St. Louis VAMC, veterans receiving narcotic substitution consent to random urine toxicology testing in accordance with federal and accrediting body regulations.[1,6,7] Testing results inform individual treatment plans and provide empirical evidence of program effectiveness, but consistent with harm reduction treatment principles,[2,8,9] the results do not affect individual eligibility for or provision of ongoing treatment. This non-punitive approach is thought to reduce falsification of or tampering with the urine sample,[1] and the results of random UDS tests have been presumed to be valid. Programs generally are not required to observe production of urine samples for testing.[7] Some programs require that patients consent to observed testing, but in our experience most do not actually perform such tests.

More than 5 years after implementing the harm reduction model, the St. Louis VAMC clinic instituted random WUDS testing. After implementation of WUDS, the percentage of opiate-positive tests increased from 25% to 41%. This 16% increase in opiate-positive tests is clinically significant as it represents the magnitude of treatment effect potentially referable to having unwitnessed (albeit random) UDS tests. Our results may actually underestimate the magnitude of the witness effect because the data were gathered as part of a routine performance improvement initiative. No additional funding was provided for the staff to perform WUDS testing, and vigilance was not incentivized. Furthermore, the addiction therapists were not monitored for compliance with the WUDS protocol. Consequently, it is likely that some tests were not witnessed despite the WUDS policy.

Institution of WUDS did not lead to more frequent opiate-positive tests in all cases. The frequency remained the same in 40 (34.8%) of the 115 patients and declined in 16 (13.9%). An increase in the frequency of opiate-positive tests was seen in just over one-half of the sample (51.3%). As expected, a higher number of opiate positive tests pre-WUDS predicted a higher number of opiate-positive tests post-WUDS. African American race was the only other independent predictor, and emerged within a regression analysis that did not control for all potential sources of confounding. Why African Americans might be more likely to

present opiate-positive tests is unclear, and the finding may simply reflect greater use by this subset during the post-WUDS interval.

Because WUDS was implemented as part of a routine performance improvement program (not as a research investigation) and had no direct consequences for the patients, WUDS met with little resistance. The numbers of pre- and post-tests were sufficient to reliably estimate the effect of observation. The study has some significant limitations. Principal among these is the use of the single group, pretest–posttest design of an intact group.[10] The design does not support causal inferences. Clinic factors other than WUDS implementation as well as factors unrelated to the clinic or the study may have caused the increase in the frequency of opiate-positive tests. The observed increases in opioid-positive test results may indicate nothing more than increased opioid use coincident with WUDS implementation. Direct observation of urine sample production certainly limited some of the opportunity for tampering with test samples. Additional studies will be required to determine the reproducibility and generalizability of our observations to women and non-veteran populations with opioid dependence disorder. The demographic features of VA treatment populations have changed in recent years reflecting with growing numbers of women and younger persons.[11,12]

The findings provide an empirical basis and impetus for additional studies that assess the value of WUDS. Further studies will be needed to examine the effects of substance use, treatment history, psychiatric comorbidity, and demographic factors including race on the validity of urine toxicology test results. Understanding the feasibility of WUDS will require studies that calculate actual costs associated with WUDS implementation (eg, infrastructure development, staffing changes) as well as barriers to its implementation (eg, issues related to privacy of patients and staff). Lastly, there is a need to improve our understanding of how best to implement WUDS in special populations, for example opioid-dependent persons with a history of sexual trauma.

For the present, increases that we observed in the frequency of opiate-positive tests with WUDS are worrisome and suggest that data from unwitnessed tests, which currently are used to plan individual treatment, calculate program effectiveness, and fashion public policy, are flawed. Replication of our results would demonstrate that the procedures governing UDS testing in opioid dependence disorder treatment and research should be revised. In turn, development of more accurate tests enables us to determine the effectiveness of current treatment and to develop more effective and individualized treatment.

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