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# Screen of drug use: Diagnostic accuracy for opioid use disorder

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ABSTRACT

*Aims:* Opioid related deaths have more than tripled in recent years. Identifying and referring individuals with opioid use disorder (OUD) to treatment is one of the promising approaches to reduce opioid related deaths. However, using urine toxicology to identify opioid misuse is not reliable. This study validates the Screen of Drug Use (SoDU) to screen for OUD in the primary care setting, and establish its concurrent diagnostic validity among diverse subgroups of patients, including age, gender, race/ethnicity, marital status, educational level, and PTSD status.

*Methods:* We used data from 1283 primary care patients recruited in the VA in CA. This sample matched patient characteristics general VA population with mean age = 62, and 95% men. A total of 10.4% met DSM-5 criteria for any drug use disorder and 2.7% met criteria for OUD (with or without other drug use disorders). An opioid use abuse or dependence diagnosis based on the Mini International Diagnostic Interview was used as the criterion for having a DSM-5 opioid use disorder.

*Results:* The SoDU was 100% sensitive (95% confidence interval [CI], 89.9%–100%), and 86.3% specific (95% CI, 84.3%–88.1%). When tested in subgroups of patients, the SoDU maintained 100% sensitivity in all subgroups. Specificity ranged from 74.5% to 94.2% for diverse subgroups of patients.

*Conclusions:* The SoDU is an appropriate instrument to screen for opioid use disorder in primary care. It is brief, easy to use, and has good concurrent diagnostic validity for diverse groups of patients.

## 1. Introduction

The opioid epidemic costs the U.S. over $78 billion annually (Florence et al., 2016). There were about 289 million prescriptions for opioids in 2012, of which nearly half were generated in primary care specialties (Levy et al., 2015). Emergency department visits for non-medical use of prescription opioids more than doubled from 2004 to 2011, accounting for an estimated 488,000 visits in 2011 (SAMHSA, 2013). Opioid related deaths have more than tripled since 1999, with an estimated 33,091 deaths involving opioids in 2015 (Chen et al., 2014; Kolodny et al., 2015; Rudd et al., 2016).

Although many approaches have been tried to address the opioid epidemic (Nelson et al., 2015), the vast majority of affected individuals do not seek or receive treatment. Among individuals identified as having an opioid use disorder in the National Survey on Drug Use and Health (NSDUH), only an estimated 19.7% received treatment in 2009–2013 (Han et al., 2015). One approach is to incorporate screening to identify individuals with opioid use disorder, following up with brief intervention, referral to treatment (Screening, Brief Intervention, and Referral to Treatment; SBIRT), or other strategies to manage patients in primary health care (Bernstein and D'Onofrio, 2013; D'Onofrio et al., 2015). However, using urine toxicology to identify opioid misuse is not reliable because it does not determine if an individual has an opioid use disorder (OUD) or is using opioids appropriately for medical purposes (Kolodny et al., 2015). For example, a positive urine test does not differentiate codeine versus heroin use because morphine is a metabolite for both; besides, it also does not identify recreational use of a prescribed medication when used above and beyond the recommended dosage (Keary et al., 2012).

Using self-report to screen for substance use disorders is an appropriate alternative. For example, the 3-item Alcohol Use Disorder Identification Test (AUDIT-C; (Bush et al., 1998) has been used widely and mandated to be used in VA primary care (Department of Veterans Affairs and Department of Defense, 2009; Tiet et al., 2015; Veterans Health Administration, 2004).

Screening and detection of a health condition before it causes

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serious harm is essential. Early detection of OUD may reduce grave consequences, including overdose and death. Primary care is an ideal setting for screening because it is where most individuals have contacts with the health care system (Ghitza and Tai, 2014; World Health Organization, 2003). From a public health perspective, secondary and tertiary prevention initiating in the primary care setting can identify early cases of OUD and reduce the adverse consequences of OUD (Kolodny et al., 2015).

The 2-item Screen of Drug Use (SoDU; Tiet et al., 2015) has been developed and validated for identifying *any* drug use disorder in primary care setting. It has excellent concurrent diagnostic validity. In its Treatment Improvement Protocol (TIP) for opioid use disorder management, SAMHSA recommended the use of the SoDU to identify patients who use drugs (SAMHSA, 2018). However, the SoDU has not been examined for its utility in identifying opioid use disorder (OUD) specifically. This study examined the sensitivity, specificity, and other concurrent diagnostic properties of the SoDU in identifying OUD in a primary care patient sample and its performance in subgroups of patients identified by sex, age, race/ethnicity, education, marital status, and posttraumatic stress disorder diagnosis status.

## 2. Methods

### 2.1. Data source and study population

This study used data from the *Drug Screen for Primary Care Patients Study* ("*Drug Screen Study*"; Tiet et al., 2015), which was initially collected to develop and validate the Screen of Drug Use (SoDU) to identify *any* drug use disorder in primary care (PC). Research staff in the *Drug Screen Study* recruited patients from February 2012 through April 2014 in the waiting areas at two VA primary care clinics in Northern CA. Only primary care patients who had visited the clinics within 2 weeks were included. Research staff approached 3173 patients, 1518 declined to participate, 355 did not follow through with the appointment or consent, and 1300 (41.0%) provided informed consent and were interviewed. Of the 1300 participants, the study excluded 17 individuals (5 for cognitive issues, 2 for repeated recruitment, 6 for incomplete data, and 4 for being a spouse and not a clinic patient). Trained research staff conducted computer-assisted, structured diagnostic interviews in a private setting in the primary care clinics. A total of 1167 participants (91%) consented to audio-recording of the interviews; 130 (11%) randomly selected interviews were reviewed by another research staff member to confirm the accuracy of data. The Stanford University School of Medicine institutional review board approved all study procedures.

### 2.2. Measures

#### 2.2.1. Screening measure

*2.2.1.1. Screen of Drug Use (SoDU).* The SoDU is a 2-item screening instrument developed and validated to identify *any* drug use disorder in the primary care setting. It was 100% sensitive and 93.73% specific in a development sample and 92.31% sensitive and 92.87% specific in a validation sample (Tiet et al., 2015). It had excellent sensitivity and specificity in identifying any drug use disorder in diverse subgroups of patients identified by age, sex, race and ethnicity, marital status, educational level, and PTSD status. It had a 1-week test-retest reliability of kappa = 0.9.

*2.2.1.2. Participants were provided the following instruction.* "I'm going to read you questions concerning information about your potential involvement with drugs, excluding alcohol and tobacco, during the past 12 months. When the word "drug" is used, it includes various types of drugs, such as marijuana, tranquilizers, barbiturates, cocaine, etc. Drug does NOT refer to a medication used in the manner it was prescribed or recommended (for example, include only your use of marijuana if you are using it above and beyond what it was recommended for by a doctor or a state-licensed physician or if you are using it recreationally). Questions will be related to the last 12 months so your answers can vary from 0 to 365 days." The first question of the SoDU asks: "How many days in the past 12 months have you used drugs other than alcohol?" Patients meet diagnostic criteria with a response of 7 or more days. The second question asks: "How many days in the past 12 months have you used drugs more than you meant to?" A response of 2 or more days meets the diagnostic criteria.

#### 2.2.2. Criterion measure

The Mini International Neuropsychiatric Interview (MINI) (Sheehan et al., 1998) was used as the criterion measure. The MINI is a structured, diagnostic interview and has good concordance with the Composite International Diagnostic Interview (Lecrubier et al., 1997; World Health Organization, 1990) and the Structured Clinical Interview for DSM-IV Disorders (Sheehan et al., 1997, 1998). It is compatible with both the DSM-IV and the International Classification of Diseases, 10$^{th}$ Revision (ICD-10) (Lecrubier et al., 1997; Sheehan et al., 1998). DSM-5 combined DSM-IV abuse and dependence criteria into a single "substance use disorder" based on consistent findings from studies relying on over 200,000 participants (Hasin et al., 2013); comparison between lifetime prevalence of patients with OUD based on DSM-IV versus DSM-5 were not significantly different (Boscarino et al., 2011). Based on 130 randomly selected audio-recorded interviews, interrater reliability at the item level was $\kappa > 0.95$ and was perfect at the diagnosis level in this study.

The MINI assessed eight categories of drugs, including both prescribed medications and illicit substances: opioids, stimulants, cocaine, hallucinogens, inhalants, marijuana, tranquilizers, and miscellaneous. Research staff showed participants a list of substances and read the following instructions: "I am going to show you and read to you a list of street drugs. The list also includes some medicines. Please only describe your use of a listed medicine if the medicine was not prescribed to you by a doctor or other qualified medical providers." The category of opioid included "narcotics, heroin, opium, Morphine, Methadone, Dilaudid, Demerol, Codeine, Percodan, Darvon, OxyContin, Vicodin, Percoet." The MINI then assessed symptoms of drug use based on *DSM-IV* and *ICD-10* criteria. An opioid use abuse or dependence diagnosis based on the *DSM-IV* was considered positive for an opioid use disorder (OUD) for DSM-5 in this study.

### 2.3. Statistical analysis

Using OUD from the MINI as the criterion, we calculated the concurrent diagnostic properties of the SoDU. We calculated sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, efficiency, test positive rate, and area under the receiver operator characteristics (AUC). To calculate these properties, we used a publicly available signal detection software for receiver operator characteristics ("tree-based" ROC, https://web.stanford.edu/~yesavage/ROC.html).

## 3. Results

Among the 1283 participants, 95.2% were male, 54.7% non-Hispanic white, and 62.3% single (never married, separated, divorced, or widowed). Their mean age was 62.2 (SD = 12.6), and 75.5% had some post high-school education. Based on the MINI diagnostic interview, 34 participants (2.65%) met criteria for OUD, 133 (10.4%) met criteria for a drug use disorder with or without OUD. A total of 164 (12.8%) met criteria for an alcohol use disorder and 191 (14.9%) met criteria for PTSD.

### 3.1. Concurrent diagnostic validity of the SoDU for OUD

When tested against the MINI structured diagnostic interview,

**Table 1**
Concurrent diagnostic properties of the Screen of Drug Use (SoDU) on opiates use disorder for overall sample and subgroups of patients based on sex, age, racial/ethnic background, marital status, educational level, and posttraumatic stress disorder status.

| | | Opiates Use Disorder | | | | | |
|---|---|---|---|---|---|---|---|
| Group | *n* | SENS [95% CI] | SPEC [95% CI] | Efficiency | LR+ [95% CI] | LR- [95% CI] | AUC |
| Total Sample | 1283 | 100 [89.90–100] | 86.31 [84.29–88.10] | 86.67 | 7.30 [6.35–8.40] | 0 [N/A] | .93 |
| Male | 1222 | 100 [89.28–100] | 86.30 [84.23–88.14] | 86.66 | 7.30 [6.33–8.42] | 0 [N/A] | .93 |
| Female | 61 | 100 [34.24–100] | 86.44 [75.46–92.97] | 86.89 | 7.38 [3.87–14.05] | 0 [N/A] | .93 |
| Age, Younger | 642 | 100 [88.65–100] | 78.10 [74.66–81.20] | 79.13 | 4.57 [3.93–5.30] | 0 [N/A] | .89 |
| Age, Older | 641 | 100 [51.10–100] | 94.19 [92.10–95.76] | 94.23 | 17.22 [12.59–23.54] | 0 [N/A] | .97 |
| Non-Hispanic White | 698 | 100 [79.61-100] | 88.43 [85.82-90.62] | 88.68 | 8.65 [7.03-10.64] | 0 [N/A] | .94 |
| Minority | 579 | 100 [83.18–100] | 83.57 [80.28–86.41] | 84.11 | 6.09 [5.05–7.34] | 0 [N/A] | .92 |
| Married/Partnered | 484 | 100 [60.97–100] | 92.47 [89.75–94.51] | 92.56 | 13.28 [9.70–18.18] | 0 [N/A] | .96 |
| Single/Sep/Div/Wid | 799 | 100 [87.94–100] | 82.49 [79.65–85.01] | 83.10 | 5.71 [4.90–6.66] | 0 [N/A] | .91 |
| ≤ HS | 314 | 100 [75.75-100] | 77.81 [72.80-82.13] | 78.66 | 4.51 [3.65-5.57] | 0 [N/A] | .89 |
| Some College + | 969 | 100 [85.13–100] | 89.02 [86.87–90.85] | 89.27 | 9.11 [7.60–10.92] | 0 [N/A] | .95 |
| PTSD | 159 | 100 [81.57–100] | 74.46 [66.91–81.09] | 77.36 | 3.94 [2.97–5.23] | 0 [N/A] | .87 |
| No PTSD | 1122 | 100 [80.64–100] | 87.88 [85.83–89.68] | 88.06 | 8.25 [7.04–9.67] | 0 [N/A] | .94 |

*Note.* Opiate Use Disorder (OUD) = OUD based on the Mini International Neuropsychiatric Interview; SENS = Sensitivity; SPEC = Specificity; LR = Likelihood Ratio; CI = Confidence Interval; Married/Partnered = Married or Living with Domestic Partner; Single/Sep/Div/Wid = Single/Separated/Divorced/Widowed; ≤HS = High School graduate or less than HS; Some College + = Some college or achieving higher educational levels; PTSD = Posttraumatic Stress Disorder.

Table 1 shows the SoDU was 100% sensitive (95% confidence interval [CI], 89.9%–100%), and 86.3% specific (95% CI, 84.3%–88.1%). It was 86.67% efficient, had a positive likelihood ratio of 7.3 (95% CI, 6.4–8.4), a negative likelihood ratio of 0.0, and an AUC of 0.93.

When tested in subgroups of patients, the SoDU maintained 100% sensitivity in all subgroups (Table 1). Specificity ranged from 74.46% to 94.19%, (with 2 subgroups in the 90's, 7 subgroups in the 80's and 3 subgroups in the 70's). Its efficiency ranged from 77.36% to 95.23%, and AUC ranged from 0.87 to 0.97. Finally, the positive likelihood ratio ranged from 3.94 to 17.22; the negative likelihood ratio was 0.0 for all subgroups.

## 4. Discussion

To our knowledge, this is the first study that has validated a screening instrument specifically for identifying opioid use disorder (OUD) in primary care. Our findings show that the Screen of Drug Use (SoDU) was 100% sensitive both for the whole sample and for subgroups of patients stratified by age, sex, race/ethnicity, marital status, education, and PTSD status. Other indicators of concurrent diagnostic validity were also very good for the entire sample and all subgroups.

The sensitivity and specificity of the SoDU in identifying OUD compare favorably with the sensitivity and specificity of other commonly used screening instruments for substance use and psychiatric disorders in primary care. For example, the commonly used 3-item Alcohol Use Disorders Identification Test (AUDIT-C) has been shown to be 86% sensitive and 89% specific for men and 73% sensitive and 91% specific for women in a primary care sample (Bradley et al., 2007). The Patient Health Questionnaire, depression module (PHQ-9) (Kroenke et al., 2001) was shown to be 88% sensitive and 88% specific. Another example is the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5) (Prins et al., 2016) that is 95% sensitive and 85% specific.

The SoDU was originally developed and validated for detecting *any* drug use disorder among primary care patients (Tiet et al., 2015). This study shows that the SoDU is also suitable for detecting OUD. The SoDU was 92% sensitive and 93% specific for detecting *any* drug use disorder in the validation sample (Tiet et al., 2015). The SoDU has higher sensitivity (100%) but lower specificity (86.3%) in detecting OUD. Thus, it is less likely to miss an OUD than to miss *any* drug use disorder. However, the lower specificity shows that when the SoDU classifies a patient as negative for OUD, the patient may have a drug use disorder other than an OUD.

The instruction for the SoDU in this study used a conservative definition of "drug" such that it excluded "medication used in the manner it was prescribed or recommended." With this instruction, patients who took opioid analgesics as prescribed *and* had an OUD might not have been detected by the SoDU, which potentially would have reduced the sensitivity of the SoDU. However, even with this conservative definition of "drug," the SoDU was found to be 100% sensitive, in the whole sample as well as in all subgroups of patients. This finding suggested that patients who had an OUD also used other drugs or also took their prescribed medications in a manner that was not prescribed or recommended.

Using the SoDU to routinely screen for OUD in primary care may be one of the strategies to reduce opioid overdose. Prescription drug monitoring programs (PDMPs), one commonly used approach to combat the opioid epidemic, were unable to detect many patients with OUD (Hawk et al., 2017). Also, urine toxicology is unreliable in identifying opioid misuse due to its inability to determine if a patient has an OUD or is using opioid appropriately for medical purposes (Kolodny et al., 2015). Thus, using the SoDU to routinely screen for OUD in primary care and enhance referral to treatment may be an alternative strategy to help reduce opioid overdose.

If OUD is identified early in primary care settings, efforts to provide brief intervention and/or referral to opioid addiction treatment are likely to reduce the risk of overdose, OUD-related physical and psychosocial deterioration, and transition to injection drug use (Bernstein and D'Onofrio, 2013). Treatment following screening is promising because there are efficacious treatments for OUD. For example, D'Onofrio and colleagues randomized 329 opioid-dependent patients into three intervention arms after screening and found that buprenorphine treatment group resulted in a significant increase in treatment engagement, reduced self-reported illicit opioid use, and decreased use of inpatient addiction treatment services as compared to referral and brief intervention (D'Onofrio et al., 2015). Saunders and colleagues conducted an RCT and found that medication assisted treatment (MAT) plus integrated cognitive behavioral therapy (ICBT) is associated with more significant improvement in substance use as compared with TAU or TAU plus individual addiction counseling in a sample of 126 participants with opioid use disorder and PTSD (Saunders et al., 2015)

There are several limitations of the study. This study mainly relied on an older, male VA sample, although the sample matched the patient characteristics of those of the general VA population (Frayne et al., 2014) and the SoDU showed excellent concurrent diagnostic validity for both the entire sample and for subgroups of patients stratified by age, sex, race/ethnicity, marital status, educational level, and PTSD status. It is also unclear how the results would hold for non-VA primary care patients. Future studies should examine the concurrent diagnostic

validity of the SoDU for non-VA patients and in diverse samples, including younger and women patients.

## 5. Conclusion

The SoDU is an appropriate routine screening instrument for opioid use disorder in primary care. It is brief, easy to use, and has good concurrent diagnostic validity for diverse groups of patients who vary in age, sex, race/ethnicity, marital status, educational level, and PTSD status. Using the SoDU to screen for OUD in primary care may be one strategy to help reduce deaths and other negative consequences from opioid overdose.

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## Contributors

Drs Tiet and Leyva had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analyses.

Study concept and design: Tiet and Moos. Acquisition, analysis, or interpretation of data: Tiet, Leyva. Drafting of the manuscript: Tiet, Leyva, Moos. All authors have approved the final article.

## Conflict of interest

No conflict declared

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