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## Comparison of opiate-primary treatment-seekers with and without alcohol use disorder

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### Abstract

Many persons seeking opiate treatment present with complex clinical challenges, which may be exacerbated by alcohol misuse. This report details secondary data analyses aggregating treatment-seeking samples across ten NIDA Clinical Trials Network treatment trials to examine alcohol-related characteristics of opiate-primary (OP) clients and compare broad pre-treatment characteristics of those with and without an alcohol use disorder (AUD). Analysis of this aggregate OP client sample (N=1397) indicated that 38% had comorbid AUD, and that a history of alcohol treatment episodes and recent alcohol problems were common. Further, comparisons of OP clients with and without AUD revealed the former were more likely to have had a history of pervasive difficulties in psychosocial functioning. Findings suggest need for detection of and intervention for alcohol misuse at the outset of opiate treatment, and support the practice of availing medical, psychological, case management, and other support services.

### 1. Introduction

Persons seeking treatment for problematic opiate use often present with a host of additional clinical challenges. Beyond the salience of acute opiate withdrawal, health providers encounter issues of comorbid psychiatric and medical illness, poverty and unemployment, criminality, sexual risk, and compromised familial/social relationships [for review, see (Marsch & Bickel, 2009)]. Further, opiate misusers may often present for treatment amidst ongoing polysubstance abuse. Alcohol misuse is, in fact, prevalent among enrollees for opiate treatment (Dobler-Mikola *et al.*, 2005; Hillebrand *et al.*, 2001; Kreek, 1991; Rittmannsberger *et al.*, 2000). This is cause for concern, given that alcohol misuse during opiate treatment accelerates what for many are serious liver disease processes (Rodger *et al.*, 2000; Sendi *et al.*, 2003). Further, it may exacerbate other medical or psychiatric illnesses, induce re-engagement in criminality and discontinuance of treatment services, and otherwise lessen quality of life (Degenhardt & Hall, 2003; Rowan-Szal *et al.*, 2000; Sebanjo *et al.*, 2006; Westreich, 2005). Ultimately, alcohol misuse during opiate treatment may be

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implicated in increased mortality rates (Coffin *et al.*, 2003; Zador & Sunjic, 2000). Consequently, greater understanding of the causes and correlates of concurrent alcohol problems among opiate-misusing treatment-seekers is needed.

Establishing a prevalence estimate for alcohol use diagnoses (AUDs) among misusers of opiates is important yet difficult, given potential variance between settings and treatment-seeking populations as well as lack of uniformity in measurement of problematic alcohol use in extant literature. Early research of methadone maintenance enrollees in the U.S. suggested more than half exhibit problem drinking (Joseph & Appel, 1985; Maddux & Elliot, 1975). Subsequent research utilizing DSM-based criteria suggested 23% meet one or more AUD criteria—of which half are alcohol dependent (Chatham *et al.*, 1997). Reported prevalence of problem drinking among European methadone treatment enrollees also varies, ranging from 24 – 52% (Hillebrand *et al.*, 2001; Rittmannsberger *et al.*, 2000; Sebanjo *et al.*, 2006; Wurst *et al.*, 2008), though both sets of estimates are influenced by method variance concerning choice of diagnostic instrument and nosological threshold. Even in studies with consistent methodological features, prevalence rates differ dramatically. For instance, two studies (Stastney & Potter, 1991; Teplin *et al.*, 2007) utilizing the Michigan Alcoholism Screening Test (MAST; (Selzner, 1971)), a well-known instrument with an established threshold to identify problem drinking, report prevalence of 31% vs. 76% in respective samples of methadone treatment enrollees. In any event, a review by Ottomanelli (1999) conservatively suggests that alcohol use by opiate treatment enrollees is, on average, comparable to other groups engaged in high-risk or stressful activity (e.g., emergency room visitors) and excessive relative to the general population.

Recent research documents that problematic drinking at treatment outset hampers the effectiveness of services provided to opiate-misusing clientele (Stapleton & Comiskey, 2010). Beyond compromise in adherence to pharmacological regimens, problem drinking may promote relapse to opiates or other illicit drugs, diminish employment prospects, damage familial/social relations, or prompt legal difficulty. It may also exacerbate psychiatric difficulties, which is noteworthy given that depression, trauma, and suicidality each has elevated prevalence among opiate-misusing treatment-seekers (Aharonovich *et al.*, 2001; Lloyd *et al.*, 2007; Oyefeso *et al.*, 2008). Interestingly, some research suggests heavy-drinking opiate treatment enrollees, despite greater range and severity of problems at treatment entry, are apt to be retained in treatment longer than their counterparts (Chatham *et al.*, 1995). However, the larger literature evaluating outcome for heavy drinkers in opiate treatment is equivocal (Chatham *et al.*, 1997; Joseph & Appel, 1985; Rounsaville *et al.*, 1982; Stapleton & Comiskey, 2010; Stimmel, 1981). Consequently, improving our understanding of pre-treatment characteristics of such treatment-seekers may be beneficial in design and delivery of services with enhanced therapeutic potential.

Difficulties inherent in comparing individual studies with methodological variance were noted earlier, most of which relate to generalizability of study findings. One means for a given study to enhance generalizability of its findings is via conduct of a multi-site treatment trial, which by definition employs consistent methodology at a series of participating sites to promote more representative client recruitment (Friedman *et al.*, 1998). To that end, if one's interest were estimating AUD prevalence among opiate-misusing treatment-seekers, aggregation of treatment-seeking samples across multi-site trials should strengthen confidence in the resulting prevalence estimate. Though not often possible given the noted method variance between many trials, the NIDA Clinical Trials Network (Carroll *et al.*) provides a vehicle to accomplish this aim. For a decade, the CTN has tested promising innovations via multi-site trials at community-based addiction treatment agencies (Hanson *et al.*, 2002; Tai *et al.*, 2010), and invites use of its existing databases for secondary analyses. At its inception, the CTN established a common *pre-treatment* assessment battery to

facilitate comparisons of baseline client characteristics across trials. Though scientific progression has led to changes over time, the CTN common pre-treatment assessment battery has consistently included baseline administration of an AUD diagnostic instrument and the Addiction Severity Index – Lite (McLellan *et al.*, 1992, 1985, 1980) in its treatment trials. The former provides rates of AUD diagnoses, whereas the latter gathers data concerning alcohol-related phenomena and indicators of psychosocial functioning in a range of relevant domains (e.g., medical, legal, employment, family/social relationships, psychiatric).

The current study is a CTN-approved secondary data analysis project, and represents one of the first attempts to examine pre-treatment characteristics of treatment-seeking clientele across a large set of CTN protocols. The target of this examination is the subpopulation of treatment-seekers for whom opiates were deemed the primary substance of abuse. The initial aim is to describe pre-treatment rates of alcohol use, AUD diagnoses, and alcohol-related phenomena in this group of opiate-primary (OP) treatment-seekers aggregated across 10 multi-site clinical trials within the CTN. Additional aims center on comparison of OP treatment-seekers with and without concurrent AUD diagnoses on a range of pre-treatment indices of psychosocial functioning. In light of the collective literature to date, high rates of alcohol use, AUD diagnoses, and correlates involving difficulty in psychosocial functioning by OP treatment-seekers were anticipated. In terms of comparative analyses, OP participants with AUD were expected to report poorer psychosocial functioning than OP without AUD across a range of indices including ASI-Lite composite scores in medical, employment, drugs, legal, family/social, and psychiatric domains. Further, OP participants with AUD were expected to be more likely to report prior experience of a range of psychiatric symptomatology.

## 2. Materials and Methods

### 2.1 Project Concept Development

**Approval Processes**—The original project concept was developed in response to a call for proposals for secondary data analysis projects within the National Institute on Drug Abuse Clinical Trials Network. The initial process involved submission of the project concept to a review panel at the NIDA Center for Clinical Trials Network (CCTN). Pending approval, the agreement was for investigators to collaborate with data analyst personnel at Duke Clinical Research Institute (DCRI), which served as the data management and statistical center for the CTN and oversaw de-identification and maintenance of datasets for completed protocols. CCTN approval of the project concept occurred in March, 2008, and investigators submitted a DCRI services request the following month. Notably, as these datasets were both de-identified and publicly-available, no local IRB approvals from the investigators' institution were necessary.

**Protocol Selection**—A unique and salient aspect of this project concept is that it proposed for analyses to be conducted across common measurement constructs of several CTN protocols, and for the current report to evaluate pre-treatment characteristics of OP treatment-seekers. Study investigators identified ten completed protocols (CTN 0001, 0002, 0004, 0006, 0007, 0009, 0013, 0017, 0018, and 0019) meeting the following trial inclusion criteria: 1) enrollment of a treatment-seeking population, and 2) pre-treatment administration of a DSM-IV diagnostic instrument for substance use disorders and CTN version of the ASI-Lite. Thus, analyses reflect an aggregate of OP enrollees from the ten noted CTN protocols.

## 2.2 Measures

**AUD Diagnoses**—Study data include the substance use disorder diagnostic instrument utilized at the outset of each noted CTN protocol. Resulting data were the absence/presence of diagnoses for alcohol abuse and dependence, described separately herein as suggested by Babor (2008). Instruments were the: 1) DSM-IV Checklist, a clinician-administered instrument (utilized in CTN 001, 002, 006, 007 & 009) with evidence of concurrent validity (Hudziak *et al.*, 1993) for DSM substance use disorder diagnoses; 2) Substance Dependence Severity Scale (SDSS), a clinician-administered instrument (utilized in CTN 004) with evidence of concurrent validity, internal consistency, and test-retest reliability for DSM substance use disorder diagnoses (Miele *et al.*, 2000); 3) DSM-IV Diagnostic Interview, a semi-structured, clinician-directed interview (utilized in CTN 013) used to determine DSM substance use diagnoses; and 4) Composite International Diagnostic Interview 2.1 Substance Use Module (CIDI 2.1, SUD module), a semi-structured, clinician-directed interview (utilized in CTN 017, 018, & 019) with demonstrated validity and reliability for DSM substance use diagnoses (Kessler *et al.*, 1994).

**Addiction Severity Index – Lite**—The ASI-Lite is derived from the Fifth Edition of the ASI (McLellan *et al.*, 1992), a structured clinical interview assessing recent (past 30 days) and lifetime alcohol and drug use behavior that yields composite scores for Medical, Employment, Alcohol, Drug, Legal, Family/Social, and Psychiatric domains. Instrument reliability and validity are well-established (McLellan *et al.*, 1985). Further, individual ASI-Lite items were also used, including those targeting: 1) demography/background (e.g., age, gender, race/ethnicity, education/training, marital status, residential tenure), 2) past month alcohol use and related phenomena (e.g., money spent on alcohol, frequency of problems, perception of magnitude of recent problems), 3) prior alcohol treatment episodes, and 4) lifetime and recent psychiatric difficulties (e.g., number of symptoms and prior treatment episodes, suicidal ideation and/or attempts). Notably, the ASI-Lite also includes interviewer notation of the respondent's primary substance of abuse. This notation was used to identify, from among the much larger aggregate set of CTN enrollees, those for whom opiates were the primary substance of abuse<sup>1</sup>.

## 2.3 Data and Statistical Analysis

**Data Source**—The data source for this study is the NIDA Clinical Trials Network Data Share (<http://www.ctndatashare.org>). The web site is an electronic environment that allows data from completed clinical trials to be shared publicly. Data are de-identified and in Study Data Tabulation Model (SDTM) standard format sponsored by the Clinical Data Interchange Standards Consortium (CDISC). Data are available for download approximately 18 months after trial completion or after acceptance for publication of its primary manuscript (whichever occurs first). The data for the last trial included in the current study became available in March, 2009.

<sup>1</sup>In 73 instances (5% of aggregate OP sample) where interviewer notation was absent or unclear, an algorithm was implemented to determine a given enrollee's substance of primary concern. This algorithm was as follows:

Primary substance of concern =

Step 1: the substance category for which the greatest # of diagnostic criteria are endorsed (range of 0–11)

Step 2: if multiple substance categories are equivalent on Step 1, the substance category for which endorsed criteria correspond to dependence diagnoses supercedes those that correspond only to abuse diagnoses

Step 3: if multiple substance categories are equivalent on Steps 1 and 2, the substance category for which the greatest # of dependence criteria are endorsed (range of 0–7)

Step 4: if multiple substance categories are equivalent on Steps 1, 2, & 3, the substance category for which the most frequent use is reported in the prior 30 days via ASI-Lite

Step 5: if multiple substance categories are equivalent on Steps 1, 2, 3, & 4, the substance category for which the enrollee's CTN treatment protocol is most targeted (if determinable). With respect to this report, the focal substance category for enrollees of CTN 001, 002, & 007 protocols was opiates.

**Statistical Analysis**—Analyses were performed on all 10 trials with available data. Trial and participant characteristics as well as rates of AUD diagnoses were summarized using unweighted descriptive statistics (e.g., count, proportion, mean/median, standard deviation, range). Clinical characteristics measured by ASI indices were synthesized via meta-analytic pooling across all 10 trials. Meta-analytic weighted means, proportions, and odds-ratios were estimated using a random-effects model that accounts for trial sample size and inter-trial variation (i.e., study heterogeneity) when weighting the strength of associations between independent and dependent variables (Borenstein *et al.*, 2009; DerSimonian & Laird, 1986; Hedges & Olkin, 1985). Meta-analytic means, proportions, and odds-ratios are expressed with 95% confidence intervals. All calculations were performed in SAS (Version 9, SAS Institute Inc., Cary, NC) and Comprehensive Meta-Analysis (Version 2, Biostats Inc.).

### 3. Results

#### 3.1 Trial and Participant Characteristics

Table 1 outlines characteristics of the ten trials and respective trial samples. Noted trial characteristics include timing of their conduct, target population, diagnostic instrument utilized, sample size, and both the size and proportion of the OP subsample. As indicated in Table 1, conduct of trials encompassed the years 2001 – 2006, and they targeted a variety of treatment-seeking populations. Two trials recruited females specifically, and another recruited only male treatment-seekers. Half the trials (5) utilized the DSM-IV Checklist as the diagnostic instrument, whereas three relied on the CIDI, and one apiece utilized a DSM-IV interview and the SDSS. Collectively, trials enrolled 4,811 participants, of which 1396 (29%) were identified as OP. As indicated in Table 1, this percentage varied considerably across trials (inter-trial range: 3 – 98%). Table 1 also notes some demographic characteristics of the OP subsamples for each trial as well as aggregated across the ten trials. Noted OP sample demographics include age, gender, and distribution of ethnicity and race. In terms of the aggregate OP sample, the mean age was 40.5 years (S.D. = 10.0, range of 18 – 65). Gender distribution slightly favored males (56%), though as noted above, this varied considerably across trials as expected given their respective target populations. In the aggregate OP sample, 21% identified with Hispanic ethnicity. In terms of racial identification, the aggregate OP sample was comprised of 43% White/Caucasian, 30% Black/African-American, 12% Spanish/Latino, 10% Multi-racial, and 5% Other.

#### 3.2 AUD Rates Among OP Sample

**Prevalence**—Of the aggregate OP sample (N=1,396), 1,096 (79%) had data regarding absence/presence of an AUD diagnosis. This high rate of missing data appears due to inter- and intra-trial procedural variance in thoroughness of instrument administration and documentation in eventual CTN datasets. Unfortunately, required de-identification of CTN datasets minimized opportunity to resolve issues of apparent procedural variability. Table 2 outlines AUD rates<sup>2</sup> among OP subsamples for each trial and aggregated across trials. The aggregate AUD prevalence rate was 38%, and varied widely between trials (range of 7.7 – 78.6%). Of 420 OP treatment-seekers with concurrent AUD, 322 (77%) met criteria for alcohol dependence.

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<sup>2</sup>In instances where a trial participant met criteria for both alcohol abuse and dependence, the dependence diagnosis was given precedence per standard DSM-IV diagnostic classification.

### 3.3 ASI-Lite Alcohol-Related Indices

Indices were computed for the aggregate group of 420 OP participants with AUD, and presented in Table 3. Distribution of Alcohol composite scores (based on available data,  $n=399$ ) was asymmetrical ( $Md = .04$ ,  $M = .13$ ,  $SD = .19$ , skewness = 1.82, kurtosis = 2.79), with 40% of this aggregated subsample having a zero score. Table 3 consequently provides, for OP participants with AUD, the proportion/percentage having an Alcohol composite score of zero, as well as measures of central tendency and dispersion (e.g., median, mean, standard deviation) among the remaining OP with AUD subsample with Alcohol composite scores greater than zero. Similar distribution was found for other ASI-Lite alcohol indices. For instance, large percentages of the aggregate OP with AUD subsample endorsed no prior alcohol treatment (68%) as well as no recent alcohol consumption (46%), expenditure on alcohol (49%), and alcohol problems (85%). Further, 83–85% of the aggregate subsample perceived minimal magnitude or importance of current alcohol problems. Consequently, individual items with an open/continuous response format were approached similarly to Alcohol composite scores, with proportion/percentage of negative endorsement documented, and descriptive statistics computed for those with some level of affirmative response (see Table 3). Individual items concerning perceived magnitude and importance of current alcohol problems were treated as categorical variables, given similarly skewed distribution, and these are presented descriptively in Table 3.

### 3.4 Comparison of OP With AUD vs. OP Without AUD Participants

Comparison of aggregated OP with AUD ( $n=420$ ) and OP without AUD ( $n=675$ ) subsamples targeted ASI-Lite indices. These included demography/background variables (e.g., age, education, residential tenure, marital status), composite scores for Medical, Employment, Legal, Family/Social, Drug, and Psychiatric domains, and specific Psychiatric domain items.

**Demographics**—OP with and without AUD subsamples differed little demographically. For instance, mean age was 39.4 years ( $SD = 9.7$ ) and 40.9 years ( $SD = 9.9$ ), and mean years of education was 12.2 ( $SD = 2.0$ ) and 12.1 ( $SD = 2.1$ ), respectively. Similarly, the subsamples did not differ in residential tenure. Among OP with AUD clientele, 18% had maintained current residence for less than 3 months, 21% for between 3 and 12 months, and 61% for over a year. Rates among their counterparts were 13%, 16%, and 71%, respectively. Likelihood of currently being married did not differ between the subsamples (22.8% vs. 25.4%, OR 1.18 (0.57, 1.19)), but OP with AUD clients were more likely to have been divorced (27.4% vs. 19.4%, OR 1.57 (1.13, 2.18)) and less likely to never have been married (28.4% vs. 41.7%, OR 0.56 (0.41, 0.75)).

**Composite Scores**—Distribution of composite scores for Medical, Legal, Family/Social, and Psychiatric domains also showed heavy positive skew. For each domain, analyses first compared subsample proportions with a zero-value composite score. As noted in Table 4, subsample differences were found in Medical, Family/Social, and Psychiatric domains (range of odds-ratios: 0.51 – 0.63; all  $p < .05$ ), and the subsample difference in the Legal domain trended toward significance (odds-ratio = 0.75;  $p = .063$ ). In each case, greater proportion of zero-value composite scores was found in the OP without AUD subsample. Subsequent analyses, utilizing published ASI norms for opiate treatment clients (McLellan *et al.*, 2006), compared subsample proportions for which a given composite score was above vs. below median normative values (Medical, .30; Legal, 17; Family/Social, .15; Psychiatric, .22). Table 4 lists results of these comparisons, for which subsample differences were evident for Family/Social (odds-ratio = 1.66) and Psychiatric (odds-ratio = 1.45) composite scores. In each instance, this represented a greater proportion of above-median composite score values in the OP with AUD subsample.

Composite scores for the Employment domain were also asymmetrically distributed, albeit with strong negative skew and a preponderance of maximum-value scores (e.g., 1.00). Consequently, a similar analytic approach was adopted—though with the initial comparison testing proportions of maximum-values scores between OP with AUD and OP without AUD subsamples. No difference was found (see Table 4). Subsequent analysis compared subsample proportions of Employment scores above and below the published median value for opiate treatment clientele (.70), but again no difference was found (see Table 4). Composite scores for the Drug domain were symmetrically distributed, and consequently the corresponding analysis compared subsample proportions of Drug composite scores above and below the published median value for opiate treatment clientele (.26). A significant difference was revealed favoring a higher proportion of above-median values in the OP with AUD subsample.

**Individual Psychiatric Domain Items**—Individual Psychiatric domain items concerned recent (past month) and lifetime endorsement of six psychiatric symptoms (i.e., depression, anxiety/tension, hallucinations, cognitive difficulty, dyscontrol of violence, suicidal ideation, attempted suicide) as well as client ratings of the perceived magnitude and importance of treatment for psychological/emotional problems. In terms of lifetime symptom endorsement, significant subsample differences were found for anxiety/tension, hallucinations, and dyscontrol of violence (range of odds-ratios: 1.46–1.69; all  $p < .05$ ). A subsample difference for lifetime endorsement of suicidal ideation also trended toward statistical significance (odds-ratio = 1.31;  $p < .10$ ). In each instance, greater endorsement occurred in the OP with AUD subsample. In terms of recent symptom endorsement, a set of subsample differences trended toward statistical significance for depression, anxiety/tension, and cognitive difficulty (range of odds-ratios: 1.31–1.35; all  $p < .10$ ). In each instance, greater endorsement occurred in the OP with AUD subsample. Significant subsample difference was found in perceived magnitude of psychological/emotional problems (odds-ratio = 1.32;  $p < .05$ ), and a subsample difference in perceived importance of treatment for these problems trended toward statistical significance (odds-ratio = 1.27;  $p < .10$ ). Strong perceived magnitude of problems and importance of their treatment was endorsed in greater proportion by the OP with AUD subsample. Comparisons are summarized in Table 5.

## 4. Discussion

The current report, which details a secondary data project approved by NIDA's Center for Clinical Trials Network, examined alcohol-related characteristics of OP treatment-seekers and compared broader pre-treatment characteristics of OP clients with and without AUD across samples of 10 completed CTN protocols. To our knowledge, this represents one of two initial attempts to utilize existing CTN datasets to examine baseline characteristics of treatment-seekers in an aggregated, 'trans-protocol' fashion (Brooks *et al.*, in press). Study findings provide a more comprehensive, generalizable, and conclusive AUD prevalence estimate for OP treatment-seekers than has been previously available (Ottomanelli, 1999), document the importance of AUD detection at the outset of opiate treatment, and inform targets for clinical intervention during opiate treatment for clients with comorbid AUD.

Current findings suggest a fairly high rate (38%) of AUD among OP treatment-seekers. Documentation of this prevalence estimate, and its derivation as a product of the aggregation of treatment-seeking samples from ten multi-site treatment protocols (encompassing a total of 60 community-based treatment programs), provides needed clarity for the variable AUD rates reported for this population in extant, single-study literature [see Ottomanelli (1999) for review]. The absence of recent alcohol use and related phenomena (e.g., problems, money spent) by many OP treatment-seekers was unexpected, as was the positively-skewed distribution of Alcohol composite scores. Current misuse of alcohol may be evident in a

minority of OP treatment-seekers, yet other study findings underscore the importance of its detection in this population. Among 240 OP treatment-seekers with Alcohol composite scores above zero, many had multiple prior alcohol treatments. This subsample also reported frequent drinking ( $M = 11.6$  days,  $SD = 1.30$ ) and alcohol problems ( $M = 11.7$  days,  $SD = 2.2$ ) in the 30 days prior to assessment. Thus, this subset of OP treatment-seekers evidenced a pattern that, on average, was suggestive of chronic and recent alcohol misuse. Notably, a recent study documents poor prognosis for those exhibiting these characteristics at the outset of opiate treatment (Stapleton & Comiskey, 2010).

The collective sample size and aggregation of treatment-seeking samples across ten multi-site trials lend weight to the generalizability of study findings describing OP with AUD clients and differentiating them from OP without AUD clientele. The two groups differed little demographically, with the modal OP client in middle adulthood, having attained a high-school education, and maintaining stable residence for over a year. Group differences emerged in broad indices of recent psychosocial functioning with respect to medical health, social relationships with friends and family members, and magnitude of drug problems. Taken together, findings generally support investigator hypotheses that OP with AUD clients would exhibit poorer psychosocial functioning than OP without AUD clientele.

Differences between OP clients with and without AUD in psychiatric functioning were of greater focus, given extant literature documenting elevated prevalence of depression, trauma, and suicidality among opiate-misusing treatment-seekers (Aharonovich et al., 2001; Lloyd et al., 2007; Oyefeso et al., 2008). Current findings indicate OP clients with AUD were more likely to have had a history of psychiatric problems, and for these to have reached an elevated magnitude. In terms of lifetime symptomatology, OP with AUD clients were roughly 1.5 times as likely than OP participants without AUD to endorse prior serious anxiety, hallucinations, and dyscontrol of violence. Further, this group's greater likelihood of prior suicidal ideation trended toward statistical significance. Group differences in endorsement of these psychiatric symptoms in the month prior to assessment were consistent in direction with lifetime history of these symptoms, though failed to achieve statistical significance. OP with AUD clients were also more likely to rate the magnitude of these psychiatric difficulties more seriously, and their rating of greater importance of treatment for these difficulties trended toward statistical significance. Collective findings underscore need for therapeutic services (e.g., provision/monitoring of medication, behavioral counseling) in addiction treatment delivery for OP with AUD clientele.

Several caveats bear mention. This CTN secondary data analysis project capitalized on existing datasets from ten completed trials, and is bound by limitations of those original trials. Consistent CTN conduct of multisite trials, and the aggregation of treatment-seeking samples across ten such trials, may mitigate concerns about selection bias and generalizability. A related caveat may be variance in the client populations targeted by the individual trials, though the commonality across trials was enrollment of adults seeking addiction treatment. It should be noted that current findings analyzed pre-treatment client data only, and no longitudinal analyses were possible due to between-trial methodological variance in nature and duration of treatment protocols as well as focus and timing of subsequent assessments. Though pre-treatment AUD assessment was included across trials, it was not a focus of treatment or follow-up assessments in most protocols. Also, organizational features and staff attitudes at CTN-affiliate treatment agencies have been found to differ from unaffiliated agencies (Ducharme & Roman, 2009; Knudsen *et al.*, 2007), though this alone does not suggest trial enrollees were unrepresentative. A further caveat is between-trial AUD instrument variance. All four instruments have sound psychometric properties, including concurrent validity, though a formal consensus-building process eventually determined one instrument of choice for future CTN trials (Forman *et al.*,



2004). Unfortunately, this occurred after or amidst several trials included in the current analyses so it is possible instrument variance contributed measurement error in AUD rates.

From a data-analytic perspective, a further caveat is potential for inflated false positive rates associated with this number of simultaneous comparisons. Thus, caution is warranted when interpreting statistical significance. Other data-related caveats relate to challenges presented by inter- and intra-trial procedural variance in its collection. Most prominent was the amount of missing data encountered, particularly for AUD diagnoses. It remains unclear to what extent this was attributable to instrument administration or documentation processes. As multiple trials targeted opiate treatment-seekers, it is conceivable that AUD assessment was de-emphasized by some trial investigators or research personnel. CTN data management policy, requiring de-identification of data before publicly-shared in accord with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, also contributed a caveat. Specifically, site variables that were consequently excluded from datasets may have aided resolution of quandaries about missing data and procedural variance in data collection procedures, but were unavailable.

Caveats notwithstanding, this report describes rates of AUD and alcohol-related indices among OP treatment-seekers and documents poorer psychosocial functioning among those with an AUD diagnosis at treatment outset. This subset of OP clientele appears more likely to have a serious drug problem as well as medical difficulties, problematic social relationships with family and friends, and history of psychiatric symptoms. Collective findings suggest need for detection of alcohol misuse at the outset of opiate treatment, and alcohol-focused pharmacological and behavioral interventions for indicated OP clientele. More generally, findings support the practice of making medical, psychological, case management, and other support services available in organizations offering opiate treatment services. Doing so may allow more tailored treatment provision that responds to a range of psychosocial challenges for opiate-misusing clients, and thereby promotes greater client engagement and retention in opiate treatment services.

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**Table 1**

Trial characteristics

CTN Trial #	Years Conducted	Target population	Diagnostic Instrument	Trial Sample	Opiate-Primary Subsample	OP Subsample Characteristics				
						Age Mean (SD)	Male %	White race %	Black race %	Other race %
0001	2001–02	Enrollees for inpatient opiate detoxification services	DSM-IV Checklist	138	130 (94%)	36.3 (9.8)	60.8	56.2	16.9	26.9
0002	2001–02	Enrollees for outpatient opiate detoxification services	DSM-IV Checklist	277	272 (98%)	38.7 (10.3)	71.6	37.3	35.8	26.9
0004	2001–04	Seekers of substance abuse treatment services	SDSS	392	40 (10%)	36.7 (10.3)	60.0	72.5	12.5	15.0
0006	2001–03	Seekers of substance abuse treatment services (drug-free clinics)	DSM-IV Checklist	469	13 (3%)	34.6 (8.8)	46.2	53.9	23.1	23.1
0007	2001–03	Seekers of substance abuse treatment services (methadone clinics)	DSM-IV Checklist	454	214 (47%)	42.6 (8.5)	54.7	22.3	62.6	15.2
0009	2003–04	Seekers of smoking cessation services at substance abuse treatment clinics	DSM-IV Checklist	366	177 (48%)	44.5 (9.6)	58.2	29.6	30.1	40.3
0013	2003–06	Pregnant seekers of substance abuse treatment services	DSM-IV Interview	232	27 (12%)	26.1 (4.3)	0	29.6	7.4	63.0
0017	2004–06	IV drug users enrolled in drug detoxification services	CIDI	679	108 (16%)	37.8 (9.4)	73.1	70.4	4.6	25.0
0018	2004–05	Male seekers of substance abuse treatment services	CIDI	990	173 (17%)	42.9 (10.0)	100	52.3	26.2	21.5
0019	2004–05	Female seekers of substance abuse treatment services	CIDI	814	242 (30%)	41.6 (8.9)	0	50.0	21.9	28.1
Aggregate				4,811	1,396 (29%)	40.5 (10.0)	55.6	43.5	30.0	27.5

**Notes:**

Trials selected by virtue of their enrollment of a treatment-seeking population and pre-treatment administration of both a DSM-IV diagnostic instrument and ASI-Lite. ‘Other race’ subsumes racial categories of Spanish/Latino, ‘Other,’ and multi-racial identification.

Additional information concerning individual trials is available at: <http://ctndisseminationslibrary.org>

**Table 2**

Rates of AUD Diagnoses and Criteria Among the OP Sample

CTN Trial #	OP Sample	OP Subsample with Alcohol Abuse Diagnosis Prevalence and Rate		OP Subsample with Alcohol Dependence Diagnosis Prevalence and Rate		OP Sample AUD Prevalence and Rate	
		N	%	N	%	N	%
0001	75	11	14.7	13	17.3	24	32.0
0002	232	51	22.0	16	6.9	67	28.9
0004	40	1	2.4	10	24.4	11	26.8
0006	13	0	0.0	1	7.7	1	7.7
0007	214	10	4.7	24	11.2	34	15.9
0009	173	6	3.5	26	15.0	32	18.5
0013	22	4	18.2	11	50.0	15	68.2
0017	103	2	1.9	79	76.7	81	78.6
0018	99	7	7.1	63	63.6	70	70.7
0019	124	6	4.8	79	63.7	85	68.5
Aggregate	1,096	98	8.9	322	29.4	420	38.3

**Notes:**

Trial participants who met diagnostic criteria for both abuse and dependence were categorized as dependent.

**Table 3**

ASI Alcohol-Related Indices Among Aggregate OP with AUD Sample

<b>ASI Index</b>	<b>OP with AUD Having An Alcohol Composite Score of 0</b>	<b>OP with AUD Having An Alcohol Composite Score &gt; 0</b>
<b>Continuous Indices</b>	<b>Proportion (%)</b>	<b>N Mean (95% C.I.)<sup>^</sup></b>
Alcohol Composite Score	159/399 38.7%	240 0.22 (0.17, 0.26)
Prior Alcohol Treatments (lifetime)	No Prior Treatments	279/409 67.6% 130 2.96 (2.06, 3.87)
Recent Drinking Frequency (days) <sup>*</sup>	No Consumption	185/409 45.8% 224 11.16 (8.61, 13.70)
Recent Alcohol Expenditures (\$ amount) <sup>*</sup>	No Expenditure	228/409 48.5% 181 65.83 (47.08, 84.59)
Recent Frequency of Alcohol Problems (days) <sup>*</sup>	No Problems	355/409 84.6% 54 11.68 (7.34, 16.02)
Lifetime frequency of delirium tremens	No Delirium Tremens	353/409 87.1% 56 3.94 (2.33, 5.54)
<b>Categorical Indices</b>	<b>OP with AUD</b>	<b>Proportion (%)</b>
Perceived Magnitude of Recent Alcohol Problems <sup>*</sup>	Not at all	347/399 84.8%
	Slight/Moderate	29/399 8.6%
	Considerable/Extreme	23/399 6.6%
Perceived Importance of Recent Alcohol Problems <sup>*</sup>	Not at all	341/399 82.9%
	Slight/Moderate	22/399 6.7%
	Considerable/Extreme	37/399 10.4%

**Notes:**

Statistics based on aggregate OP with AUD sample of N=409, though Alcohol Composite Score and both categorical indices are based on N=399 due to instances of missing data

Alcohol Composite Score has possible range of 0.00 – 1.00

Responses for both categorical indices provided on a 5-point (0 – 4) rating scale

<sup>\*</sup> 'Recent' defined as the 30 days prior to assessment

Weighted results by meta-analysis  
^

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**Table 4**  
Comparisons of OP With AUD and OP Without AUD Subsamples on ASI composite scores

ASI Composite Score Domain	Aggregate Subsample of OP With AUD (n = 420)	Aggregate Subsample of OP Without AUD (n = 675)	Odds-Ratio (95% C.I.) <sup>a</sup>		
	N	% <sup>b</sup>	N	% <sup>b</sup>	Odds-Ratio (95% C.I.) <sup>a</sup>
<b>Medical</b>					
= 0.00	167	37.4%	328	48.4%	0.62*
>= 0.30 <sup>d</sup>	183	42.1%	234	38.0%	1.18
<b>Legal</b>					
= 0.00	230	58.9%	413	66.4%	0.75 <sup>b</sup>
>= 0.17 <sup>d</sup>	140	32.2%	168	27.4%	1.29
<b>Family/Social</b>					
= 0.00	164	39.7%	352	55.6%	0.51***
>= 0.15 <sup>d</sup>	207	50.8%	230	37.7%	1.66***
<b>Psychiatric</b>					
= 0.00	105	25.0%	222	34.9%	0.63***
>= 0.22 <sup>d</sup>	238	58.4%	295	48.7%	1.45*
<b>Employment</b>					
= 1	148	36.9%	238	34.6%	1.02
>= 0.70 <sup>d</sup>	224	54.8%	354	53.7%	1.01
<b>Drug</b>					
>= .26 <sup>d</sup>	244	63.8%	370	53.6%	1.58*

**Notes:**

Reference group for odds-ratios is the OP without AUD subsample.

<sup>a</sup> denotes median published composite score value for opiate treatment clientele, per McLellan et al. (2006).

<sup>b</sup> denotes comparison with trend toward statistical significance (p = .063).

^ Weighted results by meta-analysis

\*\*\* p<.001,

\*\* p<.01,

\* p<.05

**Table 5**  
 Comparisons of OP With AUD and OP Without AUD Subsamples on ASI Psychiatric items

	Aggregate Subsample of OP With AUD (N=420)		Aggregate Subsample of OP Without AUD (N=675)		Subsample Comparison
Past Month Symptoms	Endorsement	% <sup>^</sup>	Endorsement	% <sup>^</sup>	Odds-Ratio (95% C.I.) <sup>^</sup>
Depression	174	43.8%	222	35.8%	1.35 <sup>a</sup> (1.00, 1.82)
Anxiety/Tension	218	53.5%	290	44.7%	1.31 <sup>a</sup> (0.98, 1.75)
Hallucinations	21	6.3%	24	5.6%	1.39 (0.71, 2.75)
Cognitive Difficulty	152	37.8%	204	32.2%	1.32 <sup>a</sup> (0.96, 1.80)
Dyscontrol of Violence	50	13.7%	62	10.4%	1.47 (0.70, 3.10)
Suicidal Ideation	28	7.4%	30	5.6%	1.76 (0.88, 3.51)
Suicide Attempt	3	1.6%	5	1.7%	1.11 (0.30, 4.15)
<b>Lifetime Symptoms</b>	<b>Endorsement</b>	<b>%</b>	<b>Endorsement</b>	<b>%</b>	<b>Odds-Ratio (95% C.I.)</b>
Depression	287	68.5%	384	60.7%	1.38 (0.89, 2.15)
Anxiety/Tension	286	69.9%	391	61.4%	1.46* (1.06, 2.02)
Hallucinations	68	17.4%	73	13.1%	1.63* (1.05, 2.53)
Cognitive Difficulty	36	45.8%	65	36.0%	1.37 (0.52, 3.62)
Dyscontrol of Violence	180	43.7%	188	30.0%	1.69** (1.15, 2.48)
Suicidal Ideation	155	35.2%	185	30.4%	1.31 <sup>a</sup> (0.96, 1.80)
Suicide Attempt	101	22.6%	118	20.5%	1.29 (0.90, 1.85)
<b>Client Ratings</b>	<b>Endorsement</b>	<b>%</b>	<b>Endorsement</b>	<b>%</b>	<b>Odds-Ratio (95% C.I.)</b>
Magnitude of problems					

Past Month Symptoms	Aggregate Subsample of OP With AUD (N=420)		Aggregate Subsample of OP Without AUD (N=675)		Odds-Ratio (95% C.I.) <sup>^</sup>
	Endorsement	% <sup>^</sup>	Endorsement	% <sup>^</sup>	
Not at all	150	37.4%	303	47.2%	
Slightly/moderately	90	21.4%	118	20.2%	1.32*
Considerably/extremely	167	41.6%	201	32.6%	(1.02, 1.72)
Importance of treatment					
Not at all	174	42.5%	325	47.5%	
Slightly/moderately	61	14.6%	75	12.0%	1.27 <sup>a</sup>
Considerably/extremely	172	42.9%	228	40.5%	(0.96, 1.69)

**Notes:**

All comparisons reflect synthesized results by meta-analysis. Reference group for the odds-ratio is the OP without AUD subsample.

<sup>a</sup> denotes comparison with trend toward statistical significance ( $p < .10$ ).

<sup>^</sup> Weighted results by meta-analysis