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REVIEW

# Selection and utilization of assessment instruments in substance abuse treatment trials: the National Drug Abuse Treatment Clinical Trials Network experience



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**Abstract:** Based on recommendations from a US Institute of Medicine report, the National Institute on Drug Abuse established the National Drug Abuse Treatment Clinical Trials Network (CTN) in 1999, to accelerate the translation of science-based addiction treatment research into community-based practice, and to improve the quality of addiction treatment, using science as the vehicle. One of the CTN's primary tasks is to serve as a platform to forge bi-directional communications and collaborations between providers and scientists, to enhance the relevance of research, which generates empirical results that impact practice. Among many obstacles in moving research into real-world settings, this commentary mainly describes challenges and iterative experiences in regard to how the CTN develops its research protocols, with focus on how the CTN study teams select and utilize assessment instruments, which can reasonably balance the interests of both research scientists and practicing providers when applied in CTN trials. This commentary also discusses the process by which the CTN further selects a core set of common assessment instruments that may be applied across all trials, to allow easier cross-study analyses of comparable data.

**Keywords:** addiction, assessment, drug abuse treatment, drug dependence, NIDA Clinical Trials Network, substance use disorder

## Introduction

The US National Institute on Drug Abuse established the National Drug Abuse Treatment Clinical Trials Network (CTN) to accelerate the translation of science-based addiction treatment research into community-based practice. Based on recommendations from an Institute of Medicine report,[1] one of the CTN's primary tasks is to serve as a functional bridge to forge bi-directional communications between providers from community-based drug abuse treatment programs and scientists from university-based research centers. Thus, the CTN not only engages community providers, but also brings research into real-world clinical settings, to enhance its relevance to practice.[2] This approach is based on several premises. First, randomized controlled trials are considered "the gold standard" in establishing evidence-based medical practices. Second, with input from providers, the selected research questions are considered, to enhance their clinical relevance to practice. It is expected that research findings, derived from clinically-relevant assessments and research questions, will be useful to clinicians and to transform practice. Third, to consider real-world settings, CTN's substance abuse treatment trials will use community-based treatment settings as study sites,

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and treatment-seekers as study participants. The design of each study and trial procedures will also emulate real-world clinical practice, or integrate trial procedures into practice. Many challenges, however, have surfaced during the course of implementing CTN studies.

In applying these approaches when implementing CTN trials, investigators first face the challenge of selecting clinically-relevant research questions. The next challenge, no less critical than the first one, is the selection and use of clinical assessments and instruments for measuring participants' clinical needs and treatment responses, which also factor in workflow considerations at busy practice settings (eg, time constraints, staffing patterns, and resources, etc). The selected instruments should not only be feasible and of high clinical relevance to community-based providers and their systems of care (ie, brief, user-friendly, important to clinical decision, and capturing indices for health conditions which are prevalent, costly, or challenging to their practice), but also be useful to researchers for assessing participants' treatment status in a reliable, sensitive, specific, and valid manner for the study conditions. During the protocol development process of CTN trials, iterative bi-directional conversations between practicing providers and researchers in the protocol development teams help to ensure that assessment instruments selected for trials balance the needs and interests of both groups when applied.

The different perspectives between both groups in selecting the instruments used in CTN trials arise from fundamental differences in training, expertise, and expectations between researchers and clinicians/providers. For instance, researchers may be primarily interested in collecting data to test their experimental hypotheses, and for future hypothesis-generating purposes. Providers, on the other hand, may be primarily interested in integrating new, safe, efficacious, and cost-effective treatments into their current practice and systems of care. Hence, new treatments should be compatible with their organizations' beliefs and workflow, as well as acceptable to patients. Specifically, the time spent on administering an instrument and collecting data needs to be reasonable, to minimize the burden on patients, providers, and administrators. More importantly, implementation of a new intervention or treatment should be within an organization's financial means. So, the instruments used to assess treatment response need to be brief, easy to administer, without requiring extensive training, and cost-effective, in order to be adopted by busy practitioners.[2] These differences are exemplified by the selection of assessment instruments used in each CTN protocol. For instance, researchers typically take into account the psychometric qualities of an assessment instrument, specifically its empirical reliability, validity, sensitivity, and specificity, whereas providers typically factor in the brevity of an instrument, and need for reimbursement.

Through this process, the CTN has identified several factors worthy for the study team to consider when designing a substance abuse treatment clinical trial:

1. Start the selection of assessment instruments early in the trial protocol design. This should facilitate the identification of instruments that are empirically valid, reliable, sensitive, and specific to the clinical population(s) of interest. It is important to consider the different types of validation (eg, construct, discriminative, predictive, and concurrent validities) and their relevance to clinical decision making, in research intended to mimic clinical practice.
    a. Construct validity: evidence that the instrument conforms to the hypothetical construct or concept under study.
    b. Concurrent validity: the ability of a test or instrument to correlate well with a measure that has previously been validated.
    c. Discriminant validity: the ability of an instrument to discriminate between persons according to different groups or characteristics (eg, identifies different levels of risk or severity, including non-dependence and dependence).
    d. Predictive validity: the ability of an instrument to indicate and/or predict future risk or disease in the absence of a clinical intervention (eg, at 2 time points, 3 months apart).
2. Consider collecting data relevant to clinical practice and treatment of substance use disorders as a chronic disease, in a continuing care model[2,3] (eg, assessments to measure addiction status and drug use, other health-related/medical conditions, family and social support, quality of life, etc) (see Table 1).
3. Include clinically-relevant assessments and outcome measures that capture at least one major domain, beyond drug use or abstinence, with sufficient statistical power to detect meaningful clinical changes in that domain over time. Assessments should measure outcomes that may impact substance abuse treatment, with a broad clinical and/or societal relevance, ideally pertinent to people dependent on multiple substances of abuse.

This commentary describes the process and negotiation that the CTN has used, utilizing the factors listed above, to select assessment instruments among many diverse clinical trials, and presents the lessons learned from this process.

**Table 1** Selected instruments and assessments used in the US National Drug Abuse Treatment Clinical Trials Network

| Instruments/assessments | Time to complete assessment | Domains | Description |
|---|---|---|---|
| **1. Demographics** | | | |
| Demographics | 5–8 minutes | Race, ethnicity, sex, age | Standard form. |
| ASI | 5 minutes | Income, employment, marital, and financial status | Derived from the 5th Edition of the ASI, a structured clinical interview that yields scores for seven areas of functioning.[6] This is a valid, reliable instrument that was developed to evaluate treatment outcomes and has been used in numerous studies. The ASI is widely used in clinical practice. The ASI is also available in Spanish. |
| **2. Addiction history and status** | | | |
| ASI | 15–25 minutes | Substances used, frequency, and route of administration (oral, smoking, injection, etc) | Self-reported substance(s) use (alcohol, drugs) in the past 30 days and lifetime (see ASI description above). |
| TLFB | 5–20 minutes | Drug use | TLFB[8,9] assesses recent substance use. It can be administered by an interviewer, self-administered, or administered by computer. It involves asking individuals to retrospectively estimate their substance use 7 days to 2 years prior to the interview date. |
| SUC | 10–20 minutes | Drug use | SUC is an interview assessment of self-reported substance use, completed at each contact by a research assistant. (Adapted from the TLFB interview).[8,9] |
| Toxicology | 10–20 minutes | Urine and hair testing for drug use | Includes testing for the following drugs: opiates, cocaine, amphetamines, cannabis, and additional drugs of abuse, as appropriate (eg, PCP, methamphetamine, and benzodiazepines). |
| Fagerström | 5–10 minutes | Nicotine dependence | The Fagerström Test for Nicotine Dependence is a brief, subject-administered assessment of the subject's smoking habits.[16] Brand of cigarette, how many smoked per day, when cigarettes are smoked, and the relationship of smoking behavior to physical health and social function are assessed. |
| COWS | 5–10 minutes | Drug withdrawal symptoms, used in opiate protocols | COWS[11] is an 11-item, interviewer-administered questionnaire, designed to provide a description of signs and symptoms of opiate withdrawal observed directly (eg, sweating, runny nose). |
| ARSW | 5–10 minutes | Drug withdrawal symptoms, used in opiate protocols | ARSW[17–19] is comprised of 16 signs and symptoms of opioid withdrawal. Participants rate on the following items: muscle cramps, depressed or sad, painful joints, excessive yawning, hot or cold flashes, trouble getting to sleep, sick to stomach, irritable, runny nose, poor appetite, weak knees, excessive sneezing, tense and jittery, watery eyes, abdominal cramps, and fitful sleep. |
| SOWS | 5 minutes | Drug withdrawal symptoms, used in opiate protocols | SOWS[20] is a 10-item, self-report scale, easy to understand, and found to provide a reliable and valid means of measuring the signs and symptoms of withdrawal among persons with opioid dependence. |

(*Continued*)

**Table 1** (*Continued*)

| Instruments/assessments | Time to complete assessment | Domains | Description |
|---|---|---|---|
| CCQ | 5 minutes | Drug withdrawal symptoms, used in stimulant protocols | CCQ-brief[12] assesses current craving, with answers ranging from "strongly disagree" to "strongly agree." |
| URICA | 10 minutes | Readiness for change | URICA[21] assesses the participant's motivation to change his/her substance-use behavior. |
| SOCRATES | 2–5 minutes | Readiness for change | SOCRATES[22] assesses readiness for change in alcohol and other drug abusers. The instrument yields three factorial-derived scale scores: Recognition (Re), Ambivalence (Am), and Taking Steps (Ts). SOCRATES differs from URICA in that the SOCRATES poses questions specifically about alcohol or other drug use, whereas URICA asks about the client's "problem" and change in a more general manner. |
| **3. Diagnosis and mental health status** | | | |
| CIDI | 25–50 minutes | Alcohol/drug abuse or dependence diagnosis. More widely used at CTPs | The CIDI-2 (SUD module)[7] is a structured, lay-interview for diagnosing psychiatric disorders with demonstrated reliability and validity. This assessment is also available in Spanish. |
| DSM-IV checklist | 15–25 minutes | Alcohol/drug abuse or dependence diagnosis | The DSM-IV checklist (modified from Hudziak et al)[23] is a structured interview that determines the participant's Axis I substance abuse and dependence diagnoses. The questionnaire determines the participant's dependence on opiates, benzodiazepines, alcohol, amphetamines, cocaine, cannabis, hallucinogens, inhalants, and sedatives. This diagnostic tool is used at baseline to determine whether the participant currently meets criteria for substance use dependence. |
| SDSS | 15–30 minutes | Alcohol/drug abuse or dependence diagnosis | SDSS[24] is a semi-structured interview that provides a current severity rating for each symptom (eg, tolerance, withdrawal, inability to cut down). |
| DISC | 10–20 minutes | Alcohol/drug abuse or dependence diagnosis (adolescents) | The DISC Substance Abuse/Dependence Module[25] is a highly structured diagnostic interview, designed for use by non-clinicians to assess mental health diagnosis. DISC adheres tightly to DSM-IV criteria. A scoring algorithm permits diagnosis to be established based either on symptom criteria alone or symptom criteria and a minimum level of diagnosis-specific impairment. |
| KSADS | 45–60 minutes | Mental health problems | K-SADS-E is a psychiatric diagnostic interview with known psychometric properties.[26] The K-SADS-E modules used were: Affective Disorders (Depression and Mania modules), Psychotic Disorders (Psychosis module), and Behavioral Disorders (Conduct Disorder module). |

| Instruments/assessments | Time to complete assessment | Domains | Description |
|---|---|---|---|
| MINI | 10–40 minutes | Mental health problems | MINI[27] is a short, structured diagnostic interview, designed to screen for Axis I psychiatric disorders in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, 4th ed). and International Classification of Diseases (ICD-10, 10th ed). |
| BDI | 5 minutes | Mental health problems | BDI-II[28] is a subject-administered questionnaire designed to assess the intensity of depression in a subject over the past 2 weeks. |
| BSI | 5 minutes | Mental health problems | BSI[29] is a self-report scale that was developed to assess psychological problems. It includes 53 items, rated on a five-point scale, with each item representing a symptom or a negative state of mind. Symptoms are scored along nine primary dimensions: somatization, obsessiveness, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. |
| ASI | 5 minutes | Mental health problems | Psychiatric status section. See description above. |
| **4. Health-related/medical conditions** | | | |
| SF-36 | 10 minutes | Health-related quality of life (medical health questions) | SF-36[13] is a multi-item, subject-administered instrument that examines eight general health concepts: general health perceptions, mental health, physical functioning, social functioning, bodily pain, vitality, role limitations due to physical health problems, and role limitations due to emotional problems. In addition, there is a single question that is a measure of health transition. |
| ASI | 5 minutes | General health | General health status section. See description above. |
| HRBS | 15–20 minutes | HIV/AIDS risk behaviors. HRBS is less burdensome than RBS | HRBS[30] is a brief, 12-item, interviewer-administered scale that examines the behavior of intravenous drug users in relation to both injecting and sexual behavior. |
| RBS | 5–10 minutes | HIV/AIDS risk behaviors | RBS is an abbreviated version of the Risk Behavior Assessment (RBA), developed by NIDA.[10] It measures HIV and HCV risk behaviors in the areas of drug use and risky sex practices in the previous 30 days. |
| **5. Legal/criminal status** | | | |
| ASI | 5 minutes | Legal status section | Legal status section. See description above. |
| **6. Family and social support** | | | |
| ASI | 5 minutes | Family/social relationships | Family/social relationship section. See description above. |
| **7. Quality of life** | | | |
| WHOQOL-BREF | 5–15 minutes | Quality of life | WHOQOL-BREF[14] comprises 26 items, measuring the following broad domains: physical health, psychological health, social relationships, and environment. It assesses the individual's perceptions in the context of their culture and value systems, and their personal goals, standards, and concerns. |
| SF-36 | 10 minutes | Quality of life | See description above. |

(*Continued*)

**Table 1** (*Continued*)

| Instruments/assessments | Time to complete assessment | Domains | Description |
|---|---|---|---|
| Q-LES-Q | 5–10 minutes | Quality of life | The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q)[31] evaluates general activities. Participants rate their satisfaction with the following domains of activity: physical health, feelings, work, household duties, school/course work, leisure time activities, and social relations. |
| Euro QOL | 5–10 minutes | Quality of life | Euro QOL (EQ-5D)[32] is a self-administered, standardized instrument used as a measure of health outcomes. It comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels (some, moderate, extreme problems), generating a total of 243 theoretically possible health states. Also available in Spanish. |

**Notes:** Times to complete assessments are approximate; examples of variables impacting the duration include: participant history, interviewer skills/experience and level of training, number of days or substances assessed, number or modules used, time for data entry, etc. Diagnostic Instruments are administered by skilled clinicians or trained interviewers.

**Abbreviations:** NIDA, US National Institute on Drug Abuse; ARSW, Adjective Rating Scale for Withdrawal; ASI, Addiction Severity Index; BDI, Beck Depression Scale; BSI, Brief Symptom Inventory; CCQ, Cocaine Craving Questionnaire; CIDI, Composite International Diagnostic Interview; CTP, Clinical Treatment Programs; COWS, Clinical Opiate Withdrawal Scale; DISC, Diagnostic Interview Schedule for Children; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, 4th Edition; HRBS, HIV Risk Behavior Scale; HCV, hepatitis C virus; KSADS, Kiddie-Schedule for Affective Disorders and Schizophrenia; MINI, Mini International Neuropsychiatric Interview; Q-LES-Q, Quality of Life Enjoyment and Satisfaction Questionnaire; RBS, Risk Behavior Survey; SDSS, Substance Dependence Severity Scale; SF-36, Short Form Health Survey (36-item); SOCRATES, Stages of Change Readiness and Treatment Engagement Scale; SOWS, Short Opiate Withdrawal Scale; SUC, Substance Use Calendar; TLFB, Time Line Follow Back; URICA, University of Rhode Island Change Assessment; WHOQOL-BREF, World Health Organization Quality of Life Brief Version.

## Assessment instruments used in CTN Trials

As of September 30, 2011, the CTN had randomized approximately 14,000 participants in its 28 clinical trials.[4] CTN's research portfolio spans pharmacological, behavioral, and combined pharmacological/behavioral interventions for various substance abuse problems (eg, opioid dependence, stimulant abuse) across a variety of treatment settings (eg, inpatient, outpatient). Participants include adults, adolescents, pregnant women, and non-English speaking minorities.[3] The CTN has established a public-use data share website[5] to encourage the use of existing, de-identified data from completed CTN studies, for secondary analysis to generate future research projects.

This section summarizes the main assessment instruments used in CTN trials. To organize the information, these instruments are summarized in Table 1, and divided into seven domains: Demographics, Addiction history and status, Diagnosis and mental health status, Health-related/medical conditions, Legal/criminal status, Family and social support, and Quality of life. The decision in selecting these assessments weighs the factors and general principles discussed in the section above (for instance, empirical data on the reliability, validity, sensitivity, and specificity of an instrument; assessment burden on patients, providers, and researchers; time and training needed to administer an instrument; cost of an instrument [relevant to the CTN budget for each trial]; reimbursement needs of providers in community clinics; and research aims [selecting instruments which are relevant to primary and secondary research questions]).

For example, the ASI-Lite version of the Addiction Severity Index (ASI), derived from the Fifth Edition of the ASI,[6] was used as a common assessment in almost all CTN studies. ASI-Lite is an abbreviated version of the general ASI, composed of seven areas of functioning, including alcohol use, drug use, medical, psychiatric, legal, family/social, and employment domains. It has been commonly used in almost all CTN studies, since they are addiction treatment trials, and because the ASI provides assessments on multiple domains of health indicators related to drug use/abuse (eg, consequences, problems), not merely drug use per se. Another example, illustrating the decision-making process in selecting assessments, is the selection of the alcohol and drug sections of the Composite International Diagnostic Interview (CIDI)[7] as a substance use disorder (SUD) diagnostic instrument in many CTN studies. This example is described in the following section ("The CTN common assessment battery").

Depending on the study aims, some instruments were used at baseline only, for the purpose of collecting participants' key demographic information (eg, gender, race/ethnicity),

and of assessing inclusion and exclusion criteria to establish study eligibility (eg, SUD and mental health status). Many instruments (for example, those listed in Table 1 to assess alcohol use, drug use, medical, psychiatric, legal, family/social, and employment domains) were used repeatedly to assess primary and secondary outcomes. Since CTN trials are highly variable in their study goals, study populations, and trial designs, the specific instruments used, frequency of assessments, and stage at which to administer them depend on each study's objectives (ie, primary and secondary research questions). For example, all studies measured drug use as the primary outcome, using urine drug tests and/or self-report (Time Line Follow Back [see Table 1 for definitions]).[8,9] On the other hand, ASI-Lite was used mainly at baseline, and an even briefer version of ASI, derived from the Fifth Edition of ASI, was used to collect data for secondary outcomes at follow up visits. Similarly, all trials where HIV risk behavior was measured captured that information at baseline and/or the last follow-up visit. However, when HIV risk behavior was an outcome of interest, the risk behaviors were assessed repeatedly throughout the study, to track changes in HIV risk behaviors.[10] In addition, for trials targeting treatment for drug addictions (eg, opioid dependence), assessments for symptoms of withdrawal or craving are included as secondary outcome measures (eg, COWS[11] or CCQ[12]). However, all trials used the same instrument to collect data on legal and family/social relationships (ASI-Lite) and on quality of life (eg, SF36[13], WHOQOL-BREF[14]).

## The CTN common assessment battery

In 2000, the CTN formed a committee of researchers and providers to discuss the rationale and feasibility of using a common assessment battery (CAB) across all trials in the network, with the main goal of establishing standardized data collection forms to facilitate future cross-study comparisons and meta-analyses. The selection of assessment instruments for the CAB was a complex task, which was resolved through a multi-stage, inclusive process, including the review and ranking of instruments by committee members, followed by an open debate and vote. Committee members included researchers and providers, who jointly reviewed and discussed the scientific validity and reliability of the instruments used in the CTN trials, their importance to clinical practice, and the overall feasibility and practicality of applying these instruments in busy clinical practices. All these considerations factored into the reviews and ranking of the instruments.

The initially-identified CAB (2000) include five major domains, measured at baseline: (1) demographics; (2) substance (alcohol or drug) dependence diagnosis; (3) biomarkers for substance use (urine drug screening for ten substance classes); (4) severity of substance use and associated problems (ASI-Lite); and (5) HIV risk behaviors and psychiatric symptoms. Because the CTN trials are variable in their goals and designs, CAB data collection was required at the baseline visit only, with the option, at another point, to generate proper comparisons. During the active trial period, each protocol team was given options to adopt or exempt its collection, based upon each individual study's research aims and foci.

Although CTN-affiliated investigators and providers generally recognized the merit of having a CAB across trials, achieving a consensus among providers and researchers in determining specific CAB instruments was not an easy task. Initially, the CAB committee identified three commonly used diagnostic instruments in research and practice: (1) The Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) checklist; (2) the Substance Dependence Severity Scale (SDSS); and (3) the alcohol and drug sections of the CIDI. Beyond the issues of reliability and validity of each instrument, additional considerations for selecting a diagnostic instrument included: (1) the extent of training needed for an experienced clinician to properly administer the instrument, versus a research assistant; (2) structured versus semi-structured instruments; (3) reimbursement consideration (fulfilling clinic administrative or billing purposes); and (4) the extent of burden to interviewers and participants. Through extensive discussions, the CAB committee favored the CIDI over the other diagnostic instruments, based on the fact that it is a structured instrument (administered by trained research assistants) and that it includes International Statistical Classification of Diseases, 10th revision (ICD-10) codes, to facilitate billing at the community clinics. If the chosen instrument were to be useful to community clinics, it would need to be able to generate both DSM-IV and ICD-10 coded diagnoses. The CIDI fulfills this criterion. The CIDI also provides past-year symptoms required for DSM-IV and ICD-10 diagnoses, an important consideration for community clinics. An additional benefit of using the CIDI is the fact that the instrument has several other language versions, which can facilitate its use in a non-English speaking population. In this instance, these considerations were considered a worthy trade-off for the brevity of the DSM-IV checklist and the SDSS.

However, after a total of 21 CTN studies were completed, the CTN's CAB requirements for specific instruments were deemed completely optional, because these assessments were

reported by research staff and investigators as too burdensome and time-consuming to administer. One of the major reasons for this was that the CAB was applied in addition to, rather than in lieu of, the many instruments the protocol team has selected to use. Records showed that, in some extreme cases, the time to complete all baseline assessments (CAB and other protocol-specific assessments designed by protocol team) exceeded 6 hours. This concern caused a study team to change the diagnostic instrument from the CIDI to the DSM-IV checklist in the middle of the study, because of the assessment burden. Learning from this lesson, the CTN Steering Committee was forced to recommend that investigators may consider the CAB optional. Nonetheless, most of the CTN studies were able to incorporate part of the CAB into their protocols.

The concept of implementing a CAB among network trials has merits, especially with regard to the CTN data share website, which has gained popularity for use in secondary data analysis research. However, in practice, there is give-and-take in implementing the CAB. Specifically, the protocol team should exercise discipline in streamlining and simplifying its research aims and questions for a study, to avoid having an overly lengthy set of assessments. Deciding which assessment instruments to use has become a critical trial design issue for the network, and this decision is often informed and influenced by factors early in the protocol development process, such as those mentioned in the first section of this commentary. A streamlined CAB can be pivotal for the success of large, simple trials. However, simplification of the set of assessments chosen is a major challenge in any trial, due to the diverse interests and needs of providers and researchers.

In 2009, the CTN assembled a taskforce, the Treatment Effect and Assessment Measures (TEAM) taskforce,[15] to consider the lessons learned from its first decade, and re-evaluate the need for and utility of a CAB for CTN trials. In brief, the TEAM taskforce recommended that future CTN trials be required to collect the following outcomes: (1) key demographics; (2) drug use by both biological and self-report measures, specifically regarding primary drugs of use, and age at first use; (3) consequences of drug use, as measured by ASI-Lite, and quality of life, measured using the World Health Organization's Qualify of Life BREF Instrument (WHOQOL-BREF). This list of CAB measures is required for all studies; waivers can only be granted with specific justifications from a particular protocol. Accordingly, the CTN's Data and Statistics Center has created standardized electronic case report forms, which can be used in newer, ongoing trials to standardize data collection, with the vision that standardized electronic data collection will facilitate data sharing and secondary/meta-analyses across CTN trials.

## Conclusion

The mission of the CTN is to translate addiction treatment research into clinical practice. To that end, the CTN has successfully engaged community providers in collaborative studies with academic addiction treatment researchers, moved research into community clinics, and recruited treatment-seeking substance abusers in the community as study participants. This network infrastructure has also transformed "conventional" research processes. Specifically, the research questions studied in CTN have been framed by providers to address treatment-related questions faced by clinicians in real-life practice settings. The design of CTN studies also has attempted to mimic conditions in real-life practice. This includes the selection of treatment outcomes and common assessment instruments that are not only validated and have sound psychometric properties, but are also user-friendly for real-life practice in busy community practice settings. The process described above, to develop common assessment instruments to facilitate cross-study analyses, has been difficult, for various practical reasons described in this commentary. The advantage of having a CAB is worthy for study teams to consider, and to negotiate early in the study design phase.

In conclusion, this commentary describes challenges and iterative experiences regarding how the CTN selects and utilizes assessment instruments that can reasonably balance the interests of both research scientists and practicing providers when applied in CTN trials. This commentary also discusses the process through which the CTN further selects a core set of common assessment instruments that may be applied across all trials, to allow easier cross-study analyses of comparable data. The CTN experience, in selecting and utilizing a CAB to measure participants' clinical status and treatment outcomes across trials, highlights the importance of standardizing a collection of assessments and instruments, to facilitate future meta-analyses of CTN data. While we believe that further discussion is needed to reach a better consensus, our recommendations of factors worthy for study teams to consider early in the trial design phase may be useful to researchers, concerning the process involved in selection of assessment instruments, and for specifying a CAB. Collecting clinically-relevant data in a uniform manner over time, using the CAB, will greatly facilitate future cross-study analyses, which could yield rich and important information to improve treatment of individuals with SUD, and to enhance the advancement of SUD-related clinical research.

## Disclosure

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