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Validation of the alcohol use item banks from the Patient-Reported Outcomes Measurement Information System (PROMIS®)

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ABSTRACT

Background: The Patient-Reported Outcomes Measurement Information System (PROMIS®) includes five item banks for alcohol use. There are limited data, however, regarding their validity (e.g., convergent validity, responsiveness to change). To provide such data, we conducted a prospective study with 225 outpatients being treated for substance abuse.
Methods: Assessments were completed shortly after intake and at 1-month and 3-month follow-ups. The alcohol item banks were administered as computerized adaptive tests (CATs). Fourteen CATs and one six-item short form were also administered from eight other PROMIS domains to generate a comprehensive health status profile. After modeling treatment outcome for the sample as a whole, correlates of outcome from the PROMIS health status profile were examined.
Results: For convergent validity, the largest correlation emerged between the PROMIS alcohol use score and the Alcohol Use Disorders Identification Test ($r = .79$ at intake). Regarding treatment outcome, there were modest changes across the target problem of alcohol use and other domains of the PROMIS health status profile. However, significant heterogeneity was found in initial severity of drinking and in rates of change for both abstinence and severity of drinking during follow-up. This heterogeneity was associated with demographic (e.g., gender) and health-profile (e.g., emotional support, social participation) variables.
Conclusions: The results demonstrated the validity of PROMIS CATs, which require only 4–6 items in each domain. This efficiency makes it feasible to use a comprehensive health status profile within the substance use treatment setting, providing important prognostic information regarding abstinence and severity of drinking.

1. Introduction

The Patient-Reported Outcomes Measurement Information System (PROMIS®) is an NIH Roadmap initiative devoted to developing better measurement tools for constructs relevant to the investigation and treatment of all diseases—constructs such as pain, fatigue, physical functioning, emotional distress, sleep, and alcohol and substance use (Buysse et al., 2010; Cella et al., 2007b, 2010; Fries et al., 2014; Pilkonis et al., 2011, 2013, 2015). PROMIS has created and refined a comprehensive methodology for developing item banks for these health-related constructs using both qualitative and quantitative techniques and modern psychometric methods, e.g., item response theory (IRT; Cella et al., 2007a, 2010; Hilton, 2011; Reeve et al., 2007). The use of IRT models to calibrate items results in greater precision at both the item and test levels and reduces respondent burden because of the small number of items (usually 4–6) needed to determine a respondent's status when items are administered as computerized adaptive tests (CATs). Additional discussion of the advantages of IRT and CAT is included as Supplementary material.

Following creation of item banks, our priority has been to validate them, most often in prospective observational studies. We report here on a study designed to validate the PROMIS alcohol use item banks with outpatients who had begun treatment for substance use disorder within the past 30 days. There were three specific goals for the protocol. The first was to demonstrate the utility (acceptability and ease of use) of the PROMIS measures, even

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when administered within an active clinical setting. The second goal was to demonstrate the convergent validity of the PROMIS alcohol item banks with existing alcohol instruments and to examine the responsiveness to change of the alcohol use item bank during treatment. All patients completed assessments at three points: shortly after intake (T1), one month following intake (T2), and three months following intake (T3). In addition to the alcohol use item banks, 14 other CATs and one 6-item short form from 8 other PROMIS domains were administered to generate a comprehensive health status profile for all participants. After modeling treatment outcome for alcohol use for the sample as a whole, the third goal was to identify correlates of outcome from the PROMIS health status profile.

To achieve the first goal (demonstration of utility), we conducted interviews with patients and their clinicians at T1 and T3 about their experience of completing the PROMIS measures. We provided feedback not only on alcohol use scores but also on the other domains of the health status profile, and we asked about the value of receiving such feedback for clinical care. A report of this work has documented the feasibility and perceived value of the PROMIS battery (Johnston et al., 2016).

With regard to the second goal, we examined convergent validity at the intake assessment by correlating scores on the PROMIS item banks with the Alcohol Use Disorders Identification Test (AUDIT; Saunders et al., 1993); the CAGE Questionnaire (Ewing, 1984); the 6-item set of "recommended alcohol questions" developed by a National Institute on Alcohol Abuse and Alcoholism (NIAAA) task force (2003), which assess frequency and quantity of alcohol use and patterns of consumption; and the Comprehensive Alcohol Expectancy Questionnaire (CAEQ; Nicolai et al., 2010). In addition, we examined the PROMIS equivalents of clinically meaningful ranges and thresholds on the AUDIT, AUDIT-C, and CAGE, e.g., a score of 20 or higher on the AUDIT, a score of 2 or more on the CAGE.

The analysis of longitudinal outcome data regarding alcohol use presents special challenges. Before asking about aspects of drinking, the item banks for alcohol use and negative and positive consequences include a screening question: "Have you had a drink of alcohol in the past 30 days?" It is common for periods of abstinence to alternate with periods of use or abuse, especially in samples of patients for whom abstinence is a goal but in whom relapses may be common. Thus, the item banks provide information about two related but distinct phenomena: abstinence (versus exposure to any alcohol) and severity of use when exposed. Analyzing such data requires novel models, and the approach we chose was the two-part random-effects model for semi-continuous data described by Olsen and Schafer (2001). The model allows simultaneous analysis of binary (yes/no) and continuous (severity) data, yielding parameter estimates (intercepts and slopes) for functions that model both exposure and severity.

After modeling treatment outcome for the sample as a whole, the third goal was to identify correlates of outcome from the PROMIS health status profile. Comorbid conditions such as depression, anxiety, and sleep disturbance are common among individuals with substance use disorders (Stinson et al., 2005). However, comprehensive assessment of physical and mental health may not always be done during their care. The efficiency of the PROMIS measures makes it feasible to generate a health status profile at a small cost of time and effort. We predicted that substance use patients would show elevations on emotional distress, sleep disturbance, and cognitive concerns and that these variables would be related to treatment outcome. Other relevant demographic variables (gender, race, age, and educational attainment) were also included in the prognostic analyses.

2. Method

2.1. Inclusion criteria

Men and women 18 years and older who were able to read and understand English were enrolled in the protocol. Participants were required to have begun outpatient treatment for substance use within the past 30 days at the Center for Psychiatric and Chemical Dependency Services, a treatment program in Addiction Medicine Services at the University of Pittsburgh Medical Center. Only participants who indicated that they had had a drink of alcohol within the past 30 days were screened into the study because of the 30-day time frame for the alcohol use and consequences item banks. In addition, patients had to have attended at least one treatment session after their initial assessment to be eligible for the second and third assessments. Informed consent was obtained from all participants included in the study.

2.2. Exclusion criteria

Clinical exclusions were dementia, other major cognitive impairment, any major medical condition that may have a significant impact on the central nervous system (e.g., Parkinson's disease, stroke, aneurysm), or a history of any psychotic disorder that might compromise the validity of self-reports or interfere with questionnaire completion.

2.3. Sample

An initial sample of 225 patients completed the intake assessment (T1), 164 completed the second assessment (T2) one month later, and 158 completed the third assessment (T3) three months later. Attrition in a range from 26–60% has been documented in the first month of treatment in substance use samples (Graff et al., 2009; Loveland and Driscoll, 2014; SAMHSA, 2010; Stark, 1992). Our attrition of 27% at one month and 30% at three months is close to the lower bound of this range. The mean age of the sample was 38 (SD = 12). In terms of gender, ethnicity, and race, 44% of the sample was female, 6% identified as Hispanic, and 44% was non-white (with the large majority of these participants being African-American, 40% of the sample). In terms of educational attainment, 39% had a high school diploma or less. The majority of the sample (65%) had an annual household income of less than $20,000 per year.

2.4. Test administration

Participants received the CAT versions of PROMIS measures, including alcohol use, emotional distress, sleep disturbance, fatigue, pain, physical functioning, cognitive concerns, and social participation and support. The fixed, six-item form for sexual interest was also administered. The PROMIS measures are scored on a T-score metric, with a mean of 50 (normed to the US general population) and a standard deviation of 10. With T-scores, a score of 60 (one SD above the mean) is often used as a clinically significant elevation, and there is evidence to support the validity of this threshold with PROMIS measures (Pilkonis et al., 2014).

There are five PROMIS alcohol use item banks: alcohol use, negative and positive consequences of alcohol use, and negative and positive expectancies regarding drinking (Pilkonis et al., 2013). The labels for the latter four item banks are self-explanatory, but it should be noted that the general "alcohol use" item bank focuses on problematic drinking rather than the frequency, pattern, and volume of consumption *per se*. Such items about consumption are included in the bank, but the most informative items that emerged from our IRT-calibration analyses were items reflecting struggles to control drinking and cravings for alcohol. Additional discussion of