Introduction and Aims

• Patient experience is starting to play a larger role in regulatory decision making in opioid use disorder (OUD); currently, there is no validated instrument that can be easily incorporated into clinical practice and research.

• The Treatment Effectiveness Assessment (TEA) is an efficient, patient-centered instrument for evaluating progress in recovery from OUD.

• The TEA consists of 4 single-item domains (Substance Use, Health, Lifestyle, and Community) measuring treatment-related improvement. Domain scores range from 1 ("not much") to 10 ("much better") and total scores range from 4 to 40.

• Since its publication in 2012, the TEA has been adopted in clinical practice and research.

• This study evaluated the TEA's psychometric properties among treatment participants with moderate to severe OUD and determined minimally important differences (MIDs) for total and subscale scores.

Design and Methods

Study Design

• This analysis was based on data in a Phase III open-label safety study of BUP-XR (buprenorphine extended-release monthly injection, for subcutaneous use [CII], SUBLOCADETM), known as RB-6000 during development, involving participants to severe OUD (NCT02510145).7

• Participants completed the TEA and other measures (Figure 1). Baseline was defined as the measurements at injection 1.

• Only participants who answered at least 1 TEA item at baseline were included in the present psychometric validation analysis.

Statistical Analysis

• Internal consistency for TEA total score was assessed at baseline using Cronbach’s alpha (threshold: 0.7).5

• Test-retest reliability (threshold: 0.7) for TEA single-item domains and total scores was examined among participants (n=177) with stable urine drug screen results between injection 12 and end of study (EOS).

• Known groups validity was assessed using 1-way ANOVA, grouping patients by current health status (SF-36v2 Item 1).

• Convergent/divergent validity were evaluated using Pearson’s correlation coefficient to test for convergent/ divergent validity of domains with health measures at baseline and EOS.

• Test-retest reliability, convergent/divergent validity, and internal consistency were retained when analyzing participants who completed all 12 injections (86.5%); however, a forgotten lesson of Pythagoras. Theoretical considerations and an example application of change in health status.

• The TEA exhibited strong internal consistency (Cronbach’s α = 0.897), which was retained when analyzing participants who completed all 12 injections (86.5%); however, a forgotten lesson of Pythagoras. Theoretical considerations and an example application of change in health status.

• The TEA instrument was sensitive to change in current health status (P<.001). For convergent and divergent validity, the directionality of correlations of TEA scores with other outcomes was consistent with hypotheses, but weaker than anticipated between like domains (Table 1).

• The TEA instrument was sensitive to change in current health status (P<.001). For convergent and divergent validity, the directionality of correlations of TEA scores with other outcomes was consistent with hypotheses, but weaker than anticipated between like domains (Table 1).

• MIDs for TEA total score were highly dependent on method used. When using distribution-based measures and ROC methods, MIDs ranged from 4.8 to 8.0. However, anchoring results on having ≥80% urine drug screen negative between week 5 and EOS, the MID was 6.8 (Table 3).