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Title: Measurement properties of exacerbations of chronic pulmonary disease tool (EXACT) in a clinical trial of patients with moderate to severe COPD

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Body: Aims: EXACT is a patient reported outcome (PRO) measure designed to evaluate the frequency, severity, and duration of exacerbations in COPD. Performance properties were examined in the context of a clinical trial. Methods: Patients with moderate to severe COPD completed EXACT as a daily electronic diary for 6 months. EXACT score and numbers of exacerbations, medically treated events (MTEs) and symptom-defined (EXACT), were secondary endpoints in a phase 2, randomized, double-blind, placebo-controlled trial. Assessments of EXACT included reliability (internal consistency, reproducibility) and validity (correlation of baseline EXACT score with St. George's Respiratory Questionnaire-COPD score, FEV₁ %Predicted, GOLD stage, and rescue medication use). Results: The intent-to-treat population included 614 subjects (71% male, ages 41-76 years with mean FEV₁ %Predicted=47.7). Overall diary compliance was 94%. Score reliability (Cronbach's alpha) was 0.93; reproducibility (ICC) in stable patients (baseline, Day -7 to Day -1) was 0.82. Validity coefficients were as follows: SGRQ-C (r=0.58), FEV₁ %Predicted (r= -0.18), GOLD stage (r=0.16), and rescue medication use (r=0.40) (p<0.0001 for all). For MTE, 173 (28.2%) subjects had ≥1 event, range=1-4, total events=232. For EXACT, 266 (43.3%) subjects had ≥1 event, range=1-5, total events=411. Mean (SD) severity of EXACT events was 52.4 (13.2) points and event duration was 17 days. Conclusions: Results support the reliability and validity of EXACT scores and provide insight into the frequency and severity of reported and unreported events in a clinical trial setting.