

## **Reliability and Validity of the Exacerbations of Chronic Pulmonary Disease Tool (EXACT): A New Outcome Measure for Evaluating Exacerbations in COPD**

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**Background:** Although exacerbations are an important problem for patients with COPD, there is no standardized tool for evaluating their frequency, severity, and duration in clinical trials. Instrument development, content validation, and item-reduction procedures for the EXACT are described elsewhere. **Objective:** To evaluate reliability, validity, and responsiveness of the new tool in patients with a confirmed exacerbation and those considered clinically stable. **Methods:** Prospective, two-group, observational study. Acute patients completed the EXACT daily via PDA on Days 1-29 and 60-67; Stable patients for seven days. Criterion variables: Acute - Clinician and patient assessment of exacerbation, St. George Respiratory Questionnaire (SGRQ-C) at clinic visit Days 1, 29, 60; Stable - Clinical history and SGRQ-C Day 1. **Results:** Sample: N=410 (222 Acute; 188 Stable) Mn age = 65 ( $\pm$  10); 48% male; stable FEV-1 = 51% pred ( $\pm$  20). EXACT: Internal consistency (Day 1, N=410) = 0.91; breathlessness=0.87; cough and sputum=0.69; chest symptoms=0.87. Reproducibility (ICC) in stable patients (N=171) Day 1 to 7 = 0.77; 0.71; 0.66; 0.64, respectively. Correlation with SGRQ-C Day 1 (N=395): r = 0.64; 0.66; 0.35; 0.46, respectively (p<0.001). Significant differences in EXACT scores were found across clinician and patient-rated exacerbation severity Day 1 (p<0.001) and in EXACT change scores between responders and non-responders Day 1 to 10 (p<0.0001). **Conclusions:** Measurement properties of the EXACT were demonstrated to be adequate for use in clinical trials with a similar population.

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