Identification of Clinically Relevant Changes in HRQoL

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BACKGROUND / RATIONALE:

Numerous health-related quality of life (HRQoL) instruments have emerged during the past two decades. Two broad purposes of these instruments have been the cross-sectional comparison of groups, and the longitudinal monitoring of groups or individuals. To date, most HRQoL investigations have focused on either the former, or on group evaluative aspects of the latter. Little attention has been given to the statistical assessment of intra-individual change over time, or to determining the magnitude of intra-individual change necessary to establish clinical relevance. Moreover, suitable methods for linking statistical evaluations and clinically meaningful standards for change have yet to be developed.

OBJECTIVE(S):

The specific aims of this study are to: (1) refine and extend minimal clinically important differences (MCIDs) for three disease-specific and one generic HRQoL measures; and, (2) determine the values of the standard error of measurement (SEM; i.e., standard deviation of each domain multiplied by the square root of one minus its reliability coefficient) that correspond to these MCIDs. The disease-specific measures are the Chronic Heart Questionnaire (CHQ; modified for use with coronary artery disease and/or congestive heart failure [CAD/CHF] patients), the Chronic Respiratory questionnaire (CRQ; used with chronic obstructive pulmonary disease [COPD] patients), and the Asthma Questionnaire of Life Quality (AQLQ; used with asthma patients). The generic measure is the SF-36.

METHODS:

To accomplish these specific aims we will collect three streams of data. The first stream of data comes from three national panels of expert physicians who treat middle aged or older adults with the target diseases.

One panel will focus on CAD/CHF, one will focus on COPD, and one will focus on asthma. Each panel will review the appropriate disease-specific HRQoL measure and the SF-36, and following previously developed methods will determine MCIDs for both. The second stream of data comes from enrolling 1,800 patients (300 in each disease group at both the Indianapolis and St. Louis primary

care sites) in a longitudinal study that includes a brief in-clinic screening interview, a 30-minute baseline telephone interview, and six 30-minute follow-up telephone interviews at fixed two-month intervals unless exacerbation-driven or regularly scheduled visits to their regular primary care physician occur that trigger follow-up interviews within 48 hours of these visits. The third stream of data comes from the regular primary care physicians of these patients, who will complete a brief questionnaire at the baseline visit about the patient's current health status, and another brief questionnaire at each exacerbation-driven or regularly scheduled follow-up visit concerning changes in the patient's health status and the treatment actions that these changes prompted. There are two major analytic phases. Using previously developed methods we will: (1) consolidate MCIDs for the CHQ, CRQ, AQLQ, and SF-36 measures from the expert panel, patient, and primary care physician perspectives; and, (2) determine the SEM values that correspond to the consolidated MCIDs.

IMPACT:

We have provided the first triangulated (expert, patient, and primary care physician) estimates of clinically important differences (CIDs) for three disease-specific HRQoL measures (CHQ, CRQ, and AQLQ) and one generic HRQoL measure (SF-36). These estimates can now be used in RCTs and other evaluations to determine whether clinically relevant change has occurred.

PUBLICATIONS:

Journal Articles

1. Wolinsky FD, Wyrwich KW, Babu AN, Kroenke K, Tierney WM. Age, aging, and the sense of control among older adults: a longitudinal reconsideration. The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences 2003; 58: S212-S220.

2. Wolinsky FD, Wyrwich KW, Kroenke K, Babu AN, Tierney WM. 9-11, personal stress, mental health, and sense of control among older adults. The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences 2003; 58: S146-S150.

3. Wolinsky FD, Wyrwich KW, Metz SM, Babu AN, Tierney WM, Kroenke K. Test-retest reliability of the Mirowsky-Ross 2 x 2 Index of the Sense of Control. Psychological Reports 2004; 94: 725-732.

4. Wyrwich KW, Fihn SD, Tierney WM, Kroenke K, Babu AN, Wolinsky FD. Clinically important changes in health-related quality of life for patients with chronic obstructive pulmonary disease: an expert consensus panel report. Journal of General Internal Medicine 2003; 18: 196-202.

5. Wyrwich KW, Nelson HS, Tierney WM, Babu AN, Kroenke K, Wolinsky FD. Clinically important differences in health-related quality of life for patients with asthma: an expert consensus panel report. Annals of Allergy, Asthma & Immunology : Official Publication of The American College

of Allergy, Asthma, & Immunology 2003; 91: 148-153.

6. Wyrwich KW, Spertus JA, Kroenke K, Tierney WM, Babu AN, Wolinsky FD. Clinically important differences in health status for patients with heart disease: an expert consensus panel report. American Heart Journal 2004; 147: 615-622.