DEFINING CLINICALLY MEANINGFUL CHANGE IN HEALTH-RELATED QUALITY OF LIFE
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OBJECTIVES: This paper reviews current approaches to defining clinically meaningful change in health-related quality of life (HRQL). METHODS: Definitions of clinically meaningful change are discussed. Psychometric properties of HRQL instruments necessary for identifying clinically meaningful change are identified. Two broad methods for identifying clinically meaningful change are contrasted: anchor-based methods and distribution-based methods. Anchor-based methods include forced-choice paradigms, global change ratings, receiver operating characteristic techniques, goal attainment scaling and external event methods. Distribution-based methods include individual effect size, the Guyatt responsiveness index, the Jacobson-Traux reliable-change index (and subsequent variations), standard error of measurement, and hierarchical linear modeling. Strategies for validating clinically meaningful change measures are discussed. RESULTS: Anchor-based and distribution-based methods have both advantages and limitations, and neither appears superior to the other. Anchor-based methods provide a source for external validation, but are dependent on the specific anchors being used. Distribution-based methods provide a statistical basis for decision-making, but may vary on the basis of sample characteristics. CONCLUSIONS: The use of multiple methods to define clinically meaningful change is strongly recommended. Factors to consider in defining clinically meaningful change include the severity of the baseline value, the direction of change, and the importance of the change to the individual.

CROSS-CULTURAL VARIATIONS IN SF-12 SCORES AMONG INDIVIDUALS WITH VARIOUS HEALTH CONDITIONS
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OBJECTIVE: To examine the cross-cultural differences of health-related quality of life among people with various health conditions across four countries. METHODS: Analyses were based on 12-page questionnaires mailed to adults in 2000. A total of 38,677 responses were received from France, Germany, Great Britain, and the US. Results were subsequently weighted and projected to the national populations of these four countries. Weighting was based on gender, age, and region for the European countries and gender, age, race, and region for the US. Participants reported whether they were diagnosed with the following: arthritis, asthma, depression, diabetes, GERD, high blood pressure, high cholesterol, migraines, nasal allergies, or osteoporosis. Physical and mental health status were defined by summary measures of the SF-12 scale. RESULTS: The French reported lower mental health status but better physical health status than people in Germany, Great Britain, and the US, regardless of diagnosed health conditions. The opposite was found among arthritis, asthma, and GERD sufferers in Germany, who reported the best mental health status but the lowest physical health. Respondents from Great Britain and the US generally reported SF-12 scores that fell between those of France and Germany, with three notable exceptions. Among people diagnosed with depression, those in the US reported better mental health status. Among people diagnosed with high blood pressure or high cholesterol, those in Great Britain reported the lowest physical health status. CONCLUSION: Self-reported quality of life varied by country regardless of condition. Researchers should consider cross-cultural variations in self-reported quality of life measures when conducting multinational trials. Collapsing data could obscure effects.