

PRO Development Process

QualityMetric's scientists developed the world's most widely used patient-reported outcome (PRO) tool, the SF-36v2[®] Health Survey. However, our expertise does not end there. It extends to the creation and development of other PROs as well. We have established a comprehensive and thorough PRO development process that is in accordance with many guidelines by the U.S. Food and Drug Administration (FDA). Below are the key stages of this process.

Conceptual Framework

This initial stage involves a literature review, patient and key opinion leader interviews, creation of a disease model, and consultation with governing or regulatory bodies. To assist with conceptual framework, QualityMetric has access to clinical experts that include physicians representing a broad range of medical specialties.

Survey Development

This stage focuses on the creation of items for key concepts, including symptoms, functioning, and well-being. Many considerations are taken into account during item generation – such as who completes the instrument (patient, caregiver, provider), the number of items needed to cover content (content validity/content coverage), the response continuum (frequency, duration, intensity), the mode of administration, and the survey translation.

Cognitive/Pilot Testing

This testing stage allows QualityMetric to gain insight into a respondent's interpretation of items and terms, and identifies items that are vague or difficult to understand. Cognitive testing can also confirm appropriateness of the response continuum and choices, and confirm content coverage. In addition, the mode of administration (e.g. paper/pencil, online, PDA, IVR) can be evaluated during this stage for feasibility and acceptance.

Validation Studies

Validation is a crucial part of the development process in which PRO tools are tested to make sure they measure what is intended. A primary purpose of validation is item reduction – to identify and keep the best performing items. These decisions are based on psychometric properties of individual items as well as tests of scaling structure. In addition, scoring methods are developed and tested, and thresholds for screening or treatment response can be created.

Validation is comprised of various elements that include scoring, psychometric testing, and responsiveness. The method of scoring scales is cross-validated and cut-points for screening are confirmed. Psychometric testing includes the testing of scaling assumptions, estimating reliability, and evaluating validity. Also, responsiveness assesses whether changes in scores correspond to changes in criterion measures of control, and also determines minimally important changes in scores.

A key advantage at this stage is access to well-defined patient populations, which QualityMetric can obtain through our relationship with i3 and Ingenix.

Dissemination

This stage is extensive and includes the development of a user's manual that outlines the administration and interpretation of the survey. In addition, the use and understanding of the new survey is promoted. Finally, abstracts are submitted to key conferences and manuscripts prepared on the development and cross-validation of the survey.

To learn more, please visit our website at www.qualitymetric.com/consulting.