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Steps for PRO Development

Adapted from Rothman, M., Burke, L., Erickson, P., et al. (2009). Use of Existing Patient-Reported Outcome (PRO) Instruments and Their Modification: The ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report. *Value in Health*, 12(8), 1075-83.

INTRODUCTION

This document provides a brief summary of key steps in developing a new PRO or revising existing instruments based on recommendations from the 2009 *ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report*. If you have any questions or need additional information regarding PRO development, revision, administration, or other related issues, please feel free to contact Quality and Compliance Consulting's clinical outcomes assessment consultants at qc2@qc2.com.

PRO development and revision activities can be divided into four general steps: 1) Conceptualization; 2) Information Gathering; 3) Data Collection; and 4) Integration, Revision, and Finalization.

STEP 1: CONCEPTUALIZATION

This initial step involves identifying and developing the concept to be measured.

A. What concept would you like to measure?

- A "concept" can be thought of as a general/broad idea that is derived or inferred from more specific instances/occurrences/components.
  - Example: Pain
- Identify the domains to which it is relevant.
  - Example: general pain, disease-specific pain, pain intensity, pain interference with daily life
- Identify the specific components that are thought to make up the concept.
  - Example: specific characteristics of pain associated with disease-specific pain

B. What is the labeling claim, and how does the concept to be measured relate to it?

- Identify whether the concept will be a primary (related to efficacy and appropriate use of investigational product/treatment), secondary (related to understanding treatment benefit or communicating product attributes to patients), or exploratory (not used to support labeling or promotional claims) endpoint.

C. Who is the target population for the investigational product and questionnaire?

- Identify key target population characteristics such as age, disease characteristics, etc.

STEP 2: INFORMATION GATHERING

This step involves conducting an exhaustive literature search on existing instruments and research previously conducted on your concept, target population, and/or disease.

A. What instruments currently exist?

- Identify instruments that have been previously used to measure your concept/disease, administered to your target population, etc. Define and map out the conceptual framework underlying the instruments and their development (e.g., identify the relationships between constructs, sub-constructs, etc.). If possible, evaluate the methods that were used to develop the existing instruments.

STEP 3: COLLECTING DATA

This step involves conducting qualitative research to determine the content for the instrument to be used to measure your concept.

A. How does your target population describe, talk about, and think about your concept?

- Conduct concept elicitation via focus groups and 1:1 interviews with target population to identify key words and phrases used to describe your concept to the point of saturation (i.e., when no new key words/phrases are elicited).

B. What are the important components to include in your instrument?

- Along with developer expertise, use findings from #5 to determine wording of items and response options, and structure of the instrument including the length of recall, mode of administration, instructions to be provided, format, etc.

STEP 4: INTEGRATE, REVISE, AND FINALIZE

This step involves integrating the findings and feedback obtained in the information gathering and data collection steps and refining and finalizing the instrument.

A. What should be done before finalizing the instrument?

- After a draft has been completed, administer and obtain feedback about it from your target population by conducting cognitive interviews to ensure they fully understand the meaning and interpretation of the items. Refine and revise the instrument as needed.

NEXT STEPS: VALIDATING THE INSTRUMENT

Establishing the psychometric properties of the instrument, scales, and items.

A. What's the next step after the instrument has been created?

- Once the instrument has been constructed, it should be administered to a sample of the target population to test the psychometric properties of the scales (e.g., distribution of scores, test-retest reliability, factor-structure, shared variance of items, correlations with other measures, etc.). Findings may lead to further revision of the instrument.

Quality and Compliance Consulting offers customized consulting services in the area of clinical outcomes assessment. If you have any questions or need additional information regarding PRO development, revision, administration, or other related issues, please feel free to contact QC2 at qc2@qc2.com.