

BEST PRACTICES FOR SELECTING PATIENT-REPORTED OUTCOME MEASURES: A METHODOLOGICAL FIVE-STEP APPROACH



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Objective: *To identify the most appropriate Patient-Reported Outcome Measures (PROMs) for a given topic and target population, ensuring relevant and reliable measures for patient-reported health outcomes.*

Patient-Reported Outcome Measures (PROMs) play a central role in health outcome evaluation, providing insight directly from patients on their quality of life and well-being, and the impact of the care they received. However, selecting an appropriate PROM can be complex, requiring a methodical approach that balances scientific rigor with practical and contextual considerations. Identifying the right instrument involves choosing a reliable, valid, change-sensitive tool that is suited to the target population. This article presents a structured methodology for selecting a relevant PROM, based on psychometric criteria, practical considerations, and a collaborative approach involving all stakeholders, then outlines a practical application.

STEP 1: Identifying Instruments That Align with Research Objectives

PROM identification and selection should begin as soon as the research objective is clearly defined, specifying which aspect of health or quality of life will be measured. A systematic literature review and exploration of specialized databases is required to identify potentially appropriate PROM.

The first step in this systematic review is to develop a search strategy by defining keywords and indexing terms related to the evaluated domain. Relevant databases such as PubMed, Embase, PsycINFO (a specialized database in psychological and behavioral sciences), and CINAHL (Cumulative Index to Nursing and Allied Health Literature) should be consulted to conduct a comprehensive review. For PROM-specific searches, platforms like PROQOLID (Patient-Reported Outcome and Quality Of Life Instruments Database), the COSMIN database (COnsensus-based Standards for the selection of health Measurement Instruments), and PROMIS (Patient-Reported Outcomes Measurement Information System) provide detailed information on existing PROMs, covering their psychometric properties and applications.

STEP 2:

Evaluating the Psychometric Properties of Patient-Reported Outcome Measures

Following this first step, selected articles must be reviewed for relevance through full-text analysis. PROM psychometric properties must be assessed to ensure that the chosen PROM aligns with research objectives and clinical practice. This evaluation is crucial for ensuring reliability and suitability for the intended context. Three key evaluation criteria should be considered:

- **Validity:** Ensuring the PROM measures what it is intended to measure. Different types of validity should be considered: **Content validity** (correspondence between PROM items and the targeted concept), **Construct validity** (relationship between the PROM and the theoretical constructs, assessed using three methods: correlations with another version of the same instrument, convergent and divergent correlations, and factor analysis), and, lastly, **Criterion validity** (comparison of the PROM with a "gold standard" or another instrument measuring the same concept).
- **Reliability:** Ensuring that the PROM is reproducible and precise. This includes evaluating **Internal consistency** (homogeneity of items within a domain), **Test-retest reliability** (stability of results over time), and **Inter-rater reliability:** agreement between different evaluators)
- **Sensitivity to change:** Evaluating the instrument's ability to detect clinically significant variations (e.g., standard error of measurement, and minimal detectable change).

STEP 3: Considering Practical Study Constraints

As well as the scientific and psychometric criteria detailed above, practical constraints must be considered to ensure the feasibility of PROM utilisation in a specific study context. The primary practical considerations include:

- **Time required for questionnaire completion:** Lengthy or complex questionnaires may discourage participants, leading to lower response rates and incomplete data.
- **Administration format:** Whether paper-based, electronic, or voice-assisted, the PROM format should be ergonomic and intuitive. It should also align with the technological capabilities of users and involved institutions. For electronic versions, system reliability and interoperability must be ensured to prevent data loss or alteration.
- **Accessibility and ease-of-use:** PROM should accommodate the needs of diverse populations, including elderly patients, individuals with cognitive impairments, or those with physical limitations. Adaptations may include simplified or audio versions, caregiver assistance, increased font size and contrast, or screen readers.
- **Logistical constraints:** Some PROMs require licensing fees, which may pose budgetary challenges, especially for large-scale studies. Additionally, verifying whether validated translations exist for the studied populations is essential for consistent data collection across countries and languages. If translations or electronic versions are unavailable, validation time should be incorporated into project timelines.

Addressing these practical aspects will help to ensure that the selected PROM align with study objectives as well as facilitating effective real-world implementation.

STEP 4:

Incorporating Stakeholder Input

To ensure that the PROM meets expectations, is relevant and will be adopted, it is essential to engage with all stakeholders, including patients, clinicians, researchers, and health policymakers. Engagement should take into account these factors:

- **Patient voice:** Patients can provide valuable insights into question relevance and the extent to which the PROM reflects their lived experiences. Their input can also help identify potential barriers to completion, such as ambiguous wording, intrusive questions, or poor ergonomics.
- **Clinician perspective:** Clinicians can assess the PROM's value for clinical decision-making and care pathway optimization.
- **Researcher perspective:** Researchers contribute to evaluating methodological robustness and adherence to regulatory standards.
- **Health policymaker perspective:** Regulatory bodies assess the PROM's applicability in public health contexts and economic evaluations.

Structured consultation methods include expert committees, focus groups, and individual interviews. Additionally, pilot testing in real-world conditions can help assess questionnaire usability and relevance.

This collaborative approach ensures the selected PROM is well-accepted, understood, and effectively implemented, ultimately enhancing data quality and project impact.

STEP 5:

Instrument Comparison and Selection

After completing the first four steps (literature review, psychometric evaluation, logistical assessment, and stakeholder engagement), a comparative table can help identify the most appropriate PROM for a given topic and population. A detailed report should be prepared outlining the selection strategy, evaluation criteria, and justification for the final choice to ensure transparency and reproducibility.

By following these steps, researchers can select a PROM based on strong evidence and tailored to the project's specific needs.

PRACTICAL APPLICATION:

Three Standardized Tools for Patient-Reported Outcome Measure Selection

Standardized methodological frameworks are essential to ensure rigorous PROM selection. These tools help guarantee that selected measures meet high-quality standards and are relevant to the target population, clinical domain, and study objectives. Three useful and relevant frameworks are outlined below.

COSMIN Framework

The COSMIN (Consensus-based Standards for the selection of health Measurement Instruments) framework is a key reference for PROM evaluation. It guides users to identify relevant PROMs, assess their psychometric properties, and rank them based on methodological robustness. It includes:

- Standards for psychometric property evaluation.
- A methodology for conducting systematic PROM reviews.
- A practical tool (COSMIN Risk of Bias checklist) to assess study quality and minimize selection bias.

OMERACT Framework

Initially developed for rheumatology, the OMERACT (Outcome Measures in Rheumatology) framework can be applied to other fields. It emphasizes:

- **Clinical relevance:** Does the tool align with patient and clinician priorities?
- **Feasibility:** Can the PROM be easily implemented in clinical practice?
- **Scientific validation:** Is the instrument reliable and precise?

PROMIS System

The PROMIS (Patient-Reported Outcomes Measurement Information System) offers a library of validated PROMs across multiple domains (pain, fatigue, quality of life, etc.). It utilizes modern measurement models, such as Item Response Theory (IRT), to:

- Enhance measurement precision.
- Provide flexible administration (short forms tailored to patient needs).

By following this methodical approach, researchers and healthcare professionals can maximize the impact of PROMs, placing patients at the heart of health outcome evaluation while ensuring data quality and public health relevance.