## World Journal of *Methodology*

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MINIREVIEWS

### Voices that matter: The impact of patient-reported outcome measures on clinical decision-making

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#### Abstract

The critical role of patient-reported outcome measures (PROMs) in enhancing clinical decision-making and promoting patient-centered care has gained a profound significance in scientific research. PROMs encapsulate a patient's health status directly from their perspective, encompassing various domains such as symptom severity, functional status, and overall quality of life. By integrating PROMs into routine clinical practice and research, healthcare providers can achieve a more nuanced understanding of patient experiences and tailor treatments accordingly. The deployment of PROMs supports dynamic patientprovider interactions, fostering better patient engagement and adherence to treatment plans. Moreover, PROMs are pivotal in clinical settings for monitoring disease progression and treatment efficacy, particularly in chronic and mental health conditions. However, challenges in implementing PROMs include data collection and management, integration into existing health systems, and acceptance by patients and providers. Overcoming these barriers necessitates technological advancements, policy development, and continuous education to enhance the acceptability and effectiveness of PROMs. The paper concludes with recommendations for future research and policy-making aimed at optimizing the use and impact of PROMs across healthcare settings.



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Key Words: Patient-reported outcome measures; Clinical decision-making; Patient-centered care; Healthcare technology; Data management; Policy development

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**Core Tip:** Patient-reported outcome measures (PROMs) are essential for patient-centered care, offering insights into patients' health status and treatment impact. Addressing technological, policy, and educational advancements to maximize PROMs' effectiveness in healthcare, future efforts should focus on optimizing PROMs' integration and utility in clinical practice and research.

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#### INTRODUCTION

Patient-reported outcome measures (PROMs) represent a significant evolution in healthcare, emphasizing the subjective experiences of patients alongside traditional clinical metrics[1]. The genesis of PROMs traces back to a growing acknow-ledgment that patient perspectives are crucial for a holistic understanding of health outcomes. These tools capture a range of patient experiences and outcomes, from physical symptoms and functional status to psychological well-being and life satisfaction, directly reported by patients themselves without interpretation by clinicians or others[2]. This direct feed-back from patients helps to map out the impact of diseases and treatments on daily living, providing insights that purely clinical parameters might miss. The role of PROMs in healthcare extends beyond mere measurement. They are increasingly integrated into clinical practice as vital components of patient care and clinical decision-making. PROMs serve not only to monitor disease and treatment response but also to guide clinical interventions and ongoing management strategies[3]. This integration reflects a broader shift towards patient-centered care, where healthcare systems aim to align treatments more closely with patient preferences, enhancing both the effectiveness and acceptability of care.

The importance of PROMs lies in their ability to bring the patient's voice into the clinical arena, ensuring that the care provided aligns with what matters most to the patients themselves. By systematically capturing how patients feel and function, PROMs provide a richer, more nuanced picture of the patient experience than traditional clinical outcomes alone[4]. This enhancement in data collection helps clinicians to tailor treatments to individual needs, potentially leading to improved health outcomes. In clinical settings, PROMs have been pivotal in expanding the understanding of various health conditions. For instance, in mental health, PROMs are utilized to assess conditions like depression and anxiety, often influencing treatment decisions such as the choice of therapeutic interventions and the monitoring of patient progress over time. Similarly, in chronic conditions like arthritis or diabetes, PROMs help in monitoring disease progression and the impact of treatments on patient quality of life, thereby guiding adjustments in management plans. The integration of PROMs into clinical practice has encouraged a more dynamic interaction between patients and healthcare providers[5,6]. It facilitates a dialogue where patients can express concerns about their health, which may be overlooked in standard clinical assessments. For example, in oncology, PROMs have guided discussions about symptoms and side effects that are critically relevant to patients' quality of life but might not be routinely solicited during clinical visits[7]. This ongoing feedback loop not only enhances patient satisfaction and engagement but also fosters a therapeutic alliance that supports better health outcomes.

#### UNDERSTANDING PROMS

#### Definition and types

PROMs are standardized, validated questionnaires used by patients to report on aspects of their health status that matter most to them, such as symptoms, functionality, and quality of life, without interpretation by clinicians or anyone else[8]. The core intent of PROMs is to capture data that reflect patients' perceptions of their health conditions, providing a direct insight into the impact of diseases and treatments from the patient's perspective[9]. PROMs can be broadly categorized into several types based on the nature of the information they aim to collect.

**Symptom scales:** These are designed to measure the severity and frequency of symptoms associated with specific health conditions. For instance, the Beck Depression Inventory and the Asthma Symptom Utility Index provide insights into the mental and respiratory symptoms patients experience, respectively[10].

**Functional scales:** These assess the impact of a health condition on a patient's ability to perform daily activities. The Health Assessment Questionnaire used in rheumatology and the Stroke Impact Scale are examples where patients' functional abilities and limitations are evaluated[10].

**Quality of life assessments:** These encompass broader aspects of a patient's life, including physical, mental, and social health. Tools like the 36-Item Short-Form Health Survey and the European five-dimensional health questionnaire are used across various diseases to assess overall well-being and quality of life[10].

Each type of PROMs is tailored to capture specific information that is relevant to different therapeutic areas, disease states, or treatment responses, allowing for a comprehensive understanding of patient outcomes[11,12]. The summary of commonly used PROMs in various health conditions is tabulated in Table 1.

#### Development and validation

The development of PROMs is a rigorous process that involves multiple phases to ensure that the measures are both reliable and valid[13,14] as shown in Figure 1. Initially, the conceptual framework of the measure is established, which involves defining what the PROMs aims to measure and why. This phase often includes extensive literature reviews, expert consultations, and patient interviews to identify relevant items that should be included in the measure. Following the conceptualization, item development begins. This stage involves creating the actual content of the questionnaire, including the questions and the response options. The items are then subjected to cognitive interviewing with patients to ensure that the language is clear and reflects the intended dimensions of health. Once a draft version of the PROMs is assembled, it undergoes psychometric testing to evaluate its reliability and validity.

Reliability refers to the consistency of the results produced by the PROMs when used in similar conditions over time. This includes testing for internal consistency and test-retest reliability to ensure stable performance.

Validity involves several assessments to confirm that the PROMs accurately measures the constructs it is intended to measure. This includes content validity, construct validity, and criterion validity, among others.

Validation may also involve exploratory and confirmatory factor analysis to understand the underlying relationships between items and to refine the scale based on statistical data.

#### Applications

**Clinical trials:** In clinical trials, PROMs are increasingly used as primary or secondary endpoints to determine the effectiveness of interventions from the patient's perspective[15]. For example, in trials for new oncology drugs, PROMs can provide data on how treatment impacts patients' symptom severity and quality of life, which is vital for regulatory approval and clinical practice.

**Routine care:** In everyday healthcare settings, PROMs assist clinicians in monitoring disease progression and treatment response[16]. For instance, in the management of chronic diseases such as diabetes, PROMs help track patients' self-reported symptoms and functional status over time, guiding adjustments in treatment plans and enhancing patient engagement in their care.

**Policy-making:** At the policy level, PROMs inform health services research and quality improvement initiatives. They are used to evaluate the quality of care delivered across different healthcare systems and to benchmark outcomes for healthcare providers. PROMs data contribute to the development of performance indicators and standards that ultimately shape health policy and practice, ensuring that the systems are responsive to the needs of patients[17,18].

#### **BENEFITS OF PROMS IN HEALTH CARE**

#### Enhancing patient-centered care

Patient-centered care is a critical component of modern healthcare, emphasizing the importance of incorporating the patient's perspective into the medical care process. PROMs are instrumental in this paradigm, as they provide a structured way to capture how patients perceive their health status and the impact of their treatments on their daily lives [19,20]. This inclusion of patient voices facilitates a more comprehensive approach to care assessment and planning, fostering a healthcare environment that respects and responds to individual patient preferences, needs, and values. PROMs empower patients by involving them directly in their care. By regularly gathering data on how patients feel and function, healthcare providers can gain a clearer understanding of the benefits and downsides of treatments as experienced by the patients themselves. For example, PROMs can reveal issues that are not typically covered during routine medical examinations, such as the impact of a chronic condition on a patient's mental health or social life. This can lead to more meaningful conversations between patients and healthcare providers, where decisions about treatments can be jointly discussed and aligned with what is truly important to the patient. Moreover, PROMs enhance patient engagement and satisfaction by demonstrating that healthcare providers value the patient's input in the care process. Engaged patients are more likely to adhere to treatment plans, attend follow-up appointments, and engage in proactive health management-all of which are crucial for effective disease management and prevention[21]. By systematically integrating patient feedback through PROMs, healthcare systems can create a more dynamic, responsive, and patientfocused service delivery model (Table 2).

#### Table 1 Overview of commonly used patient-reported outcome measures in various health conditions

Disease category	PROMs Name	Focus of PROMs	Description and use case
Mental health	Beck depression inventory	Symptoms	Used to measure the severity of depression. Commonly used in both clinical settings and research to monitor treatment effects
Respiratory conditions	Asthma symptom utility index	Symptoms	Assesses the frequency and severity of asthma symptoms, guiding treatment adjustments
Chronic conditions	Health assessment questionnaire	Functionality	Evaluates functional ability in patients with rheumatoid arthritis, influencing therapy and patient management
General well- being	The 36-Item Short-Form Health Survey	Quality of life	Broad assessment of patient quality of life across physical and mental health domains, used widely in various chronic conditions
Cardiovascular	Stroke impact scale	Functionality and symptoms	Measures the impact of stroke on physical and emotional aspects, aiding in recovery management
Oncology	European organisation for research and treatment of cancer quality of life questionnaire-core 30	Quality of life and symptoms	Commonly used in clinical trials for cancer to assess the quality of life and symptom burden during treatments

PROMs: Patient-reported outcome measures.

#### Table 2 Benefits and challenges of implementing patient-reported outcome measures

Benefits	Description	Challenges	Description
Enhanced patient- centered care	PROMs empower patients, leading to tailored treatments and higher engagement, which are critical for effective care	Data collection and management	Managing large volumes of patient data securely and efficiently poses significant logistical challenges
Improved clinical outcomes	Real-time data from PROMs facilitate timely adjustments in treatment, improving health outcomes	Integration into clinical practice	Modifying existing systems and workflows to include PROMs can be costly and time- consuming
Increased patient safety	Early detection of adverse effects or complications through PROMs enhances patient safety	Patient and provider acceptance	Skepticism about the accuracy and utility of PROMs may hinder their adoption by clinicians
Supporting research and policy	PROMs data enrich health services research and inform policy-making, leading to improved care standards	Training needs	Adequate training is required for healthcare providers to effectively interpret and use PROMs data

PROMs: Patient-reported outcome measures.

#### Improving clinical outcomes

The utilization of PROMs in clinical settings has a profound impact on improving clinical outcomes. These tools provide real-time data that help clinicians monitor and adjust treatments in ways that are most beneficial to patients[22,23]. In the management of chronic diseases, for example, PROMs allow for the continuous monitoring of symptoms and functional statuses, helping clinicians tailor interventions more precisely and promptly. In conditions like rheumatoid arthritis or multiple sclerosis, where patient conditions can fluctuate significantly, PROMs offer insights into the daily experiences of patients, enabling adjustments in medications or therapies before acute issues arise[24]. In the realm of mental health, PROMs facilitate the early detection of deteriorations in patient conditions, such as increases in depression or anxiety levels, that might not yet be clinically apparent. This early detection enables timely intervention, potentially averting more severe health crises. PROMs also allow for the tracking of patient responses to medications or other treatments over time, providing a basis for ongoing adjustments to therapeutic approaches[25,26].

Moreover, the use of PROMs in guiding treatment decisions has significant implications for improving patient safety [26]. By providing a direct feedback loop from the patient to the provider, PROMs help identify adverse effects or complications associated with treatments earlier than traditional clinical indicators might. For instance, in oncology, PROMs can track the side effects experienced by patients undergoing chemotherapy, allowing for faster interventions to mitigate these effects and thus improving the patient's quality of life and potential treatment adherence[7]. PROMs also play a crucial role in surgical care, where postoperative recovery can vary widely among patients. By implementing PROMs, surgeons can follow up on patients' self-reported recovery trajectories, identify those who may be at risk of poor outcomes, and intervene accordingly. This approach not only improves individual patient outcomes but also contributes to broader efforts to standardize postoperative care and enhance recovery protocols based on patient-reported data (Table 2)[27].



Figure 1 The patient-reported outcome measures cycle. PROMs: Patient-reported outcome measures.

#### CHALLENGES IN IMPLEMENTING PROMS

#### Data collection and management

The successful implementation of PROMs hinges significantly on the ability to efficiently collect, manage, and analyze large volumes of data. However, these processes come with several logistical challenges that can impede the effectiveness of PROMs. Firstly, the collection of PROMs data typically requires patients to complete questionnaires, which can be time-consuming and may lead to survey fatigue, particularly if surveys are lengthy or frequent. This fatigue can result in lower response rates or incomplete data, which diminish the reliability of the measures. Once collected, the management and analysis of PROMs data pose additional challenges. Healthcare organizations must ensure that data storage complies with privacy regulations such as the Health Insurance Portability and Accountability Act in the United States or the General Data Protection Regulation in Europe. Ensuring data security while maintaining easy access for authorized users requires sophisticated information technology systems, which can be costly and complex to implement[28]. Analyzing PROMs data also requires specialized statistical expertise. Health outcomes are often subjective and can vary significantly between patients, making it challenging to interpret results without advanced analytics techniques. Moreover, to be truly informative, PROMs data should be integrated with other clinical data, which involves additional layers of data management and analysis (Table 2)[27].

#### Integration into clinical practice

Integrating PROMs into routine clinical workflows presents its own set of barriers. One major challenge is the modification of existing electronic health records (EHR) systems to accommodate PROMs data. Many EHR systems are not initially designed to handle the free-text or varied format data provided by PROMs. Modifying these systems to integrate PROMs can be costly and time-intensive, and often requires ongoing maintenance and updates[16]. Furthermore, the integration of PROMs into clinical practice requires changes to the workflow of healthcare providers. Clinicians are often under significant time pressures, and adding the requirement to review PROMs data during patient visits can be seen as an additional burden. There is also the challenge of training staff to understand and effectively use PROMs data in their clinical decision-making processes. Without adequate training and perceived value in the PROMs, healthcare providers may be reluctant to adopt this practice fully (Table 2)[16].

#### Patient and provider acceptance

The acceptance and engagement of both patients and providers play critical roles in the successful implementation of PROMs. From the patient's perspective, the willingness to regularly complete PROMs can vary widely depending on factors such as the perceived relevance of the questions, the ease of completing the questionnaires, and the patient's overall engagement with their healthcare [29,30]. Some patients may also be concerned about privacy or skeptical about how their data will be used, which can further reduce their willingness to participate. Provider acceptance is equally crucial and similarly challenging. Some healthcare providers may doubt the reliability and validity of PROMs, particularly if the results contradict their clinical assessments or if they are unfamiliar with the use of PROMs in practice [31,



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32]. There can also be a cultural barrier in healthcare organizations accustomed to prioritizing clinical over patient-reported data. Overcoming these barriers often requires demonstrating the value of PROMs through education and by showing evidence of their impact on patient outcomes (Table 2)[16].

#### FUTURE DIRECTIONS AND INNOVATIONS IN PROMS

#### Technological advances

The rapid evolution of digital technology has opened up new avenues for enhancing the capture and utility of PROMs. Digital health platforms and mobile applications are at the forefront of this transformation, providing innovative ways to collect, manage, and utilize PROMs data more efficiently and effectively[33,34]. Mobile apps, for example, can facilitate the regular collection of PROMs data by allowing patients to easily record their symptoms and quality of life in real-time, using their smartphones or other mobile devices. This real-time data collection can provide clinicians with more dynamic and timely insights into patient conditions, potentially leading to quicker adjustments in treatment plans. Moreover, these apps can be integrated with reminders and educational materials to enhance patient engagement and adherence to treatment protocols.

Digital health platforms that integrate PROMs data with EHR are another key innovation. These platforms can automate the flow of PROMs data into a patient's health record, making it immediately accessible to healthcare providers during clinical assessments[35,36]. Furthermore, advanced analytics can be applied to this integrated data to identify trends and patterns that might not be evident from manual analysis. For instance, machine learning algorithms can predict patient outcomes based on PROMs data, thereby informing more personalized and proactive care strategies[28].

#### Policy and standardization

As the use of PROMs expands across different health systems and disciplines, there is a growing need for comprehensive policy development and standardization. Standardization of PROMs is essential to ensure that data collected are comparable across different settings and populations, which is crucial for benchmarking and improving healthcare quality on a larger scale[30]. Policy development should focus on establishing clear guidelines for the selection, use, and interpretation of PROMs. These guidelines should address which PROMs are appropriate for different clinical conditions and care settings, how frequently they should be administered, and how the data should be interpreted and acted upon [37,38]. Furthermore, policies should ensure that PROMs are used ethically, protecting patient privacy and ensuring that data collection does not become burdensome or intrusive for patients[39,40]. Standardization efforts could also involve the development of universal PROMs that can be used globally across various health systems. This would facilitate international research and collaborations, enabling healthcare providers to learn from global best practices and innovations in patient-centered care[3].

#### **Research opportunities**

There are numerous areas for further research to improve the design, implementation, and interpretation of PROMs. One primary area is the development of more sophisticated measures that are sensitive enough to detect subtle changes in patient conditions but robust enough not to be affected by irrelevant factors. Research into patient psychology and behavior could inform the design of PROMs that better capture the nuances of patient experiences and expectations[24]. Another research opportunity lies in the integration of PROMs with other types of health data, such as physiological measurements and genomic data. This integration could lead to a deeper understanding of how patient-reported outcomes relate to other indicators of health and disease, potentially uncovering new insights into disease mechanisms and treatment effects[27].

Further research is also needed to explore the effectiveness of PROMs in different demographic groups, including those with varying levels of health literacy, language barriers, or cultural backgrounds. Studies could investigate how different populations interact with PROMs and how these tools can be adapted to meet diverse needs. This research would ensure that PROMs are inclusive and effective across all segments of the population[21]. There is a need for ongoing research into the use of artificial intelligence and machine learning to analyze PROMs data. These technologies have the potential to identify patterns and predict outcomes in ways that are not possible with traditional statistical methods, providing a more granular understanding of patient-reported outcomes and their implications for care[28].

#### CONCLUSION

PROMs are indispensable tools that enrich clinical decision-making and patient care by incorporating the patient's voice into health assessments. The integration of PROMs into clinical and research settings underlines a shift towards patient-centered healthcare, wherein the subjective experiences of patients are given weight comparable to traditional clinical indicators. While the implementation of PROMs presents challenges, including data management, integration into clinical practice, and acceptance by patients and providers, the benefits, notably in enhancing patient engagement and improving clinical outcomes, are profound. Recommendations for advancing the use of PROMs include investing in technological innovations to streamline data collection and analysis, developing comprehensive policies for the standardized use of PROMs, and continuous research to refine their validity and application. Further efforts should focus on training healthcare providers and educating patients to foster acceptance and maximize the utility of PROMs data in clinical and

#### FOOTNOTES

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