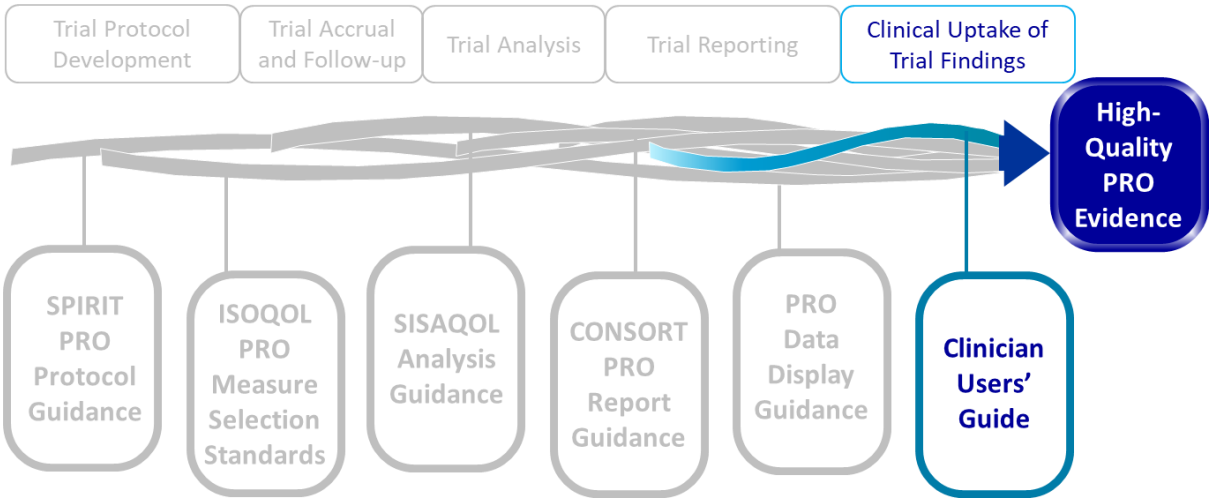
Chapter 7. Interpreting PRO Papers



Clinician's Checklist for Reading and Interpreting an Article that Includes PROs

The Clinician's Checklist for interpreting journal articles that include PROs provides clinicians who are not experts in PRO research with guidance on how to evaluate whether PRO findings are useful for their clinical practice.

This chapter summarizes the checklist items for clinicians to consider when evaluating articles with PROs.

View Clinician Users' Guide for Evaluating Studies with PROs article

View Checklist for the Clinician Users' Guide for Evaluating Studies with PROs

References

Acknowledgements

Why is This Resource Needed?

To help clinicians assess the quality of PRO research studies and determine whether findings are useful for clinical practice

Provides a checklist to evaluate the quality of studies that use PROs

In order to use PRO results to inform patient care, clinicians need to be able to evaluate published literature that includes PROs. However, clinicians face some barriers in applying PRO findings in clinical practice, including:

- a lack of education and training on the measurement and interpretation of PROs
- the wide variety of PRO measures available
- variation in how PRO findings are reported in the literature

Objective of Resource

The objective of this resource is to help practicing clinicians apply results of clinical research studies that include PROs in their patient care by providing a brief checklist to help them review published research studies that include PROs.

Methods for Resource Development

This Clinician's Checklist builds on guidelines published by Guyatt et al. (1997). Key elements to consider when reading a published study using PROs include:

- Assessment strategy and study design
- Performance of the PRO tool
- Validity of results
- Context of results
- Generalizability to one's own clinical setting and patient population

Clinician's Checklist to Evaluate Studies Using PROs

The items in the clinician's checklist address the key elements mentioned above to help clinicians evaluate a study with PROs.

1. Was the PRO assessment strategy appropriate?

Consideration	Explanation
a. PRO hypothesis stated?	*A priori* hypothesis explicit for PROs
b. PRO measures described?	PRO measures used, and timing/follow-up of subjects
c. PRO content appropriate?	Investigators measured aspects of patients' lives that patients consider important PRO domains correspond to anticipated effects of disease and treatment All important aspects of patient-reported outcomes included

Elements that are important to the conceptualization and design of any clinical research study apply equally to studies that include PROs. The research question, study design, patient population, and primary/secondary outcomes should be clearly identified within the scientific article. The research article should also clearly specify whether any primary and/or secondary outcomes are measured from the patient perspective, using PRO measures. A rationale for PRO assessment should be included and relevant PRO findings from previous studies should be described, especially if the PRO is a primary outcome. PRO hypotheses should be stated explicitly *a priori*.

The PRO measurement strategy should be described, including the timing of initial and follow-up assessments; this timing should be consistent with knowledge about the expected trajectory of patient outcomes over time in the patient population and, if possible, based on any information regarding the timing of treatment-related changes in patient health status. Pre-treatment "baseline" PRO assessment is critical and follow-up assessment time points should be appropriate to capture differences specified in the hypothesis.

The PRO measure content should correspond to the extent and breadth of problems observed in the patient population. To evaluate this, the reader should determine whether the PRO measure captures the expected effects of treatment on patient outcomes. Although there is often pressure to measure only symptoms and adverse effects in research studies, it is important to evaluate the "reach" of these symptoms to the patient's day-to-day functioning. For example, a phase II trial may have a more restricted focus on symptoms, but a phase III study should have a more comprehensive assessment of the effect of treatment on patient functioning. The reader should check to see whether important aspects of PROs have been omitted, because their omission could lead to incorrect conclusions.

2. Did they measure PROs effectively?

Consideration	Explanation
a. Evidence for reliability, validity?	The PRO instruments appear to work as intended; evidence of internal consistency and/or test retest reliability, and construct validity are cited or are well established
b. Were missing data handled appropriately?	Similar number of questionnaires completed by respondents in all treatment groups at every time point Missing data management strategy described Presence of data analysis plan for handling death, if frequent

When reading a research article, the reader should determine whether there is sufficient evidence cited to suggest that the PRO measures used are valid and reliable. The Methods section should cite evidence of the PRO measure's internal consistency reliability, test-retest reliability, and construct validity, ideally in the clinical population of interest. There should also be evidence that the questionnaire is responsive to expected changes in health status over time. In addition, the authors should describe how they handled missing data and report the extent and pattern of missing PRO data. If a substantial incidence of death was anticipated, the method of handling death should be stated. The absence of any aforementioned elements should lead the reader to question the study findings, particularly if the conclusions suggest no treatment effect or no difference between groups.

3. Should I believe the results?

Consideration	Explanation
a. Internal validity	Findings established; observed effects likely to be caused by intervention If non-treatment factors affect PRO, risk adjustment needed

The PRO results should be clearly described. The study's internal validity should be established, addressing whether the observed effects likely result from the intervention. To do so, the authors should assess differences between treatment groups at baseline and ensure that known confounding variables have been measured. When non-treatment factors are known to affect PRO scores, a system for risk adjustment should be applied to ensure fair comparison between groups. Results should be presented for important patient subgroups that might be expected to show heterogeneity of treatment effects. Ideally, these subgroups should be identified *a priori* or results should be qualified as exploratory.

To evaluate the internal validity of a study, the reader should assess whether it seems likely that the observed results can be attributed to the intervention rather than to other factors, whether a risk adjustment strategy was used successfully, and finally, whether they believe the effects are clinically plausible.

4. Were the results placed in a clinical context?

Consideration	Explanation
a. Was the clinical meaning of results explained?	Magnitude of effect on PROs described Clinical importance of observed differences in PRO scores demonstrated
b. Will the results help me in caring for my patients?	Benefits and harms recognized and reconciled, including potential trade-offs between quality and quantity of life Description of what a clinician should do with the results; study information helps clinicians communicate with patients about treatment options; applicability of group results to individual patient

The clinical significance of PRO results must be discussed explicitly, including whether the observed change was large enough to be noticeable to the patient or to compel a treatment change. PROs can provide comprehensive information about both positive and negative effects of disease and treatments. If an intervention has both positive and negative effects, the discussion should balance benefits and harms. This is especially important when there are trade-offs between quality and quantity of life, such as when a treatment extends life but decreases quality of life (e.g., toxic chemotherapy). Given a study's PRO results, it may or may not be obvious what management option a clinician would consider. If the article includes recommendations from the authors, this increases the likelihood that the study findings will be translated to practice change.

The reader should identify the magnitude of effect on the PROs and determine whether it is large enough to motivate changes in patient care. The reader should consider potential trade-offs involving the benefits and harms suggested by the study findings.

5. Do the results apply to my patients?

Consideration	Explanation
a. External validity to clinician's practice	Study population is similar enough to clinician's patient population to apply to practice

External validity of the findings is important to clinicians if they are going to engage in a dialogue with patients about treatment options. The reader should judge how well the study simulates clinical practice in general, and whether or not the results are generalizable to his or her own patient population. Ideally, study authors will address the generalizability of study results, including PROs, to help clinicians with this task.

Checklist for Clinicians for Evaluating Studies with PROs

Consideration	Explanation	Notes/ comments
1. Was the PRO assessment strategy appropriate?		
a. PRO hypothesis stated?	*A priori* hypothesis explicit for PROs	
b. PRO measures described?	PRO measures used, and timing/follow-up of subjects	
c. PRO content appropriate?	Investigators measured aspects of patients' lives that patients consider important PRO domains correspond to anticipated effects of disease and treatment All important aspects of patient-reported outcomes included	
2. Did they measure PRO effectively?		
a. Evidence for reliability and validity?	The PRO instruments appear to work as intended: evidence of internal consistency and/or test retest reliability, and construct validity are cited or are well established	
b. Were missing data handled appropriately?	Similar number of questionnaires completed by respondents in all treatment groups at every time point Missing data management strategy described Presence of data analysis plan for handling death, if frequent	
3. Should I believe the results?		
a. Internal validity	Findings established; observed effects likely to be caused by intervention If nontreatment factors affect PRO, risk adjustment used	
4. Were the results placed in clinical context?		
a. Was clinical meaning of results explained?	Magnitude of effect on PROs described Clinical importance of observed differences in PRO scores demonstrated	
b. Will the results help me in caring for my patients?	Benefits and harms recognized and reconciled, including potential trade-offs between quality and quantity of life Description of what a clinician should do with the results; study information helps clinician communicate with patients about treatment options; applicability of group results to an individual patient.	
5. Do the results apply to my patients?		
a. External validity to clinician's practice	Study population is similar enough to clinician's patient population to apply to practice	

References

Wu AW, Bradford AN, Velanovich V, Sprangers MAG, Brundage M, Snyder C. Clinician's checklist for reading and using an article about patient-reported outcomes. *Mayo Clinic Proc*. 2014;89:653-661.

Further Readings

Guyatt GH, Naylor CD, Juniper E, Heyland DK, Jaeschke R, Cook DJ. Users' guides to the medical literature, XII: how to use articles about health-related quality of life. Evidence-based Medicine Working Group. *JAMA*. 277(15):1232-1237; 1997

Back to Table of Contents

Please Note: When referencing information included in this Chapter, we recommend citing the primary sources rather than this Handbook.