

Clinician Users' Guide 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?	<p>Investigators measured aspects of patients' lives that patients consider important</p> <p>PRO domains correspond to anticipated effects of disease and treatment</p> <p>All important aspects of patient-reported outcomes included</p>	
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?	<p>Similar number of questionnaires completed by respondents in all treatment groups at every time point</p> <p>Missing data management strategy described</p> <p>Presence of data analysis plan for handling death, if frequent</p>	
3. Should I believe the results?		
a. Internal validity	<p>Findings established; observed effects likely to be caused by intervention</p> <p>If nontreatment factors affect PRO, risk adjustment used</p>	
4. Were the results placed in clinical context?		
a. Was clinical meaning of results explained?	<p>Magnitude of effect on PROs described</p> <p>Clinical importance of observed differences in PRO scores demonstrated</p>	
b. Will the results help me in caring for my patients?	<p>Benefits and harms recognized and reconciled, including potential trade-offs between quality and quantity of life</p> <p>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.</p>	
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	