



PRO TASK FORCE: Changing Mode of Administration / ePRO

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selected to reflect a range of stakeholders

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ePRO Background

- Migrating from paper to electronic data collection is one of the most significant movements in the PRO measurement field
- There is growing recognition of the many advantages of ePROs, including:
 - less administrative and subject burden
 - avoidance of secondary data entry errors
 - easier implementation of skip patterns
 - more accurate and complete data
- ePRO modalities include: digital pen, handheld (e.g. PDA), interactive voice response (IVR), tablet, interactive web response (IWR)

Regulatory Statements

- “When a PRO instrument is modified, additional validation studies may be needed....”, Line 581
- “The extent of additional validation recommended depends on type of modification made.”, Line 582

FDA draft guidance on PROs, February 2006

Scope of the ePRO Consensus Paper

- Includes: What are the best practices for converting a paper PRO to an ePRO?
- Excludes:
 - Systems Validation and User Acceptance Testing
 - Migration of clinician administered assessments

Level of Additional Testing Depends on the Level/Type of Change

Level of Modification	Rationale
Minor	The modification can be justified on the basis of logic and/or existing literature. No change in content or meaning.
Moderate	Based on the current empirical literature, the modification cannot be justified as minor. May change content or meaning.
Substantial	There is no existing empirical support for the equivalence of the modification and the modification clearly changes content or meaning

Level of Additional Testing Depends on the Level/Type of Change

Level of Modification	Examples
Minor	<ol style="list-style-type: none">1) Non-substantive changes in instructions (e.g., from circling the response to touching the response on a screen).2) Minor changes in format (e.g., one item per screen rather than multiple items on a page).
Moderate	<ol style="list-style-type: none">1) Changes in item wording or more significant changes in presentation that might alter interpretability.2) Change in mode of administration involving different cognitive processes (e.g., paper [visual] to IVR [aural]).
Substantial	<ol style="list-style-type: none">1) Substantial changes in item response options2) Substantial changes in item wording

Level of Additional Testing Depends on the Level/Type of Change

Level of Modification	Level of Evidence
Minor	Cognitive debriefing Usability testing
Moderate	Equivalence testing Usability testing
Substantial	Full psychometric testing Usability testing

Adapted from Shields et al.

Study Designs for Moderate Modifications

Measurement equivalence testing options include:

- *Randomized crossover design* - the random assignment of respondents to complete either a paper PRO or ePRO questionnaire for the first administration and then the other mode for the second administration.
- *Randomized parallel groups design* - patients are randomly assigned to one of two study arms. Patients in one study arm complete the original paper version of the PRO questionnaire and patients in the other arm complete the ePRO version.

Statistical Methods for Assessing Measurement Equivalence

Main recommendations include:

- Tests of agreement (e.g., ICC, Kappa coefficient)
- Comparison of mean scores
- Other
 - variance and distribution of scores
 - where appropriate, internal consistency reliability (e.g., Cronbach's alpha coefficient)

Full Psychometric Validation for Substantial Modifications

When substantial change has occurred in the PRO migration process that has the potential to impact fundamental psychometric properties of the measure, then the measure should be evaluated as if it were a new measure.

ePRO Working Group: Next Steps

- *ViH* publication online November 18, 2008 & hard copy June 2009
 - ePRO Case Studies Project
 - Suggestions and volunteers welcome
- Contact Elizabeth Molsen RN, ISPOR Staff Liaison to the ePRO Working Group
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