

White Paper | PRO Consulting

Equivalence of Computerized and Paper and Pencil PRO Measures

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Date:
June 16, 2006

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Introduction

Patient-reported outcome (PRO) data are inputs collected directly from patients. PROs are often used to measure treatment efficacy in clinical trials, and may serve as primary or secondary endpoints. To date, PRO data have typically been collected using paper-and-pencil measures. However, computerized PRO measures are increasingly being used for several reasons.

Computerized measures:

- 🔹 Eliminate missing data within assessments
- 🔹 Minimize missing assessment in the eDiary
- 🔹 Eliminate out of range or ambiguous data
- 🔹 Date- and time-stamp data
- 🔹 Automate item branching
- 🔹 Reduce effort and error in entering data
- 🔹 Simplify patient data entry (research shows that computerized measures are typically preferred by patients over paper-and-pencil measures)

Despite these clear advantages, there has been some concern that migrating a PRO measure from paper to computer will affect its performance. Additionally, the FDA draft guidance on PROs states that migrating from paper to computer will be considered a modification of the measure, which may require additional validation evidence. The degree of new evidence required for a specific migration should be informed by the scientific literature on how migration to ePRO influences the performance of PRO measures. In order to better understand the effect of migrating PRO measures from paper to computer, we conducted a meta-analysis of published studies that compared the two modes of administration.

Equivalence of paper and computer PROs: A meta-analysis

We identified 47 studies that assessed the equivalence of paper-based and electronic measures, covering 293 scales. The studies included a variety of patient samples (e.g., arthritis, cancer, asthma) and examined a variety of PROs, including both symptom and quality of life measures. Our analysis examined two measures of equivalence. We also compared the paper-to-ePRO migration to the test-retest correlation between two administrations of the paper measure:

- 🔹 We assessed differences between the mean scores of the paper and computerized measures (30 studies, 214 scales). Differences were expressed as a percent of the scale range. For example, a difference between the means of 3 points on a 100-point scale was expressed as a 3% difference.

- ⇒ The average mean difference was -0.3%. In other words, the means of the paper and computerized measures differed by .3 points on a 100-point scale. The average absolute mean difference was 2.6% of the scale range.
- ⇒ The difference between the paper and computer means was within 5% of the scale range in 89% of cases.

- 🔹 We also assessed correlations between the paper and computerized measures (32 studies, 205 scales). A correlation of .70 is considered an acceptable level of agreement.
 - ⇒ The average correlation between the modes was .90
 - ⇒ 93% of the correlations were \geq .70

- 🔹 We also compared the test-retest correlation between two administrations of a paper measure and equivalence of paper and ePRO.
 - ⇒ The average test-retest correlation for paper was .90
 - ⇒ The average paper-to-ePRO correlation was .89
 - ⇒ Thus, migration to ePRO preserved equivalence to the paper measures

Conclusions

A substantial published literature demonstrates that computerized PRO measures are equivalent to their paper-and-pencil counterparts broadly. Validation studies should not generally be required when migrating a PRO measure from paper to computer. Cognitive interviewing may be useful to ensure that patients are interpreting the migrated or reformatted items in the intended manner. Use of computerized measures in clinical trials should not be impeded by concerns about equivalence.