Assessing the Equivalence of Electronic and Paper Data Collection of EQ-5D Data in Rheumatoid Arthritis

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Electronic Patient-Reported Outcomes (ePRO)

- Improved, documented compliance with protocol
- Time-stamping helps ensure data integrity
- Rapid review of results
- Acceptable to patients – often preferred to paper

Migration

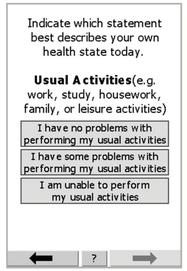
When an instrument has been migrated from a validated paper version to ePRO, it is necessary to review the changes and assess their implications for data equivalence.

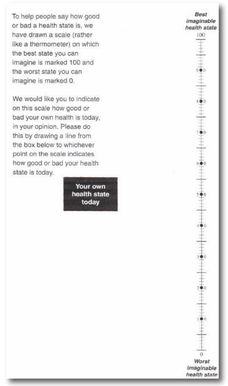
EQ-5D: Domains

The EQ-5D has five domains, Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. Each domain has one question with three response options. On paper, all five questions are on a single A4 page. Here is the question for Usual Activities from the paper version:

Usual Activities (e.g. work, study, housework, family or leisure activities)
I have no problems with performing my usual activities
I have some problems with performing my usual activities
I am unable to perform my usual activities

When migrating to a device with a small screen, such as a personal digital assistant (PDA), it is necessary to present the questions one per screen. There is considerable evidence from equivalence studies indicating that the change to presenting a single question at a time does not in general affect the data collected (see e.g. Gwaltney et al., 2008). The ePRO implementation of the Usual Activities question on the PDA is shown on the right. The patient taps on the desired choice, which highlights, and then taps => to move to the next question.





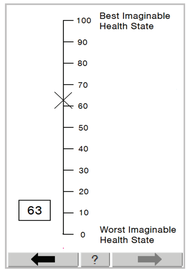
EQ-5D Health State Scale

The second page of the EQ-5D has the line scale shown on the left. There are two points here. First there is quite a lot of text. This means that scale and text will not all fit on a single PDA screen. Secondly, the scale is 200 mm long, and must be shortened to fit. This means that it is impossible to display 100 graduations as with paper.

The approach we took was to present instructions on one screen, and the scale on the next. In place of the graduations, we displayed the pointer position as a numerical output, in % of scale length. The use of the display box is similar to that described by Ramachandran et al. (2009), but they used a horizontal scale.

The PDA scale is shown on the right. The cursor does not appear until the patient taps on the scale to indicate a position.

While the changes to the five domain questions are considered minor, and supported by available evidence, the changes to the health state scale are more significant, and required a study to establish equivalence between paper and ePRO versions. Coons et al. (2009) discuss the criteria for determining what type of evidence is appropriate for different levels of change in migration.



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The Study

Forty-three patients (12 male, 31 female) with a diagnosis of rheumatoid arthritis took part in the study. They were aged between 32 and 83 years, with 25 (58%) being under 60, and 18 (42%) being 60 or over (median age 57). Patients were excluded if they had any condition other than RA likely to cause pain or fatigue, to affect quality of life, or to impair functioning. They took part in a two-period within-subjects design comparing electronic (E) and paper (P) modes. Patients took part in a single session in which they completed a set of scales, including EQ-5D, in the first mode, then in the second mode, with an interval of 45 min in between. Half the patients completed E then P, half P then E, in randomised order. Electronic assessments were carried out on a Palm TX (screen size 75 X 55 mm). A profile score was calculated for the EQ-5D using weights derived from a UK population. Patients also completed a final questionnaire which included questions on acceptability of the questionnaires and mode preference.

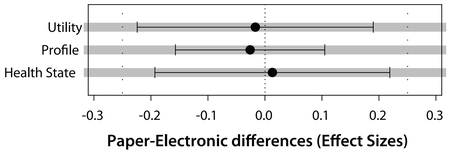
Results

Data for the agreement between E and P are shown in the Table. The E-P differences rescaled as effect sizes (ES) are shown in the Figure. All Intraclass correlation coefficients (ICC) were at least 0.75, the a priori criterion for excellent agreement (Gwaltney et al., 2008). The mean E-P differences were close to zero for for all measures, and the confidence intervals were completely contained within a range of ES of ± 0.25.

All patients found both modes acceptable. More patients preferred E (53%) than preferred P (14%) and this was true for the older patients and those less familiar with technology as well as for the younger.

Agreement between paper and electronic assessments

Questionnaire/ Item or Subscale	Paper		Electronic		ICC
	Mean	S.D.	Mean	S.D.	
Utility	0.612	0.239	0.608	0.249	0.79
Profile	1.65	0.35	1.64	0.35	0.91
Health State Scale	64.2	22.5	64.5	19.2	0.75



Discussion

The values for ICC found here are generally similar to those seen for paper-paper retest reliability. For example, Fransen et al. (1999) reported retest ICC values of 0.70 for the EQ-5D index (utility) and 0.73 for the health state scale after 1 week in knee arthritis, while König et al. (2002) reported ICCs of 0.89 and 0.77 respectively after two weeks for inflammatory bowel disease. Ramachandran et al (2008) reported an ICC of 0.75 for a comparison of a tablet-based ePRO implementation of the health state scale with paper.

A number of previous studies have shown that ePRO scales are acceptable to patients, who often prefer them to paper. Previous work has also shown that acceptability and preferences are similar in older patients and those who are not familiar with computers (see e.g. Drummond et al., 1995; Ring et al., 2008).

Conclusion

These results support the validity of the PDA version of the EQ-5D, and confirm that the electronic version is suitable for use in a wide range of patients

References

Drummond et al. (1995) Quality of Life Research 4:21; Fransen et al. (1999) Rheumatology 38:807; König et al. (2002) Eur J Gastroenterol Hepatol 14:1205; Gwaltney CJ et al. (2008) Value in Health 11:322; Ramachandran S (2008) Quality of Life Research 17:1117; Ring et al. (2008) The Patient 1:105; Coons SJ et al. (2009) Value in Health 12:419