EVALUATING THE CONCEPTUAL EQUIVALENCE BETWEEN PAPER AND THREE ELECTRONIC DATA COLLECTION MODES OF THE EQ-5D-5L HEALTH STATUS INSTRUMENT

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INTRODUCTION

- Collection of patient-reported outcome (PRO) data electronically often involves migrating an existing measure to an electronic format, such as a handheld device, tablet, web via personal computer, or telephone, using an interactive voice response (IVR) system.
- The EuroQol Research Foundation and the Electronic Patient-Reported Outcome (ePRO) Consortium jointly funded a project aimed at comprehensively examining the equivalence of different modes of administration of the EQ-5D-5L utilizing both qualitative and quantitative research.
- The results of the project are intended to provide evidence regarding the equivalence of EQ-5D-5L data collected on paper, handheld, tablet, web, and IVR modes of administration.

OBJECTIVES

- The objective of this component of the project was to examine the conceptual equivalence of paper, handheld, web, and IVR modes of the EQ-5D-5L, as well as the usability of the electronic mode, using qualitative methods, in accordance with the ISPOR task force report on evidence needed to support measurement equivalence between paper and electronic-based measures.[1]
- The ISPOR Task Force recommends a small qualitative cognitive interview/usability testing (CI/UT) study when only minor modifications are needed to migrate the measure from one mode to another. [1, 2]

RESULTS

Sample Characteristics	Handheld (N=10)	IVR (N=10)	Web (N=10)
Age, years			
Mean	43.0	38.3	43.6
(SD)	(20.0)	(11.2)	(9.7)
Range	20-79	27-60	31-65
Sex, n			
Female	6	8	5
Male	4	2	5
Chronic health condition, n			
Yes	6	9	8
No	4	1	2
Race/Ethnicity, n			
White British	5	5	7
Black African/Caribbean/Black British	3	1	
Indian	1	1	
Mixed/multiple ethnic groups	1		
Pakistani		1	
Irish		1	
Mixed White and Asian			
Asian		1	1
White Other			2
Education, n			
Left school with no qualifications	1		
GCSE or equivalent			1
A level or equivalent	1	1	2
Technical/vocational qualifications from a college or job	2	1	
University undergraduate degree	6	4	5
University postgraduate degree		3	2
Not answered		1	
Device familiarity, n			
A little familiar	1	1	2
Moderately familiar	5	1	3
Very familiar	4	8	5
Device confidence, n			
A little confident			2
Moderately confident	5	3	2
Very confident	5	7	6
Health conditions affecting device use (multiple answers possible), n			
Difficulty in reading		1	1
Difficulty in handling small devices		3	
No difficulties	10	7	9

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METHODS

Conceptual Understanding and Usability Study Procedures

Sample

- This was a single-visit, qualitative CI/UT study among participants (n=30) from the general population in the United Kingdom
- There was a recruitment target of at least 15 participants with a chronic health condition causing daily pain or discomfort, depression or anxiety, problems dressing/washing, walking or performing usual activities
- Sample diversity was also sought with respect to age, sex, and education level

Informed Consent

- Before the study visit began, the interviewer explained the purpose of the study and interview methodology to each participant.
- Participants were given the opportunity to ask questions, and then asked to read and sign the informed consent form.

Interviews

- Participants completed the EQ-5D-5L on paper and one of the three electronic modes (handheld [n=10], IVR [n=10], or web [n=10]) followed by an interview about understanding and usability.
- The handheld device used was a BLU Life Play smartphone with a screen size of 4.7". No stylus was allocated for the handheld. Web was accessed via a non-touchscreen laptop computer available on site. IVR testing was done using recorded prompts while responses were noted by the interviewers.
- The order of completion of the paper and electronic mode was alternated, with half of the participants in each group completing paper followed by electronic and half completing electronic followed by paper. Participants completed the two modes consecutively.
- Interviews were conducted by researchers trained in cognitive interviewing, the use of the electronic devices, and the project-specific objectives and procedures.
- Participants were asked to explain their understanding of the questions being asked and the meaning of each response option provided, whether any of their answers were different due to differences in the layout from paper to electronic mode, and whether they had any difficulty completing the questionnaire on the electronic version being tested.
- At the end of each interview, participants completed a socio-demographic and device familiarity questionnaire. Each interview lasted approximately 45 to 60 minutes. Each participant received £30 reimbursement for his or her participation.

Transcripts

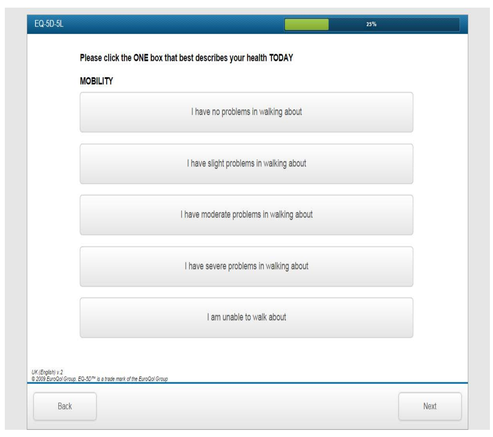
- Interviews were audio-recorded and transcribed verbatim for reference and analysis purposes.
- Transcripts were reviewed, de-identified, and coded.

Coding

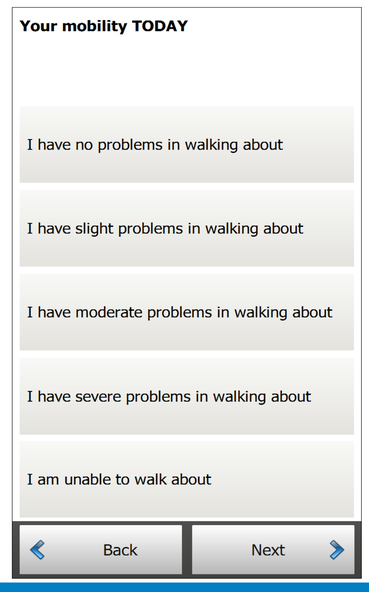
- Coding was performed using a qualitative software tool, MAXQDA 11.[3]
- Coding enabled organization of interview responses across participants and modes and allowed for focused evaluation related to conceptual understanding and usability.

Example Item on Each Data Collection Mode

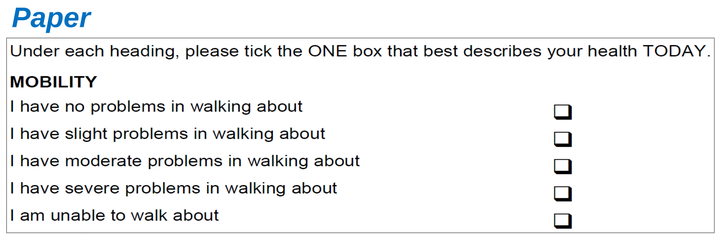
Web



Handheld



Paper



IVR Script

Item	IVR Prompt
Instructions	Now, I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.
Please select how your mobility is TODAY	First I will ask you about your Mobility. If you have no problems walking press 1 If you have slight problems walking press 2 If you have moderate problems walking press 3 If you have severe problems walking press 4 If you are unable to walk press 5

RESULTS

- A total of 30 participants completed this component of the project, most of whom (n=23; 77%) had a chronic health condition.
- Overall, participants in all mode groups interpreted the measure content consistently and appropriately for each item of the EQ-5D-5L.
- When asked whether layout differences would impact their answers between paper and electronic formats, most participants (n=23, 77%) indicated there would be no difference. Reported potential discrepancies were mostly related to the 0-100 numeric rating scale (i.e., EQ VAS), where four participants noted answer discrepancies due to difficulty selecting a precise response on the handheld and web.
- All participants in the handheld, web, and IVR (n=30) groups could navigate through the measure on their respective mode without difficulty. A number of participants (n=4) noted answering differently between paper and electronic for the EQ VAS due to difficulty selecting a precise number on the scale.
- Several participants noted possible discrepancies, but the reasons noted were not related to differences in interpretation between paper and ePRO formats but rather that one mode might have resulted in a more accurate response. For example, one participant noted responding more quickly on the electronic version versus paper which could have influenced his/her response, and another participant noted that the instruction to answer based on "today" was less prominent in the paper version, and so he/she may have answered more generally on paper rather than only focusing on "today."

CONCLUSIONS

- Consistent interpretation of items in the EQ-5D-5L by participants using paper, handheld, IVR, or web supports the conceptual equivalence of the items across modes.
- Minor differences in presentation did not appear to undermine the understanding of these items; however, usability issues potentially affected measurement equivalence for the EQ VAS item, highlighting the importance of usability testing to address such issues prior to implementation.

REFERENCES

1. Coons SJ, Gwaltney CJ, Hays RD, Lundy JJ, Sloan JA, Revicki DA, Lenderking WR, Cella D, Basch E. Recommendations on evidence needed to support measurement equivalence between electronic and paper-based patient-reported outcome (PRO) measures: ISPOR ePRO Good Research Practices Task Force Report. *Value in Health* 2009;12:419-429.
2. Eremenco S, Coons SJ, Paty J, Coyne K, Bennett A, McEntegart D. PRO data collection in clinical trials using mixed modes: report of the ISPOR PRO Mixed Modes Good Research Practices Task Force. *Value in Health* 2014;17:501-516.
3. MAXQDA, software for qualitative data analysis, 1989-2017, VERBI Software – Consult – Sozialforschung GmbH, Berlin, Germany.

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