

Development of an instrument to measure face validity, feasibility and utility of patient questionnaire use during health care: the QQ-10

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Abstract

Objective. To develop and establish the psychometric properties of an instrument to measure face validity, feasibility and utility of patient questionnaires used during health care.

Design. Our instrument, QQ-10, is a 10-item self-completed questionnaire, which was developed during the evaluation of another questionnaire (ePAQ-PF), to assess patients' views on questionnaire use during health care.

Setting. Urogynaecology Department, Royal Hallamshire Hospital, Sheffield, UK.

Participants. The Sheffield maternity patient user group identified 10 key themes relating to patients' views on using questionnaires; these themes translated into 10 statements, each using the same 5-point Likert response scale.

Intervention. Not applicable.

Outcome Measures. Principal component analysis established the factor structure of our instrument. Internal reliability was assessed using Cronbach's alpha. Construct validity was assessed using Spearman's rho.

Results. Factor analysis yielded two meaningful factors: Value and Burden, both achieving Cronbach's alpha scores >0.7. Significant correlations were found between scores for Value and communication experience and between scores for Burden and barriers to health care.

Conclusions. Our instrument offers a valid, reliable measure of patients' views relating to value and burden of using health-related quality of life questionnaires. Its two domains show good internal reliability and with its free text items, it may offer a valuable, standardized assessment of face validity and utility of other questionnaires used in health care.

Keywords: patient satisfaction, factor analysis, statistical, questionnaire, quality of life, psychometrics

Introduction

The measurement of health-related quality of life (HRQoL) in clinical practice is increasingly recommended for the monitoring of outcome, but may also be of clinical benefit in terms of improved doctor–patient communication, increased discussion about the quality of life and improved emotional function [1–3]. HRQoL assessments are frequently an integral part of clinical trials. However, if such measures are to form part of clinical care, they should be practical and acceptable to users [4–7]. The psychometric testing of

questionnaires demands an assessment of face validity, often employing qualitative methods to ascertain levels of understanding and comprehension, relevance and meaning [8, 9]. Studies of clinical utility may also include measures of patient experience and opinion regarding interventions or investigations [10]. Qualitative methods for assessing face validity can be time consuming and expensive [10–12]. Our study reports on a quantitative measure of face validity and utility of questionnaires that offers a simple and effective tool for collecting standardized information on important aspects of a questionnaire's qualities, from the patient's perspective.

Such quantitative data will also allow comparisons to be made between different versions of an instrument in development, as well as different instruments applied in different clinical settings or populations.

QQ-10 is a 10-item self-completed questionnaire, designed to assess patients' views on their experience of using questionnaires during their medical care (Appendix I). It was designed as a measure of face validity and utility during the evaluation phase of ePAQ-PF (electronic Personal Assessment Questionnaire, Pelvic Floor) [8]. This paper describes the development and testing of QQ-10: a measure for measures.

Methods

In 2003, a focus group meeting was held involving women from the Sheffield Maternity User Group and members of the research team to discuss the development of a new questionnaire (ePAQ-PF) intended for clinical use. These women attended a meeting in the gynaecology out-patient department, in advance of which all were sent a paper version of the questionnaire under evaluation (ePAQ-PF) for review and comment. On arrival, the women were asked to review, comment on and complete the electronic version of ePAQ-PF. A tape-recorded semi-structured interview was then conducted, asking the women to give their views on the two versions of the questionnaire. In particular, women were specifically asked to comment on the attributes of ePAQ-PF. The transcript of this meeting was reviewed by the research team, identifying 10 key themes relating to questionnaire use. A series of 10 statements was produced, each statement using the same 5-point Likert response scale measuring levels of agreement, thereby creating a new instrument: the QQ-10.

Between November 2006 and April 2008, QQ-10 was administered to 265 women, all of whom had completed ePAQ-PF as part of their clinical care; 210 women completed QQ-10 immediately following an outpatient visit in the gynaecology clinic (when ePAQ-PF had been completed prior to and then used during their clinic consultation) and 55 women in the Virtual Urogynaecology Clinic (who completed ePAQ-PF prior to a telephone consultation). Women in the Virtual Clinic also completed the Patient Experience Questionnaire (PEQ); a validated 18-item consultation-specific instrument, measuring patients' views on five dimensions: communication; emotions; short-term outcome; barriers and relations with auxiliary staff (Appendix II) [1]. QQ-10 and PEQ data were anonymized and analysed using SPSS (version 14.0).

In order to establish the factor structure and underlying scales of QQ-10, principal component analysis (varimax rotation) was carried out [13]. Values of >0.5 , which were derived from the rotated component matrix, were considered meaningful. Internal reliability was assessed using Cronbach's alpha [14, 15]. An alpha value of 0.7 or more was considered acceptable. Response rates and levels of missing data for each item were determined. Construct validity was assessed

using Spearman's rho correlations between QQ-10 and PEQ scores. In the absence of another questionnaire designed to measure face validity, we hypothesized that if patients had a positive experience of using the ePAQ-PF questionnaire, i.e. patients found it valuable to their care, in terms of helping communication, being relevant to their condition, easy to complete, included their concerns, was enjoyable and they would be happy to complete it again (QQ-10: value items), this would correlate positively with the patients' communication experience of the consultation, as reflected by the PEQ communication experience scores, i.e. patients had a good talk, felt reassured, the doctor understood and they felt taken care of. In addition, we hypothesized that if the patient had a negative experience of using ePAQ-PF, i.e. they found it too long, embarrassing, complicated and upsetting (as reflected by QQ-10 burden scores), this would correlate with negative scores on the PEQ items for barriers to health care. Free text responses were grouped into positive and negative comments with categories relating to time efficiency, utility, comprehension and embarrassment associated with questionnaire use.

Results

The ePAQ validation study involved 265 women (mean age: 54 years, SD = 15.1, range: 20–87 years). When administered in clinic, all 210 women completed QQ-10; however, two women completed page 1 of 2 only and one woman omitted a single question. When administered postally to 55 women, 41 completed both QQ-10 and PEQ, giving a response rate of 75% (12 women failed to complete or return either questionnaire, 1 patient had missing items in both QQ-10 and PEQ and 1 had missing items in QQ-10).

The 10 statements relating to patients' views on questionnaire use translated into six positive or 'Value' items (helped communication, relevant, easy to use, comprehensive, enjoyable, willing to repeat) and four negative 'Burden' items (overlong, embarrassing, overcomplicated and upsetting). The 10 items of QQ-10 initially loaded onto three factors, the percentage cumulative variance of which was 63.5 (Table 1). The third factor included only two items (willingness to repeat and enjoyable); reliability analysis was enhanced when these two items were grouped into factor 2 (Value), producing two meaningful factors, which were felt to measure Value and Burden. Both factors achieved a Cronbach's alpha statistic of >0.7 . The alpha values were 0.74 for Factor 1 (Burden) and 0.76 for Factor 2 (Value). Each domain was transformed onto a scale of 0–100: 0 = minimum Value and minimum Burden, 100 = maximum Value and maximum Burden. Table 2 shows the internal reliability scores for Value and Burden and Cronbach's alpha values when individual items were omitted from the domains. A significant positive correlation was found between QQ-10 (Value) scores and PEQ scores for communication experience. Individual QQ-10 Value scores for 'helped me to communicate about my condition' and 'relevance to my condition' correlated positively with the PEQ

Table 1 Factor analysis of QQ-10 items (rotated component matrix^a)

QQ-10 items	Component		
	1	2	3
Helped communication	0.037	0.816	0.221
Relevant	0.069	0.847	0.057
Easy to use	0.489	0.554	-0.020
Comprehensive	-0.035	0.675	0.284
Willing to repeat	0.216	0.282	0.748
Enjoyable	0.114	0.162	0.835
Overlong	0.636	0.048	0.200
Embarrassing	0.806	-0.063	0.162
Overcomplicated	0.807	0.184	-0.138
Upsetting	0.659	0.026	0.371

Bold values represent significant values.

Factor analysis was performed on the 10 items of the 248 completed QQ-10 questionnaires, which initially loaded onto three factors. The extraction method used principal component analysis and the rotation method varimax with Kaiser normalization.

^aRotation converged in five iterations.

Table 2 Internal reliability of scale scores for QQ-10 domains

Domains	N	Internal reliability
Value		0.76
Helped communication	207	0.61 ^a
Relevant	207	0.62 ^a
Easy to use	207	0.75 ^a
Comprehensive	207	0.72 ^a
Willing to repeat	207	0.71 ^a
Burden		0.74
Overlong	208	0.73 ^a
Embarrassing	208	0.61 ^a
Overcomplicated	208	0.68 ^a
Upsetting	208	0.70 ^a

Bold values represent significant values.

^aCronbach's alpha if item omitted.

Table 3 Construct validity for QQ-10 using Spearman's rho correlations

QQ-10	Number	Value	Burden
	Correlation coefficient (two-tailed significance)		
Value	41	—	-0.515** (0.001)
Burden	41	-0.515** (0.001)	—
PEQ			
Outcome	40	0.186 (0.250)	0.063 (0.702)
Communication	40	0.490** (0.001)	-0.339* (0.032)
Barriers	41	0.614** (0.000)	-0.535** (0.000)

**Correlation is significant at the 0.01 level (two-tailed).

*Correlation is significant at the 0.05 level (two-tailed).

communication experience item 'had a good talk' as shown by Spearman's rho correlations of 0.338* and 0.544**, respectively [*correlation significant at the 0.05 level; **correlation significant at the 0.01 level (two-tailed)]. A significant negative correlation was seen between QQ-10 (*Burden*) scores and PEQ scores for barriers to health care (Table 3). The mean score for Value was 82 (SD 14, median 83, range 29 to 100) and the mean Burden score was 25 (SD 21, median 25, range 0–88). The percentage minimum and maximum scores for Value were 0.48 and 9.1, respectively, and the percentage minimum and maximum scores for Burden were 16.75 and 0.48, respectively. Figure 1 shows the Value and Burden scores categorized into quartiles. Only 2.8% of Value scores fell into the first and second quartiles, compared with 91.4% of Burden scores. However, 97.2% of Value scores, compared with only 8.6% of Burden scores, grouped into the third and fourth quartiles.

The free text option was utilized by 49% of respondents. These three items seek written comments from subjects regarding the questionnaire that they have just used, suggestions for improvement, as well as items or issues that they felt were under or over represented; 42% of comments made related to the process of using the questionnaire and 39% of comments related to the questionnaire in the context of their personal condition. Positive comments included issues such as being able to complete the questionnaire in private, having time to consider their answers, finding ePAQ-PF easy to complete and less embarrassing than face-to-face consultation. Negative comments included ePAQ-PF being too time consuming, response options being too limited or that specific symptoms or problems were inadequately covered (Table 4).

Discussion

HRQoL measurement is increasingly recognized as an important component of health care and patient reported outcome measures (PROMs) are increasingly advocated [9, 16]. Such measures may be particularly relevant when symptoms and their impact on the quality of life represent key elements in diagnosing conditions, assessing severity

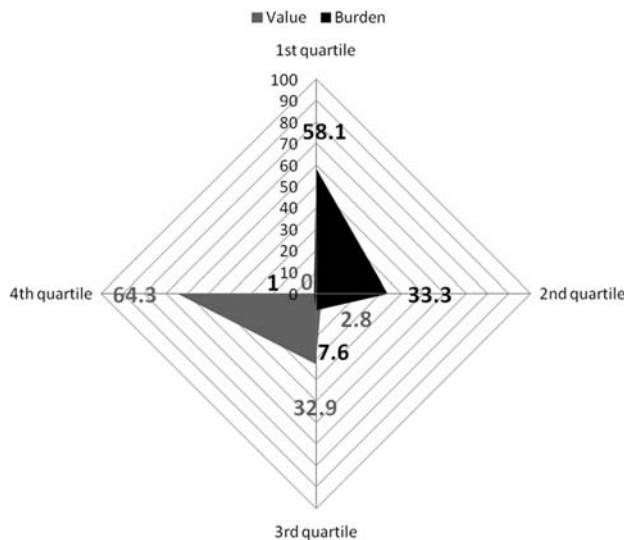


Figure 1 Percentage scores for Value and Burden. Value and Burden scores categorised into quartiles; 2.8% of value scores fell into the first (0%, $n = 0$) and second (2.8%, $n = 6$) quartiles, compared with 91.4% of Burden scores, 58.1% ($n = 122$) in the first quartile and 33.3% ($n = 70$) in the second quartile. 97.2% of Value scores, 32.9% ($n = 69$) and 64.3% ($n = 135$) grouped into the third and fourth quartiles, respectively, compared with 8.6% of Burden scores, 7.6% ($n = 16$) and 1% ($n = 2$) into the third and fourth quartiles, respectively.

and monitoring outcome. The validity and reliability of instruments are commonly reported [8, 17]. However, patients' experiences and views are also important, particularly if instruments primarily designed to meet the requirements of research outcome measures are applied in routine clinical practice [18]. If patients find an instrument valuable, relevant and easy to use, compliance and uptake are likely to be high, whereas if burdensome, unhelpful or irrelevant, the converse is likely to occur [19]. Instruments may enhance as well as detract from the clinical episode and an objective measure of patients' experiences and views may be highly relevant when designing, selecting and adapting instruments for clinical practice [19, 20].

This study has established the internal reliability of the two domains of QQ-10 (Value and Burden), which show good internal consistency and item correlation. High completion rates and low rates of missing data suggest that QQ-10 was itself easy to administer (both directly to patients in clinic as well as by post) and that subjects found it acceptable and understandable. In the context of evaluating ePAQ (the questionnaire being evaluated with QQ-10), the QQ-10 proved helpful; the high Value and low Burden scores suggested that ePAQ impacted positively on the clinical episode for the majority of women. The three free-text items in the QQ-10 provided qualitative data in the form of written feedback on (i) possible improvements, (ii) missing items or issues and (iii) over represented areas. 49% of respondents

made free text comments. Several patients reported improved communication by allowing the disclosure of issues that they would otherwise be too embarrassed to discuss face-to-face and additionally, that the questionnaire helped to focus the consultation on issues that they themselves perceived as being important. Positive comments such as 'Less embarrassing to tell computer', 'Helped me focus' and 'Saved time', proved helpful in implementing and supporting the implementation of ePAQ. Negative comments, such as 'Website did not respond some of the time' and 'No room to expand answers', provided specific patient-based data to direct enhancements to the questionnaire, such as the re-engineering of the ePAQ web-site and the creation of free-text items in ePAQ itself to allow self-expression.

Significant correlations were found between QQ-10 (Value) and PEQ communication experience scores, and between individual QQ-10 Value scores for 'helped me to communicate about my condition' and 'relevance to my condition' with the PEQ communication experience item 'had a good talk'. This suggests that if patients' have a positive experience of using the ePAQ-PF questionnaire, and find it a valuable part of their care, in terms of helping communication, being relevant and easy to complete, including their concerns, being enjoyable and they would happily complete it again, then the patient will also have a positive experience of the consultation. Questionnaires that patients find burdensome risk poor compliance and low completion rates, with consequent high levels of missing or inaccurate data and a negative impact on the clinical episode. A measure of burden may be of value when trying to understand poor completion rates or data quality issues associated with a questionnaire. A significant negative correlation was seen between QQ-10 (Burden) scores and PEQ scores for barriers to health care, which suggests that if the patient finds completing the ePAQ-PF questionnaire, which is completed prior to the consultation, burdensome, as reflected by their QQ-10 Burden scores, the content and quality of the patients' consultation will be adversely affected, given that the consultation is based upon the outcome data of the ePAQ-PF questionnaire.

Clinician-patient communication is a central element in medical consultations and can be enhanced by questionnaires [3, 4]. In a randomized controlled trial evaluating HRQoL assessment tools, all physicians and 87% of patients believed that the instrument used facilitated communication and heightened awareness of HRQoL [3]. A meta-analysis of PROMs for mental health evaluation found increased documentation of diagnoses in case notes [21]. Other studies have reported promotion of shared decision-making, improved monitoring of disease progression and response to treatment, identifying vulnerable patients and enabling continuous assessment of quality of care [18, 22]. The use of PROMs in health care can be argued for a number of reasons; the definitions of many diseases and disorders relate to the concept of function, which is inextricably linked to outcome. In these instances, utilizing patient-based outcome measures may be extremely valuable in assessing the impact

Table 4 QQ-10 free text comments

	Comments Positive	Negative	Suggestions
Process of using questionnaire (<i>n</i> = 111)			
Time efficiency	Quick Saved time Saved hospital appointment/car parking Nice to have time to consider answer	Time consuming when done in clinic rather than at home Too long	
Utility and understanding	Done easily online Good visual tool Very easy to use Easy to answer Relaxed Helped me focus Very good idea Nice to share with partner	Website did not respond some of the time Range of answers not always fully comprehensive No room to expand answers	Try paper version for people not computer literate Some questions not relevant, try a N/A box Try optional free text box
Embarrassment	Less embarrassing to tell computer Easier for women too embarrassed to tell doctor Good to complete in private	Would rather talk to doctor Prefer to see doctor than telephone interview	
Questionnaire and subject's condition (<i>n</i> = 104)			
	Able to explain answers to doctor afterwards	Difficult to describe my bowel problems	Item on occupation if relevant More items on exercise Item on state of mind Item on medication

of interventions [23]. Our study has shown that QQ-10 can be a valuable tool in providing a standardized assessment of the face validity and utility of an instrument.

Despite reports of potential benefits and increasing interest in the use of HRQoL measurement, questionnaires have yet to be widely implemented in clinical practice. This may be in part due to a lack of evidence regarding benefits to patients and patient outcomes. A previous literature review regarding HRQoL measures in clinical practice found that patient outcomes were not substantially affected, though clinicians reported value in terms of overall patient assessment and increased detection of psychological and functional problems [24]. A systematic review found that the benefits of PROMs were limited or unproven [25]. HRQoL measurement can be extremely costly and with little or no robust evidence of benefit in improving psychosocial outcomes of patients managed in non-psychiatric settings, justifying their adoption is therefore inevitably difficult [11]. Questionnaire data may be perceived as vague, when compared with 'hard data' from laboratory tests [17]. Other reservations include potential interference with doctor–patient communication and patients' concerns regarding data protection [12]. Practical and attitudinal barriers include technical challenges associated with the creation of user friendly interfaces and safe data handling [1]. Scepticism about the validity and

utility of PROM data, unfamiliarity with interpretation, the need for rapid data processing and the lack of available resources pose additional barriers [10–12].

This study reports on a 10-item instrument specifically designed for evaluating such measures, in terms of their value and burden. The QQ-10 offers a standardized measure of face validity that may be valuable during the development of an instrument as well as during the implementation and clinical testing. QQ-10 data may provide insight into low compliance and high levels of missing data and help inform modifications or upgrades with a view to enhancing performance. Further studies are needed to further establish other aspects of the external validity of QQ-10 (e.g. construct and criterion validity), including studies involving other questionnaires in different healthcare settings and patient populations. Such studies will allow valid comparisons to be made between different instruments as well as evaluating the impact on patient experiences of modifications, such as creating electronic versions and short forms of existing instruments and the application of existing research outcome measures in clinical practice. QQ-10 is the first reported instrument designed for use in assessing HRQoL assessment tools in the clinical setting and may be of value to researchers and clinicians who wish to evaluate questionnaire use in this context; a measure for measures.

Details of ethics approval

Ethics approval was not sought for our study. All persons gave their informed consent prior to inclusion in the study.

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Conflict of interests

S.R. is a director and shareholder in EPAQ Systems Ltd, an NHS Spin out technology company.

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Appendix I

QQ-10

.....

QQ-10 Please circle the answers below each of the following 10 statements that best fit your feelings about the questionnaire that you recently completed. Please use the boxes at the bottom of the next page to make additional comments.

The questionnaire helped me to communicate about my condition
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

The questionnaire was relevant to my condition
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

The questionnaire was easy to complete
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

The questionnaire included all the aspects of my condition that I am concerned about
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

I enjoyed filling in the questionnaire
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

I would be happy to complete the questionnaire again in the future as part of my routine care
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

The questionnaire was too long
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

The questionnaire was too embarrassing
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

The questionnaire was too complicated
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

The questionnaire upset me
 Strongly agree Mostly agree Neither agree or disagree Mostly disagree Strongly disagree

Do you have any comments or suggestions on how the questionnaire you used could be improved (e.g. its structure, appearance or design)?

Were any of your important symptoms, problems or concerns missed out by the questionnaire you used?

Do you feel that any areas or problems in the questionnaire you used were over-represented?

Appendix II

Patient experience questionnaire (PEQ)

PEQ

In order to provide better service, we ask for your experience in this medical visit, what it felt like for you and what you think it will mean to you and your health situation.

Outcome of this specific visit

Do you know what to do to reduce your health problem(s)? (or how to prevent problems?)

Much more Some more A bit more Not much more No more

Do you know what to expect from now on?

Much more Some more A bit more Not much more No more

Will you be able to handle your health problems differently?

Much more Some more A bit more Not much more No more

Will it lead to fewer health problem(s)? (or help prevent problems?)

Much more Some more A bit more Not much more No more

Communication experience

We had a good talk

Agree completely Agree So-so Disagree Disagree completely

I felt reassured

Agree completely Agree So-so Disagree Disagree completely

The doctor understood what was on my mind

Agree completely Agree So-so Disagree Disagree completely

I felt I was taken care of

Agree completely Agree So-so Disagree Disagree completely

Barriers to healthcare

It was a bit difficult to connect with the doctor

Agree completely Agree So-so Disagree Disagree completely

Too much time was spent on small talk

Agree completely Agree So-so Disagree Disagree completely

It was a bit difficult to ask questions

Agree completely Agree So-so Disagree Disagree completely

Important decisions were made over my head

Agree completely Agree So-so Disagree Disagree completely

Experience with the auxiliary staff

I sensed that other patients could listen in when I was talking to the staff

Agree completely Agree So-so Disagree Disagree completely

I felt like one of the crowd

Agree completely Agree So-so Disagree Disagree completely

Emotions immediately after the visit

After this visit I felt (please circle one number for each line)

Relieved 7 6 5 4 3 2 1 Worried

Sad 7 6 5 4 3 2 1 Cheerful

Strengthened 7 6 5 4 3 2 1 Worn out

Relaxed 7 6 5 4 3 2 1 Tense