

Computer interviewing in urogynaecology: concept, development and psychometric testing of an electronic pelvic floor assessment questionnaire in primary and secondary care

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Objective To develop and evaluate a Web-based, electronic pelvic floor symptoms assessment questionnaire (e-PAQ)¹ for women.

Design A cross-sectional study in primary and secondary care.

Setting Two general practices, two community health clinics and a secondary care urogynaecology clinic.

Sample A total of 432 women (204 in primary care and 228 in secondary care) were recruited between June 2003 and January 2004.

Methods The e-PAQ was located on a workstation (computer, touchscreen and printer). Women completed the e-PAQ prior to their appointment. Untreated women in primary care were asked to return seven days later to complete the e-PAQ a second time (test–retest).

Main outcome measures Factor analysis, reliability, validity, patient satisfaction, completion times and system costs.

Results In secondary care, factor analysis identified 14 domains within the four dimensions (urinary, bowel, vaginal and sexual symptoms) with internal consistency (Cronbach's alpha) ≥ 0.7 in 11 of these. In primary care, alpha values were all ≥ 0.7 and test–retest analysis found acceptable intraclass correlations of 0.50–0.95 ($P < 0.001$) for all domains. A measure of face validity and utility was gained using a nine-item questionnaire, which yielded strongly positive patient views on relevance and acceptability.

Conclusions The e-PAQ offers a user-friendly clinical tool, which provides valid and reliable data. The system offers comprehensive symptoms and quality of life evaluation and may enhance the clinical episode as well as the quality of care for women with pelvic floor disorders.

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Introduction

It is estimated that approximately 20% of adult women experience regular urinary incontinence, 5% are incontinent of faeces and 10% suffer with prolapse.^{1–3} Many pelvic floor disorders have common aetiologies and commonly coexist. A comprehensive approach to the evaluation of pelvic floor symptomatology is therefore desirable. Questionnaires are

increasingly used to reliably and objectively measure health-related quality of life in outcomes research and epidemiology.⁴ In clinical practice, however, the burden of completing and processing paper questionnaires limits their use.⁵ The concept of an electronic pelvic floor assessment questionnaire (e-PAQ) arose from a desire to reduce this burden by using computer interviewing. Previous research has found that electronic systems can achieve superior response rates and subjects may find them easier and more enjoyable to complete.⁶ Computerised questionnaires are comparable in terms of reliability and validity and can be

¹ The e-PAQ can be accessed online at the following website: <<http://www.epaq.co.uk>>.

superior in terms of efficiency and acceptability.^{7–9} Cost analysis has shown that for large surveys, they may also have economic advantages.^{8–11} However, despite encouraging and enthusiastic reports, this technology has yet to find widespread clinical use.

The aim of this study was to develop and evaluate a new Web-based, electronic pelvic floor symptoms assessment questionnaire (e-PAQ). The objectives were to establish its feasibility, psychometric properties (reliability and validity) and application in women attending a urogynaecology unit and unscreened women in primary care.

Methods

The e-PAQ was developed following experience with existing paper-based instruments. The Birmingham Bowel and Urinary Symptoms Questionnaire (BBUS-Q),¹² Sheffield Prolapse Symptoms Questionnaire (SPS-Q)¹³ and Female Sexual Function Index (FSFI)¹⁴ were initially administered together in a battery of questionnaires. Consultation with specialists in urology, gynaecology, colorectal surgery and sexual medicine identified additional items, whose format was then unified to achieve consistency across different dimensions. Sub-questions on impact were included [as used in the ICS (Male) and Bristol Female Lower Urinary Tract Symptoms Questionnaires].¹⁵

A prototype electronic version was developed with the aim of facilitating self-entry of data by patients directly to a database. In order to assess the acceptability of this approach, the instrument was reviewed by the local maternity user group who provided critical feedback. Further modifications were followed by a pilot study involving 213 women, evaluating its form, content and relevance.¹⁶ On the basis of these findings and further user-group review, version 2 of the instrument was produced and underwent evaluation in the present study.

The e-PAQ is a Web-based system originally constructed around a Microsoft Access database. This incorporated all the technical elements; physical layout and display (e.g. colours, buttons and font sizes), item content and response data. Active Server Pages (ASP) were used to add dynamic and interactive elements, providing the patient–database interface, which was accessed using Internet Page Display via Microsoft Internet Explorer. The use of a resistive 15-in. touch screen allowed subjects to complete the questionnaire without the use of a keyboard or mouse (Fig. 1).

The subject's demographic details are entered, following which introductory pages provide subjects with instruction in the use of 'Help' 'Back', 'Next' and 'Skip' functions, which assist unsupervised completion of the questionnaire. Accidental non-response (a fundamental problem with paper-based instruments) is effectively eliminated as progression is only permitted once a response has been selected. Items may be skipped depending on responses to earlier screening questions

and supplementary questions relating to bother are only displayed if symptoms are reported. All responses are stored as numeric code in a secure password protected central database. On completion, a printout is available, presenting the subject's responses to individual items in each dimension and highlighting their most bothersome symptoms.

To assess the feasibility and psychometric properties of the e-PAQ (reliability and validity), the questionnaire was administered to a cross section of patients attending primary care (two general practices and two community health clinics) and secondary care (urogynaecology clinic) in Sheffield. Approval for this study was obtained from the Local Research Ethics Committee. Only women over 16 years old and able to read English were approached. All potential recruits were given an information sheet to read describing the study and an opportunity to discuss the study with a research nurse. Women who agreed to participate were asked to sign a consent form.

Questionnaires completed in the urogynaecology clinic were automatically entered into a database located in a share (protected area) on the central hospital server, access to which was restricted to named investigators. On completion, each participant was seen in clinic by the clinician (SCR), who was provided with a printout of the subject's data. Before leaving clinic, all women were asked to complete a nine-item questionnaire relating to their views on the acceptability, relevance and value of using the e-PAQ.

In primary care, self-referring women were recruited without prior knowledge of any pre-existing pelvic disorders in order to assess its application in an unscreened population.

Women attending the two GP practices and two community health clinics were informed of the study and asked to attend early in order to complete the questionnaire prior to their appointment. The e-PAQ was located on a portable workstation in each clinic. This included a computer, touchscreen and printer. The research nurse entered the patient's demographics and introduced the patient to the questionnaire, which was then completed in private. Data were transferred on a weekly basis to the secure central hospital server. Once this transfer had been carried out, all data on the portable workstations were erased.

Questionnaire data were transferred to SPSS for statistical analysis. e-PAQ domains were re-coded into scores, with each scale transformed on a range from 0 (indicating best health status) to 100 (worst health status) enabling the extent of ill health to be measured (domain score = total of raw scores for each item in the domain / maximum possible raw score × 100).

Factor analysis is a statistical procedure, which enables the underlying domains of a questionnaire to be determined.¹⁷ Therefore, in order to identify the domains (scales) of the e-PAQ, factor analysis (principal component analysis using varimax rotation) was carried out on the secondary care data. This analysis was then repeated using the data obtained in primary care.

Figure 1. Examples of e-PAQ items. Touching the buttons on the screen changes them from yellow to red. The supplementary question 'How much of a problem this is for you?' is only displayed if the patient has symptoms. The tool bar at the bottom of the screen allows subjects to move forwards or backwards through the questionnaire, as well as access to Help pages.

To measure the reliability of the questionnaire, both internal consistency reliability and test-retest reliability were assessed. Internal consistency reliability is an indication of how well the items within a scale are associated with each other and Cronbach's α is the measure which is most frequently used for establishing this. Scores greater than 0.7 usually indicate that scale items are measuring related constructs.¹⁸

Test-retest reliability provides a measure of an instrument's stability over time.¹⁷ Women who completed the e-PAQ in primary care were asked to re-attend seven days later to complete it a second time. They were also asked to answer a single question enquiring whether or not there had been any change in their health in between completing the two questionnaires; test-retest analysis was only undertaken on women who reported 'no change at all' in their health status. Test-retest reliability was not assessed in secondary care as these women typically receive pelvic floor interven-

tions and/or advice at the time of their first consultation. Wilcoxon-signed rank test (non-parametric) was used to detect any statistical differences between scores. The intraclass correlation coefficient was calculated to examine the relationship between scale scores at time 1 and time 2. The results were taken to be significant if $P < 0.05$.

To establish the validity of the questionnaire, both face and construct validity were assessed. Face validity is a measure of how relevant, appropriate and understandable items in a questionnaire are to its overall focus or aim.⁴ Although on its own, face validity does not ascertain the true validity of a questionnaire, it is important to establish as it can identify ambiguities in the wording of items, identify irrelevant or missing items and improve the cooperation of respondents.¹⁷

To measure the acceptability and face validity of the e-PAQ, patients' views were assessed using a nine-item paper questionnaire. This recorded subjects' agreement or disagreement with five positive and four negative statements about

whether they found the e-PAQ to be helpful, relevant, easy to use, happy to use again, comprehensive, overlong, upsetting, over-complicated or embarrassing. In addition, women from the local maternity user group ($n = 6$) were also asked to review the instrument and to comment on items they felt may be missing, difficult to understand, upsetting or offensive.

An instrument's construct validity is usually determined by assessing the relationship between scores produced by the instrument and existing hypotheses or theories of health.¹⁹ We hypothesised that lower mean scores would be obtained in each domain from the data obtained from unscreened women in primary care (indicating better health), compared with those obtained in women attending the urogynaecology clinic. We also hypothesised that the range of recorded symptoms and the proportion of women who recorded maximal symptoms would be less for each domain in primary care, compared with women in the urogynaecology clinic.

Results

A total of 228 women were recruited in secondary care (mean age 52 years, SD = 14) and 204 women were recruited in primary care (mean age 53 years, SD = 13).

The automatic skipping of non-relevant items was disabled for the purposes of this study. This 'non-interactive' version of the questionnaire had a median completion time of 26 minutes (range 14–38 minutes, SD = 14) in secondary care and 33 minutes (range 12–103 minutes, SD = 16) in primary care.

Factor analysis (principal component analysis, varimax rotation) using the secondary care data produced 14 clinically meaningful factors, comprising a total of 58 items, accounting for a cumulative 79% of the variance (i.e. most of the variance for the original 94 items is accounted for in the 14 common factors produced) (Table 1). Secondary factor analysis of the 58 items using the primary care data supported the same factor structure derived from the analysis carried out in secondary care.

The internal reliability of the 14 domains was assessed using Cronbach's alpha (Table 2). In secondary care, 11 domains achieved an alpha value of ≥ 0.7 . In primary care, 13 domains achieved alpha values of ≥ 0.7 (the bowel symptoms and sex domain had an α value of 0.67).

Table 3 shows the mean domain score for each scale and shows the most prevalent and troublesome pelvic floor disorders in the two groups. Each domain scored from 0 to 100 (higher scores representing more troublesome symptoms).

Table 1. Domains of the e-PAQ produced from factor analysis of secondary care data

Summary of individual items	
Urinary domains	
Pain* (U12 and U13)	Bladder pain, pain relieved by micturition
Overactive bladder (U19–U22)	Urgency, urgency incontinence, hand wash incontinence, key in the door incontinence
Stress incontinence (U25–U27)	Cough and sneeze incontinence, exercise incontinence, movement incontinence
Quality of life (U31–U33)	Impact on physical activities, impact on social activities, impact on enjoyment of life
Bowel domains	
Constipation (B4 and B5)	Stool frequency, stool consistency
Evacuation (B6–B13)	Straining, incomplete emptying, painful evacuation, laxative use, duration of defecation, anal digitation, vaginal digitation, urge without evacuation
Incontinence (B15–B20, B22)	Urgency, inability to defer, faecal urge incontinence, flatus incontinence, liquid stool incontinence, solid stool incontinence, insensible faecal incontinence
Quality of life (B23–B25)	Impact on physical activities, impact on social activities, impact on enjoyment of life
Vaginal domains	
Sensation (V5–V8)	Dryness, soreness, reduced sensation, dragging pain
Prolapse (V9, V12, V13, V14)	Something coming down, vaginal laxity, awareness of lump, complete prolapse
Quality of life (V15–V17)	Impact on physical activities, impact on social activities, impact on enjoyment of life
Sexual domains	
Urinary and sex (S4–S8)	Incontinence during sex, avoids sex c/o bladder, partner avoids c/o bladder, bladder worries and sex, overall impact on sex
Bowel and sex (S9–S13)	Incontinence during sex, avoids sex c/o bowel, partner avoids c/o bowel, bowel worries and sex, overall impact on sex
Vaginal and sex (S14–S18)	Pain/discomfort and sex, avoids sex c/o vagina, partner avoids c/o vagina, vaginal worries and sex, overall impact on sex

Extraction method: principal component analysis. Rotation: varimax with Kaiser normalisation.

*NB: The letter and numbers refer to the questions on the e-PAQ questionnaire.

Table 2. Internal reliability of scale scores for e-PAQ domains in primary and secondary care

Domains	Primary care		Secondary care	
	Internal reliability	No.	Internal reliability	No.
Urinary				
Pain	0.84	203	0.73	221
Overactive bladder	0.90	204	0.75	225
Stress incontinence	0.94	204	0.72	227
Quality of life	0.94	202	0.86	227
Bowel				
Constipation	0.93	202	0.60	220
Evacuation	0.93	202	0.78	220
Incontinence	0.89	199	0.65	219
Quality of life	0.93	202	0.79	222
Vaginal				
Sensation	0.89	196	0.60	220
Prolapse	0.82	149	0.81	207
Quality of life	0.95	201	0.88	220
Sexual				
Urinary and sex	0.97	120	0.85	116
Bowel and sex	0.66	121	0.87	110
Vaginal and sex	0.96	138	0.90	128

One hundred and twenty-six women (62%) returned a second time to complete the questionnaire in primary care. The test–retest results for the 14 clinically relevant domains are shown in Table 4.

The results from the follow up questionnaire assessing patients' views are shown in Table 5. In primary care, 105 (52%) of these questionnaires were returned. In secondary care it was completed by 140 women (61%). An open free-text question sought women's criticisms of the instrument. This identified a lack of items relating to urinary voiding problems and irritable bowel as well as the issue that the questionnaire did not address their partner's health as a cause of sexual dysfunction. The problem that irrelevant items were not skipped automatically was also commonly cited (automatic skipping of items had been disabled for the purposes of this validation).

As hypothesised, all mean domain scores in secondary care were higher than those in primary care (Table 3). These differences were most pronounced in urinary and vaginal domains, reflecting the case mix of the urogynaecology clinic. The ranges of recorded symptoms and the proportion of women recording maximal symptoms were greater in secondary than primary care.

The costs of computer hardware relate to the units currently in use and are based on retail prices (not including VAT) at time of going to press. The computers used were Dell Optiplex GX270 PCs with 2.8 GHz Pentium processors

installed with the Windows XP operating system (total cost £600). Touchscreens are Protouch resistive 15-in. A-frame TS15LBREI001 screens (cost £590). The installation, networking and maintenance of touchscreen computers are dependent on local IT department costings. In our unit this amounts to £200 per unit.

Discussion

We report the results of a study assessing the validity and feasibility of using an e-PAQ in primary and secondary care. The study found the instrument to be both feasible to administer and psychometrically robust. Despite the taboo nature of many of the items, the questionnaire was well received by women in both settings. The e-PAQ was originally developed in secondary care, based on experience in developing and validating paper questionnaires for outcomes research and was primarily intended to reduce the burden of data entry and analysis. However, the outcome of this work appears to be a system that is meaningful, valuable and relevant to both patients and clinicians.

Preliminary psychometric testing suggests that the instrument has good stability, internal reliability and validity in both primary and secondary care. Expected differences were observed between primary and secondary care samples in the profile and magnitude of symptoms, thereby supporting construct validity.¹⁹ In keeping with previous epidemiological studies, constipation, stress urinary incontinence and overactive bladder were highly prevalent in both samples.^{20,21} Most women found the instrument to be straightforward, relevant and acceptable, further supporting the view that this form of computer interviewing may provide a worthwhile and valuable addition to both clinical practice and research.²²

The longer completion times observed in primary care may be attributable to the fact that these unscreened women had not previously considered many of the issues addressed by the instrument. The greater internal reliability observed in the primary care population may be a reflection of the higher proportion of asymptomatic individuals (and therefore greater homogeneity) in this cohort, although overall internal reliability was demonstrated in the secondary care (symptomatic) group. With the introduction of interactive skipping, based on responses to initial screening items, it is anticipated that completion times will improve, as will the intuitive nature of the instrument, minimising respondent burden while ensuring detailed, relevant and appropriate assessment. The reliability, validity and utility of this upgraded, amended and fully interactive version will need to be established in future studies. In particular, the factor structure and reliability of the domains will again require testing.

In the light of the study findings, modifications have been made, with additional items relating to urinary voiding dysfunction, irritable bowel symptoms and vaginal capacity. The

Table 3. Distribution of scale scores for the e-PAQ domains in primary and secondary care

Domains	Primary care				Secondary care					
	Mean	SD	Percentage with minimum score	Percentage with maximum score	Range	Mean	SD	Percentage with minimum score	Percentage with maximum score	Range
Urinary										
Pain	5.7	12.1	78	1	0–62.5	30.3	29.0	30	4	0–100
Overactive bladder	10.7	12.4	38	1	0–56.3	15.4	21.0	58	1	0–83
Stress incontinence	11.6	14.8	39	1	0–75.0	27.7	19.2	9	1	0–92
Quality of life	7.1	14.2	67	2	0–75.0	30.9	26.2	19	1	0–100
Bowel										
Constipation	42.0	14.9	1	3	0–77.8	56.8	18.7	2	2	0–100
Evacuation	10.9	10.3	12	1	0–59.4	17.2	13.4	7	1	0–62.5
Incontinence	9.4	7.7	13	1	0–37.9	16.6	10.8	6	1	0–48
Quality of life	3.5	7.3	73	1	0–50.0	8.6	15.4	64	1	0–89
Vaginal										
Sensation	9.3	10.4	38	2	0–43.8	21.0	17.6	17	1	0–100
Prolapse	3.1	6.9	54	1	0–37.5	19.0	24.4	42	1	0–100
Quality of life	2.5	8.3	85	1	0–58.3	13.6	22.4	58	1	0–100
Sexual										
Urinary and sex	3.4	9.6	46	1	0–60.0	18.2	21.4	35	1	0–93
Bowel and sex	1.8	4.6	48	2	0–20.0	6.3	14.0	62	1	0–100
Vaginal and sex	7.0	12.6	40	1	0–70.0	25.2	26.1	25	2	0–100

sexual dimension now includes an item relating to the subject's willingness to answer as well as the influence of their partner's health on sexual activity. It is anticipated that these modifications, as well as the introduction of automatic inter-

active skipping of irrelevant items, will further enhance the utility of the instrument. Further psychometric testing of the questionnaire is now under way, including the assessment of responsiveness, reliability and validity in different healthcare settings.

Future evaluations and experience in different centres will also assess the impact of the e-PAQ on clinical decision making, diagnosis and management, using outcome measures such as referral rates, prescribing patterns, cost and satisfaction. The criterion validity of the instrument has yet to be fully established and further studies are needed to compare each domain of the e-PAQ with relevant existing instruments and measures.²³

Equipment costs, logistics, IT support, data security and patient confidentiality need careful consideration. Many of these issues are becoming less problematic with the advent of governmental and trust initiatives towards electronic patient records, enhanced network access, reliability and data security using NHS servers. It is worth considering that paper-based systems also present important data protection challenges and that electronic systems may have some advantages in this respect, for example, the final question in the e-PAQ now routinely records patients' willingness for their data to be used for service evaluation and audit.

Conclusion

Although the potential benefits of computerised questionnaires have previously been described, the failure of this tech-

Table 4. Test–retest analysis ($n = 126$)

Domains	Intraclass correlation	95% confidence interval	α
Urinary			
Pain	0.73	0.63–0.80	0.84
Overactive bladder	0.82	0.75–0.87	0.90
Stress incontinence	0.90	0.85–0.93	0.94
Quality of life	0.89	0.84–0.92	0.94
Bowel			
Constipation	0.87	0.82–0.91	0.93
Evacuation	0.87	0.81–0.91	0.93
Incontinence	0.80	0.72–0.86	0.89
Quality of life	0.88	0.83–0.91	0.93
Vaginal			
Sensation	0.80	0.73–0.86	0.89
Prolapse	0.70	0.59–0.78	0.82
Quality of life	0.91	0.87–0.94	0.95
Sexual			
Urinary and sex	0.95	0.92–0.96	0.97
Bowel and sex	0.50	0.35–0.63	0.67
Vaginal and sex	0.93	0.90–0.95	0.96

$P < 0.001$ for each analysis.

Table 5. Percentage of patients' views on the acceptability and value of using the e-PAQ in primary and secondary care (105 patients in primary care; 140 in secondary care). Percentages rounded up for clarity. Not all rows add up to 100% because of missing data

	Setting	Strongly agree	Mostly agree	Neither agree or disagree	Mostly disagree	Strongly disagree
Positive statements						
Helpful	1° care	19	43	33	3	1
	2° care	46	40	12	1	0
Relevant	1° care	9	42	40	2	1
	2° care	43	43	11	1	1
Straightforward	1° care	67	28	3	1	1
	2° care	51	37	3	1	0
Happy to do again	1° care	55	30	9	2	4
	2° care	66	21	5	4	1
Comprehensive	1° care	12	38	37	7	1
	2° care	40	40	9	5	0
Negative statements						
Overlong	1° care	2	13	21	30	34
	2° care	4	11	29	26	30
Upsetting	1° care	0	2	9	12	77
	2° care	1	0	9	15	74
Complicated	1° care	0	4	12	34	50
	2° care	1	6	10	30	52
Embarrassing	1° care	1	5	20	34	40
	2° care	1	6	18	29	46

nology to be widely adopted in clinical practice may be a reflection of resistance to change as well as cost, feasibility and utility. The costs of hardware have fallen dramatically over recent years, mirrored by substantial advances in the sophistication, reliability and accessibility of electronic systems, now making computer interviewing a truly realistic and affordable proposition. The programmed ability of the e-PAQ to present data in a clinically meaningful way means that the accuracy and reliability of questionnaire data, traditionally employed for research purposes, can now be translated into tangible clinical benefits.

The utility of the e-PAQ is being further enhanced by engineering the software for use on tablet and hand-held computers as well as including information links and inbuilt clinical algorithms. Its anticipated use in other centres will establish its value across a wider spectrum of disciplines (e.g. colorectal surgery, urology, physiotherapy and primary care), where it may be a welcome addition to routine clinical practice. It has obvious potential for use in service evaluation, audit and outcomes research. The software has also been engineered to facilitate the transfer of this approach to other areas of healthcare, where it may be of particular value in areas that also require a detailed evaluation of symptomatology.

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