



Contents lists available at ScienceDirect

# European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: [www.elsevier.com/locate/ejogrb](http://www.elsevier.com/locate/ejogrb)

Full length article

## Development and initial validation of an electronic personal assessment questionnaire for menstrual, pelvic pain and gynaecological hormonal disorders (ePAQ-MPH)

Thomas G. Gray<sup>a,\*</sup>, Karen L. Moores<sup>b</sup>, Ellie James<sup>c</sup>, Mary E. Connor<sup>a</sup>, Georgina L. Jones<sup>d</sup>, Stephen C. Radley<sup>a</sup>

<sup>a</sup> Obstetrics, Gynaecology and Neonatology directorate, Sheffield Teaching Hospitals NHS Foundation Trust, Jessop Wing, Tree Root Walk, Sheffield, S10 2SF, UK

<sup>b</sup> University Hospitals Leicester NHS Trust, Infirmary Square, Leicester, LE1 5WW, UK

<sup>c</sup> University of Sheffield Medical School, Beech Hill Road, Sheffield, S10 2SA, UK

<sup>d</sup> Leeds Beckett University, City Campus, Leeds, LS1 3HE, UK



### ARTICLE INFO

#### Article history:

Received 22 November 2018

Received in revised form 15 March 2019

Accepted 18 May 2019

#### Keywords:

Patient reported outcome measures  
Menstruation  
Pelvic pain  
Pre-menstrual syndrome  
Quality-of-life

### ABSTRACT

**Objective:** Menstrual disorders, pelvic-pain and gynaecological hormonal conditions in women can have a significant impact on quality-of-life. Reliable assessment and monitoring of these intimate conditions is challenging. Patient reported outcome measures (PROMs) can be invaluable in providing objective assessment, but no comprehensive PROM assessing all of these conditions and their impact on quality of life is currently available. The purpose of this study was to develop and undertake initial psychometric testing of a comprehensive interactive electronic patient reported outcome measure for these conditions. **Study design:** A prototype electronic PROM (ePAQ-MPH) was developed following systematic literature review, semi structured interviews with 25 patients and expert panel review. Exploratory factor analysis was undertaken in 291 women attending a menstrual-disorders clinic; establishing a domain structure and enabling item reduction. Two validated PROMS (Women's Health Questionnaire and Menstrual Distress Questionnaire) were completed to assess criterion validity in 213 patients. Test-retest reliability was carried out in 30 women completing ePAQ-MPH at least one week apart. Patients' views on 'Value' and 'Burden' were assessed in 278 women using a validated 10-item survey measuring questionnaire utility (QQ-10). Confirmatory factor analysis (CFA) of the revised version of ePAQ-MPH following item reduction was undertaken in a different sample of 254 women.

**Results:** Exploratory factor analysis identified 18 domains (Cronbach's  $\alpha > 0.7$ ) and 30 redundant items. Test-retest analysis found acceptable intra-class correlations of 0.6–0.9 ( $p < 0.05$ ). Eight domains were compared with Menstrual Distress Questionnaire showing moderate or strong correlation in seven domains. Ten domains were compared with Women's Health Questionnaire, six of which showed moderate correlation. Mean QQ-10 Value and Burden scores were 76 and 25, respectively (SD=15.8 and 15.5). The mean completion time for ePAQ-MPH was 31 min. CFA of the revised version 2 instrument with 15 domains showed good model fit.

**Conclusions:** Whilst wider psychometric testing of the revised version of ePAQ-MPH is required, including in different settings and in assessments of data quality and responsiveness, initial analysis provides some evidence for reliability, validity and acceptability of this multi-dimensional electronic PROM. ePAQ-MPH shows potential for both patient assessment and roles in service evaluation and research.

© 2019 Elsevier B.V. All rights reserved.

### Introduction

Menstrual disorders and associated pelvic pain and gynaecological hormonal symptoms are common and can have a profound and debilitating effect on health-related quality of life (HRQoL) [1–5]. There is often an overlap between heavy menstrual bleeding, pelvic pain and gynaecological hormonal symptoms such as premenstrual syndrome and perimenopausal symptoms [6].

\* Corresponding author at: Room 15, Level 4, Jessop Wing, Tree Root Walk, Sheffield, S10 2SF, UK.

E-mail address: [Thomas.Gray@doctors.org.uk](mailto:Thomas.Gray@doctors.org.uk) (T.G. Gray).

The main aim of treatment for menstrual disorders is to improve HRQoL and therefore it is important that valid and reliable patient reported outcome measures (PROMs) are available to measure both symptoms and their impact on HRQoL.

PROMs are instruments designed to provide means of measuring conditions, their impact and outcome following intervention, from the patient's perspective. [7] The use of PROMs in all areas of healthcare has become increasingly widespread [8,9] and their use in sensitive conditions, where patients may not disclose embarrassing symptoms is potentially invaluable [10–12].

A number of PROMs have been described for use in women with menstrual, pelvic pain and gynaecological hormonal disorders. However, existing instruments are either condition specific [13–15] or limited to one symptom area of menstrual disorders; specifically assessing heavy menstrual bleeding [16–18], pelvic pain [19], sexual function [20], health related quality-of-life [21–24] or premenstrual syndrome alone. [25–28]. The majority of instruments are paper-based, adding a significant administrative burden to their use in clinical practice [29].

The objective of this study was to develop and undertake psychometric testing of a comprehensive electronic PROM instrument for women with menstrual symptoms, pelvic pain and gynaecological hormonal symptoms, including assessments of HRQoL and sexual function. The context of use (COU) for this PROM would be for both baseline assessment of women referred to secondary care in gynaecology with these conditions and when they are reviewed for follow up.

## Materials and methods

Ethical approval was obtained from the Sheffield Local Research Ethics Committee (Reference number 09/H1308/21).

### Instrument development

The platform technology (ePAQ) used to create this electronic PROM was first developed in urogynaecology [30]. Design features

of ePAQ were incorporated into the new instrument, but with entirely new content.

To form a basis for sound content and face validity, development of the PROM started with a systematic literature review of existing women's health PROMs and semi-structured interviews with 25 patients conducted by a social scientist experienced in PROM development, these were voice-recorded, transcripts made and subjected to thematic content analysis [31].

Drafting of items, identified as relevant from both the systematic review and the content of the semi-structured interviews, was then undertaken following Food and Drug Administration (FDA) guidance on PROM development [32] and an initial paper-based prototype PROM was developed by an expert panel (two gynaecologists, social scientist and specialist nurse) before converting to a first electronic prototype comprising of 102 scored items. This PROM is called electronic Personal Assessment Questionnaire- Menstrual, Pain and Hormonal (ePAQ-MPH).

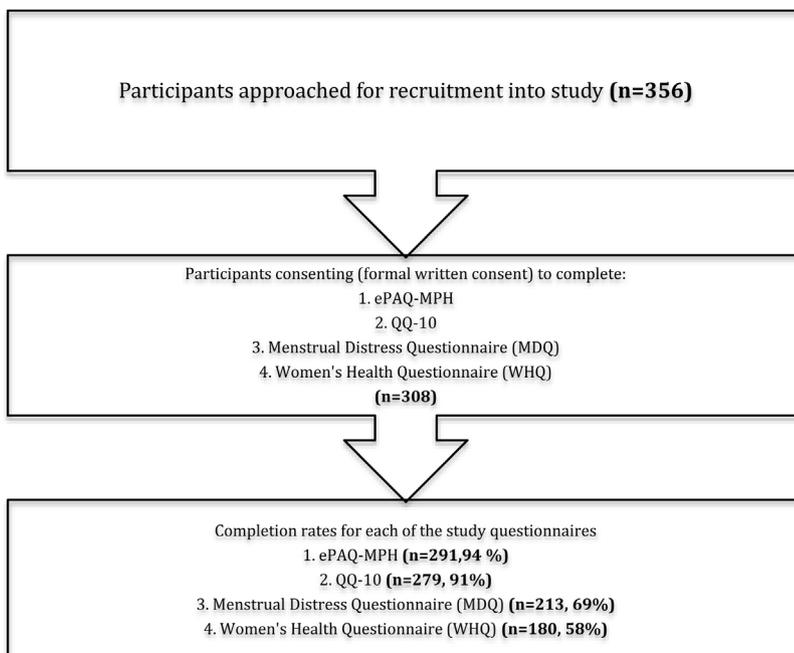
Eligible patients (female, age over 18, able to understand written English and attending the menstrual disorder outpatient clinic) were recruited into the study between August 2015–June 2016 and formal written consent was taken. Participants were asked to complete ePAQ-MPH followed by three paper based questionnaires which would assess acceptability and criterion validity. Table 1 presents a flow chart detailing recruitment and completion rates.

### Scale generation and internal reliability

ePAQ MPH was administered to 308 consenting female patients attending the menstrual disorders gynaecology clinics at Sheffield Teaching Hospitals. Data collected were analysed using SPSS (IBM, Version 22.0, IBM Corporation, 2013, Armonk, New York).

Psychometric testing consisted of exploratory factor analysis with Varimax rotation. Factor analysis is a statistical procedure which enables the underlying domains or scales of an instrument to be determined. Initially, factors (groups of items) which gained an Eigen value (raw sum of the squares) of >0.5 were considered as

**Table 1**  
Recruitment into study and completion rates for ePAQ-MPH and study questionnaires.



constituting potential domains, each of which contained a minimum of three items [33]. A potential domain structure and redundant items were thereby identified.

Internal reliability is the extent to which items within an instrument measure the same concepts [34]. It also ensures that no two items are measuring exactly the same concept and may be used as a tool for item reduction. Cronbach's  $\alpha$  was used to measure this; scores greater than 0.7 usually indicate that scale items are measuring related constructs. Items failing to be included in any domain were reviewed by the expert panel regarding their value and possible removal.

#### Criterion validity

Two-hundred and thirteen participants also completed the Women's Health Questionnaire [35] (WHQ) and the Menstrual Distress Questionnaire [36] (MDQ). These two PROMs were used as there is evidence for their validity and both instruments cover almost all the content incorporated in ePAQ-MPH. Scores from ePAQ-MPH were compared with salient domain scores from WHQ and MDQ using rank correlation to assess the degree of association.

#### Stability

Test-retest reliability to evaluate stability over time was undertaken with 30 participants who completed ePAQ-MPH on two occasions, at least one week apart. Wilcoxon signed-rank test was used to measure differences between Cronbach's alpha values for the two completions and inter-class correlations were calculated.

#### Patient experience and acceptability

Patients' views of ePAQ-MPH were evaluated for 279 participants using QQ-10, a validated 10-item instrument which measures face validity, feasibility and utility of PROM use during their clinical episode [37]. The established QQ-10 scoring algorithm for measuring value and burden in was used [37].

#### Instrument modification and confirmatory factor analysis

Following revision of the instrument and item reduction, to confirm the conceptual model of ePAQ-MPH, a confirmatory factor analysis (CFA) using Mplus version 8.0 (Muthen & Muthen, 2017, Los Angeles, CA) was undertaken on 254 completed questionnaires (ePAQ-MPH Version 2) from patients who had

given consent for the use of their data via the PROM between January 2017–January 2018. Given the nature of the scales used in ePAQ-MPH the estimator chosen was weighted least squares means and variance adjusted (WLSMV). This estimator does not assume normally distributed variables and therefore has been argued as providing the best estimator for modelling categorical or ordered data [38]. A number of model fit indices were evaluated for confirmation of the CFA which included a chi-square, root mean square error of approximation (RMSEA), comparative fit index (CFI) and the Tucker–Lewis index (TLI). We should expect a non-significant chi-square for confirmation of the CFA ( $p > 0.05$ ) [39]. The RMSEA, is a measure of fit [40]; a value  $< 0.05$  suggests good model fit, although values  $< 0.08$  are considered reasonable. The CFI ranges from 0 for a poor fit to 1 for a good fit. The TLI is another index for comparative fit. It can be interpreted in a similar fashion as CFI, but it can have a value outside of the range of 0 to 1. We should expect good fit statistics for CFI and TLI to be  $> 0.95$  although values exceeding 0.90 are considered acceptable.

## Results

#### ePAQ-MPH

ePAQ-MPH is completed online; patients use a unique 16-digit voucher code which is automatically generated and embedded in a posted clinic letter. This code is entered by the patient, along with their date of birth to log-in and pseudonymously complete the questionnaire on-line. Patients unable to complete the PROM at home can complete it in the menstrual disorders clinic using a touch-screen or tablet computer in a private room, with the support of a nurse if needed. Key elements of ePAQ-MPH include introductory pages, explaining how to use the 'Help', 'Back', 'Next' and 'Skip' navigation functions.

Each item is presented on one screen and presents stem questions relating to symptom frequency and severity, sub-questions regarding the impact of symptoms are displayed if the particular symptom is reported. Each item offers a four-point response scale (Fig. 1). Domain scores are computed using a standard algorithm used in the urogynaecology version of ePAQ, providing scales from 0 (best health status) to 100 (worst health status). Responses from completed questionnaires are stored as numeric code in a secure central database, located behind a firewall on a secure NHS N3 server.

Version one of ePAQ-MPH comprised four symptom dimensions: Menstruation, Pelvic Pain, Hormonal Conditions and

The screenshot shows a digital questionnaire interface. At the top, it says 'M12 Thinking about the last 6 months...'. The main question is 'Do you feel that your periods are ever heavy?'. Below this, there are four buttons for frequency: 'Never', 'Occasional periods', 'Most periods', and 'Every period'. A second question asks 'How much of a problem is this for you?'. Below this, there are four buttons for impact: 'Not a problem', 'A bit of a problem', 'Quite a problem', and 'A serious problem'. At the bottom, there are four navigation buttons: 'Previous' (green), 'Help' (blue), 'Skip' (red), and 'Next' (green). A large, faint watermark 'ePAQ' is visible in the background.

Fig. 1. An example of the question format used in ePAQ-MPH, assessing symptom frequency and impact; in this case for heavy menstrual bleeding.

Non-Menstrual Bleeding & Discharge. The PROM also included a fifth non-scored Personal Data dimension, recording additional information, such as self-reported height and weight (computed BMI), previous hysterectomy, parity and free-text items relating to patient concerns and treatment goals. Each symptom dimension contains screening questions, identifying whether the participant is affected by symptoms from the relevant dimension. Therefore, the PROM only presents questions relevant to the symptoms the patient will be suffering from. For example, if a participant does not have periods, they will not be presented with questions about how heavy their periods are, how many days they bleed for etc. Data from each patient automatically populates a one-page summary (Fig. 2) and detailed ePAQ-MPH report, with one page each for the raw data from each symptoms dimension which can be viewed on screen or printed for inclusion in patient case-notes.

Domain structure, internal reliability and item reduction

Complete questionnaire data were obtained from 291 of the 308 women in the study (94.5%). The age range was 22–63 years (mean 43). Mean completion time was 31 min.

Eighteen domains of ePAQ-MPH with Cronbach's alpha values of >0.7 were identified. These domains each contained between 3–7 items and Cronbach's alpha values ranged from 0.70–0.96. A summary of internal reliability statistics for the 18 domains is shown in Table 2. Factor analysis demonstrated that the Menstrual dimension had two redundant items and identified six domains; the Pelvic Pain dimension had four redundant items and five domains; the Hormonal dimension had seven redundant items and four domains. Within the hormonal dimension a putative polycystic ovary syndrome domain including items relating to hair loss, acne and hirsutism was evaluated; these items were

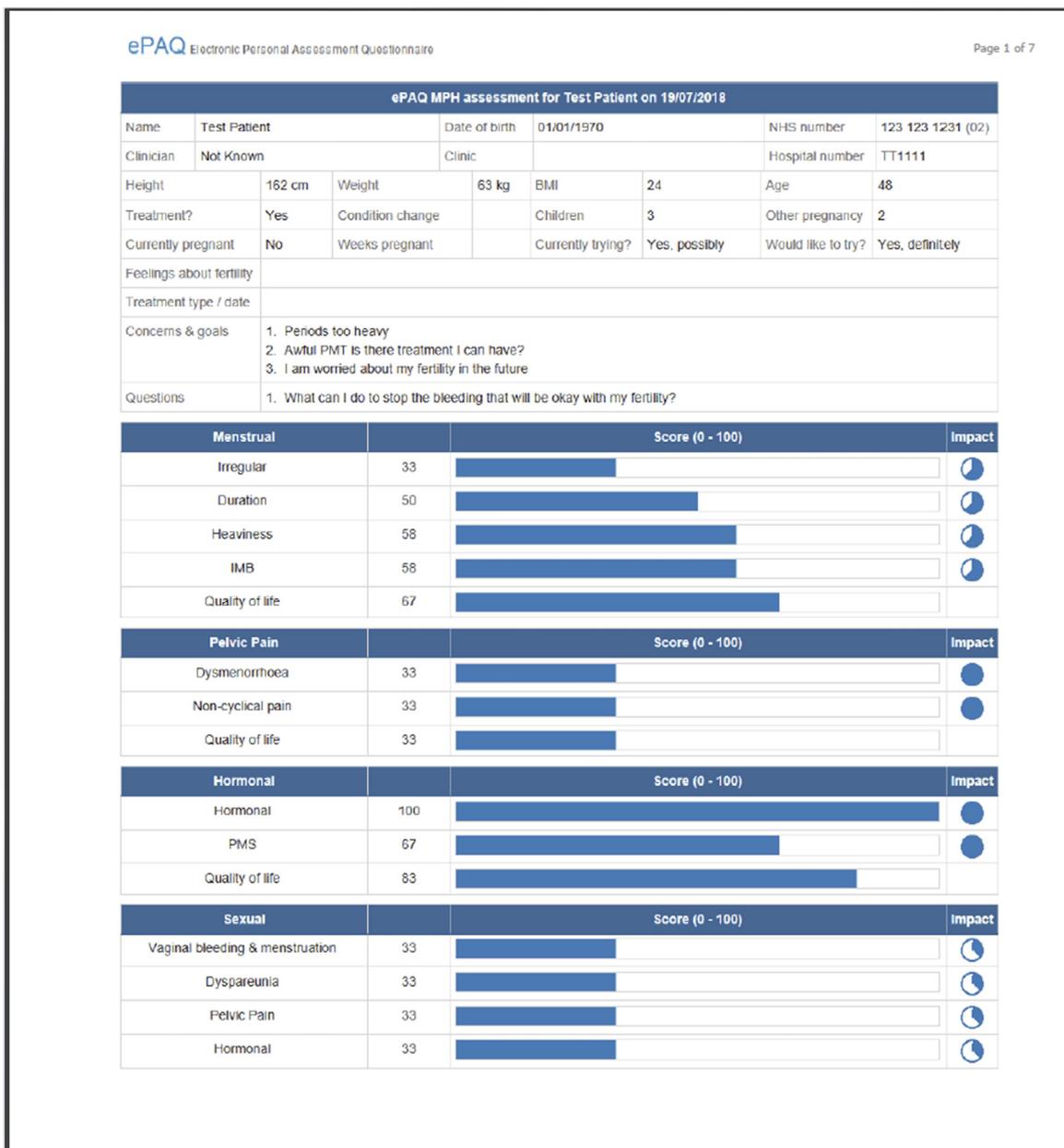


Fig. 2. An example of the report produced by ePAQ-MPH, showing domain scores and impact on quality-of-life.

**Table 2**  
Domain structure and internal reliability of ePAQ-MPH Version 1.

<b>Menstrual dimension</b>		
<b>Domains</b>	<b>Summary of items</b>	<b>Cronbach's <math>\alpha</math></b>
Regularity	Irregularity, Regularity, Predictability	0.87
Cycle length	Length of period, Stop & start, Post-menstrual spotting, Bleed free days	0.78
Heavy Menstrual Bleeding (HMB)	HMB, Days heavy bleeding, Clots, Clots/day, Clot size	0.83
Protection	Leak onto clothes, Leak onto bedding, Pad change, Tampon change, Double protection	0.77
Menstruation & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety	0.86
Menstruation & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact	0.94
<b>Pain dimension</b>		
<b>Domains</b>	<b>Summary of items</b>	<b>Cronbach's <math>\alpha</math></b>
Dysmenorrhoea	Dysmenorrhoea presence, Dysmenorrhoea days/month, Dysmenorrhoea severity, Dysmenorrhoea nausea, Bladder pain menstrual, Bowel pain menstrual, Fails to relieve	0.84
Non-cyclical pain	Non-cyclical pain, NCP days per month, Duration of NCP, NCP severity, NCP bladder, NCP bowel	0.79
Dyspareunia	Dyspareunia, Post coital pain, Dyspareunia: dryness, Dyspareunia: sensation, Dyspareunia: tightness, Dyspareunia: obstruction	0.80
Pain & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety	0.92
Pain & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact	0.96
<b>Hormonal dimension</b>		
<b>Domains</b>	<b>Summary of items</b>	<b>Cronbach's <math>\alpha</math></b>
Hypo-oestrogenism	Mood swings, Concentration, Hot flushes, Night sweats, Loss of libido, Vaginal dryness	0.70
Pre- Menstrual Syndrome (PMS)	Cyclical mood changes, Aggression, Cyclical concentration, Bloating, Breast tenderness, Cyclical irritability	0.85
Hormones & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety	0.90
Hormones & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact	0.95
<b>Non-menstrual bleeding and Discharge (NMBD) dimension</b>		
<b>Domains</b>	<b>Summary of items</b>	<b>Cronbach's <math>\alpha</math></b>
Inter Menstrual Bleeding (IMB)	Intermenstrual bleeding, IMB heaviness, IMB duration, Post coital bleed	0.88
NMBD & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety	0.93
NMBD & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact	0.95

tested for internal reliability and produced a Cronbach's alpha value of 0.42 suggesting that this was not a reliable domain. The final dimension of Non-menstrual Bleeding & Discharge (NMBD) had 5 redundant items and three domains were identified. A putative vaginal discharge domain within this dimension produced a Cronbach's alpha value of 0.46, again suggesting that this was not a reliable domain. All redundant items were removed from version 1 of ePAQ-MPH (102 items reduced to 72 items).

#### Test retest reliability

Test retest reliability was undertaken with 30 participants using version 1 of ePAQ-MPH (Table 3). Intra-class correlation coefficient

values ranged from 0.45 to 0.9; the minimum accepted value of 0.5, was not achieved in the hormonal / sexual function domain (0.45). Interclass correlation >0.5 was seen in all other domains.

#### Criterion validity

Of the 308 participants completing version 1 of ePAQ MPH, in order to assess criterion validity, 180 (58%) completed MDQ and 213 (69%) completed WHQ. No corresponding domains could be identified for two of the 18 ePAQ-MPH domains (Dyspareunia and Intermenstrual Bleeding), two of the 18 domains had a relevant domain in both MDQ and WHQ. Eight domains were compared with MDQ showing moderate or strong correlation in seven

**Table 3**  
Test retest reliability: ePAQ domains with first and second completion Cronbach's alpha, Wilcoxon signed rank test and intra-class correlations.

Domain	First completion (Cronbach's alpha(number of completions))	Second completion (Cronbach's alpha(number of completions))	Intra-class correlation (2-tailed significance)
<b>Menstrual dimension</b>			
Regularity	0.87 (280)	0.87 (27)	0.87
Cycle length	0.78 (273)	0.64 (26)	0.80
Heavy Menstrual Bleeding	0.83 (275)	0.92 (28)	0.81
Protection	0.77 (129)	0.90 (16)	0.92
Menstruation & Sexual Function	0.86 (266)	0.89 (24)	0.76
Menstruation & Quality of Life	0.94 (281)	0.95 (27)	0.86
<b>Pain dimension</b>			
Dysmenorrhoea	0.83 (249)	0.82 (26)	0.80
Non-cyclical pain	0.79 (210)	0.73 (19)	0.88
Dyspareunia	0.80 (263)	0.74 (25)	0.84
Pain & Sexual Function	0.92 (262)	0.91 (24)	0.75
Pain & Quality of Life	0.96 (281)	0.95 (29)	0.88
<b>Hormonal dimension</b>			
Hypo-oestrogenism	0.70 (266)	0.72 (27)	0.90
Pre-Menstrual Syndrome	0.87 (264)	0.84 (28)	0.83
Hormones & Sexual Function	0.90 (235)	0.92 (23)	0.45
Hormones & Quality of Life	0.95 (271)	0.96 (29)	0.76
<b>Non-menstrual bleeding &amp; Discharge dimension</b>			
Intermenstrual bleeding	0.88 (235)	0.89 (25)	0.68
NMBD & Sexual Function	0.93 (238)	0.94 (23)	0.70
NMBD and Quality of Life	0.95 (263)	0.85 (29)	0.58

**Table 4**

Criterion Validity for Salient ePAQ-MPH and Menstrual Distress Questionnaire (MDQ)/Women's Health Questionnaire (WHQ) domains and the Spearman's rank correlations.

ePAQ-MPH domain	Related MDQ domain	Spearman's rank (2-tailed significance)
Menstrual Quality of Life	Behaviour Change Menstrual	0.46 (<0.001)
Dysmenorrhoea	Pain Menstrual	0.52 (<0.001)
Non-cyclical pain	Pain Postmenstrual	0.34 (<0.001)
Pain & Quality of Life	Behaviour Change Menstrual	0.42 (<0.001)
Hypo-oestrogenism	Autonomic Reactions Menstrual	0.40 (<0.001)
Pre-Menstrual Syndrome	Water Retention Premenstrual	0.38 (<0.001)
Hormones & Quality of Life	Behaviour Change Menstrual	0.48 (<0.001)
NMBD & Quality of Life	Behaviour Change Menstrual	0.12 (0.153)
ePAQ-MPH domain	Related WHQ domain	Spearman's rank (2-tailed significance)
Regularity	Menstrual	0.15 (0.041)
Cycle Length	Menstrual	0.24 (0.001)
Heavy Menstrual Bleeding	Menstrual	0.39 (<0.001)
Protection	Menstrual	0.27 (<0.001)
Menstruation & Sexual Function	Sex	0.36 (<0.001)
Hypo-oestrogenism	Vasomotor	0.49 (<0.001)
Pre-Menstrual Syndrome	Menstrual	0.47 (<0.001)
Hormones & Sexual Function	Sex	0.50 (<0.001)
Pain & Sexual Function	Sex	0.38 (<0.001)
NMBD & Sexual Function	Sex	0.26 (0.001)

domains. Ten domains were compared with WHQ, six of which showed moderate correlation (Table 4).

#### PROM acceptability

A total of 279 (91%) women completed the QQ-10 instrument. Summary statistics for value and burden, as measured by QQ-10, are shown in Table 5. Mean scores for Value and Burden were 76 (SD = 15.8) and 25 (SD = 15.5), respectively, suggesting high Value and low Burden for the majority of patients. Of the six items relating to Value, 'ease of use' and 'happy to complete again' were the most highly rated responses (92% and 90%, respectively). Of the four Burden items; 'The questionnaire is too long' was the most frequently reported response (25% of subjects).

#### Revised instrument and confirmatory factor analysis

The revised version 2 of ePAQ-MPH (Table 6) consisted of four dimensions and fifteen domains containing 72 items, 30 redundant items having been removed and domain structure modified. The mean completion time of the revised instrument was 22 min. Table 6 shows the fit indices for the CFA model for each ePAQ-MPH dimension.

For all dimensions, the p-value for the  $\chi^2$  goodness of fit test was  $p < 0.001$  indicating that the overall model did not fit the data well; as should be expected from this test for CFA. The RMSEA was small ( $p < 0.005$ ) suggesting good model fit for the Menstrual, Hormonal and NMBD dimensions. The RMSEA was 0.086 for the pain domain suggesting a reasonable fit. The CFI and TFI values were  $> 0.95$  for all

dimensions indicating good model fit. Therefore, overall, the findings suggest that that the ePAQ-MPH structure fits the data moderately well. Having confirmed the conceptual framework for ePAQ-MPH, the PROM structure for patient administration was reorganised. The single NMBD domain (intermenstrual bleeding) was relocated into the Menstrual dimension and the five domains relating to sexual function (menstruation and sexual function, dyspareunia, pain and sexual function and hormones and sexual function) were moved into a new Sexual dimension (Table 7).

#### Comment

ePAQ-MPH is a condition-specific ePROM which provides comprehensive assessment of symptomatology associated with menstrual disorders, pelvic pain and gynaecological hormonal conditions and their associated impact on sexual function and quality of life.

ePAQ-MPH combines detailed assessment of menstrual disorders, including heavy menstrual bleeding, cycle regularity, intermenstrual bleeding, dysmenorrhea, menopausal symptoms and pre-menstrual syndrome. The PROM also assesses non-cyclical pelvic pain and hormonal symptoms. For each dimension of ePAQ-MPH the impact of symptoms on HRQoL and sexual function is assessed. Due to the significant overlap between menstrual, pelvic pain and gynaecological hormonal conditions, the ability to assess for symptoms and their impact on HRQoL in all of these conditions simultaneously is potentially valuable.

The instrument aims to process, with graphic and concise presentation, a large volume of information regarding both

**Table 5**

QQ-10 results for face validity/patient experience of ePAQ-MPH (version 1) including percentage and count for each response.

Statement	% Strongly disagree (n)	% Mostly disagree (n)	% Neither agree or disagree (n)	% Mostly agree (n)	% Strongly agree (n)
<b>Value</b>					
1. Improved communication	1.4 (4)	6.1 (17)	14.0 (39)	57.9 (161)	20.5 (57)
2. Relevance	1.4 (4)	5.0 (14)	10.4 (29)	52.2 (145)	30.9 (86)
3. Ease of use	2.2 (6)	2.2 (6)	3.9 (11)	37.3 (104)	54.5 (152)
4. Comprehensive	1.1 (3)	6.8 (19)	12.6 (35)	47.1 (131)	32.4 (90)
5. Enjoyable	1.8 (5)	5.0 (14)	42.1 (117)	36.7 (102)	14.4 (40)
6. Happy to complete again	2.2 (6)	2.9 (8)	5.8 (16)	39.6 (110)	49.6 (138)
<b>Burden</b>					
7. Too long	10.9 (30)	24.3 (67)	40.2 (111)	18.5 (51)	6.2 (17)
8. Too embarrassing	43.5 (120)	30.4 (84)	23.9 (66)	2.2 (6)	0.0 (0)
9. Too complicated	41.1 (113)	42.2 (116)	14.5 (40)	1.8 (5)	0.4 (1)
10. Upsetting	68.1 (188)	17.4 (48)	13.0 (36)	1.1 (3)	0.4 (1)

**Table 6**  
Dimensions and domain structure ePAQ-MPH Version 2 with associated fit indices for each dimension derived from confirmatory factor analysis.

<b>Menstrual dimension</b>				
<b>X<sup>2</sup></b>	<b>df</b>	<b>RMSEA</b>	<b>CFI</b>	<b>TFI</b>
818.402	165	0.001	0.970	0.965
<b>Domains</b>				
Regularity	Irregularity, Regularity, Predictability			
Cycle length	Length of period, Stop & start, Post-menstrual spotting, Bleed free days			
Heavy Menstrual Bleeding (HMB)	HMB, Days heavy bleeding, Clots, Clots/day, Clot size			
Menstruation & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety			
Menstruation & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact			
<b>Pain dimension</b>				
<b>X<sup>2</sup></b>	<b>df</b>	<b>RMSEA</b>	<b>CFI</b>	<b>TFI</b>
920.172	319	0.086	0.982	0.980
<b>Domains</b>				
Dysmenorrhoea	Dysmenorrhoea presence, Dysmenorrhoea days/month, Dysmenorrhoea severity, Dysmenorrhoea nausea, Bladder pain menstrual, Bowel pain menstrual, Fails to relieve			
Non-cyclical pain	Non-cyclical pain, NCP days per month, Duration of NCP, NCP severity, NCP bladder, NCP bowel			
Dyspareunia	Dyspareunia, Post coital pain, Dyspareunia: dryness, Dyspareunia: sensation, Dyspareunia: tightness, Dyspareunia: obstruction			
Pain & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety			
Pain & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact			
<b>Hormonal dimension</b>				
<b>X<sup>2</sup></b>	<b>df</b>	<b>RMSEA</b>	<b>CFI</b>	<b>TFI</b>
889.560	168	0.001	0.963	0.958
<b>Domains</b>				
Hypo-oestrogenism	Mood swings, Concentration, Hot flushes, Night sweats, Loss of libido, Vaginal dryness			
Pre- Menstrual Syndrome (PMS)	Cyclical mood changes, Aggression, Cyclical concentration, Bloating, Breast tenderness, Cyclical irritability			
Hormones & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety			
Hormones & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact			
<b>Non-menstrual bleeding and Discharge (NMBD) dimension</b>				
<b>X<sup>2</sup></b>	<b>df</b>	<b>RMSEA</b>	<b>CFI</b>	<b>TFI</b>
15.250	2	0.005	0.998	
<b>Domains</b>				
Inter Menstrual Bleeding (IMB)	Intermenstrual bleeding, IMB heaviness, IMB duration, Post coital bleed			

frequency and bothersomeness of symptoms. This can then be used to enhance the acuity of a consultation through the inclusion of self-reported key components of a patient's presenting complaint and her perspective of her condition. This PROM is not intended to replace clinical consultation, but to assist and objectively augment the clinical assessment and diagnosis. The PROM could also be used in ethically approved research projects to assess both baseline symptoms and impact on HRQoL and change following intervention.

Initial psychometric testing of ePAQ-MPH has shown good internal reliability, test-retest reliability and criterion validity. The

results of the initial psychometric testing has enabled remodelling of the instrument. The confirmatory factor analysis of the revised instrument has shown that the domain structure of ePAQ-MPH fits the data it is intended to collect moderately well and good model fit was also demonstrated, confirming the conceptual framework of the instrument.

The burden of ePAQ-MPH was low when assessed, despite the length of the PROM, for which the first iteration (version 1, prior to item reduction) was reported as being 'Too long' by 25% of patients. Completion times of twenty minutes may be unacceptable for some users, particularly in under-resourced clinics when patients

**Table 7**  
Dimensions and domain structure ePAQ-MPH Version 3 following development of conceptual framework.

<b>Menstrual dimension</b>	
<b>Domains</b>	<b>Summary of items</b>
Regularity	Irregularity, Regularity, Predictability
Cycle length	Length of period, Stop & start, Post-menstrual spotting, Bleed free days
Heavy Menstrual Bleeding (HMB)	HMB, Days heavy bleeding, Clots, Clots/day, Clot size
Inter Menstrual Bleeding (IMB)	Intermenstrual bleeding, IMB heaviness, IMB duration, Post coital bleed
Menstruation & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact
<b>Pain dimension</b>	
<b>Domains</b>	<b>Summary of items</b>
Dysmenorrhoea	Dysmenorrhoea presence, Dysmenorrhoea days/month, Dysmenorrhoea severity, Dysmenorrhoea nausea, Bladder pain menstrual, Bowel pain menstrual, Fails to relieve
Non-cyclical pain	Non-cyclical pain, NCP days per month, Duration of NCP, NCP severity, NCP bladder, NCP bowel
Pain & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact
<b>Hormonal dimension</b>	
<b>Domains</b>	<b>Summary of items</b>
Hypo-oestrogenism	Mood swings, Concentration, Hot flushes, Night sweats, Loss of libido, Vaginal dryness
Pre- Menstrual Syndrome (PMS)	Cyclical mood changes, Aggression, Cyclical concentration, Bloating, Breast tenderness, Cyclical irritability
Hormones & Quality of Life (QoL)	QoL overall impact, QoL physical impact, QoL social impact, QoL responsibilities impact
<b>Non-menstrual bleeding and Discharge (NMBD) dimension</b>	
<b>Domains</b>	<b>Summary of items</b>
Menstruation & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety
Dyspareunia	Dyspareunia, Post coital pain, Dyspareunia: dryness, Dyspareunia: sensation, Dyspareunia: tightness, Dyspareunia: obstruction
Pain & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety
Hormones & Sexual Function	Impact on sex, Sex: avoids, Sex: partner avoids, Sex: anxiety

have failed to pre-complete the questionnaire at home. However, ePAQ-MPH is considerably shorter than the previously developed 132 item urogynaecology PROM (ePAQ-Pelvic Floor), which has been found to be acceptable and valuable in clinical practice [30,41,42]. ePAQ-MPH may be similarly useful as a clinical and research tool. Barriers to completing PROMs in clinical practice can include licensing costs and additional staff training needed to set such tools up. However, once in place they are often cheap and reduce consultation burden.

Limitations of this study are the lack of detailed demographic data for the 308 participants including race/ethnicity, first language spoken and educational level. A further limitation is whether the patients recruited, presented with a full range of the conditions that ePAQ-MPH aimed to address, including premenstrual syndrome, perimenopausal symptoms and non-menstrual pelvic pain. The two PROMS used to assess criterion validity focus principally on HRQoL rather than symptomatology [35,36] therefore the domains compared were not directly measuring an identical concept. As this was a research project, requiring consent, women who were participants may have been more motivated to provide questionnaire responses and have a more positive attitude towards questionnaire completion. Another limitation is that women unable to understand written English were excluded from the study as were those lacking basic computer literacy and willingness complete the instrument in the electronic format.

Whilst this paper reports the development of version 3 of ePAQ-MPH in order to allow other research groups to scrutinize and review the data generated thus far, wider evaluation and psychometric testing of this latest and current version of the instrument is now required in larger samples and in different settings, including tests of stability, tests of data quality, sensitivity and responsiveness to change.

Cognitive interviewing will provide further assessment of content and face validity. So far, ePAQ-MPH shows good potential as a PROM; providing objective patient-based data which could be utilised for assessment, service evaluation and research.

### Funding statement

No funding was received for this study. Study participants did not receive any financial or other types of compensation for their role.

### Conflicts of interest statement

Professor Stephen Radley is a director and shareholder of ePAQ systems limited, an NHS spin-out technology company ([www.epaq.co.uk](http://www.epaq.co.uk)). The other authors declare they have no conflicts of interest. Both the ethical review board and all research participants were made aware of the potential for commercial use of ePAQ-MPH in the future.

### Acknowledgements

The authors would like to acknowledge Dr Rupal Swami, Ms Lucy Shuttleworth and Dr Marcin Klingbajl for their role in the development and testing of ePAQ-MPH.

### References

- Zondervan KT, Yudkin PL, Vessey MP, Dawes MG, Barlow DH, Kennedy SH. Prevalence and incidence of chronic pelvic pain in primary care: evidence from a national general practice database. *Bjog Int J Obstet Gynaecol* 1999;106(11):1149–55.
- Vessey MP, Villard-Mackintosh LA, McPherson K, Coulter A, et al. The epidemiology of hysterectomy: findings in a large cohort study. *Bjog Int J Obstet Gynaecol* 1992;99(5):402–7.
- Santer M, Wyke S, Warner P. What aspects of periods are most bothersome for women reporting heavy menstrual bleeding? Community survey and qualitative study. *BMC Womens Health* 2007;7(1):8.
- Unsal A, Ayranci U, Tozun M, Arslan G, Calik E. Prevalence of dysmenorrhea and its effect on quality of life among a group of female university students. *Ups J Med Sci* 2010;115(2):138–45.
- Liu Z, Doan QV, Blumenthal P, Dubois RW. A systematic review evaluating health-related quality of life, work impairment, and health-care costs and utilization in abnormal uterine bleeding. *Value Health* 2007;10(3):183–94.
- Marjoribanks J, Lethaby A, Farquhar C. Surgery versus medical therapy for heavy menstrual bleeding. *Cochrane Database Syst Rev* 2006.
- McKenna SP. Measuring patient-reported outcomes: moving beyond misplaced common sense to hard science. *BMC Med* 2011;9(1):86.
- Moss HA, Havrilesky LJ. The use of patient-reported outcome tools in Gynecologic Oncology research, clinical practice, and value-based care. *Gynecol Oncol* 2018;148(1):12–8.
- Dawson JD, Doll Helen, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. *BMJ* 2010;340:c186.
- Dua A, Jones G, Wood H, Sidhu H. Understanding women's experiences of electronic interviewing during the clinical episode in urogynaecology: a qualitative study. *Int Urogynecol J* 2013;24(11):1969–75.
- Schüssler-Fiorenza Rose SM, Gangnon RE, Chewning B, Wald AJ. Increasing discussion rates of incontinence in primary care: a randomized controlled trial. *Womens Health* 2015;24(11):940–9.
- Gray T, Li W, Campbell P, Jha S, Radley S. Evaluation of coital incontinence by electronic questionnaire: prevalence, associations and outcomes in women attending a urogynaecology clinic. *Int Urogynecol J* 2018;29(7):969–78.
- Spies JB, Coyne K, Guaou NG, Boyle D, Skyrnarz-Murphy K, Gonzalves SM. The UFS-QOL, a new disease-specific symptom and health-related quality of life questionnaire for leiomyomata 2. *Obstet Gynecol* 2002;99(2):290–300.
- Jones G, Kennedy S, Barnard A, Wong J, Jenkinson C. Development of an endometriosis quality-of-life instrument: the endometriosis health Profile-30. *Obstet Gynecol* 2001;98(2):258–64.
- Deal LS, DiBenedetti DB, Williams VS, Fehnel SE. The development and validation of the daily electronic endometriosis pain and bleeding diary. *Health Qual Life Outcomes* 2010;8:64.
- Toxqui L, Perez-Granados AM, Blanco-Rojo R, Wright I, Vaquero MP. A simple and feasible questionnaire to estimate menstrual blood loss: relationship with hematological and gynecological parameters in young women. *BMC Womens Health* 2014;14:71.
- Bushnell DM, Martin ML, Moore KA, Richter HE, Rubin A, Patrick DL. Menorrhagia impact questionnaire: assessing the influence of heavy menstrual bleeding on quality of life. *Curr Med Res Opin* 2010;26(12):2745–55 2010.
- Mansfield PK, Voda A, Allison G. Validating a pencil-and-paper measure of perimenopausal menstrual blood loss. *Womens Health Issues* 2004;14(6):242–7.
- Melzack R, Katz J. The McGill pain questionnaire: appraisal and current status. Surrey: Guilford Press; 2001.
- Marnach ML, Long ME, McGree ME, Weaver AL, Casey PM. Female sexual function improves after endometrial ablation. *J Womens Health* 2016;25(2):149–54.
- Pattison H, Daniels JP, Kai J, Gupta JK. The measurement properties of the menorrhagia multi-attribute quality-of-life scale: a psychometric analysis. *Bjog Int J Obstet Gynaecol* 2011;118(12):1528–31.
- Ross C, Coleman G, Stojanovska C. Factor structure of the modified Moos Menstrual Distress Questionnaire: assessment of prospectively reported follicular, menstrual and premenstrual symptomatology. *J Psychosom Obstet Gynecol* 2003;24(3):163–74.
- Jenkinson C, Peto V, Coulter A. Making sense of ambiguity: evaluation in internal reliability and face validity of the SF 36 questionnaire in women presenting with menorrhagia. *Quality Health Care* 1996;5(1):9–12.
- Clark TJ, Khan KS, Foon R, Pattison H, Bryan S, Gupta JK. Quality of life instruments in studies of menorrhagia: a systematic review. *Eur J Obstet Gynecol Reprod Biol* 2002;104(2):96–104.
- Steiner M, Streiner D. Validation of a revised visual analog scale for premenstrual mood symptoms: results from prospective and retrospective trials. *Canadian Journal of Psychiatry - Revue Canadienne de Psychiatrie* 2005;50(6):327–32.
- Blaisdell-Gross B, Gajria K, Guo A, Hagan M, Kornstein SG, Yonkers KA. Development and validation of the Premenstrual Symptoms Impact Survey (PMSIS): a disease-specific quality of life assessment tool. *Wallenstein GV; J. Women's Health* 2008;17(3):439–50.
- Read JR, Perz J, Ussher JM. Ways of coping with premenstrual change: development and validation of a premenstrual coping measure. *BMC Womens Health* 2014;14:1.
- Steiner M, Peer M, Macdougall M, Haskett R. The premenstrual tension syndrome rating scales: an updated version. *J Affect Disord* 2011;135(1-3):82–8.
- Bachman JW. The patient-computer interview: a neglected tool that can aid the clinician. *Mayo Clin Proc Innov Qual Outcomes* 2003;78:67–78.
- Radley SC, Jones G, Tanguy E, Stevens V, Nelson C, Mathers N. Computer interviewing in urogynaecology: concept, development and psychometric testing of an electronic pelvic-floor assessment patient-reported outcome measure in primary and secondary care. *Bjog* 2006;113:231–8.
- Bryman A. *Social Research Methodology*. 3<sup>rd</sup> edition Oxford: Oxford University Press; 2008.

- [32] FDA. Guidance for Industry: Patient-Reported Outcome Measures. Use in Medical Product Development to Support Labeling Claims. Washington, DC: US Food and Drug Administration.; 2009.
- [33] Fayers PM, Machin D. *Quality of Life: The assessment, analysis and interpretation of patient-reported outcomes* 2<sup>nd</sup> Edition. New York: Wiley; 2013.
- [34] Fink A. *Reliable and Valid Survey Instruments. The Survey Handbook.* Thousand Oaks, CA: SAGE Publications Inc.; 2003.
- [35] Hunter MS. The Women's Health Questionnaire: a measure of mid-aged women's perceptions of their emotional and physical health. *Psychol Health* 1992;7:45–54.
- [36] Moos RH. The development of a menstrual distress questionnaire. *Psychosom Med* 1968;30(6):853–67.
- [37] Moores KL, Jones GL, Radley SC. Development of an instrument to measure face validity, feasibility and utility of patient questionnaire use during health care: the QQ-10. *Int J Qual Health Care* 2012;24(5):517–24.
- [38] Ullman JB, Bentler PM. *Structural equation modeling. Handbook of Psychology (Second Edition).* Chichester: John Wiley & Sons; 2012.
- [39] Schermelleh-Engel K, Moosbrugger H, Müller H. Evaluating the fit of structural equation models: tests of significance and descriptive goodness-of-fit measures. *Methods Psychol Res Online* 2003;8(2):23–74.
- [40] Steiger JH, Lind JC. May. Statistically based tests for the number of factors. Annual Meeting of the Psychometric Society 1980.
- [41] Jones GL, Radley SC, Lumb J, Jha S. Electronic pelvic-floor symptoms assessment: test of data quality of ePAQ-PF. *Int Urogynecol J Pelvic-floor Dysfunct* 2008;19:1337–47.
- [42] Jones GL, Lumb J, Radley SC, Farkas AG. Responsiveness of the electronic Personal Assessment Patient-reported outcome measure- Pelvic-floor (ePAQ-PF). *Int Urogynaecol J Pelvic-floor Dysfunct* 2009;20(5):557–64.