

Citation:

Scurr, K and Gray, TG and Jones, GL and Radley, SC (2020) Development and initial psychometric testing of a body-image domain within an electronic pelvic floor questionnaire (ePAQ-pelvic floor). International Urogynecology Journal. ISSN 0937-3462 DOI: https://doi.org/10.1007/s00192-020-04247-y

Link to Leeds Beckett Repository record: https://eprints.leedsbeckett.ac.uk/id/eprint/6626/

Document Version: Article (Accepted Version)

The aim of the Leeds Beckett Repository is to provide open access to our research, as required by funder policies and permitted by publishers and copyright law.

The Leeds Beckett repository holds a wide range of publications, each of which has been checked for copyright and the relevant embargo period has been applied by the Research Services team.

We operate on a standard take-down policy. If you are the author or publisher of an output and you would like it removed from the repository, please contact us and we will investigate on a case-by-case basis.

Each thesis in the repository has been cleared where necessary by the author for third party copyright. If you would like a thesis to be removed from the repository or believe there is an issue with copyright, please contact us on openaccess@leedsbeckett.ac.uk and we will investigate on a case-by-case basis.

Title

Development and initial psychometric testing of a domain to assess body-image within a comprehensive electronic pelvic floor questionnaire (ePAQ-Pelvic Floor)

Authors details:

Kaia Scurr¹, Thomas G Gray², Georgina L Jones³, Stephen C Radley²

- 1. Academic Unit of Reproductive & Developmental Medicine, University of Sheffield, Sheffield, UK /Women's Services, Newcastle-upon-Tyne Hospitals NHS Foundation Trust, Newcastle-upon-Tyne, UK
- 2. Department of Urogynaecology, Sheffield Teaching Hospitals NHS Foundation Trust Sheffield UK
- 3. Professor of Health Psychology, Leeds Beckett University, Leeds, UK

Corresponding author: Thomas Gray

Room 15, Level 4, Jessop Wing, Sheffield Teaching Hospitals NHS Foundation Trust, Tree Root Walk, Sheffield, S10 2SF

thomas.gray@doctors.org.uk

00447763686015

Financial Disclaimers/Conflict of Interest statement

Professor Stephen Radley is a director and shareholder of ePAQ Systems Limited, an NHS spin-out technology company largely owned by Sheffield Teaching Hospitals NHS Foundation Trust. Professor Radley did not collect or analyse any data included in this study. The other authors have no financial or commercial interests in ePAQ Systems Limited, and no other conflicts of interests to declare. No funding was received for this study.

Each author's contribution

Scurr: Project development, Data collection, management and analysis, Manuscript writing.

Gray: Project development, Data collection and analysis, Manuscript writing.

Jones: Data analysis, Manuscript editing.

Radley: Project development, Manuscript editing

Word Count

Abstract - 249 Main body - 3620

Abstract

Introduction Urogynaecological conditions have been shown to negatively impact on body image in a number of previous studies. ePAQ-Pelvic Floor (ePAQ-PF) is a patient reported outcome measure used in clinical practice to assess urogynaecological symptoms and their impact on quality-of-life. This study aimed to develop and undertake initial psychometric testing of a new domain to assess urogynaecological body image within ePAQ-PF.

Methods A patient involvement group, analysis of free-text data from ePAQ-PF and a systematic review of available PROMs to assess urogynaecological body image informed the content of a new body image domain within ePAQ-PF. Data collected from 208 patients who consented to the use of their anonymised ePAQ-PF responses for research purposes underwent factor analysis, internal consistency reliability and item-total correlation testing. Data from previous studies were used to formulate hypotheses to test construct validity. Criterion validity was assessed against the Body-image Scale (BIS). Patients completed a separate questionnaire (QQ-11) to measure face validity of ePAQ-PF.

Results Factor analysis revealed a 4-item body-image domain with good internal consistency reliability (Cronbach's α =0.899) and item-total correlations (Spearman's rank r >0.40). ePAQ-PF body-image domain scores correlated significantly with the BIS scores (r=0.501). Age, prolapse, sexual dysfunction, pelvic pain and urinary incontinence scores correlated significantly with body image domain score. QQ-11 value scores outweighed burden scores.

Conclusions Body image assessment should form part of routine care in urogynaecology. Preliminary results support validity, reliability and functionality of ePAQ-PF incorporating the new body image domain. Further psychometric testing of this is required, including tests of responsiveness and stability.

Brief summary (25 words)

Urogynaecological conditions negatively impact body image. A new domain to assess body image in a urogynaecology as part of ePAQ-PF

has shown evidence for reliability, validity and functionality.

Key words: body-image, patient reported outcome measure, pelvic floor disorders, urogynaecology

Introduction

Body-image is a multi-faceted psychological experience, encompassing body-related self-perceptions and self-attitudes, including thoughts, feelings and behaviours [1]. The concept refers particularly, but not exclusively, to appearance and is a contributor to health-related quality of life (HRQoL) [2]. The concept of genital self-image or identity has been described in the literature as 'self-definitions, self-attitudes and subsequent feelings which arise from specific interactions and experiences, which either indirectly or directly involve the genitals' [3]. It therefore follows that genital self-image could be seen as a component of body-image as a whole [4]. This is important to consider in the context of urogynaecological disorders.

Previous studies have shown urogynaecological disorders including pelvic organ prolapse, perineal trauma and overactive bladder to have a negative effect on body-image as a whole and specifically on genital self-image [5-8]. These studies also demonstrated further effects that body-image may have on both HRQoL and sexual function, including the suggestions that sexual dysfunction is attributed more to body-image perception in patients with urogynaecological disorders compared to controls [5]. The impact of urogynaecological disorders on body image may be difficult to assess in clinical practice, especially considering the sensitive and taboo nature of urogynaecological conditions which often leads to under-reporting of symptoms in clinical consultations [9, 10]. This is why the use of patient reported outcome measures (PROMs) in urogynaecology is potentially of such great value.

The electronic Personal Assessment Questionnaire-Pelvic Floor (ePAQ-PF) is a web-based self-administered PROM developed to evaluate pelvic floor symptomology and its impact on HRQoL across 19 symptom areas (or domains) [11]. The instrument uses both

multiple choice questions and free-text responses to collect data. There is good evidence from multiple studies for reliability, validity and functionality of this instrument [11-13]. A previous content analysis study of responses to the free-text item in ePAQ-PF, which asks patients 'Considering the issues that currently concern you the most, what do you hope to achieve from any help, advice or treatment?', assessed responses from almost two thousand urogynaecology clinic patients and found that 11% of patients reported bodyimage concerns via the free text item [14]. Body image is not currently assessed by ePAQ-PF in any of its 19 symptom domain areas which use multiple choice questions assessing frequency and impact of symptoms.

A systematic review of available PROMs used to assess body-image in urogynaecology patients identified just two PROMs appropriate for use in patients with pelvic organ prolapse. However, there was limited evidence for appropriately developed and psychometrically tested tools for urogynaecology populations, including both urinary and faecal incontinence [15].

To address the unmet need to assess body image patients with urogynaecology problems a new domain within ePAQ-PF was proposed. The aim of this study therefore, was to develop and undertake initial psychometric testing of a new body-image domain within ePAQ-PF.

Methods

Ethical approval was obtained from the University of Sheffield Research Ethics Committee (project number 018432). All data were handled in line with the European Union General Data Protection Regulations (GDPR).

ePAQ-PF

ePAQ-PF consists of four dimensions relating to urinary, bowel, vaginal and sexual symptoms. Within each dimension are four to five domains, with each domain containing up to seven related items or questions. An algorithm used to score each domain results in a scale from 0-100, where 0 represents the best health status and 100 represents the worst health status. Individual domain scales allow insight into specific symptom areas. The questionnaire also includes a free-text item, asking patients what their main concerns and goals are in their own words. Patients are also asked if they consent to their anonymised responses being used for approved service evaluation, audit or research purposes. For this study, ePAQ was modified to include a new bodyimage domain within the vaginal dimension of the PROM (Figure 1).

Content validity: patient involvement and development of the body-image domain

The development of a new body-image domain of ePAQ-PF was discussed at the Sheffield Teaching Hospitals Jessop Wing Patient and Public involvement group, where patient and public views were sought.

The content analysis of free text responses to ePAQ-PF identified 160 specific body image concerns which were recorded by 136 patients. These body concerns were grouped into themes of smell (16.3%), scarring (6.9%), appearance (37.5%) and emotions (39.3%).

Responses from the patient involvement group, content analysis of free-text from ePAQ-PF and the results from the systematic review of PROMs available to assess body image in urogynaecology informed the content of the domain developed to assess body image in ePAQ-PF. Common themes identified regarding body image in urogynaecology relating to appearance, smell, scarring, and emotions led to a five-item domain being

drafted and added via software engineering to the existing ePAQ-PF. This was placed at the start of the vaginal dimension of ePAQ-PF, which now contains 20 symptom domains.

Determination of scale structure and internal reliability

Patients attending the outpatient urogynaecology department at Sheffield Teaching Hospitals NHS Foundation Trust (STH) are invited to complete ePAQ-PF as part of their routine care. During the study period the new version of ePAQ-PF including the bodyimage domain was completed by patients attending the urogynaecology clinic. Data from consenting patients who completed this version of ePAQ-PF between 5th March 2018 and 31st May 2018 were analysed using SPSS (Version 25.0. Armonk, New York: IBM Corp) and GraphPad Prism (Version 7.0c. San Diego: California) As well as descriptive statistics such as demographics, item response frequencies, skewness, response rate, and floor and ceiling effects, the following psychometric statistical analyses were undertaken.

Factor analysis (principal component analysis using varimax rotation) is a statistical procedure to reduce a collected dataset into a set of measurement variables (domain scales) based upon correlations (REF). Factor analysis was performed within the vaginal dimension of ePAQ-PF to establish the communality value of items, with values of >0.5 indicating which items should form scored domains [16]. Items obtaining a factor loading of >0.40 were retained, and the number of suggested domains was indicated by components achieving an Eigenvalue (raw sum of the squares) of 1 or more [17]. Items which should be grouped together to form separate scored domains are described by factor analysis as items loading onto factors or components, the number of which should account for over 60% of variance of responses (REF). To test statistical power, the Kaiser-Meyer-Olkin measure of sampling adequacy was carried out. Collected data is suitable for

factor analysis if >0.5, and the Bartlett's Test of Sphericity significance, as also undertaken with a value <0.05 suggesting that there are some relationships between the variables and therefore factor analysis is suitable.

Cronbach's alpha was used to test internal consistency reliability (how strongly items within a domain are related to each other), with an acceptable value being reported as 0.70-0.95. Item-total correlations (how strongly item scores within a domain are related to the total domain score – corrected for overlap?) were calculated using Spearman's rank (r), with an accepted value being > 0.40 [12].

After finalising the domain structure as described above, it was then possible to score the questionnaire responses according to the established ePAQ-PF algorithms. A uniform maximum score of 100 for each domain allows comparison of domain scores irrespective of how many items they include. The primary use of scoring domains for this study was to test criterion and construct validity.

Criterion validity

Criterion validity (testing a new measure against something that provides an assessment of the true value) can be challenging as a "gold standard" does not always exist [18]. Outcomes of a systematic review were used in order to establish the most appropriate existing tool with which to compare the ePAQ-PF body-image domain [15]. The Body-image Scale (BIS) in its original format was selected as the most appropriate comparator PROM [19]. Although psychometric testing for this tool in urogynaecology populations is limited, it is the most widely used instrument to assess body-image in urogynaecology patients [15]. Patients attending outpatient urogynaecology clinics from 3rd April 2018 until 31st May 2018, who had completed ePAQ-PF incorporating the new body-image

domain prior to their appointment, were also invited to complete the BIS. Scores were paired to their corresponding ePAQ-PF body-image domain scores and analysed using Spearman's rank correlation coefficient (r), after confirming non-normally distributed data by means of a Shapiro-Wilk's W test of normality value of <0.05.

Face validity

Face validity measures how appropriate, relevant and comprehensible an instrument is to its overall purpose [11]. Patients attending the outpatient urogynaecology clinic from 3rd April 2018 until 31st May 2018 who had answered ePAQ-PF in the past four weeks were invited to complete the Questionnaire Quotent-11 (QQ-11), an updated version of the QQ-10, a psychometrically tested instrument to measure the value and burden of a PROM from a patient's perspective [20]. A similar, as yet not validated, tool assessing the clinician's perspective, (Q1-10) was distributed to all clinicians who may have used ePAQ-PF with the new body-image domain with their patients.

Construct validity

Construct validity describes the extent to which a questionnaire measures the 'construct' it was developed to measure. One way to measure construct validity is to test hypotheses based on the expected direction of scores between two constructs, which should ideally be formulated 'a priori' before analysing responses to the instrument. Convergent construct validity is one aspect of this and it refers to the degree to which two constructs that should be related, are fact related. (REF) Add in something about divergent validity here if you do decide to include these tests.

. In order to measure an aspect of convergent construct validity for the new body-image domain in ePAQ-PF, outcomes of studies identified by a systematic review of PROMs to assess body-image in urogynaecology [15] were used to formulate the following hypotheses: poorer body-image is associated with pelvic organ prolapse [5,6], sexual dysfunction [5,8], younger age [7], poorer HRQoL [6], urinary incontinence [22] and vulvovaginal pain and dyspareunia [23]. Relevant ePAQ-PF domain scores for these hypotheses were correlated with the ePAQ-PF body image domain scores using Spearman's rank (r). after confirming non-normally distributed data by means of a Shapiro-Wilk's W test of normality value of <0.05......?

Results

Descriptive Statistics

Two-hundred and eight patients completed ePAQ-PF and consented for their anonymised responses to be used for research purposes. The mean age was 56 years (range 18-87 years) and mean time taken to complete the PROM was 26 minutes and 55 seconds. Mean parity was 2, range 0 to 6, and mean body mass index (BMI) was 26.7, range 18 to 41. One hundred and eighty-nine patients completed the body-image domain in full, giving a response rate of 90.9% (Table 1). The mean response rates for all 20 domains of ePAQ-PF was 84.6%. The results of the Kaiser-Meyer-Olkin measure of sampling adequacy was 0.825 and the Bartlett's Test of Sphericity significance was 0.000, thus suggesting the sample size was suitable for factor analysis. Item response frequencies to items of the body-image domain are shown in Table 2.

Domain Structure and Reliability

Communalities after extraction were > 0.5 for all items except the "smell" item, which scored 0.409. All rotated component matrix values were >4.0. Five components had an Eigenvalue of over 1.0, which accounted for 69.3% variance. Four items of the body-image domain ("embarrassed", "scarring", "feel less attractive" and "unhappy to look at self") loaded onto one component however the "smell" item loaded onto a different component. This inferred that the "smell" item should not belong to the same domain as the other body-image items.

For internal consistency reliability, except for the "pain and sensation" domain (α 0.69) all other values of the vaginal dimension fell between α 0.70- α 0.95. The body-image domain had the highest value of α 0.84.

For item-total correlations, in the existing five-item body-image domain, all values (r) were >0.40 except the "smell" item $(r\ 0.319)$, as shown in Table 3. When item-total correlations were calculated for the four-item body-image domain (minus smell) as suggested by factor analysis, all values remained >0.40. All domains showed positive skewness towards the best health status. Floor and ceiling effects for the body-image domain were 59.3% and 2.6% respectively.

For criterion validity, 43 patients completed both the BIS and the ePAQ-PF body-image domain. Mean BIS score was 24 (BIS is scored out of 100, with a higher score indicating worse health status and lower score indicating a better health status), range 0-89. A statistically significant positive correlation (r=0.501, p<0.05) was found between paired BIS scores and ePAQ-PF body-image domain scores.

Forty patients completed both the QQ-11 and ePAQ-PF body-image domain. Mean value score was 76 this is scored out of 100, with a lower score indicating less value and a higher score indicating more value). Mean burden score was 22 (also scored out of 100, with a lower score indicating least burden and a higher score indicating more burden).

Four clinicians completed the QI-10 (which has the same scoring algorithm as QQ-11), with a mean value score of 87 and a mean burden score of 18.

Statistically significant correlations were found between ePAQ-PF body-image domain scores and all domain scores measuring constructed hypotheses of a relationship between body-image and: pelvic organ prolapse (r=0.365, p<0.05); sexual dysfunction (r=0.423, p<0.05); poor quality of life (r=0.481, p<0.05); age (r=-0.317, p<0.05), urinary incontinence (r=0.2, p<0.05); vulvovaginal pain (r=0.341, p<0.05); and dyspareunia (r=0.4, p<0.05), as shown in Table 4.

Discussion

This study reports the development and initial psychometric testing of a new domain to assess body-image within ePAQ-PF. We present good initial evidence for reliability, content validity, face validity, criterion validity and initial evidence of convergent construct validity. The item regarding "smell" within the body-image domain will be removed prior to further psychometric testing.

The most symptomatic (i.e. highest scoring) item in the body image domain was "embarrassment", with the least symptomatic item being "scarring". This follows, as

scarring would be most relevant to patients following surgical intervention or perineal trauma, whereas ePAQ-PF is mostly completed by new referrals to clinic. Previous content analysis of ePAQ-PF free-text responses reports that 16.3% were concerned about smell and only 6.9% about scarring [14]. Comparing these figures to our results (Table 1) suggests that inclusion of these body-image items has increased symptom disclosure, highlighting the value of questionnaire interviewing in this context.

One of the main findings of this study was that the "smell" item was not found to be statistically related to the other four body-image domain items. It does make sense that the subject of smell is less strongly associated with the idea of body-image compared to the other questionnaire items, which are all linked more visual concepts [2]. Interestingly, the "smell" item loaded onto a component with items asking about other senses such as dryness, looseness and feeling of the vagina. However, this component itself did not demonstrate significant reliability. The component which consisted of the four body-image domain items excluding "smell" showed good internal consistency reliability. With the exception of "pain and sensation", the existing domain themes suggested acceptable internal consistency reliability and item-total correlations for the vaginal dimension of ePAQ-PF. After reviewing the data and consultation with the urogynaecology multidisciplinary team in the unit, a decision was made to remove the "smell" item from the body-image domain, demonstrating how the process of psychometric testing for a PROM involves synthesising sometimes conflicting results to arrive at the most suitable solution when applied to a clinical situation. This includes taking care not to prioritise statistical significance over clinical significance. In this case, 16% of body-image concerns reported by patients in the free text analysis related to

smell, which was why this item relating to smell was initially included, but it has not proven to be reliable or valid when used in the PROM as part of body image assessment.

presented with BIS scores and ePAQ-PF body-image domain scores correlating significantly. The pairing of scores reduced the risk of confounding variables such as age, BMI, parity and health status. Although the BIS is by no means a gold-standard due to the lack of evidence of psychometric testing in a urogynaecology population, it was selected by means of critically assessing the literature for the most appropriate comparator using established systematic review methodology.

The QQ-11 and QI-10 scores recorded in this study suggest that both patients and clinicians alike find ePAQ-PF to be of value in clinical practice and not unduly burdensome. The vast majority of patients found the questionnaire relevant and useful to facilitate communication, decision making and include all aspects of their condition. The highest-ranking value item was ease of completion, with the lowest value item being enjoyment. Importantly, the majority of patients would be willing to complete it again in future which is crucial as ePAQ-PF is used routinely for measuring treatment outcomes after conservative, medical or surgical intervention. Few patients found the questionnaire to be too long, upsetting or complicated, and no patients reported it as being too embarrassing, which highlights a benefit of computer interviewing compared to face to face consultation alone [24]. Additionally, clinicians found ePAQ-PF to be efficient and useful in clinical practice, and that the data whilst being easy to use in practice, was worthy of costs and resources.

All seven pre-determined hypotheses were confirmed by statistically significant correlations, presenting some initial evidence for convergent construct validity of the ePAQ-PF body-image domain. As the body-image domain accurately measured evidence-based constructs this confirms the quality of data produced by ePAQ-PF's body-image domain. Further clear demonstrations in this study of the negative effect of urinary incontinence, pelvic organ prolapse and sexual dysfunction on body-image. This also serves to highlight the importance of reliable and valid outcome measures to assess this emerging area of urogynaecological assessment. In the same way that sexual function is routinely assessed and measured in urogynaecology patients, so should body-image also be.

In this study the mean time taken to complete ePAQ-PF was in-keeping with the mean completion time of 26 minutes reported in previous ePAQ-PF validation studies, suggesting that addition of a new domain does not incur a significant time burden [11]. Patients using ePAQ-PF always have the option to skip items. As the response rate to the body-image domain (90.9%) was above the mean (84.6%), this suggests good acceptability with participants willing to answer these items and finding them relevant to their condition.

Ceiling effects below 15% confirms the ability of ePAQ-PF to recognise any worsening of symptoms should the same patient repeat the questionnaire. The floor effect was greater than desired (59.3%). This might be expected in an unscreened study population, as patients present to urogynaecology with a broad variety of symptoms. Therefore, it is not

expected that they will score highly across all domains of ePAQ-PF. Furthermore, as surgical interventions for pelvic floor disorders may cause further symptoms or side effects, it is valuable to have baseline data even if their score is at the floor of a domain.

In terms of limitations, the use of QQ-11 to measure acceptability and face validity may not be fully reliable as formal psychometric testing of this tool has not been undertaken since adding an additional item to the QQ-10.

In terms of risks of bias, it is possible that participants were subject to the Hawthorne effect; where the behaviour of participants is affected by the awareness of being studied [25]. However, this would have only been true for those patients answering the BIS to assess criterion validity and QQ-11 to measure acceptability/face validity. Completing the QQ-11 after the appointment as opposed to immediately after completing ePAQ-PF may have biased responses favourably, as positive responses may not have been a reflection of ePAQ-PF alone but a combination of ePAQ-PF and their clinical experience which potentially left them in a positive mind-set about treatment options, feelings of indebtedness towards the clinician or even relief that their appointment and examination was over. It could be argued that as an opportunistic sampling method was used to collect BIS and QQ-11 data, some selection bias may have occurred. However, attempts were made to ensure all participants who had answered ePAQ-PF were approached and given the opportunity to answer. Another limitation is the small number of clinicians completing the QI-10, although this did include all of the urogynaecology consultants and subspecialty trainee. There may have been some element of responder bias, as clinicians are unlikely to criticise their own service. Nonetheless, constructive free-text comments were given, and can be used to make improvements so that clinicians gain the maximum

benefit from the tool as well as patients. It should also be noted that the QI-11 has yet to have evidence of psychometric testing published.

As this study has suggested reduction of the body-image domain to four items by removing the "smell" item, further data must now be prospectively gathered, and confirmatory factor analysis performed in the context of an ethically approved study. This study has confirmed the psychometric properties of ePAQ-PF's body-image domain in a cross-sectional manner. In future studies, the domain must be tested longitudinally by means of test-test reliability (the ability of an instrument to record the same results if tested in the same population). Measures of responsiveness to detect clinical changes over time or after treatments are also required. If shown to have good responsiveness, there will be further evidence that this tool is suitable as an outcome measure following interventions, such as physiotherapy or surgery, which may affect body-image.

Identifying patients with poor body-image may also influence recommended treatment options and provide a more holistic approach to their management [26]. It has been suggested that psychosomatic reactions may contribute to severity of symptoms, particularly in urge incontinence [27], and psychological interventions have been suggested as a cost-effective intervention in patients with urinary incontinence [28]. Preliminary research has also shown promise in the use of cognitive behavioural therapy (CBT) in the treatment of sexual pain disorders which are associated with body-image and prolapse symptoms [29]. It follows that in patients with poor body-image, psychological interventions may be a preferred option or used as an adjunct to surgical interventions, but further research is needed in this area. The new National Institute for

Health and Care Excellence (UK) guidelines on the management of urinary incontinence in women have suggested that a clinical psychologist could now form part of the urogynaecology multidisciplinary team for regional centres dealing with complex pelvic floor dysfunction [20].

In conclusion, this study aimed to psychometrically test a body-image domain within ePAQ-PF. Good evidence for internal consistency reliability, item-total correlation, criterion validity and initial convergent construct validity has been presented. Response rates and tests of face validity showed acceptability and value to patients and clinicians. This study has again confirmed the negative effect of urinary incontinence, pelvic organ prolapse and sexual dysfunction on body-image. Further psychometric testing of this instrument is required, including tests of responsiveness and stability. The body-image domain in ePAQ-PF shows significant promise in delivering an unmet need of measuring body-image concerns in all women attending with urogynaecological problems. Further research needs to assess the impact of interventions for urogynaecological problems on body-image and also investigate the role of psychological therapies. ePAQ-PF will be well placed as a suitable tool for such studies.

Legend of figures

Figure 1: Example ePAQ-PF report including the new body-image domain

<u>Figure 2: Diagrammatic representation of the 5 proposed items of the new body image domain.</u>

<u>Table 1: Descriptive statistics and score distributions for all 20 domains of ePAQ-PF.</u>

<u>Table 2: Item response frequencies for the body-image domain.</u>

Table 3: Item-total correlations (r) and internal consistency reliability values (α) for the body-image domain following factor analysis

<u>Table 4: Spearman's rank correlations between ePAQ-PF body image domain score and domains to test construct validity</u>

Figure 1: Example ePAQ-PF report including the new body-image domain

The blue horizontal bars indicate dimensions. Within each dimension are listed the scored domains of related symptom items. The body-image domain (blue arrow) The impact circle represents the maximum impact reported for any of the symptom items within that particular domain. An empty circle represents "not a problem", 1/3 circle "a bit of a problem", 2/3 circle "Quite a problem", full circle "a serious problem".

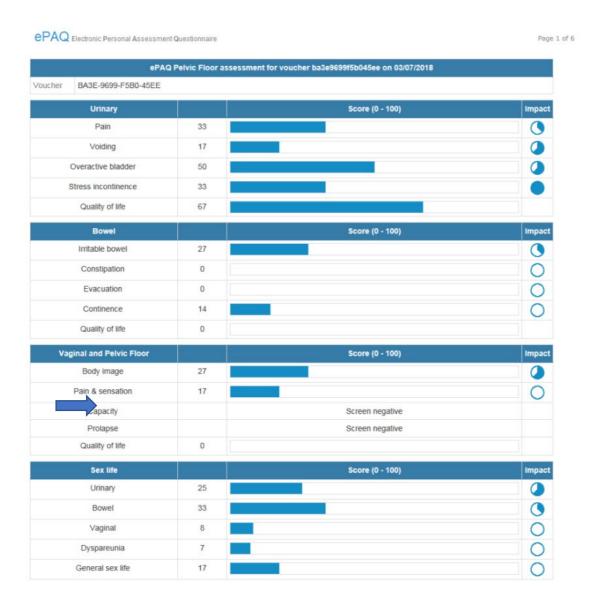


Figure 2: Diagrammatic representation of the 5 proposed items of the new body image domain.

The domain is introduced with the stem question as shown in the black circle. The participant is then asked 5 questions, with answer options on a 4-point Likert scale:

- 0= "Not at all"
- 1= "A little"
- 2 = "Moderately"
- 3 ="A lot"

If the response to the question scores 1 or more, the participant is then asked the subquestion "How much of this is a problem for you?". Answer options are:

- 0 = "Not a problem"
- 1 = "A bit of a problem"
- 2 = "Quite a problem"
- 3 = "A serious problem"

1) Do you feel embarrassed about the appearance of your pelvic area? 5) Do you feel 2) Do you feel unhappy to unhappy about scarring of **look** at your Thinking about your pelvic pelvic area how you feel yourself? about your pelvic area? area, including your pubic area, your labia around your anus & back passage, or around your vagina... 4) Does the 3) Do you feel appearance of unhappy about your pelvic the **smell** or area make you odour of your feel less pelvic area? attractive?

<u>Table 1: Descriptive statistics and score distributions for all 20 domains of ePAQ-PF.</u> All domains are scored out of 100, with 0 representing the best health status and 100 representing the worst health status.

| Dimension | Domain | Response rate (%) | c | Mean | Median | SD | Range | Floor (0%) | Ceiling (%) | Skewness |
|-----------|--------------------------------|-------------------|-----|------|--------|------|-------|------------|-------------|----------|
| Urinary | Pain & sensation | 97.6 | 203 | 13.0 | 0 | 18.2 | 78 | 57.1 | 0 | 1.3 |
| | Voiding | 95.7 | 199 | 18.0 | 16.7 | 20.2 | 92 | 36.7 | 0 | 1.2 |
| | Overactive bladder | 97.6 | 203 | 23.6 | 25.0 | 20.2 | 92 | 19.2 | 0 | 0.9 |
| | Stress Urinary Incontinence | 97.6 | 203 | 21.6 | 20.0 | 24.1 | 100 | 35.0 | 0 | 1.3 |
| | Quality of Life | 97.1 | 202 | 32.8 | 22.2 | 33.1 | 100 | 32.2 | 6.9 | 0.7 |
| Bowel | Irritable bowel | 90.4 | 188 | 34.5 | 33.3 | 26.9 | 100 | 16.0 | 0.5 | 0.6 |
| | Constipation | 91.8 | 191 | 21.9 | 11.1 | 22.0 | 100 | 24.6 | 0.5 | 1.1 |
| | Evacuation | 92.3 | 192 | 21.7 | 16.7 | 21.1 | 89 | 27.1 | 0 | 1.0 |
| | Continence | 91.8 | 191 | 16.3 | 9.5 | 17.0 | 90 | 22.5 | 0 | 1.5 |
| | Quality of life | 92.3 | 192 | 23.3 | 11.1 | 31.0 | 100 | 44.3 | 5.7 | 1.3 |
| Vaginal | Body-image | 90.9 | 189 | 16.4 | 0 | 26.6 | 100 | 59.3 | 2.6 | 1.7 |
| | Pain & sensation | 89.9 | 187 | 23.6 | 16.7 | 21.5 | 100 | 23.0 | 0.5 | 1.1 |
| | Capacity | 89.4 | 186 | 7.6 | 0 | 18.0 | 100 | 77.4 | 1.6 | 3.2 |
| | Prolapse | 88.9 | 185 | 24.8 | 16.7 | 27.7 | 100 | 37.3 | 3.2 | 1.1 |
| | Quality of life | 89.4 | 186 | 24.2 | 11.1 | 28.3 | 100 | 39.8 | 2.7 | 1.1 |
| Sexual | Sex & urinary | 62.5 | 130 | 23.8 | 8.3 | 30.2 | 100 | 45.4 | 3.1 | 1.1 |
| | Sex & bowel | 63.0 | 131 | 16.2 | 0 | 27.3 | 100 | 62.6 | 2.3 | 1.7 |

| Sex & va | gina | 60.1 | 125 | 31.7 | 25.0 | 32.1 | 100 | 33.6 | 4.8 | 0.7 |
|-----------|------|------|-----|------|------|------|-----|------|-----|-----|
| Dyspareu | unia | 57.7 | 120 | 25.3 | 20.0 | 25.0 | 100 | 25.0 | 2.5 | 1.1 |
| General s | sex | 56.3 | 117 | 41.9 | 33.3 | 29.5 | 100 | 12.8 | 5.1 | 0.3 |

<u>Table 2: Item response frequencies for the body-image domain. % participants refers to the valid percentage i.e. it does not include participants with missing data for that item.</u>

| Item | | 0 | 1 | 2 | 3 | Total |
|------------------|--------------|--------------|------------|--------------|---------|-------|
| | | (Not at all) | (A little) | (Moderately) | (A lot) | |
| Do you feel | No. | 130 | 27 | 17 | 17 | 191 |
| embarrassed | participants | | | | | |
| about the | % | 68.1 | 14.1 | 8.9 | 8.9 | 100 |
| appearance of | participants | | | | | |
| your pelvic | | | | | | |
| area? | | | | | | |
| Do you feel | No. | 150 | 19 | 10 | 12 | 191 |
| unhappy about | participants | | | | | |
| scarring of your | % | 78.5 | 9.9 | 5.2 | 6.3 | 100 |
| pelvic area? | participants | | | | | |
| Do you feel | No. | 131 | 30 | 16 | 14 | 191 |
| unhappy about | participants | | | | | |
| the smell or | % | 68.6 | 15.7 | 8.4 | 7.3 | 100 |
| odour of your | participants | | | | | |
| pelvic area? | | | | | | |
| Does the | No. | 138 | 28 | 9 | 15 | 190 |
| appearance of | participants | | | | | |
| your pelvic area | % | 72.6 | 14.7 | 4.7 | 7.9 | 100 |
| make you feel | participants | | | | | |
| less attractive? | | | | | | |
| Do you feel | No. | 137 | 29 | 7 | 17 | 190 |
| unhappy to look | participants | | | | | |
| at your pelvic | % | 72.1 | 15.3 | 3.7 | 8.9 | 100 |
| area yourself? | participants | | | | | |

Table 3: Item-total correlations (r) and internal consistency reliability values (α) for the body-image domain following factor analysis

| Body-image domain items | Spearman's rank (r) | Cronbach's alpha (α) |
|--------------------------------|---------------------|----------------------|
| Do you feel embarrassed | 0.754 | 0.89 |
| about the appearance of | | |
| your pelvic area? | | |
| Do you feel unhappy | 0.610 | |
| about scarring of your | | |
| pelvic area? | | |
| Does the appearance of | 0.804 | |
| your pelvic area make you | | |
| feel less attractive? | | |
| Do you feel unhappy to | 0.769 | |
| look at your pelvic area | | |
| yourself? | | |
| Are you unhappy about | 0.319 | |
| the smell or odour of your | | |
| pelvic area? | | |

<u>Table 4: Spearman's rank correlations between ePAQ-PF body image domain score and domains to test construct validity</u>

| Constructed hypotheses of a relationship between body-image and: | Spearman's rank (r) |
|--|---------------------|
| Pelvic organ prolapse | 0.365 |
| Sexual dysfunction | 0.423 |
| Poorer quality of life | 0.481 |
| Urinary incontinence | 0.2 |
| Vulvovaginal pain | 0.341 |
| Dyspareunia | 0.4 |

References

- 1. Cash T.F., (2004). Body-image: past, present, and future. *Body-image*. **1**(1):1–5.
- 2. Tylka T.L., (2018). Body-image: Celebrating the past, appreciating the present, and envisioning the future. *Body-image*. **24**:A1–A3.
- 3. Waltner R., (1986). Genital identity: A core component of sexual- and self-identity. *The Journal of Sex Research*. **22**(3):399–408.
- 4. Berman L., Berman J., Miles M., Pollets D., Powell J.A., (2003). Genital self-image as a component of sexual health: Relationship between genital self-image, female sexual function, and quality of life measures. *Journal of Sex & Marital Therapy.*29:11–21.
- 5. Lowenstein L., Gamble T., Sanses T,V.D., van Raalte H., Carberry C., Jakus S., Kambias S., McAchran S., Pham T., Aschkenazi S., Hoskey K., Kenton K., (2009). Sexual function is related to body-image perception in women with pelvic organ prolapse. *Journal of Sexual Medicine*. **6**(8):2286-2291.
- 6. Jelovsek, J.E., Barber, M.D., (2006). Women seeking treatment for advanced pelvic organ prolapse have decreased body-image and quality of life. *American Journal of Obstetrics and Gynecology.* **194**(5):1455–1461.
- 7. Zielinski R., Low L.K., Tumbarello J., Miller J.M., (2009). Body-image and Sexuality in Women with Pelvic Organ Prolapse. *Urologic Nursing.* **29**(4):239-46.
- 8. Handelzalts J.E., Yaakobi T., Levy S., Peled Y., Wiznitzer A., Krissi H., (2017). The impact of genital self-image on sexual function in women with pelvic floor disorders. *European Journal of Obstetrics & Gynecology and Reproductive Biology*. **211**:164-168.
- 9. Gray T., Li W., Campbell P., Jha S., Radley S., (2018). Evaluation of coital incontinence by electronic questionnaire: prevalence, associations and outcomes

- in women attending a urogynaecology clinic. *International Urogynecology Journal.* **29**(7):969-978.
- 10. Gray, T., Vickers, Holly., Jha, S., Jones, G., Brown, S., Radley, S., (2019). A systematic review of non-invasive modalities used to identify women with anal incontinence symptoms after childbirth. *International Urogynecology Journal*. 30(6):869-879.
- 11. Radley, S.C., Jones G.L., Tanguy E.A, Stevens V.G., Nelson C., Mathers N.J., (2006). Computer interviewing in urogynaecology: Concept, development and psychometric testing of an electronic pelvic floor assessment questionnaire in primary and secondary care. *BJOG: an International Journal of Obstetrics and Gynaecology.* **113**(2):231–238.
- 12. Jones, G.L., Radley S.C., Lumb J., Jha S., (2008). Electronic pelvic floor symptoms assessment: Tests of data quality of ePAQ-PF. *International Urogynecology Journal.* **19**(10):1337–1347.
- 13. Dua A., Jones G., Wood H., Sidhu H., (2013). Understanding women's experiences of electronic interviewing during the clinical episode in urogynaecology: A qualitative study. *International Urogynecology Journal.* **24**(11):1969–1975.
- 14. Gray, T., Strickland S., Pooranawattanakul S., Li W., Campbell P., Jones G., Radley S., (2018). What are the concerns and goals of women attending a urogynaecology clinic? Thematic analysis of free-text data from a patient reported outcome measure. *International Urogynaecology Journal.* **30**(1):33-41.
- 15. Gray T.G., Sneyd R., Scurr K., Jones G.L, Iles D., Jha S., Radley S.C., (2019). Patient-reported outcome measures which assess body-image in urogynaecology patients: a systematic review. *International Urogynaecology Journal.* **30**(5):673-681.

- 16. Field A., (2013). *Discovering statistics using IBM SPSS statistics*, 4th ed. Sage Publications: London. Section 17.4.
- 17. Gray T. G., Alexander C., Jones G.L., Tidy J. A., Palmer J. E., Radley S. C., (2017).

 Development and Psychometric Testing of an Electronic Patient-Reported

 Outcome Tool for Vulval Disorders (ePAQ-Vulva). *Journal of Lower Genital Tract Disease*, **21**(4):319-326.
- 18. Bolarinwa O.A., (2015). Principles and Methods of Validity and Reliability Testing of Questionnaires Used in Social and Health Science Researches. *Nigerian Postgraduate Medical Journal*. **22**:195-201
- 19. Hopwood, P. *et al.* (2001) 'A body image scale for use with cancer patients.', *European journal of cancer (Oxford, England : 1990)*, 37(2), pp. 189–97. doi: 10.1016/S0959-8049(00)00353-1.
- 20. Moores K.L., Jones G.L., Radley S.C., (2012). Development of an instrument to measure face validity, feasibility and utility of patient questionnaire use during health care: the QQ-10. *International Journal for Quality in Health Care*.
 24(5):517–524.
- 21. Terwee C.B., Bot S.D.M., de Boer M.R., van der Windt D.A.W.M., Knol D.L. Dekker J., Bouter L.M., de Vet H.C.W., (2007). Quality criteria were proposed for measurement properties of health status questionnaires. *Journal of Clinical Epidemiology*. 60:34-42.
- 22. Hunter M.M., Nakagawa S., Van Den Eeden S.K., Kuppermann M., Huang A.J.,
 (2016). Predictors of impact of vaginal symptoms in postmenopausal women. *Menopause*. 21(2)129-139.

- 23. Boyer S.C., Pukall C.F., (2014). Pelvic Examination Experiences in Women With and Without Chronic Pain During Intercourse. *Journal of Sexual Medicine*.
 11(12):3035-3050.
- 24. Bachman, J. W. (2003) 'The patient-computer interview: A neglected tool that can aid the clinician', *Mayo Clinic Proceedings*. Mayo Foundation for Medical Education and Research, 78(1), pp. 67–78. doi: 10.4065/78.1.67.
- 25. McCambridge J., Witton J., Elbourne D.R., (2014). Systematic review of the Hawthorne effect: New concepts are needed to study research participation effects. *Journal of Clinical Epidemiology*. **67**(3):267–277.
- 26. McDermott E., Moloney J., Rafter N., Keegan D., Byrne K., Doherty G.A., Cullen G., Malone K., Mulcahy H.E., (2018). The Body-image Scale: A Simple and Valid Tool for Assessing Body-image Dissatisfaction in Inflammatory Bowel Disease.
 20(2):286–290.
- 27. Chiara G., Piccioni V., Perino M., Ohlmeier U., Fassino S., Leombruni P., (1998).

 Psychological investigation in female patients suffering from urinary incontinence. *International Urogynecology Journal.* **9**(2):73-7.
- 28. Debus G., Kästner, R., (2015). Psychosomatic Aspects of Urinary Incontinence in Women. *Geburtshilfe Und Frauenheilkunde*. **75**(2):165–169.
- 29. Bergeron S., Morin M., Lord M-J., (2010). Integrating pelvic floor rehabilitation and cognitive-behavioural therapy for sexual pain: what have we learned and where do we go from here? *Sexual and Relationship Therapy*, **25**(3):289-298.
- 30. National Institute for Health and Care Excellence (2019) Urinary incontinence and pelvic organ prolapse in women: management NG23. Available at: https://www.nice.org.uk/guidance/ng123/resources/urinary-incontinence-

 $\underline{and\text{-}pelvic\text{-}organ\text{-}prolapse\text{-}in\text{-}women\text{-}management\text{-}pdf\text{-}}66141657205189}$

[Accessed 7th September 2019].