*The Journal of Sexual Medicine*, 2025, 1–11
https://doi.org/10.1093/jsxmed/qdaf025
**Original Research**

# Deep and Superficial Dyspareunia Questionnaire: a patient-reported outcome measure for genito-pelvic dyspareunia

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## Abstract

**Introduction:** Dyspareunia affects 8%-22% of women worldwide and an unknown number of gender-diverse people. Dyspareunia is commonly categorized into deep and superficial subtypes based on pain location and underlying etiology; however, current assessment tools inadequately differentiate between pain locations.

**Aim:** This study aimed to develop a patient-reported outcome measure (PROM) that independently assesses deep and superficial dyspareunia and its psychosocial correlates: the Deep and Superficial Dyspareunia Questionnaire (DSDQ).

**Methods:** The DSDQ development stages included item construction, categorization, review/revision, focus groups, cognitive interviews, final review, and factor analysis. Items were developed by reviewing pre-existing measures related to dyspareunia. Constructs of these measures were adapted to create items for the DSDQ. Developed items were categorized according to a conceptual framework. To review items, 4 patient partners, 2 gynecologists, and 1 psychiatrist participated in a modified eDelphi process. Next, 3 patient focus groups (n = 5, n = 3, n = 4), 1 clinician focus group (n = 2), and patient cognitive interviews (n = 15) were conducted over 2 rounds. A qualitative descriptive approach guided interview analysis, which informed DSDQ modifications and generated evidence of validity. Clinician-researchers (n = 4) and patient partners (n = 2) completed the final revision. Lastly, an exploratory factor analysis (EFA) and a confirmatory factor analysis (CFA) determined the most appropriate factor structure.

**Outcomes:** Generated items, validity, factor structure.

**Results:** Fifty-nine pre-existing measures were reviewed to generate an initial pool of 163 items. Items created were categorized into domains for characteristics (pain quality, timing, location, and intensity) or psychosocial correlates (impact of pain on cognitions, affect, sexuality, and behavior). The eDelphi modified 40 items, added 23, and excluded 10. After the final review, 175 items were approved for psychometric analysis. The EFA supported a 103-item, 6-factor model. The CFA supported a 45-item, 6-factor model. Factors included: (1) Vaginal Opening Pain; (2) Deep Vaginal/Pelvic/Abdominal Pain; (3) Pain Interference; (4) Affect and Cognitions Related to Provoked Pain; (5) Sexual Distress Related to Sexual Well-being; and (6) Pain Self-efficacy.

**Clinical Implications:** The DSDQ will aid diagnosis, treatment, and assessment of dyspareunia changes over time in research and clinical settings.

**Strengths and Limitations:** Strengths of this work include DSDQ co-development with patient partners, multidisciplinary clinicians, and researchers, as well as the rigorous mixed-methods development. Limitations include demographic and clinical homogeneity of the patient samples and sample sizes for the EFA and CFA.

**Conclusions:** The DSDQ is a 45-item measure intended to assess deep and superficial dyspareunia. Future psychometric evaluation will further establish validity and reliability evidence.

**Keywords:** dyspareunia; pelvic pain; provoked-vestibulodynia; endometriosis; pain measurement; pain assessment; outcome measures.

**Received:** October 17, 2024. **Revised:** January 22, 2025. **Accepted:** February 10, 2025

## Introduction

Dyspareunia, vaginal pain provoked by sexual activity involving insertion into the vagina, is associated with reduced psychosexual health and quality of life.[1-6] Dyspareunia has a worldwide prevalence in women of 8%-22%[7] and affects an unknown number of gender-diverse people. However, it is a neglected symptom in research and clinical practice because of embarrassment, normalization, and complexity.[8] A large Swedish study conducted in 2003 found that only 28% of individuals who had ever experienced severe dyspareunia had seen a physician about their pain.[9] Patients report that receiving a dyspareunia diagnosis is a priority, but unfortunately, many who seek care for this symptom are invalidated and dismissed by healthcare professionals.[10] The causes of dyspareunia can be multifactorial, multisystemic, and complex. It can be a consequence of 1 or multiple gynecological, urological, gastrointestinal, musculoskeletal, neurological, psychological, genetic, or sociocultural factors,[11] which may predispose, precipitate, and/or perpetuate dyspareunia.

Dyspareunia is commonly categorized in clinical and research settings according to the anatomic location: superficial dyspareunia, which is localized to the vaginal opening, and deep dyspareunia, which is localized deep inside the vagina and surrounding pelvic organs.[12] The value of differentiating between deep and superficial dyspareunia is oriented toward diagnosis; associations between deep versus superficial location of pain and underlying etiologies are well established.[12,13] For example, common direct causes of deep dyspareunia and superficial dyspareunia are endometriosis and provoked vestibulodynia, respectively.[12,14,15]

To add further complexity, some individuals present with concurrent deep and superficial dyspareunia.[16] For example, someone with endometriosis may have comorbidities (e.g., vulvodynia) that result in both types of dyspareunia being present. Given this complexity, a measure that differentiates between the 2 types of dyspareunia and the unique impacts of each on an individual[11,17,18] and, moreover, that encompasses a biopsychosocial approach to pain and prioritizes perspectives of persons with lived experience, is needed. To our knowledge, there are no pre-existing dyspareunia measures that independently assess deep and superficial dyspareunia, and use a biopsychosocial approach to measurement and a formal patient-reported outcome measure (PROM) development process. For example, the Female Sexual Function Index (FSFI)[19,20] and the PROMIS Sexual Function and Satisfaction Measures (SexFs)[21] are both commonly used PROMs, but they do not differentiate between deep and superficial pain and are more specific rather than comprehensively capturing biopsychosocial elements of dyspareunia such as quality of pain, pain distress, pain catastrophizing, or pain interference.

The objective of this study was to develop a PROM that independently assesses deep and superficial dyspareunia and its psychosocial correlates: the Deep and Superficial Dyspareunia Questionnaire (DSDQ).

## Methods

Our approach to the development of the DSDQ followed the Patient-Reported Outcomes Measure Information System (PROMIS) guidelines.[22] We used a qualitative item review (QIR) process to develop the DSDQ, incorporating patient and clinician feedback throughout. Then, we conducted an exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) to condense the DSDQ and derive the most appropriate factor structure. The project framework (see Figure 1) outlines each step in DSDQ development. The item pool construction, classification, and revision were completed by members of the research team and were exempt from the research ethics board review. The conduct of cognitive interviews, focus groups, and factor analyses were approved by the University of British Columbia Children's and Women's Research Ethics Board.

Members of the steering committee, including 3 patient partners and 4 clinician-researchers, contributed to the study design, data analysis, and interpretation of results. We defined the patient partner role as falling under the level of "patient involvement," characterized as a role where patients constituted members of standing working groups and research advisory committees.[23] Input from all steering committee members was equally considered throughout.

### Item pool construction

A conceptual framework was created to develop the DSDQ items.[24] This framework referenced pre-existing frameworks for pain assessment as well as literature related to the comprehensive assessment of dyspareunia. Specifically, we drew upon the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations for examining chronic pain outcomes. Prioritized domains included pain characteristics, physical functioning, emotional functioning, interpersonal functioning, and coping.[25] We also referenced a qualitative study by Wahl et al.[26] and 2 published reviews on the pathophysiology of deep dyspareunia[18,27] to incorporate patient-important dyspareunia outcomes. The framework underwent iterative review; the final version is depicted in Figure 2.

The DSDQ items were built upon existing items from well-established measures with sound psychometric properties.[22] A comprehensive literature search was conducted by NM and SL to identify pre-existing measures related to the conceptual framework; databases included PROMIS, ePROVIDE, PsycNET, PSYCTests, MEDLINE, and PubMed. We used the following search strings: deep dyspareunia, superficial dyspareunia, assessment of dyspareunia, assessment of vaginal penetration, assessment of sexual pain, assessment of painful intercourse, measures of pain quality, measures of pain intensity, measures of sexual pain, measures of sexuality, measures of anxiety, measures of self-efficacy, measures of coping, measures of physical functioning, measures of sexual relationship, measures of fatigue, measures of depression, measures of anger, measures of sexual function, and measures of self-consciousness. We only selected measures that directly related to the search string terms and included both validated and non-validated measures. An item library was created to track and accumulate items from these identified pre-established measures from the search. The library of items reported the context, stem, response options, time frame, and instrument of origin. Items from each identified measure were then assessed as relevant or not applicable to the conceptual framework. These constructs and items that were deemed relevant to the conceptual framework, along with pertinent literature, were then adapted to create DSDQ items in the scope of the conceptual framework. Novel items were also created through consultation with clinician-researchers on the steering committee to increase comprehensibility.

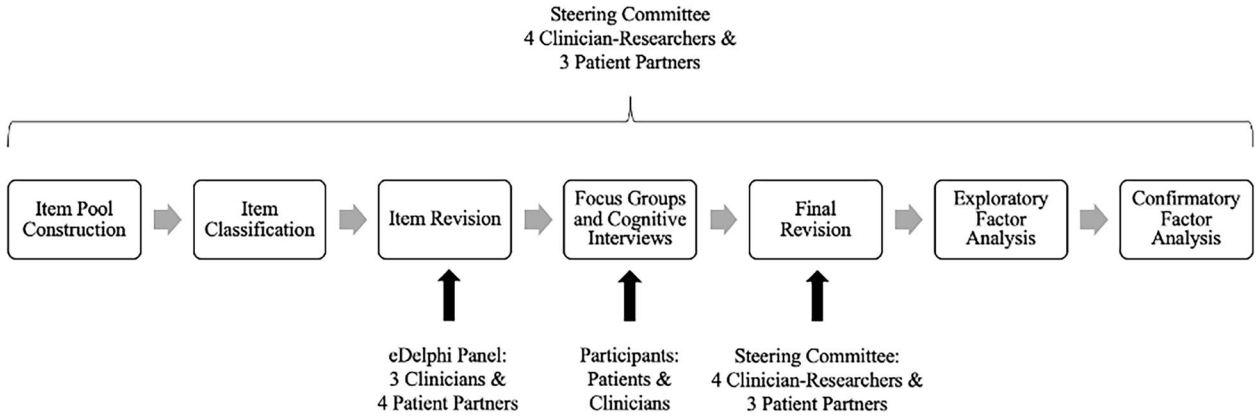


**Figure 1.** DSDQ development process framework.

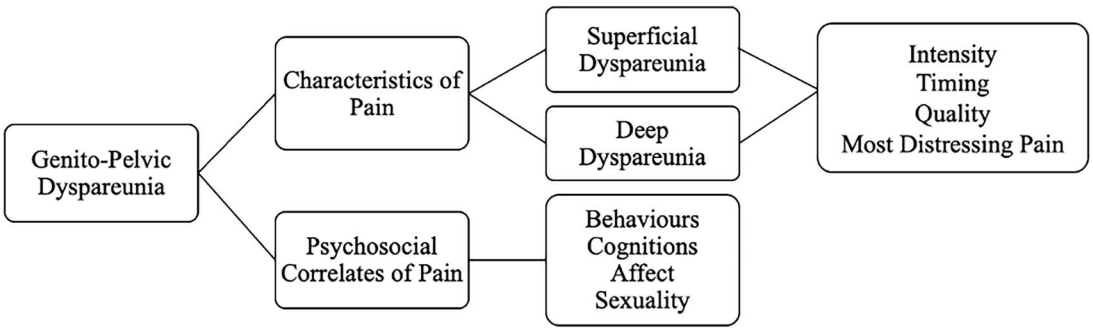


**Figure 2.** Conceptual framework for the DSDQ. Genito-pelvic dyspareunia represents the topic of the PROM and is defined as pain in the genital and/or pelvic regions that is provoked by sexual activity involving vaginal insertion.

Time frames and response options were assigned to each item. Reference time frames balanced recall bias with capturing the breadth of the dyspareunia experience. Accordingly, a 4-week time interval was allocated to all items. Response options varied throughout the measure according to the intent of each item (e.g., frequency-based scales, intensity-based scales, extent-of-agreeance scales).[22] All items had 4-6 response options per PROMIS recommendations.[22] An exception was made for items related to pain intensity, which were measured on an 11-point scale ranging from 0 = no pain to 10 = worst pain imaginable, as per IMMPACT recommendations.[28,29]

Reference images for the DSDQ were created as a visual supplement to aid patients' understanding of distinct locations of pain and different time points associated with sexual activity (see the Deep and Superficial Dyspareunia Questionnaire). These images were iteratively reviewed by clinicians at the Centre for Pelvic Pain and Endometriosis and by patient partners on the Patient Research Advisory Board for the Endometriosis and Pelvic Pain Lab at the University of British Columbia.

## Item classification

Items were classified via a binning and winnowing process to represent each construct in the conceptual framework with the smallest number of items possible. In the binning process, items were grouped by meaning and underlying latent construct according to the conceptual framework.[22] We used a rational/theoretical approach to categorize these items.[30] In the winnowing process, we reduced the item pool to the most representative set of items by eliminating items that lacked generalizability or were confusing, redundant, too narrow, too broad, or inconsistent with domain features.

## Item review and revision

The item review and revision were conducted using a modified eDelphi process, an anonymous, virtual, and iterative consensus-building process that narrowed the item list to items that concisely but comprehensively represent the domains of interest.[31] This process included 7 dyspareunia experts: 4 patient partners, 2 gynecologists, and 1 psychiatrist. Patients were recruited from the Patient Research Advisory Board for the Endometriosis and Pelvic Pain Lab at the University of British Columbia, and clinicians were recruited from the Centre for Pelvic Pain and Endometriosis, BC Centre for Vulvar Health, and the BC Centre for Sexual Medicine. A total of 2 eDelphi rounds were conducted due to consideration of respondent fatigue, attrition and the commonness of 2 rounds in the Delphi literature.[32]

The eDelphi surveys were created using Qualtrics Online Survey Software (Qualtrics, United States). Survey questions consisted of all items from the item pool construction and classification stages, including their associated range of response options and time frame. Additionally, reference diagrams created for the DSDQ were included to gain further patient and clinician input. Respondents were given 2 criteria to judge items: clarity and relevance to the dyspareunia experience. Patients considered experiential relevance, whereas clinicians considered clinical relevance. The respondents indicated whether to (1) include an item as is, (2) include a modified item, or (3) exclude an item from the PROM. If the survey respondent chose to include but modify or exclude

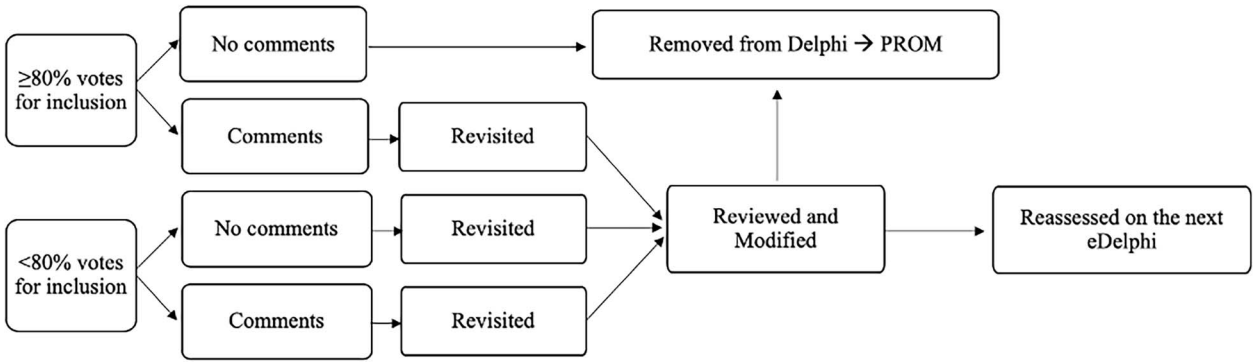


**Figure 3.** Criteria for item revision on the eDelphi surveys.

an item, they were prompted to provide a written alternative or justification for their response. Respondents were also given the opportunity to provide alternatives for items' time frame and range of responses and to suggest novel items not otherwise listed. The criteria outlined in Figure 3 were used to determine which items could be removed from the eDelphi process and included as is on the PROM, which items required modification and reassessment, and which could be excluded from the PROM (see Figure 3).

Supplement 1 contains further details on the methods used to include, exclude, or modify items.

## Cognitive interviews and focus groups

Cognitive interviews were conducted with people who experience dyspareunia to assess the language, comprehensibility, ambiguity, and relevance of each item in the DSDQ.[22] The semi-structured interview guide had open-ended questions to prompt the participant to communicate what each DSDQ question was asking, how they recalled the relevant information, how they formulated an answer, and how they mapped it onto the response categories. Focus groups were conducted with people with dyspareunia as well as clinicians who treat patients with dyspareunia. These sessions were designed to elicit feedback at the scale level with 2 primary aims: to address how well the items on the DSDQ reflected the experience of dyspareunia and to identify gaps in the items.[22] The focus group interview guides were semi-structured, with open-ended questions used to prompt the group to communicate their experiences when filling out the DSDQ in relation to either (1) their own lived experience of dyspareunia or (2) their clinical experience of working with people who experience dyspareunia. The approach to qualitative analysis of interview data was guided by the applied analytic direction of qualitative description, which was assisted by NVivo data management software (QSR International, Australia).

Supplement 1 contains the recruitment methods and eligibility criteria for the focus groups and cognitive interviews. Supplement 1 also contains details on the qualitative data analysis approach.

Cognitive interview coding used deductive and inductive codes. Codes prioritized areas of the DSDQ that required further refinement. Once coding was complete, data within each code were synthesized and codes were grouped to create themes. Themes relating to DSDQ modifications were shared with 2 steering committee members for approval. Steering committee members could veto a proposed change based on their clinical and research expertise. The iterative data collection and analysis procedure modified the DSDQ to allow for re-examining of modifications. Two rounds of cognitive interviews were completed, each with independent analyses.

The focus group analysis used a combination of deductive and inductive coding. Deductive codes centered around the prompts of the focus group discussion: overall impression, problems, relevance, ability to capture the dyspareunia experience, order, format, understandability, changes needed, questions missing or irrelevant/redundant questions, comfortability, length, and favorite/least favorite part. Data were examined to generate evidence for the DSDQ's validity. Inductive codes were created while transcripts were read and reread for discussion points the deductive coding framework did not adequately capture. If inductive codes suggested a change to the DSDQ, the same protocol for modifying the DSDQ was followed as described for the cognitive interview.

## Final item review

Per PROMIS recommendations, a final item revision was conducted before field testing.[22] Given their extensive experience of dyspareunia, the steering committee members completed this final review; they were instructed to provide insight into problematic areas of the DSDQ and inform appropriate changes.

## Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA)

An EFA was completed to determine the underlying constructs present in the DSDQ. This process facilitated the categorization of items into subscales and elimination of items. A CFA was completed with a new sample to verify the factor structure proposed in the EFA. Recruitment processes and data cleaning for the EFA and CFA are described in Supplement 1.

Data cleaning and analyses for the EFA were conducted in SPSS 25.0 (IBM Corp., Armonk). Descriptive statistics were computed to describe the characteristics of the study population. The EFA involved factor extraction and factor rotation.[33] The principal components analysis approach[34] to factor extraction was chosen, with missing values replaced with means. The Kaiser–Meyer–Olkin (KMO) test[35] and commonalities[36] were examined to ensure sampling adequacy and strength of extraction. The Scree plot[37] was used to decide on the number of factors, and, once fixed, the output component correlation matrix was reviewed to guide the selection of the rotation method. An iterative approach with a stable cut-off of 0.4[38,39] was adopted to load each item to the most relevant factor. The crude model was then assessed for reliability or internal consistency using Cronbach's $\alpha$.[40] If the calculated Cronbach's $\alpha$ for any factor was less than 0.7,

items belonging to that factor with (a) negative corrected item-total corrections, or (b) remarkable improvement in $\alpha$ if item deleted, were considered for removal one at a time until the resulting Cronbach's $\alpha$ were satisfactory.[41] Although previous work by Streiner[42] has recommended a maximum $\alpha$ of 0.9 above which certain items might be redundant, some redundancy at the EFA stage was allowed to compensate for potential overfitting resulting from imputation; this was subsequently addressed during the CFA, as outlined below. The team reviewed the updated data-driven model for content-driven fine-tuning and optimization. After the refined model was re-checked for internal consistency, it was finalized.

Statistical analyses of the CFA were conducted in MPlus 8.10 (Muthen & Muthen, Los Angeles) to confirm the factor structure using the CFA dataset. A full information maximum likelihood approach was adopted to handle missing values. Correlations between factors were examined to ensure the absence of over-parameterization. Model fit was evaluated based on criteria for absolute fit indices, including root mean square error of approximation (RMSEA) and standardized root mean square residual (SRMR), as well as incremental fit indices, including Tucker–Lewis Index (TLI) and comparative fit index (CFI).[43-47] To optimize fit measures toward a parsimonious model, items were further removed from the EFA model if their standardized factor loadings did not reach a stringent cut-off of 0.7.[48] The algorithm-driven CFA model was content reviewed collaboratively to manually add back deleted items that were intended and necessary to capture important aspects of patients' dyspareunia experience. After these questions were re-introduced, model statistics were re-assessed for adequacy before model finalization.

## Results

### Item pool construction

A total of 163 items were created in the item pool construction phase. A comprehensive list of 59 pre-established measures referenced in the DSDQ item development can be found in Appendix A1. Sixty-two items were created in the physical characteristics of pain branch of the conceptual framework, and 101 items were created in the psychosocial correlates of pain branch.

### Item classification

To cross-check the consistency of items with the scope of the DSDQ, items were categorized into 1 or more of the domains of interest outlined in the conceptual framework (Figure 2). Additionally, items were sub-categorized from the secondary branches of the conceptual framework into narrower categories to group items that captured similar dimensions (Table 1). The sub-categorizations of the conceptual framework were generated using a rational/theoretical approach, which prioritized cohesiveness and understandability.

### Item review and revision

A total of 4 patient partners were recruited for, and completed, the eDelphi process. A total of 3 clinicians were recruited for the eDelphi process; 2 completed both eDelphi surveys, while 1 completed only the first eDelphi survey. See Appendix A2 for participant characteristics.

The results from the eDelphi process are presented in Table 2. A total of 163 items entered the eDelphi process, of which 40 were modified, 23 were added, and 10 were excluded. After the review and revision stage, a total of 176 items were approved for the DSDQ.

### Cognitive interviews and focus groups

A total of 443 patients were contacted from the Endometriosis and Pelvic Pain Interdisciplinary Cohort (EPPIC) Registry (NCT02911090). Of those who were contacted and expressed interest in participating, 40 passed the post-registry screening criteria. Patients participated in the cognitive interview (n = 15) or 1 of 3 focus groups (n = 12). A total of 10 cognitive interviews and 2 focus groups were conducted in round 1, and 5 cognitive interviews and 1 focus group were conducted in round 2. A participant flow chart for the focus group and cognitive interviews can be found in Appendix A3. Participants predominantly identified as sexual minority, cisgender women who were partnered, White, and educated beyond the high school level (Table 3). The third patient focus group was excluded from this study; thus, sociodemographic information and interview data from this group were omitted. This decision was based on the minimal preparedness of the patients

**Table 1.** Item categorizations in relation to the conceptual framework.

| Primary branch | Secondary branch | Framework sub-categorizations |
|---|---|---|
| Physical Characteristics of Pain | Location | Pain During Insertion |
| | Intensity | Pain After Insertion |
| | Timing | Most Distressing Pain Locations |
| | Quality | Pain Fluctuations in Relation to the Menstrual Cycle |
| | Most Distressing Pain | Quality Features of Pain |
| | | Extent of Agreement with Pain Statements |
| Psychosocial Correlates of Pain | (Effect of pain on:) | Physiological Characteristics of Pain |
| | Behaviors | Interference with Activities as a Result of Pain |
| | Cognitions | Coping Behaviours Related to Pain |
| | Affect | Affect and Cognitions Related to Provoked Pain |
| | Sexuality | Affect and Cognitions Related to Insertion and Pain |
| | | Satisfaction with Sex |
| | | Satisfaction with Sexual Relationship(s) |
| | | Sexual Distress Related to Sexual Functioning |
| | | Frequency of Insertion Interference |
| | | Pain and Self-Consciousness |
| | | Pain and Self-Efficacy |
| | | Pain and Sexual Flexibility |

**Table 2.** Summary of modifications, additions, and exclusions to items in the eDelphi process.

| | Initial item count in eDelphi | Modified by eDelphi | Added by eDelphi | Excluded by eDelphi | Consensus reached item total |
|---|---|---|---|---|---|
| Physical characteristics | 62 | 18 | 13 | 10 | 65 |
| Psychosocial correlates | 101 | 22 | 10 | 0 | 111 |
| Total | 163 | 40 | 23 | 10 | 176 |

**Table 3.** Patient focus group and cognitive interview characteristics (n = 27).

| Characteristic | Mean ± SD, range; n (%) |
|---|---|
| **Age** | 29.3 ± 5.8, 20-40 |
| **Sexual orientation** | |
| Bisexual | 9 (39) |
| Heterosexual/Straight | 9 (39) |
| Lesbian/Gay | 2 (9) |
| Other | 1 (4) |
| Queer | 2 (9) |
| **Gender identity** | |
| No label | 1 (4) |
| Non-binary | 4 (17) |
| Woman | 18 (78) |
| **Relationship status** | |
| Divorced | 2 (9) |
| Married/Common-law/Committed/Living together | 14 (61) |
| Other | 2 (9) |
| Single | 5 (22) |
| **Parous** | 2 (9) |
| **Ethnicity** | |
| Asian | 3 (13) |
| Hispanic | 1 (4) |
| Indigenous | 1 (4) |
| Middle Eastern | 1 (4) |
| Mixed | 4 (17) |
| White | 13 (57) |
| **Education** | |
| High school | 6 (26) |
| Post–high school | 17 (74) |

in this group: 1 patient mentioned that they did not know that the focus group was going to be about the DSDQ, there was an overemphasis of the conversation centered on the demographic questionnaire of the study, and there was a lack of participation despite numerous attempts to prompt input.

Of the 3 clinicians recruited to participate in a focus group to discuss the DSDQ, 2 participated; 1 clinician was a physiotherapist, and 1 was a psychiatrist. Years of experience among these clinicians ranged from 6 to 15.

### *Cognitive interview results*

All cognitive interview transcripts were coded with our coding framework (Appendix A4). Modifications to the DSDQ were made based on the interpretation of quotes that fell under codes within the coding framework. Appendices A5 and A6 detail all modifications made to the DSDQ based on the cognitive interview analysis after round 1 and round 2, respectively.

### *Focus group interview results*

The themes presented in this section were developed with the aim of establishing the content and construct validity of the DSDQ (Table 4).

## Final review

The 6 steering committee members completed the final review: 4 clinician-researchers and 2 patient partners. Primarily grammatical changes were made to the DSDQ. A patient partner suggested the addition of 3 items to assess the time of onset of pain after an insertion experience has ended. These items were added to the DSDQ. Table 5 outlines the number of items in each sub-category within the conceptual framework. The items in each sub-category are grouped on the DSDQ.

## EFA and CFA

The sociodemographic characteristics of the independent EFA and CFA samples are summarized in Appendix A7. In the EFA sample, participants were in their early 30s on average (mean ± standard deviation [SD] = 34.2 ± 8.8), with the youngest being 19 years old and the oldest being 69 years old. In the CFA sample, participants were in their early 40s on average (mean ± SD = 41.2 ± 12.2); the youngest was 23 and the oldest was 74. In both the EFA and CFA samples, most identified as a woman, heterosexual, White, partnered, and educated at the high school level or higher.

View Appendix A8 to view the full version of the DSDQ items, based on the short forms used in the EFA and CFA analyses. In the EFA, 175 items were analyzed, resulting in a KMO score of 0.74 and communalities between 0.65 and 0.91, suggesting suitability for EFA. The scree plot supported a 5-factor solution, and the component correlation matrix indicated orthogonal rotation. After 2 iterations, in which questions with poor factor loadings were removed, the item pool was downsized to 124. From this crude model, another 13 items were eliminated, guided by Cronbach's $\alpha$. An additional content review was conducted, leading to team decisions to split 1 of the original factors into 2 subscales and amalgamate questions on pelvic/abdominal pain with those on deep vaginal pain. This decision was based on clinical insight regarding the difficulty of localizing pelvic/abdominal pain with deep vaginal pain upon insertion. After optimization, the final 103-item model consisted of 6 factors labeled as Vaginal Opening Pain, Deep Vaginal/Pelvic/Abdominal Pain, Pain Interference, Affect and Cognitions Related to Provoked Pain, Sexual Distress Related to Sexual Well-being, and Pain Self-efficacy, as outlined in Table 6 in Appendix A9; reliability testing with Cronbach's $\alpha$ showed excellent internal consistency.

In the CFA, the 103-item model developed from the EFA was downsized to 38 items purely based on statistics, which loaded well to the 6 factors proposed previously in the EFA. After content review, 7 additional questions were added back to the DSDQ (VOq9, VOq10, VOq14, VOq16, DPq13, DPq16, SDq9)—see Appendix A8 to view the items based on their short forms listed. These items were added back based on expert clinician review.

**Table 4.** Focus group themes.

| Theme | Evidence |
|---|---|
| Patients thought the DSDQ captured the entirety of their current dyspareunia experience. | *"I really liked that it was detailed, descriptive, you know, questions I wouldn't think of, but once you read them, you're like, oh yeah, that does happen to me."* (Patient in FG2)<br>*"I really appreciated seeing how intricate the answers were able to be on some of them because there is so many different kinds of pains that you can feel."* (Patient in FG1)<br>*"I do think that it captured a lot of the entirety because it [dyspareunia] is such a whole picture as opposed to just the active insertion, it can draw into three days later. Those were answers that I hadn't seen on other questionnaires before."* (Patient in FG1) |
| Clinicians indicated that the DSDQ captured important clinical features of dyspareunia. | *"I thought it was very comprehensive. I think it addressed a lot of the important aspects of somebody presenting with dyspareunia."* (Clinician in FG4)<br>*"Yeah, I agree. It was very thorough."* (Clinician in FG4) |
| Patients and clinicians indicated that the order of items on the DSDQ was logical and appropriate. | *"They [the questions] seemed to be in a good order. It flowed, it made sense, the way that which questions came first and whatnot. So, I thought it was very clear and just logical."* (Patient in FG1)<br>*"I think the way it started by kind of attempting to do some of that localizing, which of course is quite difficult for some patients, is a good way to start and then to kind of move into characteristics of the pain and then to end with kind of talking about how the pain impacts their lives. I thought that kind of flowed and made sense to me."* (Clinician in FG4) |
| Patients and clinicians thought that the format of the DSDQ was appropriate. | *"It felt like someone put a lot of thought into designing the questionnaire, because of how the questions were being asked and what, what the format was. So, I appreciated that."* (Patient in FG2)<br>*"I really like that it was multiple choice. I mean it, and it had quite a few different options, so I didn't feel like, oh, it's either black or white or... I really liked that cause I felt that I could actually answer exactly what I felt without having to write an answer."* (Patient in FG2)<br>*"I think it's [the format] appropriate for this population. I really do."* (Clinician in FG4) |
| Patients and clinicians indicated that the use of images on the DSDQ was particularly helpful for localizing one's dyspareunia. | *"I thought the use of the diagram was, at the start, especially, it was very clear, so very understandable."* (Patient in FG1)<br>*"I think the thing that really stuck out to me initially was the diagram, was incredibly helpful to know the difference between the deep penetrative/pelvic, that made it very clear."* (Patient in FG1)<br>*"I really find it great that people can click on links to see visually where things are in, what parts they're talking about. I think that is really a rich way to engage people with the questionnaire."* (Clinician in FG4) |
| Patients and clinicians shared that they thought the DSDQ was understandable. | *"I have filled out quite a few questionnaires in my lifetime. I do find some of them to be kind of you know, triggering with those personal questions. However, I did think that the questionnaire was really well written and specific and easy to answer."* (Patient in FG1)<br>*"English is not my first language and still for me, it was really easy to understand all the questions and know how to answer them. So, I think it was really well formulated."* (Patient in FG2)<br>*"I definitely think patients who experience pain will know exactly what you are asking."* (Clinician in FG4) |
| Patients and clinicians expressed that they felt comfortable answering the DSDQ despite the sensitive nature of dyspareunia. | *"I was comfortable with all of the questions. I even like kind of scanned for things that would normally make me uncomfortable."* (Patient in FG1)<br>*"Like I said, there were parts of it that were difficult and uncomfortable to answer, but honestly, I can't think about any way I would change it. It's kind of important questions just like in a depression questionnaire, they're not fun to answer, but it's important."* (Patient in FG2)<br>*"I think most of the questions were written in a way with really neutral language that would not create discomfort. And again, folks that are feeling this sort of pain, they know exactly what you're asking about and I don't think it would create any discomfort."* (Clinician in FG4) |
| Patients and clinicians expressed that the DSDQ was understandably and necessarily lengthy. | *"I mean, it was long, but there was a reason it was long. So, was it ridiculous? No. Was it long and hit all the points that it needed to? Yes."* (Patient in FG1)<br>*"For me it wasn't that long. It was detailed, but for it to be that detailed, it had to be that long, I guess. I've done other questionnaires that were way longer and I felt they were more repetitive and this one kind of touched on all the points without being too, too long."* (Patient in FG2)<br>*"Forgive me for being blunt, but I never really got the sense that it was like, oh, we're beating a dead horse here, we've already answered this. I feel like every group of questions really did touch on a separate aspect of it. So, it's a complex thing and it's gonna be therefore quite a lengthy exploration of what's happening for people. So, it makes sense that it's this long. It's just, yeah, it's just hard but necessary."* (Clinician in FG4) |
| Patients found the language of the DSDQ to be inclusive of and sensitive to different experiences of dyspareunia. | *"It seemed very patient focused in every aspect. It almost seemed like patient built or women built to me. I felt very understood in the questions."* (Patient in FG1)<br>*"I loved the inclusivity, you don't often see that in questionnaires - less kind of gender focused, more inclusive language, just kind of helps things not be super triggering."* (Patient in FG1)<br>*"I think for me personally I really appreciated the language that was used. I thought it was very mindful and inclusive. So, I appreciated that, that was certainly the best part, cause it again, felt safe."* (Patient in FG1) |
| Patients found that taking the DSDQ was mentally taxing and emotionally draining. | *"It was mentally a lot for me to go through. Like I said, we all have our own ways of kind of dealing with our pain and hiding how much we hurt."* (Patient in FG2)<br>*"It was difficult to take it. It did kind of make me re-think a lot of things that I've kind of just gotten used to over time."* (Patient in FG1)<br>*"It's good for me to think about these questions and try to answer them, but then after a while I get a bit tired from answering them."* (Patient in FG1) |
| Patients and clinicians mentioned that there may be positive benefits to filling out the DSDQ, including learning more about one's pain and feeling validated. | *"It [the questions] made me think about when exactly I'm feeling the pain. Cause sometimes I'm like, oh no, it's just painful. But answering those questions, I'm like, okay, so it's painful at this time actually and not really at this other time. So, having it very detailed, I think it helped me understand my pain as well."* (Patient in FG2)<br>*"I thought they [the questions] were very relevant. I think that people feel so validated when we get really specific with our questions."* (Clinician in FG4)<br>*"Our patients are so validated when we accurately can question them about the specifics of their experience and more so how that impacts their life, and you know. Yeah, so I really feel like your questions were relevant in that regard."* (Clinician in FG4) |

**Table 5.** Total number of items in each sub-category of the conceptual framework after the final revision.

| Primary branch | Secondary branch | Framework sub-categorizations | Item number |
|---|---|---|---|
| Pain Characteristics | Location | Pain During Insertion | 15 |
| | Intensity | Pain After Insertion | 15 |
| | Timing | Most Distressing Pain Locations | 3 |
| | Quality | Pain Fluctuations in Relation to the Menstrual Cycle | 5 |
| | Most Distressing | Quality Features of Pain | 19 |
| | Pain | Extent of Agreement with Pain Statements | 5 |
| | | **Subtotal:** | 62 |
| Psychosocial Correlates of Pain | (Effect of pain on:) | Physiological Characteristics of Pain | 5 |
| | Behaviors | Interference with Activities as a Result of Pain | 16 |
| | Cognitions | Coping Behaviours Related to Pain | 10 |
| | Affect | Affect and Cognitions Related to Provoked Pain | 26 |
| | Sexuality | Affect and Cognitions Related to Insertion and Pain | 11 |
| | | Satisfaction with Sex | 7 |
| | | Satisfaction with Sexual Relationship(s) | 4 |
| | | Sexual Distress Related to Sexual Functioning | 12 |
| | | Frequency of Insertion Interference | 3 |
| | | Pain and Self-Consciousness | 6 |
| | | Pain and Self-Efficacy | 10 |
| | | Pain and Sexual Flexibility | 3 |
| | | **Subtotal:** | 113 |
| | | **Total Item Count:** | 175 |

The final model fit indices were as follows: RMSEA = 0.08, SRMR = 0.08, TLI = 0.81, and CFI = 0.83, together indicating a fair fit, especially in the context of a small sample size relative to model size.[45,49] Between-factor correlations were weak, moderate, or insignificant, which indicates that scales captured unique but related constructs. Correlations between factors are also presented in a table in Appendix A10. Additionally, please see Figure A11.1 in Appendix A11 to view the standardized factor loadings and correlations of the updated 45-question DSDQ.

Metrics of length, readability, and range of questions are listed in Appendix A12 regarding the 103-item model. The vast majority indicated that the length of the DSDQ, readability, and range of questions were "good," "very good," or "excellent." However, a notable proportion considered the length of the 103-item DSDQ to be "fair," or "poor," which rationalized the goal of shortening the DSDQ in the next step CFA to the updated 45-item DSDQ. Additionally, in the CFA T2 dataset, 77.0% (97/126) of participants completed the DSDQ in under 90 minutes; for the remaining 33.0%, we considered it a possibility that the DSDQ was completed in multiple sittings. For this 77% of participants, the mean and median time to complete the questionnaire was 16 and 13 minutes, respectively.

The final version of the DSDQ (45 items) can be found in the Supplementary Information section.

## Discussion

This study created a patient-reported tool, the DSDQ, that differentiates between superficial and deep dyspareunia and captures biopsychosocial features of pain. Patients who experience dyspareunia and clinicians who treat individuals who experience dyspareunia collaborated with researchers to establish this project as a research priority, design project methodology, create and revise items, analyze qualitative data, and assess the measure's validity. The development of the DSDQ followed a qualitative item review process, a procedure endorsed by PROMIS to ensure representation from diverse perspectives and to establish the validity of the measure.[50] This process outlines steps for item pool construction, item review and revision, item categorization, focus groups and cognitive interviews, and a final revision.[22] An EFA and a CFA were subsequently conducted to propose a psychometric scale that is useful, sound, parsimonious, reliable, and valid. The subscales in the DSDQ included Vaginal Opening Pain, Deep Vaginal/Pelvic/Abdominal Pain, Pain Interference, Affect and Cognitions Related to Provoked Pain, Sexual Distress Related to Sexual Well-being, and Pain Self-efficacy.

The robust DSDQ development process followed was conducive to establishing evidence of construct and content validity. The QIR process required us to conceptualize the domains of interest before items were generated and prioritized expert assessment of items—key components of content validity.[51] Further, the eDelphi process as well as patient and clinician interviews acted as safeguards against inclusion of irrelevant content. The cognitive interviews ensured that patients' response processes aligned with the intended item construct. Lastly, the EFA and CFA provided preliminary evidence for the appropriate internal structure of the DSDQ. In the EFA, all item factor loadings met the recommended stable cutoff of 0.4.[38,39] The internal consistency of each factor, as indicated by the Cronbach alphas, were excellent, ranging from 0.90 to 0.95; we intentionally allowed for some room of redundancy at the EFA stage and fixed it in the CFA stage for the final version of the DSDQ in the Supplemental Information section. The EFA and CFA results also demonstrate evidence that the DSDQ can validly differentiate between deep and superficial pain as indicated by the independent factors that emerged for vaginal opening pain and deep vaginal/pelvic/abdominal pain.

The most novel aspect of the DSDQ is its independent assessment of deep and superficial dyspareunia and its inclusion of elements that expand across the physical and psychosocial domains. Other measures inadequately account for diversity in dyspareunia experiences, were not developed using a formal patient-reported outcome process, only focus on 1 type of pain, are disease-specific, and are not validated to differentiate between deep and

superficial pain. For example, the Endometriosis Phenome Harmonisation Project (EPHect)[52] developed a standardized dyspareunia questionnaire, but the questions pertain to endometriosis specifically. Some EPHect questions inquire into superficial versus deep pain, but this measure has not undergone psychometric testing. Other examples that do not differentiate between deep and superficial pain are the Vulvar Pain Assessment Questionnaire (VPAQ),[53,54] the Subjective Impact of Dyspareunia Inventory (SIDI),[55], and the Female Sexual Function Index (FSFI).[19,20] In contrast to these measures, the DSDQ was intentionally developed to differentiate between deep and superficial pain, was developed using PROMIS guidelines, utilized quota sampling to diversify the patient sample, is comprehensive, and is not disease/condition specific. The DSDQ is also unique in its ability to capture numerous elements of dyspareunia including pain intensity, frequency, quality, location, self-efficacy, sexual distress, affects and cognitions, and life interference. The comprehensiveness of the DSDQ acknowledges the complexity and multidimensional nature of dyspareunia and is thus best suited for administration by researchers and clinicians with an interest in multidisciplinary outcomes.

Patient partner involvement was another critical component in the development of the DSDQ. Uniquely, the patient partner–researcher relationship was fostered early, allowing us to highlight patient partner voices in numerous development stages. Patient partners established this project as a research priority[56] and informed the methodology. Patient partners fulfilled research collaborator roles on the steering committee, research involvement roles on the eDelphi panel, and research participant roles in the interview stage of development.[23] However, we also encountered challenges commonly faced with patient-involved research.[57] For example, we often opted to prioritize clinically relevant items on the DSDQ, given its ultimate purpose as a tool for clinicians to better understand their patients' pain. Many participants in this study voiced that the DSDQ failed to capture the longevity of their pain experience. After careful consideration, the 4-week time frame was not extended to mitigate recall biases since longer recall periods are associated with a lower prevalence of sexual pain.[58] Additionally, given the DSDQ's intended use in research settings, it will likely be applied in treatment outcome studies, which target current pain experiences. When developing PROMs, it is important to consider the balance between patient preference and clinical utility, as both are vital aspects of an adequate PROM.

There are other limitations to this study. The quota sampling technique effectively overrepresented sexual minorities and racialized groups relative to population estimates, but people who were educated at the high school level or lower were not overrepresented in the sample. Despite this, a theme from the patient focus groups centered on the understandability of the DSDQ, including patients whose first language was not English. Another limitation of this study was that all participants had received care at a clinic specializing in endometriosis. Due to well-established associations between deep dyspareunia and endometriosis, it is possible that this sample overrepresented people with primarily deep dyspareunia compared to superficial dyspareunia. Future studies should prioritize the validation of this measure in populations with primarily superficial dyspareunia and consider using clinician exams of superficial versus deep pain to compare to scores on the vaginal opening factor and deep vaginal/pelvic/abdominal pain factor of the DSDQ. Another limitation of this study was the sole use of the content validity index (CVI) to establish consensus amongst experts in eDelphi. In addition to using the CVI, the interquartile range (IQR) and the stability of items can also be used to determine the degree of consensus.[59,60] Due to the relatively small number of experts and the number of rounds conducted in the eDelphi, it was deemed that the IQR and stability were not useful metrics to determine consensus-reached items. Additionally, in the EFA, missing values were replaced with means to preserve sample size; however, imputation could theoretically add bias and potentially overlook non-random missingness.[61] While the 45-item DSDQ is lengthier compared to the commonly used 19-item FSFI, it is still shorter than other dyspareunia questionnaires such as the 59-item EPHect section for dyspareunia and the 55-item VPAQ. Additionally, the variety of domains addressed may save researchers and clinicians from needing to administer multiple measures, thus alleviating respondent fatigue. Considering that the DSDQ is half the length of what was administered in the CFA project, we expect it to take approximately 6-7 minutes to fill out for most participants, which is likely feasible in routine clinical workups and follow-ups.

Additional work should assess test–retest reliability, convergent validity, and discriminant validity of the DSDQ and potentially re-assess the communality and internal validity using a different sample. Furthermore, the DSDQ could be validated in demographic sub-populations (eg, postpartum and post-menopausal populations, populations with diverse cultural backgrounds) to examine the external validity of the measure. The DSDQ could also be prospectively implemented in a clinic setting to determine its impact on care for dyspareunia and patient outcomes.

Practical applications of the DSDQ fall in both clinical and research realms. The DSDQ will have the potential to better standardize phenotyping of dyspareunia to better inform diagnosis and treatment and quantify changes in dyspareunia over time; however, this will depend on testing in larger and more representative populations. The questionnaire is specifically designed to be an accessible tool to capture patients' nuanced lived experiences of dyspareunia more effectively and facilitate more candid and holistic representations of the dyspareunia experience. Understanding changes in pain over time is important to assess treatment outcomes and clarify clinical symptoms. The DSDQ offers a patient-centered and accessible way to describe different types of dyspareunia, to ensure the patient experience of this symptom is adequately translated into clinical and research settings.

## Acknowledgments

The authors report no acknowledgments.

## Author contributions

N.M.: Data curation [lead], Formal analysis [lead], Investigation [equal], Project administration [lead], Writing—original draft [lead]. S.L.: Data curation [equal], Formal analysis [equal], Writing - review & editing [equal]. Y.D.L.: Data curation [equal], Formal analysis [lead], Methodology [equal], Visualization [equal], Writing—review & editing [equal]. H.N.: Project administration [equal], Writing—review & editing [equal]. C.A.: Conceptualization [equal], Writing—review & editing [equal]. M.A.: Conceptualization [equal],

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## Supplementary material

Supplementary material is available at *The Journal of Sexual Medicine* online.

## Funding

This work was supported by the Canadian Institutes of Health Research Patient Oriented ResearchCatalyst Grant [201909PAO] and Canada Graduate Scholarship – Master's.

## Conflicts of interest

C. Pukall is a consultant for Pelva Health, Initiator Pharmacy and SPM therapeutics.

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*The Journal of Sexual Medicine*, 2025, 1–11
https://doi.org/10.1093/jsxmed/qdaf025
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