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Authors

Bordeianou, Liliana G

Anger, Jennifer T

Boutros, Marylise

et al.

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Measuring Pelvic Floor Disorder Symptoms Using Patient-Reported Instruments: Proceedings of the Consensus Meeting of the Pelvic Floor Consortium of the American Society of Colon and Rectal Surgeons, the International Continence Society, the American Urogynecologic Society, and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction

Liliana G. Bordeianou, M.D., M.P.H.,¹ Jennifer T. Anger, M.D., M.P.H.,² Marylise Boutros, M.D.,³ Elisa Birnbaum, M.D.,⁴ Joseph C. Carmichael, M.D.,⁵ Kathleen A. Connell, M.D.,⁶ Elise J.B. De, M.D.,⁷ Anders Mellgren, M.D., Ph.D.,⁸ Kyle Staller, M.D., M.P.H.,⁹ Sarah A. Vogler, M.D., M.B.A.,¹⁰ Milena M. Weinstein, M.D.,¹¹ Faysal A. Yafi, M.D.,¹² Tracy L. Hull, M.D.,¹³ and Members of the Pelvic Floor Disorders Consortium Working Groups on Patient-Reported Outcomes

The Pelvic Floor Disorders Consortium (PFDC) is a multidisciplinary organization of colorectal surgeons, urogynecologists, urologists, gynecologists, gastroenterologists, physiotherapists, and other advanced care practitioners. These practitioners, along with their respective societies, research foundations, and committees, are committed to enhancing the care of patients with pelvic floor disorders. The PFDC's goal is to collaborate through clinical care and research to develop and evaluate educational programs, create clinical guidelines and algorithms, and promote overall quality of care in this unique population. The recommendations arising from this effort below represent the work product of the PFDC Working Group on Patient-Reported Outcomes. The objective of this workgroup, which included specialists from 12 countries, was to generate inclusive, rather than prescriptive, guidelines for all practitioners, irrespective of discipline, in the care and treatment of patients with pelvic floor disorders.

STATEMENT OF THE PROBLEM

The patient-reported outcome (PRO) is defined as *a report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.*¹ Beginning with the introduction of the Karnofsky performance status scale in 1948,² health-related quality of life (HRQoL) has become an increasingly important metric in the field of health care research. The growing prominence of HRQoL signifies a shift in focus from clinical outcomes related solely to survival and complications, to outcomes that include the patient's perspective. Studies have shown that clinicians' assessments of outcomes that matter often differ significantly from outcomes reported by patients. A considerable disconnect can occur between what the observer deems important versus what the patient considers important in terms of symptom management and the balance between relief and quality of life.^{3,4}

¹Section Colorectal Surgery, Center for Pelvic Floor Disorders, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts; ²Department of Urology, California School of Health Sciences, Los Angeles, California; ³Department of Colorectal Surgery, McGill University, Montreal, Canada; ⁴Department of Colorectal Surgery, University of Colorado, Denver, Colorado; ⁵Division of Colon and Rectal Surgery, University of California Irvine, Irvine, California; ⁶Department of Female Pelvic Floor Medicine and Reconstruction, University of Colorado, Denver, Colorado; ⁷Department of Urology, Center for Pelvic Floor Disorders, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts; ⁸Department of Colorectal Surgery, University of Illinois, Chicago, Illinois; ⁹Division of Gastroenterology, Center for Pelvic Floor Disorders, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts; ¹⁰Department of Colorectal Surgery, Pelvic Floor Center, University of Minnesota, Minneapolis, Minnesota; ¹¹Department of Female Pelvic Floor Medicine and Reconstruction Center for Pelvic Floor Disorders, Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts; ¹²Department of Urology, Center for Men's Health, University of California Irvine, Irvine, California; and ¹³Department of Colorectal Surgery, Cleveland Clinic Hospitals, Cleveland, Ohio. Supplemental digital content is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in HTML and PDF versions of this article on the journal's Web site (www.dcrjournal.com).
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Correspondence: Liliana G. Bordeianou, M.D., M.P.H., 15 Parkman St, ACC 460, Boston, MA 02114. E-mail: lbordeianou@mgh.harvard.edu

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The importance of PROs is evident in the wide recognition they have received by major health care providers and organizations. For example, the US Food and Drug Administration enhanced its scrutiny of available instruments⁵ following the publication of guidelines for PRO instruments used as effectiveness end points in clinical trials.¹ Likewise, the National Health Service (NHS) in the United Kingdom mandated funded providers to report PRO measures for certain elective surgical procedures. Finally, many clinicians now use PROs to follow their patients over time and between treatments to help guide patient care.⁶

To function effectively as a quality-of-care instrument, the PRO must be accurately communicated and compared. This is especially critical for surgical interventions. Compared to other areas of medicine, treating pelvic floor disorders relies heavily on patient-reported symptoms, and frequently, the outcomes cannot be measured, compared, or quantified by objective tests or imaging. Hence, to ensure clear communication between providers and researchers, validated instruments have been created to reliably measure patient-reported functional status. Additionally, these instruments must have reasonable sensitivity and specificity to detect changes in patient condition over time, as well as differences between patients and patient populations. Furthermore, to achieve optimal outcomes in patients with pelvic floor disorders, a consensus is required to identify the best available validated instruments for capturing patient-reported symptoms, such as fecal incontinence, urinary incontinence, constipation, lower urinary tract symptoms, and sexual dysfunction. In general, a common language is desirable because it fosters accurate interpretation and comparison of treatments and facilitates pooling of data for meta-analysis and systematic review. Unfortunately, the failure of many recent attempts to achieve data consolidation in this area are due to the lack of consensus among clinicians and researchers regarding which instrument(s) should be used and reported in research publications.⁷

This document describes the process the PFDC working group followed to reach consensus as to which of the many existing validated instruments should be recommended to health care providers, irrespective of discipline (ie, colorectal surgeon, urogynecologist, urologist, gastroenterologist, or physiotherapist). After reviewing all of the major existing instruments and generating a standardized list of those most accurate and practical to use, the working group created a common initial patient assessment measure for every clinical setting, regardless of which specialist saw the patient first. Ultimately, consensus was reached regarding the best tool for each condition. The agreed upon battery of recommended validated instruments was ultimately labeled **IMPACT** (Initial Measurement of Patient-Reported Pelvic Floor Complaints Tool). The panel concurred that, even though it may be possible to identify a better instrument for a given symptom (eg, fecal incontinence versus urinary incontinence), not having a standardized instrument was a hindrance to large-scale multidisciplinary collaboration in clinical and scientific research. It also hindered communication between experts about specific patients and the perceived severity of their condition. The members believed strongly that a simple consensus document, such as IMPACT, could remedy the situation and foster progress toward a common language for patient-reported pelvic floor disorder clinical outcomes.

METHODOLOGY

This document was created at the initiative of the *Pelvic Floor Disorders Consortium (PFDC) Working Group on Patient Reported Outcomes*. The PFDC is composed of clinicians with demonstrated expertise in the care and treatment of pelvic floor conditions. The Working Group on Patient-Reported Outcomes was created by enlisting Pelvic Floor Consortium volunteers. Invitation criteria included leadership in the field of pelvic floor disorders with academic scholarship and history of cross-disciplinary collaboration.

Literature Search

An organized search of MEDLINE, PubMed, EMBASE, and the Cochrane Database of Collected Reviews was performed on July 1, 2018, and repeated on September 1, 2018. Retrieved publications were limited to the English language, but no limits on year of publication were applied. The search terms also included “fecal incontinence, urinary incontinence, constipation, lower urinary tract symptoms in men and women, and sexual dysfunction in men and women.” The search strategies used “patient reported outcomes,” “validated instruments,” and “questionnaires” as primary search terms. Other terms included “fecal incontinence,” “constipation,” “obstructed defecation syndrome,” “intestinal function,” “bowel function,” “gastrointestinal symptoms,” “sexual function in men,” “sexual function in women,” “urinary incontinence,” “lower urinary tract symptoms,” “bladder dysfunction,” and “quality of life.” Directed searches of the embedded references from the primary articles were also performed in certain circumstances. Thus, 3211 references were retrieved by the working groups, and most were excluded to arrive at 182 instruments. Criteria for inclusion were instruments that *underwent score validation*, scores that were commonly used in clinical practice, and scores that have been demonstrated to have ability to discriminate well by disease populations. Thus, from 182 articles, each workgroup arrived at 10 to 15 final articles selected for further detailed analysis.

Preliminary Workgroup Considerations and Deliberations

Six multidisciplinary workgroups were created, each assigned to investigate a specific symptom: fecal incontinence, constipation, urinary incontinence, lower urinary tract symptoms, male sexual function, and female sexual function. Each group evaluated the top 10 to 15 tools identified in the literature search, focusing on validity, reliability, sensitivity to change, number of questions and domains, degree of use in the literature, applicability to both sexes, and free access. The participants ranked tools by using consistent criteria to reach a >70% consensus regarding the top 3 to 4 instruments that warranted further in-depth consideration by the PFDC.

In preliminary preparations and discussions, committee members considered instrument validation to be crucial. Workgroups also confirmed whether the instruments were studied for reliability. In addition, the workgroup members also assessed the number of Google Scholar citations for each instrument, which served as a rough estimated index of scholarly impact.

Pelvic Floor Consortium Expert Meeting

The Pelvic Floor Consortium Expert Meeting convened on October 13, 2018 in Chicago, Illinois. It included more than 100 international experts from 12 countries and included 5 subspecialties: colorectal surgery, gastroenterology, urogynecology, urology, and physiotherapy. The meeting was funded by the American Society of Colon and Rectal Surgery and the American Urogynecologic Society. These experts belong to numerous societies involved in treating pelvic floor disorders, including, but not limited to, the American Society of Colon and Rectal Surgery and the American Urogynecologic Society (AUGS). Formal auditors were present from the International Continence Society, the Society of Abdominal Radiology, and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU).

The participants at the expert consensus meeting analyzed all of the proposed instruments, measuring each of the conditions reviewed in this statement, ultimately recommending instrument(s) for each set of complaints. Tools were added to the final consensus document if and when discussants reached consensus regarding the tool's usefulness and practicality. Consensus was again defined

as agreement by 70% or more of the participants. When consensus was not reached, the workgroups performed additional research and literature reviews to clarify additional questions raised. A subsequent committee meeting was held to conduct final voting on the instruments, while keeping the directives of the expert consensus panel discussions in mind.

The final recommended list of previously validated instruments was called IMPACT (Initial Measurement of Patient-Reported Pelvic Floor Complaints Tool). The IMPACT Long Form is a combination of all the tools chosen by the experts in each category in their unaltered form. An IMPACT Short Form version was also created to avoid duplication of questions.

Final Review

Once the final combined IMPACT tool long form was voted on and the short form was created, the path leading to its development was documented and presented for review by the American Society of Colon and Rectal Surgeons (ASCRS) Pelvic Floor Disorders Steering Committee. This steering committee is directed to develop clinical practice recommendations on colorectal pelvic floor disorders based on best available evidence. The ASCRS Steering Committee edited the document and sent it to the ASCRS Executive Committee for final approval for publication. Similar reviews and endorsements were also given by the American Society of Urogynecology (AUGS) Publication Committee, the International Continence Society Board of Directors and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Board of Directors. The document was also reviewed by the Executive Board of the Society of Gynecological Surgeons, who voted to support the document's recommendations for female patients (could not comment on the male instruments because their members generally do not treat males).

RECOMMENDATIONS

I. Measurement of Fecal Incontinence Severity

The consortium recommends the use of *both* the Cleveland Clinic Florida Incontinence Score (5 questions) and the St. Mark's Incontinence Score (7 questions). The use of both tools will allow assessment of the severity of fecal incontinence, while also allowing discrimination of the impact of urgency and constipating medications on the ultimate severity of fecal incontinence. Total number of questions: 12

Nine colorectal surgeons and 3 urogynecologists participated as expert workgroup panelists. The initial instruments reviewed by the workgroup members are listed in Supplemental Table 1, <http://links.lww.com/DCR/B58>. Panelists agreed that instruments should generally have the greatest applicability to the pelvic floor disorders population across disciplines and exhibit the best combination of validity, comprehensiveness, and practicality. Instruments that rate the severity of fecal incontinence and rectal urgency are preferred because this often unpredictable symptom causes much distress to people with fecal incontinence (FI).⁸ Diagnostic/severity instruments were prioritized over quality-of-life instruments. The workgroup panelists reached >70% consensus that 4 instruments would be brought for in-depth discussion before the *Pelvic Floor Consortium Expert Meeting*: the Cleveland Clinic Florida Incontinence Scale (CCFIS), Fecal Incontinence Severity Index (FISI), the Fecal Incontinence and Constipation Assessment (FICA), and the St. Mark's Incontinence Score (SMIS). These instruments were chosen over other instruments based on validity, ease of use, ability to assess change in symptoms, and recognition and familiarity across different specialties. In addition, the Fecal Incontinence Quality of

Life scale (FIQOL) was selected as the preferred quality-of-life (QOL) instrument.

Fecal Incontinence Severity Index is a tool that assesses severity of fecal incontinence using a 20-cell matrix table with 4 domains (leakage of gas, mucous, liquid stool, and solid stool).^{4,9} It has been used to evaluate the efficacy of treatments for fecal incontinence, and it is validated and reliable. It is a weighted summary score based on a combination of colorectal surgeon and patient results. It is a popular tool because it shows correlation with patient perception of symptoms related to incontinence. However, the FISI does not characterize urgency or the volume of leakage; scoring can be cumbersome and therefore difficult to complete in a clinical setting.

The Fecal Incontinence and Constipation Assessment was recommended because it is the most comprehensive, validated instrument for evaluating the severity of fecal incontinence evaluated by the workgroup.^{10–13} It is the only instrument that captures the volume of stool leakage, which was deemed essential for characterizing the severity of FI by a State of the Science Conference organized by the National Institutes of Health.¹⁴ Thus, it captures the severity of fecal incontinence, fecal urgency, and constipation, in addition to quality-of-life measurement. Although the entire instrument comprises 98 items, which is too long for a clinical visit, the severity of fecal incontinence can be fully characterized and readily analyzed with 5 questions. The length of this instrument has limited its use in the literature.

The CCFIS was published in 1993 and includes 5 questions pertaining to frequency of incontinence with different stool consistencies, use of a pad, and lifestyle alteration. Each question contributes equally to the severity score (score range 0–20).¹⁵ It was initially described as a clinical aid, but subsequent research has been conducted to validate it and to assess its reliability and sensitivity to change.¹⁶ The CCFIS allows for measurement of therapeutic success after intervention and is the most widely used instrument in the peer-reviewed literature (Google scholar citations 2504 as of September 13, 2018). It is also easily understood by patients and has been shown to have a high correlation to patients' subjective perception of symptoms.^{17–19} The results can be gathered quickly during an office visit. This instrument fails to capture the symptom of fecal urgency, volume of leakage, or impact on quality of life.

The SMIS is similar to CCFIS and incorporates the same 5 questions.¹⁶ In addition, this score also captures symptoms of urgency and quantifies the impact of constipating medications on the symptoms of incontinence, making it 7 questions in total. The SMIS defines rectal urgency as less than 15 minutes to reach the toilet. However, this is perhaps too long because, on average, healthy women reported they could defer defecation for 9 minutes.²⁰ St. Mark's Incontinence Score is validated and reliable. Similar to CCFIS it is used in numerous studies evaluating the impact of different treatments on fecal incontinence and the severity of incontinence in different patient populations (Google scholar with 906 citations as of August 14, 2018). The biggest strength of SMIS is the additional measurements captured (urgency and constipating medications) in comparison to CCFIS. However, these additional measures do make the tool slightly more difficult to use clinically.

During the discussion at the PFDC meeting, there was more than 70% consensus that the final measure chosen needed to be brief to allow for consistent use. Consensus was also reached that the measurement of mucus incontinence was not essential because mucus drainage is commonly attributed to mucosal prolapse and enlarged hemorrhoids rather than a form of true bowel incontinence. Ultimately, these considerations led to the exclusion of FISI and FICA. The expert discussions also reached significant consensus that the final tool should provide a way of discerning the impact of urgency on the severity of incontinence. The SMIS

offers this measure. However, a concern was raised that SMIS seems to paradoxically worsen when patients stop taking fiber supplementation. This weakness stopped SMIS from reaching 70% consensus as becoming the final recommended tool in isolation. The CCFIS had many supporters because it allowed for a clear and logical measurement of disease severity, but the lack of urgency measure stopped it from reaching the 70% consensus needed to become the final recommended tool in isolation. Given the impasse, the original expert workgroup used the information gained from the PFDC meeting to reevaluate the CCFIS and SMIS. This group reconvened and reached a >70% consensus that a combination of CCFIS and SMIS could be used to provide the highest level of quantifying symptoms of FI, impact of treatment, severity, quality of life, and practical ease of data collection in clinical practice, while sustaining the goal for multidisciplinary consensus.

II. Measurement of Constipation Severity

The consortium recommends the use of *both* the Patient Assessment of Constipation (12 questions) and Constipation Severity Instrument (16 questions) together. It was felt that use of both tools was needed to allow assessment of the severity of the various subsets of constipation (obstructed defecation syndrome, slow transit constipation, and irritable bowel syndrome) to allow full delineation and characterization of the full spectrum of this condition. Total number of questions: 28

Nine colorectal surgeons and 3 gastroenterologists participated as expert workgroup panelists. The initial instruments reviewed by the workgroup members are listed in Supplemental Table 2, <http://links.lww.com/DCR/B59>. Panelists agreed that instruments should generally have the greatest applicability to the pelvic floor disorders population across disciplines and exhibit the best combination of validity, comprehensiveness, and practicality. Diagnostic/severity instruments were prioritized over quality-of-life instruments. The workgroup panelists debated vigorously among a set of multiple excellent instruments, many of them highly quoted in the literature, and ultimately reached >70% consensus to bring 3 severity-measuring instruments forward before the larger *Pelvic Floor Consortium Expert Meeting: Fecal Incontinence and Constipation Assessment (FICA)*,⁹ Patient Assessment of Constipation–Symptoms (PAC-SYM),²¹ and Patient-reported Outcomes Measurement Information System (PROMIS) constipation module.²² In addition, Patient Assessment of Constipation—Quality of Life²³ was selected as the preferred QOL instrument.

At the in-person *Pelvic Floor Consortium Expert Meeting*, the strengths and weaknesses of the instruments were presented to the larger group. The FICA (98 questions, 2 domains) was felt to be the most comprehensive of instruments with construct validity, content validity, and criterion validity³ (results compared to daily bowel diaries). Additionally, FICA was the only instrument to incorporate the Bristol Stool Scale, noted by panelists to be a useful surrogate for colonic transit testing, and also distinguishes between functional constipation and constipation-pre-dominant irritable bowel syndrome.²⁴ Although FICA includes a fecal incontinence assessment, the group found its complete length, 98 questions, to be unwieldy for multi-disciplinary office use. Of these, 32 questions comprehensively characterize constipation. Additionally, severity is not measured and responsiveness to change has not been assessed. Although a condensed version was suggested, the group felt that the instrument was not validated in its component parts.

The PROMIS constipation module (9 questions, no subscales) is the newest instrument available and was noted for its validation across multiple general GI and specialty practices with easy comparison to standardized, US controls via an easily interpretable

“heatmap.” Important to a multidisciplinary group such as the PFDC, there is some experience differentiating urinary incontinence sub-types based on the constipation module alone.²⁵ Concern was raised that abdominal pain and bloating, 2 symptoms commonly seen in this population, required different modules. A recent analysis demonstrated that the PRO-MIS constipation scale was not responsive to change.²⁶

Finally, the PAC-SYM (12 questions, 3 domains) was found to be partly validated and used across multiple treatment sites and multiple populations with responsiveness over time and ability to distinguish between treatment responders and nonresponders. The gastroenterologists felt comfortable with this instrument, because it has been used in some clinical trials for chronic idiopathic constipation. However, the correlation between symptoms evaluated with the PAC-SYM instrument and daily diaries is weak, likely due to recall bias. Also, although panelists appreciated that symptoms could be divided into 3 domains (Rectal Symptoms, Stool Symptoms, and Abdominal Symptoms), there is no evidence (eg, comparison with objective features of pelvic floor dysfunction or colonic transit) to support these domains. Also, this instrument does not assess for the need for manual maneuvers to facilitate defecation, which they felt was an essential screening question in this population. Additionally, PAC-SYM was criticized for the lack of a threshold value or values with which to distinguish severe symptoms.

Although the constipation working group presented the aforementioned 3 instruments to the larger PFDC, other members of the larger body felt that that the Constipation Severity Instrument (CSI)²⁷ (ranked 4 in the panel discussion before the workgroup review) needed further consideration. They found that the CSI had been validated instrument against SF-36 (QOL) and PAC-SYM scores. Many PFDC members felt that the three domains assessed by the CSI (Obstructive Defecation, Colonic Inertia, and Pain) were useful for binning patients based on potential physiologic abnormalities. Others, however, argued that specific symptoms and the categories identified by the CSI have not been validated against physiologic abnormalities—particularly in regard to dyssynergic defecation.²⁸

In light of the input from the wider PFDC expert group, the constipation working group ultimately reconvened and reached a >70% consensus that a combination of the PAC-SYM and CSI would provide the greatest breadth of information for all PFDC specialties with an eye still toward practicality.

III. Measurement of Urinary Incontinence Severity

The consortium recommends the use of the short form of the Urogenital Distress Inventory (UDI) in the final combined IMPACT tool to allow identification of both stress and overflow incontinence and its degree of bother to patients. Number of questions: 6.

Two colorectal surgeons, 1 urologist, 5 urogynecologists, and 1 pelvic floor physiotherapist participated as expert workgroup panelists. The initial instruments reviewed by the workgroup members are listed in Supplemental Table 3, <http://links.lww.com/DCR/B60>. Panelists agreed that instruments should generally have the greatest applicability to the pelvic floor disorders population across disciplines and exhibit the best combination of validity, comprehensiveness, and practicality. Diagnostic/severity instruments were prioritized over quality-of-life instruments. The workgroup panelists reached >70% consensus that 3 instruments would be brought before the larger PFDC meeting: The chosen scores were the International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI-SF),²⁹ Urogenital Distress Inventory 6 questionnaire (UDI-6),³⁰ and ICIQ Male/ Female Lower Urinary Tract Symptom Questionnaires.^{31,32} These scores

were unanimously chosen because they were each well validated, robust, heavily cited, easy-to-use, and free to reproduce. The scores that were eliminated were either focused primarily on urinary incontinence (UI) quality of life rather than UI symptom scoring, covered a range of symptoms other than UI, or were limited to specific types of UI.

The committee presented their results to the members of the consortium in an in-person meeting. It was unanimously decided that the ICIQ Male/Female Lower Urinary Tract Symptom Questionnaires were better suited for the assessment of bladder dysfunction (a different workgroup). Thus, ICIQ-UI-SF and UDI-6 were discussed as the top 2 UI symptom scoring instruments. Both instruments were selected for their validity, sensitivity to change, brevity (4 and 6 questions, respectively), and scholarly use (2280 on October 1, 2018, and 1119 on September 30, 2018 google scholar citations, respectively). In addition, the ICIQ-UI-SF had many favorable characteristics including its suitability for both men and women, its inclusion of a symptom bother scale, and its assessment of the type of UI. Aspects of the UDI-6 that were highly favored included that it addressed a variety of UI symptoms (urine leakage, difficulty emptying, and pain), different types of UI, degree of symptom bother, and the inclusion of a summative score. Furthermore, the UDI-6 is a commonly used instrument in routine clinical work and research.

Following the consensus meeting, the UI and bladder dysfunction steering committees took a final vote and the UDI-6 was chosen as the most suitable instrument for assessing UI symptoms for clinical and research purposes across specialties. The UDI-6 only contains 6 questions and covers the type of UI, symptoms associated with UI, severity of symptoms and symptom bother. Furthermore, the UDI-6 conveniently gives a summative score that has been demonstrated to be sensitive to change with treatment and correlates with quality-of-life indices.

IV. Lower Urinary Tract Symptoms in Men and Women

The consortium recommends tailoring the measurement of lower urinary tract function in patients by sex:

- a. In women, the consortium recommends the use of the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms (ICIQ-FLUTS). Number of questions: 25
- b. In men, the consortium recommends the use of the International Prostate Symptoms Screening (IPSS). Number of questions: 8

Three colorectal surgeons, 3 urologists, and 2 urogynecologists participated as expert workgroup panelists. The initial instruments reviewed by the workgroup members are listed in Supplemental Table 4, <http://links.lww.com/DCR/B61>. The inclusion criteria for instruments were validation and reliability testing within the appropriate sexes. Questionnaires were then evaluated as to whether each tool assessed severity of symptoms vs quality-of-life measures. Priority was given to questionnaires that were free and accessible, could be easily administered, were well recognized across specialties, and could be applied to the general population.

During this process, it became clear that many of the validated questionnaires for voiding dysfunction were aimed at specific populations, disproportionately studying men and patients with neurogenic bladder. The great variability in the instruments highlighted the significant role of sex-based differences and disease processes in the symptomatology of voiding dysfunction. Therefore, the questionnaires were evaluated in terms of whether

they could be used to screen both sexes and applied to a general population. Also, many validated instruments did not screen for both severity of symptoms and QOL. Therefore, a usefulness score was devised to rank the ability of a questionnaire to screen these measures. These scores were evaluated if none, some, most, or all the questions could be used to assess severity of symptoms and QOL. A spreadsheet was compiled of the evaluations of each questionnaire from all panelists, and the usefulness scores were consistent in >90% of responses. These data were presented at the *Pelvic Floor Consortium Expert Meeting* to obtain input from the membership on how to best choose the tool most likely to be used by most members.

The top selected questionnaires recommended by the participants at the expert meeting included the International Prostate Symptoms Screening (IPSS)³³ and the ICIQ Female Lower Urinary Tract Symptoms.³⁴ The experts also took another look at the UDI-6,³⁵ which they previously voted as their instrument of choice for the measurement of urinary incontinence. The UDI-6 also has a question about bladder emptying but the committee concluded that a single question would be insufficient to screen for these symptoms.

Following this meeting, the voiding dysfunction and urinary incontinence task force groups voted on the final choice of instruments. Since no other questionnaires have been validated in both sexes, the IPSS was chosen for men and the ICIQ-FLUTS was chosen for screening women. Both tools are validated, highly reliable, and screen for the severity of symptoms and QOL in each sex. These comprehensive instruments include questions regarding urinary hesitancy, disrupted flow, and straining. The IPSS has been widely used in male voiding dysfunction research for many years, because it contains the American Urological Association symptom index as part of its core questions (Google Citations 2924, September 14, 2018). The IPSS has been validated in women in a Chinese study (Hong Kong Chinese version 1)³⁶ and later revalidated in a Chinese population (Hong Kong Chinese version 2) owing to errors in the initial questionnaire. Despite the correction in translation, their data showed that the single QOL question was not found to be reliable in women. This tool has not been validated in women in English. Therefore, it was determined that the ICIQ-FLUTS is better suited for studies evaluating voiding dysfunction in women, because it is a widely used, validated, and reliable tool (Google citations 447 on September 30, 2018).

V. Quantification of Disease-Specific Quality of Life

The consortium recommends inclusion of the short form of the Pelvic Floor Distress Inventory (PFDI) in the final combined IMPACT tool to allow for some quantification of the degree of bother to patients from their bowel dysfunction, bladder dysfunction, and pelvic organ prolapse symptoms. Number of questions: 20

The workgroups did not focus on a detailed review of all existing disease-specific quality-of-life (QOL) tools that measure all pelvic floor disorders. Nevertheless, some discussion pertaining to these instruments occurred during the *Pelvic Floor Consortium Expert Meeting* and 2 QOLs received honorable mention.

Experts universally acknowledged (97%) that the Fecal Incontinence Quality of Life⁹ tool is the most commonly used instrument among the consortium membership. The FIQOL tool could provide additional meaningful information pertaining to the impact of symptoms of fecal incontinence on quality of life. Nevertheless, the group concluded that, although FIQOL would be very valuable to clinicians planning to focus their treatment or research on patients reporting symptoms of fecal incontinence, it was too lengthy to make the cut as a recommended questionnaire for routine clinical use, and its addition would make the final

IMPACT tool too long. Similarly, the *Pelvic Floor Consortium Expert Meeting* participants acknowledged with >70% consensus that the Patient Assessment of Constipation—Quality of Life²³ tool could be helpful to clinicians performing focused clinical care or research in patients who have constipation. Similarly, however, they felt the instrument was too long to allow inclusion in the IMPACT tool.

The experts also recognized that many patients with pelvic floor disorders may report combined symptoms of multiple pelvic floor disorders and that the conditions discussed at the meeting do not cover the entire spectrum of pelvic floor disorders.^{34,37} They also recognized that, although individual bowel, bladder, or prolapse symptoms may be mild, their combination could have a profound cumulative effect on the patient's quality of life and that some measure of the degree of bother caused by various symptoms would be a meaningful addition to the IMPACT tool. This led to a discussion and vote on the Pelvic Floor Distress Inventory Short Form (PFDI-20).³⁸ The PFDI-20 was reviewed because of its high adoption in the urogynecology community (259 citations, searched January 27, 2019). The PFDI-20 was designed from a longer version of the instrument to measure the presence of common pelvic organ prolapse symptoms and the degree to which these symptoms bother women reporting their presence.³⁹ The PFDI-20 has been shown to be highly correlated with its longer counterpart while still being valid, reliable, and sufficiently sensitive to change.⁴⁰ Experts concluded that the inclusion of a measurement that assesses degree of bother caused by various pelvic floor symptoms would be a meaningful addition to the IMPACT tool. This led them to recommend (>70% consensus) inclusion of the short form of the Pelvic Floor Distress Inventory (PFDI-20) in the final IMPACT tool.

VI. Sexual Function in Men

The consortium recommends the International Index of Erectile Function (IIEF-15). Total minimum number of questions: 15

If brevity is a priority, we recommend using a minimum of 2 specific individually validated domains of the International Index of Erectile Function (IIEF-15) questionnaire to at least measure male erectile function (questions 1, 2, 3, 4, and 5) and orgasmic/ejaculatory function (questions 9/10) and its impact on quality of life (question 15). Total minimum number of questions: 8

Four colorectal surgeons, 3 urologists, and 1 biofeedback therapist participated as expert workgroup panelists. The initial instruments reviewed by the workgroup members are listed in Supplemental Table 5, <http://links.lww.com/DCR/B62>. Before the literature search, a decision was made to include only those instruments with evidence of validity and reliability. In total, 17 instruments were identified that had previously undergone testing for validity and reliability. From this group of 17, the workgroup panelists reached >70% consensus that 3 severity-measuring instruments would be brought before the larger *Pelvic Floor Consortium Expert Meeting*: the International Index of Erectile Function (IIEF),⁴¹ the Sexual Health Inventory for Men (IIEF-5/SHIM),⁴² and the Expanded Prostate Cancer Index Composite (EPIC).⁴³

The EPIC is a comprehensive 50-question instrument with HRQoL in 4 separately validated domains including urinary function (12 questions), bowel function (14 questions), sexual function (13 questions), and hormonal function (11 questions) each of which can be scored independently. This questionnaire has been cited 188 times in the literature; however, only 13 questions are specifically dedicated to sexual function. The strength of this questionnaire (its comprehensive nature and total number of questions) is also its weakness in that the workgroup felt it was impractical to utilize in clinical practice outside of a dedicated research

environment.⁴⁴ Another weakness of this questionnaire is that it has only been validated in men with prostate cancer, which may limit its application to other male patients with erectile dysfunction.

The IIEF is the most cited instrument for assessing male sexual function (4551 citations as of August 30, 2018) and includes a total of 15 questions. The IIEF is a comprehensive instrument with 5 separately validated domains, namely, erectile function (6 questions), orgasmic/ejaculatory function (2 questions), sexual desire (2 questions), intercourse satisfaction (3 questions), and overall satisfaction (2 questions). Other strengths include that it has been validated in 10 languages and it was validated in an international population of men with erectile dysfunction owing to a variety of causes (not just the treatment of prostate cancer).

The IIEF-5 or SHIM (Sexual Health Inventory for Men) is brief, practical, and highly cited in the scientific literature (2085 citations as of August 30, 2018). The questionnaire includes 5 questions from the more comprehensive IIEF. Like the longer IIEF, the IIEF-5 was validated in male patients with erectile dysfunction due to a variety of causes. The IIEF-5 consists of question items 2, 4, 5, 7, and 15 from the IIEF. These 5 questions are from the erectile function domain (2, 4, 5, and 15) and the intercourse satisfaction domain (item 7). The other remaining 3 domains (orgasmic/ejaculatory function, sexual desire, and overall satisfaction) are not represented in the IIEF-5. Previously, the erectile function domain was shown to have independent validity in the assessment of male sexual function.⁴⁵ The authors of the IIEF-5 included item 7 in addition to the 4 questions regarding erectile dysfunction to assist in establishing the gradient of erectile dysfunction severity.

At the in-person *Pelvic Floor Consortium Expert Meeting*, the strengths and weaknesses of the instruments were presented to the larger group. The experts concluded that the EPIC was far too long to utilize in routine clinical practice as an initial assessment tool for more than one pelvic floor symptom. The IIEF-5 was highly favored for its length, but they thought its narrow focus on erectile dysfunction might miss many colorectal patients who may also experience changes in orgasmic/ejaculatory function. The IIEF contains a domain that measures these symptoms with 2 questions. The consortium considered the overall IIEF to be too long (15 questions) and ultimately noted that it is valid to score IIEF domains independently. They concluded that the final IMPACT tool should only include the IIEF domains pertaining to erectile function (questions 1, 2, 3, 4, 5, and 15) and orgasmic/ejaculatory function (questions 9/10). They concluded that the other domains, while relevant, are rarely independently affected in patients with pelvic floor disorders and could be safely omitted at the original encounter for the sake of brevity.

VII. Sexual Function in Women

The consortium recommends tailoring the measurement of sexual function in women to the patient population:

- i. In women with known pelvic floor disorders, the consortium recommends the International Urogynecologic Association (IUGA)-Revised Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire. Number of questions: 21 questions if sexually active and 12 questions if not sexually active.
- ii. In women without pelvic floor disorders, or when brevity is a priority, the consortium recommends the Female Sexual Function Index Short Version. Number of questions: 9

Nine colorectal surgeons, 3 urogynecologists, and 2 urologists participated as expert workgroup panelists. The initial instruments reviewed by the workgroup members are listed in Supplemental Table 6, <http://links.lww.com/DCR/B63>. Prior to the literature

search, a decision was made that only instruments with evidence of validity and reliability would be included. In total, 12 instruments were identified that had previously undergone testing for validity and reliability. To achieve this consensus, the panelists first assessed each instrument using the predetermined criteria used by all other panels. In addition, the instruments were categorized using the following characteristics: population used for validation, validity testing in pelvic floor disorders population, assessment of female sexual function alone (versus female and male sexual function in one instrument), assessment of female sexual function/dysfunction and quality of life (QOL), assessment of sexual function in women without partners or women not sexually active, minimally important difference, and availability of validated translation into Spanish as well as questionnaire length and domains. The panel also assessed whether the selected instruments were available at no cost. From this group of 13, the workgroup panelists reached >70% consensus that 3 severity measuring instruments would be brought before the larger *Pelvic Floor Consortium Expert Meeting*: the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, short version (PISQ-12), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questions, IUGA-Revised (PISQ-IR) and The Female Sexual Function Index (FSFI).⁴⁶

Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire - short version (PISQ-12) is the short version of the first condition-specific female sexual function questionnaire developed to assess sexual function in women with prolapse and/or incontinence. The short version with only 12 questions is very useful for situations when brevity of the questionnaire is a priority. The PISQ-12 is one of the most popular questionnaires for studying women with pelvic floor disorders and it has validated translations in many languages. The main limitation of PISQ-12

(similar to many other sexual function questionnaires) is that it excluded women who were not sexually active, whether this was related to lack of partner or their pelvic floor disorders. Furthermore, PISQ-12 was not validated in women with anal incontinence.

Pelvic Organ Prolapse/Incontinence Sexual Questionnaire IUGA-Revised (PISQ-IR) is the revised version of PISQ intended to address the limitations of PISQ and PISQ-12. The PISQ-IR is a condition-specific validated questionnaire of female sexual function that can be used in women who are not currently sexually active. Sexually active women answer 21 questions in 6 domains, whereas not sexually active women answer 12 questions in 4 domains. The IUGA is currently working on developing validated translations into many languages.

The Female Sexual Function Index Short Version (FSFI-9) is the short version of a full FSFI questionnaire; FSFI is a 19-item psychometrically sound sexual function questionnaire that has demonstrated reliability and validity in a variety of populations including postmenopausal women. Despite its broad use in research, it is long, making it cumbersome for use in routine clinical practice. The FSFI-9 version is a psychometrically sound short version of FSFI tested in peri- and postmenopausal women. The authors of the short-version FSFI suggest this version is best for studies where sexual function is not the primary end point, but a secondary end point, and when brevity is a priority.

During a heated discussion at the consensus meeting, the choice was further narrowed down to the top 2 – FSFI (Rosen 2000) and PISQ-IR (Rogers 2013). These questionnaires target different patient populations. PISQ-IR is a validated condition-specific questionnaire that specifically targets women with pelvic floor disorders. It is further valuable because it captures sexual inactivity due to pelvic floor disorder or other causes. In contrast,

TABLE 1. Final List of Instruments Recommended for Inclusion in the IMPACT (Initial Measurement of Patient-Reported Pelvic Floor Complaints) Tool, Long and Short Forms

Patient-reported complaint	Sex (and additional considerations)	Consensus instrument	Individual number of questions added to IMPACT (long form)	Cumulative number of questions in the IMPACT (short form)
Fecal incontinence	Both	Cleveland Clinic Florida Incontinence Scale (CCFIS)	5	12
Constipation	Both	St. Mark’s Incontinence Score (MIS)	7	
	Both	Patient Assessment of Constipation–Symptoms (PAC-SYM)	12	
Additional relevant anorectal complaints	Both	Constipation Severity Instrument (CSI)	16	
	Both	Colorectal Anal Distress Inventory (CRADI)	8	
	Both	Bristol Stool Scale (BSS)	1	
Urinary incontinence (UI) and lower urinary tract symptoms (LUTS) other than UI	Men/UI	Urogenital Distress Inventory (UDI-6)	6	14
	Men/LUTS	International Prostate Symptoms Screening (IPSS)	8	
	Women/UI	Urogenital Distress Inventory (UDI-6)	6	24
	Women/LUTS	ICIQ-Female Lower Urinary Tract Symptom Questionnaire Short Form (ICIQ-FLUTS)	12	
Pelvic organ prolapse	Women	Pelvic Organ Prolapse Distress Inventory (POPDI)	6	
Sexual function	Men	International Index of Erectile Function (IIEF)	15	8
	Women (with known pelvic floor disorder)	Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR)	Sexually active 21 Not sexually active 12	–
	Women (without known pelvic floor disorder)	Female Sexual Function Index Short Version (FSFI-9)	9	9

IMPACT: Bowel Function Assessment Tool, Short Form

Name: _____ DOB: _____

Directions: These questions will ask you if you have certain bowel symptoms and, if you do, how much they bother you. While answering, please consider your symptoms over the last 3 months.

Please think about your typical bowel movements.

1 Please choose which stool type is most like the shape of your stools.

Type 1	Type 2	Type 3	Type 4	Type 5	Type 6	Type 7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Separate, hard lumps like nuts (hard to pass)	Sausage-shaped but lumpy	Like a sausage, but with cracks on the surface	Like a sausage or snake, smooth and soft	Soft blobs with clear-cut edges	Fluffy pieces with ragged edges, a mushy stool	Watery, no solid pieces, entirely liquid

2 During a typical month, how many times do you usually have an uncomfortable or difficult bowel movement?

Never	Daily	A few times per week	Once per week	Once every 2 weeks	Once a month
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3 Are you having difficulty with having infrequent bowel movements (less than 1 bowel movement every 3 days)?

NO
SKIP TO Q4

YES
PROCEED

Frequency	Severity	Impact
How often do you experience infrequent bowel movements? <input type="checkbox"/> Occasionally experience this <input type="checkbox"/> Sometimes experience this <input type="checkbox"/> Usually experience this <input type="checkbox"/> Always experience this	How severe is this symptom for you? <input type="checkbox"/> Not at all severe (I go almost every day) <input type="checkbox"/> Mild <input type="checkbox"/> Somewhat severe (I go 1-2 times per week) <input type="checkbox"/> Severe <input type="checkbox"/> Extremely severe (I can go up to 4 weeks without going)	How much does this symptom bother you? <input type="checkbox"/> Not at all bothersome <input type="checkbox"/> A little bothersome <input type="checkbox"/> Somewhat bothersome <input type="checkbox"/> Very bothersome <input type="checkbox"/> Extremely bothersome

4 Do you ever lack the urge to have a bowel movement?

NO
SKIP TO Q5

YES
PROCEED

Severity	Impact
How severe is this for you? <input type="checkbox"/> Not at all severe (I have a pretty good sense when I have to go) <input type="checkbox"/> Mild <input type="checkbox"/> Somewhat severe (I only have a vague sense that I might have to go) <input type="checkbox"/> Severe <input type="checkbox"/> Extremely severe (I don't have any sensation in the pelvic area)	How much does this bother you? <input type="checkbox"/> Not at all bothersome <input type="checkbox"/> A little bothersome <input type="checkbox"/> Somewhat bothersome <input type="checkbox"/> Very bothersome <input type="checkbox"/> Extremely bothersome

5 Do you feel you need to strain too hard to have a bowel movement?

NO
SKIP TO Q6

YES
PROCEED

Frequency	Severity	Impact
How often do you experience this? <input type="checkbox"/> Occasionally experience this <input type="checkbox"/> Sometimes experience this <input type="checkbox"/> Usually experience this <input type="checkbox"/> Always experience this	How severe is this for you? <input type="checkbox"/> Not at all severe (I push a little) <input type="checkbox"/> Mild <input type="checkbox"/> Somewhat severe (I bear down hard) <input type="checkbox"/> Severe <input type="checkbox"/> Extremely severe (I push on my belly, grunt and bear down very hard)	How much does this bother you? <input type="checkbox"/> Not at all bothersome <input type="checkbox"/> A little bothersome <input type="checkbox"/> Somewhat bothersome <input type="checkbox"/> Very bothersome <input type="checkbox"/> Extremely bothersome

6 Do you feel you have not completely emptied your bowels at the end of a bowel movement??

NO
SKIP TO Q7

YES
PROCEED

Frequency	Severity	Impact
How often do you experience this? <input type="checkbox"/> Occasionally experience this <input type="checkbox"/> Sometimes experience this <input type="checkbox"/> Usually experience this <input type="checkbox"/> Always experience this	How severe is this for you? <input type="checkbox"/> Not at all severe (Most of my bowel movement comes out) <input type="checkbox"/> Mild <input type="checkbox"/> Somewhat severe (There is still a lot of stool in me after a bowel movement) <input type="checkbox"/> Severe <input type="checkbox"/> Extremely severe (I feel constant pressure in my rectum from stool or keep going back to the bathroom)	How much does this bother you? <input type="checkbox"/> Not at all bothersome <input type="checkbox"/> A little bothersome <input type="checkbox"/> Somewhat bothersome <input type="checkbox"/> Very bothersome <input type="checkbox"/> Extremely bothersome

FIGURE 1. IMPACT (Initial Measurement of Patient-Reported Pelvic Floor Complaints Tool) bowel function, short form. Scoring details are included in Supplemental Table 7 (<http://links.lww.com/DCR/B64>).

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7 Do you sometimes have symptoms of constipation?

NO
SKIP TO Q8

YES
PROCEED

The following questions ask about symptoms of constipation. Please SKIP if you do not have constipation. If you have constipation, please indicate how severe your constipation symptoms have been for you during the past 2 weeks.

7a: Discomfort in your abdomen	Absent	Mild	Moderate	Severe	Very Severe
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7b: Pain in your abdomen	Absent	Mild	Moderate	Severe	Very Severe
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7c: Bloating in your abdomen	Absent	Mild	Moderate	Severe	Very Severe
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7d: Stomach cramps	Absent	Mild	Moderate	Severe	Very Severe
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7e: Rectal burning during or after a bowel movement	Absent	Mild	Moderate	Severe	Very Severe
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7f: Bowel movements that were too hard	Absent	Mild	Moderate	Severe	Very Severe
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7g: Bowel movements that were too small:	Absent	Mild	Moderate	Severe	Very Severe
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7h: Feeling like you had to pass a bowel movement but you couldn't (false alarm)	Absent	Mild	Moderate	Severe	Very Severe
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8 Do you sometimes have accidental gas or bowel leakage?

NO
SKIP TO Q9

YES
PROCEED

8A.) Do you usually lose stool beyond your control if your stool is well-formed?

NO
SKIP TO 8B

YES
PROCEED

8B.) Do you usually lose stool beyond your control if your stool is loose (liquid)?

NO
SKIP TO 8C

YES
PROCEED

8C.) Do you usually lose gas from the rectum beyond your control?

NO
SKIP TO 8D

YES
PROCEED

8D.) Do you wear pads because of fear of losing stool?

8E.) Do you take medication to make you more constipated to help with bowel leakage?

8F.) Do you adjust your lifestyle because of concerns for possible accidental bowel leakage (for example: avoid going out; avoid certain foods; avoid sex)?

Frequency	Severity	Impact
How often do you experience this?	Did you leak stool, and if so how much?	How much does this bother you?
<input type="checkbox"/> Rarely (<1/month)	<input type="checkbox"/> None	<input type="checkbox"/> Not at all bothersome
<input type="checkbox"/> Sometimes (<1/week)	<input type="checkbox"/> Stain only	<input type="checkbox"/> A little bothersome
<input type="checkbox"/> Weekly (but <1/day)	<input type="checkbox"/> More than a stain	<input type="checkbox"/> Somewhat bothersome
<input type="checkbox"/> Daily (1/day or more)	<input type="checkbox"/> Entire bowel moment	<input type="checkbox"/> Very bothersome
		<input type="checkbox"/> Extremely bothersome

Frequency	Severity	Impact
How often do you experience this?	Did you leak stool, and if so how much?	How much does this bother you?
<input type="checkbox"/> Rarely (<1/month)	<input type="checkbox"/> None	<input type="checkbox"/> Not at all bothersome
<input type="checkbox"/> Sometimes (<1/week)	<input type="checkbox"/> Stain only	<input type="checkbox"/> A little bothersome
<input type="checkbox"/> Weekly (but <1/day)	<input type="checkbox"/> More than a stain	<input type="checkbox"/> Somewhat bothersome
<input type="checkbox"/> Daily (1/day or more)	<input type="checkbox"/> Entire bowel moment	<input type="checkbox"/> Very bothersome
		<input type="checkbox"/> Extremely bothersome

Frequency	Impact
How often do you experience this?	How much does this bother you?
<input type="checkbox"/> Rarely (<1/month)	<input type="checkbox"/> Not at all bothersome
<input type="checkbox"/> Sometimes (<1/week)	<input type="checkbox"/> A little bothersome
<input type="checkbox"/> Weekly (but <1/day)	<input type="checkbox"/> Somewhat bothersome
<input type="checkbox"/> Daily (1/day or more)	<input type="checkbox"/> Very bothersome
	<input type="checkbox"/> Extremely bothersome

Never	Rarely (less than 1x/month)	Sometimes (less than 1x/week)	Weekly	Daily
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

Never	Rarely (less than 1x/month)	Sometimes (less than 1x/week)	Weekly	Daily
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FIGURE 1. (Continued)

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9 Do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?

NO SKIP TO Q10 YES PROCEED

Not at all bothersome	A little bothersome	Somewhat bothersome	Very bothersome	Extremely bothersome
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10 Do you usually have pain when you pass your stool?

NO SKIP TO Q11 YES PROCEED

Last month	At present	Impact
During the last month, on average, how severe was the pain in your rectum/anus?	Rate the level of your rectal/anal pain at the present moment.	How much suffering or bother do you experience because of rectal/anal pain?
<input type="checkbox"/> I haven't experienced this <input type="checkbox"/> Mild <input type="checkbox"/> Somewhat severe <input type="checkbox"/> Severe <input type="checkbox"/> Extremely severe	<input type="checkbox"/> No pain <input type="checkbox"/> Mild <input type="checkbox"/> Somewhat severe <input type="checkbox"/> Severe <input type="checkbox"/> Extremely severe	<input type="checkbox"/> None <input type="checkbox"/> Mild suffering <input type="checkbox"/> Somewhat severe suffering <input type="checkbox"/> Severe suffering <input type="checkbox"/> Extremely severe

11 Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?

NO SKIP TO Q12 YES PROCEED

Not at all bothersome	A little bothersome	Somewhat bothersome	Very bothersome	Extremely bothersome
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12 During the past month, due to your bowel habits, how often have you had bleeding during/after a bowel movement?

Never	Rarely	Occasionally	Usually	Always
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FIGURE 1. (Continued)

FSFI is a highly cited (3860 on September 20, 2018) and psychometrically sound instrument that has been validated in pre- and postmenopausal women, although not validated in women with pelvic floor disorders specifically. The tool gives a broader assessment of female sexual function and dysfunction. The FSFI comes in a long (19 questions) and short (9 questions) form. The FSFI-9 version was psychometrically tested and compared to the original long-version FSFI as well as the FSFI-6 Italian short-version FSFI, and was found to be valid and sensitive to change.

Ultimately, no consensus was reached at the in-person meeting between the use of the FSFI-9 vs PISQ-IR. It was therefore decided to recommend PISQ-IR for clinical practices that primarily care for women with pelvic floor disorders. For clinicians seeking to measure and monitor female sexual function outside the pelvic floor context, the FSFI-9 was recommended instead.

VIII. Creation of a Combined IMPACT (Initial Measurement of Patient-Reported Pelvic Floor Complaints) Tool

IMPACT Long Form can be used to measure and score the severity of 5 common pelvic floor symptoms. It contains all of the instruments recommended in this document in their unaltered form. If further brevity is required, bowel function instruments included in the IMPACT Long Form can be collapsed into the IMPACT Bowel Function Short Form. However, post hoc scoring will be required for the IMPACT Bowel Function-SF to permit ultimate reporting of individual bowel scores.

The Pelvic Floor Consortium Expert Meeting participants reached >70% consensus that it would be important for clinicians

to strongly consider measuring all of the aforementioned pelvic floor conditions as part of their routine clinic assessment, regardless of the presenting complaint. Ultimately, participants recommended the creation of a combined list of agreed upon instruments that could be administered together across disciplines. They labeled this combined tool IMPACT (Initial Measurement of Patient-Reported Pelvic Floor Complaints) Long Form (LF). The questionnaires included in the IMPACT Long Form are listed in Table 1.

In early discussions, the experts had projected that a tool of this type should consist of no more than 35 to 40 questions. However, the final combined IMPACT-LF is significantly longer, measuring 85 questions for men and 85 to 94 for women. Furthermore, it contains several redundant questions, especially in the bowel function domains. The Urinary Incontinence, Lower Urinary Tract Symptoms, and Sexual Function Tools do not exhibit as much question redundancy. This led the experts to propose a more streamlined version of the bowel function domains, called the IMPACT Short Form (SF) (Fig. 1). The IMPACT-SF contains all the questions contained in the IMPACT-LF, but patients encounter the redundant bowel function questions only once. In the situations where bowel function questions have a different distribution of answers from instrument to instrument, the patient is asked to respond using the highest number of answers possible within a question, thus allowing post hoc scoring of both instruments through a collapse into smaller categories from larger categories of choices during score calculation (see Supplemental Table 7, <http://links.lww.com/DCR/B64> for details). As a result, no scoring information is lost when the streamlined bowel function tool is used. Considerations included in creating the streamlined

TABLE 2. Properties of the Instruments Recommended for Inclusion in the IMPACT (Initial Measurement of Patient-Reported Pelvic Floor Complaints) Tool, Long Form

Instrument name	Cleveland Clinic Florida Incontinence Score (CCFIS)		St. Marks (Vaizey) Incontinence Score	Constipation Severity Instrument		Patient Assessment of Constipation-Symptoms (PAC-SYM)		Urogenital Distress Inventory (UDI-6)		ICIQ-Female Lower Urinary Tract Symptom Questionnaire Short Form (ICIQ-FLUTS)		
	Author	No. of items/questions		Author	No. of items/questions	Author	No. of items/questions	Author	No. of items/questions	Author	No. of items/questions	
	J. Jorge, S. Wexner	5	Vaizey CJ	7	Varma	16	Frank	12	Lemack	6	Brookes	19
No. of domains	5		5		3		3		N/A		3	
Domain names	Solid stool leakage, liquid stool leakage, gas leakage, use of pad for leakage, and lifestyle alteration		Frequency of solid and liquid stool and gas leakage, urgency (inability to defer for 15 min), use of constipating/antidiarrheal medications and pads, and the effect on social life		Obstructive defecation, colonic inertia, pain		Abdominal symptoms, rectal symptoms, and stool symptoms		N/A		Filling, voiding, incontinence; Subscale: sexual function, quality of life	
Can each domain be scored independently?	Yes, but not as useful		Yes		No		Yes		Yes		Yes	
Validity tested	Yes		Yes		Yes		Yes		Yes		Yes	
Reliability tested	Yes		Yes		Yes		Yes		Yes		Yes	
Google Scholar citations	2504		906		92		243		1119		447	
Date of Google Scholar search	9/13/2018		9/14/2018		9/14/2018		9/14/2018		09/30/2018		09/30/2018	
Open access	Yes		Yes		Yes		Yes for clinical and research use, but limitations for sponsored research. Details at https://eprovide.mapi-trust.org/instruments/patient-assessment-of-constipation-symptoms		Yes		Yes for clinical and research use. Limitations for sponsored studies. Details at http://icq.net/user-policy://icq.net/user-policy	

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TABLE 2. (continued)

Instrument name	International Prostate Symptom Score (IPSS)	International Index of Erectile Function (IIEF)	Female Sexual Function Index, short version (FSFI-9)	Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR)	Pelvic Floor Distress Inventory, Short Form (PFDI-20)
Author	Barry	Rosen	Carpenter	Rogers	Barber
No. of items/questions	8	15	9	Not sexually active: 12 Sexually active: 21	20
No. of domains	2	5	N/A	Sexually active: 6 Not sexually active: 4	3
Domain names	Urinary symptoms, quality of life	Erectile function, orgasmic function, sexual desire, sexual satisfaction, and overall satisfaction	N/A	AO = arousal orgasm PR = partner related CS = condition specific GQ = global quality related CI = condition impact D = desire	Urinary incontinence (see UDI-6), anal symptoms (CRADI-8), and pelvic organ prolapse (POPDI-6)
Can each domain be scored independently?	Yes	Yes	N/A	Yes	Yes
Validity tested	Yes	Yes	Yes	Yes	Yes
Reliability tested	Yes	Yes	Yes	Yes	Yes
Google Scholar citations	7060	4551	4	77	259
Date of Google Scholar search	09/29/2018	8/30/2018	10/30/2018	9/30/2018	1/27/2019
Open access	Yes	Yes	Yes	Yes	Yes

TABLE 3. Members of the Pelvic Floor Disorders Consortium Working Group on Patient-Reported Outcomes

Workgroup	Team Leaders and Member Names (alphabetical)	Affiliation, location, country	
Fecal incontinence	Sarah Vogler, M.D., M.B.A.*	University of Minnesota, Minnesota, USA	
	Mitchell Bernstein, M.D.*	New York University, New York, USA	
	Jasneet Bhullar, M.D.	University of Pittsburgh Medical Center, Susquehanna, Pennsylvania, USA	
	Eman Elkadry, M.D.	Harvard University, Massachusetts, USA	
	Kelly Garrett, M.D.	Columbia University, New York, USA	
	Brooke Gurland, M.D.	Stanford University, California, USA	
	Ahmed, Khawaja Fraz, M.D.	Partners HealthCare, Massachusetts, USA	
	Patrick Lee, M.D.	Providence St. Vincent Medical Center, Oregon, USA	
	Lioudmila Lipetskaia, M.D.	Cooper Medical School of Rowan, New Jersey, USA	
	Oliveira Lucia, M.D.	Hospital Casa de Saúde São José, Rio de Janeiro, Brazil	
	Rebecca Rogers, M.D.	The University of Texas at Austin, Texas, USA	
	Amy Thorsen, M.D.	University of Minnesota, Minnesota, USA	
	Massarat Zutshi, M.D.	Cleveland Clinic, Ohio, USA	
	Constipation	Kyle Staller, M.D., M.P.H.*	Harvard University, Massachusetts, USA
		Anders Mellgren, M.D., Ph.D.*	University of Illinois, Illinois, USA
Adil E. Bharucha, M.D., M.B.B.S.		Mayo Medical School, Minnesota, USA	
Darren Brenner, M.D.		Northwestern University, Illinois, USA	
Andreas Kaiser, M.D.		University of Southern California, California, USA	
James Ogilvie, Jr., M.D.		Spectrum Health, Michigan, USA	
Arecu Scanavini Neto, M.D.		University of São Paulo, Brazil	
Jenny Speranza, M.D.		University of Rochester, New York, USA	
Sharon Stein, M.D.		Case Western Reserve, Ohio, USA	
Urinary incontinence		Jennifer Anger, M.D.*	California School for Health Sciences, California, USA
	Marylise Boutros, M.D.*	Mc Gill University, Montreal, Canada	
	Heidi Brown, M.D.	University of Wisconsin, Wisconsin, USA	
	Nikki Cotterill, M.D.	University of the West of England, Bristol, UK	
	Elise De, M.D.	Harvard University, Massachusetts, USA	
	Eman Elkadry, M.D.	Harvard University, Massachusetts, USA	
	Richard Garfinkle, M.D.	Mc Gill University, Montreal, Canada	
	Ankita Gupta, M.D.	University of Louisville, Kentucky, USA	
	Oz Harmanli, M.D.	Yale University, Connecticut, USA	
	Juana Hutchinson-Colas, M.D.	Rutgers University, New Jersey, USA	
	Kathleen Kobashi, M.D.	Virginia Mason Hospital, Washington, USA	
	Shane McNevin, M.D.	Providence Health, Washington, USA	
	Miles Murphy, M.D., M.S.P.H.	Abbingdon–Jefferson Health, Pennsylvania, USA	
	Cristina Naranjo Ortiz, D.M.P.	Universidad Complutense de Madrid, Spain	
	Gareth Warren, M.D.	University of Rochester, New York, USA	
Lower urinary tract symptoms in men and women	Elisa Birnbaum, M.D.*	University of Colorado, Colorado, USA	
	Kathleen Connell, M.D.*	University of Colorado, Colorado, USA	
	Joshua Bleier, M.D.	University of Pennsylvania, Pennsylvania, USA	
	Ian Paquette, M.D.	University of Cincinnati, Ohio, USA	
	Lee Ann Richter, M.D.	Georgetown University, District of Columbia, USA	
	Ajay Kumar Singla, M.D.	Harvard University, Massachusetts, USA	
	Janine Oliver, M.D.	UCHealth University of Colorado Hospital, Colorado, USA	
	May Wakamatsu, M.D.	Harvard University, Massachusetts, USA	

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TABLE 3. (Continued)

Workgroup	Team Leaders and Member Names (alphabetical)	Affiliation, location, country
Sexual function in men	Joseph Carmichael, M.D.*	University of California Irvine, California, USA
	Faysal Jaffi, M.D.*	University of California Irvine, California, USA
	Nelson E Bennett, M.D.	Northwestern Medicine Feinberg School of Medicine, Chicago, USA
	Nathan M Hinkle, M.D.	University of Tennessee Health Science Center, Tennessee, USA
	Lawrence Jenkins, M.D.	The Ohio State University Wexner Medical Center, Ohio, USA
	Nathalie Mantilla, M.D.	Rush University, Illinois, USA
	Lieba R Savitt, N.P.	Massachusetts General Hospital, Massachusetts, USA
	Maxwell Towe, B.S.	University of California Irvine, California, USA
	Steven D. Wexner, M.D., Ph.D.	Cleveland Clinic Florida, Florida, USA
	Sexual function in women	Milena Weinstein, M.D.*
Alex Ky, M.D.*		Mount Sinai School of Medicine, New York, USA
Holly Bonnette, N.P.		Massachusetts General Hospital, Massachusetts, USA
Cynthia Hall, M.D.		University of Massachusetts Memorial Medical Center, Massachusetts, USA
Deborah Keller, M.S., M.D.		Columbia University Medical Center, New York, USA
Christina Lewicky-Gaup, M.D.		Northwestern University Feinberg School of Medicine, Illinois, USA
Rebecca Rogers, M.D.		University of Austin Dell Medical School, Texas, USA
Alexis Schizas, M.D.		Guy's and St Thomas' NHS Foundation Trust, London, UK
Konstantin Umanskiy, M.D.		University of Chicago, Illinois, USA
Madhulika Varma, M.D.		University of California San Francisco, California, USA

Some participated in the more than one workgroup and are listed twice.
*Workgroup team leaders.

tool are further described in the Supplemental Table 8, <http://links.lww.com/DCR/B65>. With these adjustments, the number of bowel function questions was reduced from 49 to 12 and the overall IMPACT-SF measures 45 questions for women and 34 for men (Table 1). The psychometric details of the chosen scores are further summarized in Table 2. These instruments are open access and free to use for clinical use and in clinical research, although some fees may be applicable for sponsored research projects, and these rare exceptions are highlighted in Table 2.

CONCLUSION

A reasonable consensus was reached by the Pelvic Floor Disorders Consortium on the pelvic floor symptom measurement tools and patient-reported instruments and questionnaires that should be recommended in a routine clinical setting and as a baseline measure in clinical research addressing common pelvic floor symptoms, including a long and short form. These tools can be augmented with additional quality-of-life tools and more robust measurement tools when detailed information about a condition is needed to fine-tune decision making.

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