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The Standardization of Terminology for Researchers in Female Pelvic Floor Disorders

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Abstract: The lack of standardized terminology in pelvic floor disorders (pelvic organ prolapse, urinary incontinence, and fecal incontinence) is a major obstacle to performing and interpreting research. The National Institutes of Health convened the Terminology Workshop for Researchers in Female Pelvic Floor Disorders to: (1) agree on standard terms for defining conditions and outcomes; (2) make recommendations for minimum data collection for research; and (3) identify high priority issues for future research. Pelvic organ prolapse was defined by physical examination staging using the International Continence Society system. Stress urinary incontinence was defined by symptoms and testing; 'cure' was defined as no stress incontinence symptoms, negative testing, and no new problems due to intervention. Overactive bladder was defined as urinary frequency and urgency, with and without urge incontinence. Detrusor instability was defined by cystometry. For all urinary symptoms, defining 'improvement' after intervention was identified as a high priority. For fecal incontinence, more research is needed before recommendations can be made. A standard terminology for research on pelvic floor disorders is presented and areas of high priority for future research are identified.

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Introduction

Female pelvic floor disorders are a wide variety of clinical conditions, including urinary incontinence, fecal incontinence, pelvic organ prolapse, sensory and emptying abnormalities of the lower urinary tract, and defecatory dysfunction. The most prevalent syndromes (urinary incontinence, fecal incontinence and pelvic organ prolapse) afflict women three to seven times more often than men. The highest gender disparity is seen between the ages of 45 and 69 years [1]. The earlier age of onset in women magnifies the impact of pelvic floor dysfunction on years of healthy life for women, who are not only more likely to suffer from these problems but who will spend more of the productive years of their lives doing so. This is of particular relevance to all clinicians who care for women. United States Census projections estimate that the number of women aged 45–69 years will increase from 27% of the total female population in 2000 to 31% in 2020, and the number of women aged 65 years and older in the year 2000 will more than double by the year 2050 [2]. An analysis of surgical procedure codes estimates that over 500 000 procedures are performed in the United States annually

for prolapse and urinary incontinence [3]. These numbers are certain to increase in accordance with the predicted demographic changes.

Unfortunately, most of the literature describing the results of these procedures does not meet contemporary scientific standards for outcomes analyses. The 1996 Update of the Agency for Health Care Policy and Research (AHCPR) Urinary Incontinence Clinical Practice Guidelines concluded that the surgical literature is deficient in standards 'for describing the patient population, the type of incontinence, the methods for accurate diagnosis, the techniques of the surgical procedure, or the outcome in different domains' [4]. The AHCPR conclusions are substantiated by a comprehensive review by Black and Downs that documented the poor quality of published literature on surgical treatment of urinary incontinence and led the authors to conclude that 'recommendations as to the best clinical practice cannot be based on scientific evidence' [5]. Major methodological flaws identified by Black and Downs included variability in or a complete lack of case definition for stress incontinence; failure to control for confounding by random assignment, or to account for unknown confounders by reporting their distribution; lack of standardization of surgical technique; variability in duration of follow-up; low or indeterminate external validity (generalizability); inadequate power to detect clinically important differences; lack of comprehensive assessment of postoperative complications; and marked variability in outcome assessment. Outcome assessment was especially criticized for lack of blinding, for the use of non-validated and non-standardized outcome measures, and for failure to obtain patients' views through the use of valid and reliable clinimetric methods and questionnaires. Although these assertions applied specifically to urinary incontinence, a similar assessment can be made of literature on other pelvic floor disorders, such as pelvic organ prolapse [6]. Most of these research flaws could be addressed initially by the institution of specific standardized definitions of conditions and criteria for the reporting of research studies.

Data are particularly deficient in the description of these conditions in women of minority race [7]. This lack, coupled with the increased prevalence and severity of conditions such as incontinence in the elderly, particularly the institutionalized [8], and the projected increase in racial diversity of the elderly [2], emphasize the need for high-quality research in these women. Geriatric populations may present a special challenge to standard protocols and datasets because of logistic limitations in their evaluation (e.g. the reliance on self-reporting of symptoms in patients with dementia).

In September 1998, the National Institute of Child Health and Human Development (NICHD), with other Institutes at the National Institutes of Health (NIH), sponsored a workshop to examine the state of basic, epidemiological and clinical research addressing female pelvic floor disorders. Lack of standardization of terminology was identified as a critical obstacle to performing high-quality research. To address this need, in December 1999 another workshop was held by NICHD and other NIH Institutes, bringing together national and international researchers in the fields of urology, gynecology and urogynecology, colorectal surgery and nursing. The objectives of this meeting were to define the various conditions of female pelvic floor disorders; to develop a minimum dataset of standard, validated baseline and follow-up variables in multiple domains to be applied as uniformly as possible in studies of these conditions; and to identify areas of high priority for further research. Such standards are crucial to the generation of reliable, cogent research on the epidemiology, natural history and efficacy of therapy that will advance the field of knowledge and improve the level of care for all women with these disorders. The goal of this report is to introduce these standards to clinicians and researchers.

Acknowledgement of these standards in written publications and scientific presentations should be indicated in the Methods section with the following statement: 'Methods, definitions, and descriptions conform to the recommended standards except where specifically noted'.

Minimum Data Set for All Pelvic Floor Disorders

To ensure an adequate description of population characteristics and allow comparison between studies, it is important that a certain standard minimum amount of data be collected when studying and reporting on subjects with similar conditions. In general, scientific evaluation of outcomes after intervention requires comparison of the same assessments performed before and after therapy. No simple measure can completely express the outcome of therapeutic interventions. Both subjective and objective measures should be included, incorporating improvements and deteriorations in function as well as complications of the intervention. The following applies to studies involving women with all types of pelvic floor disorders; recommendations related to specific conditions will be described in subsequent sections. It should be emphasized that these recommendations represent the minimum or most basic data collection; additional data should be obtained specific to each study's primary and secondary research objectives. In addition, different study designs have different requirements for data collection; for example, epidemiological studies based only on questionnaires would not include data based on physical examination.

Table 1 lists recommendations for minimum data collection related to characteristics of the study population. As regards the tracking of subjects in follow-up, we support reporting by the same standards as in the CONSORT document for randomized clinical trials [9].

In general, minimum data for all pelvic floor disorders should be recorded and reported from at least five domains [10,11]: (1) the subject's observations (symp-

Table 1. Recommendations for data collection related to characteristics of study population

1. Age
2. Obstetric history (including parity)
3. Menopausal status
4. Race/ethnicity
5. Body mass index (weight and height)
6. Smoking status
7. Past surgical history
8. Medication use
9. Medical conditions (such as neurologic conditions, diabetes, pulmonary conditions)
10. Functional description of physical and mental capabilities (e.g. level of physical activity, mental status)
11. Prior therapy for pelvic floor disorders, particularly the condition under study (including behavioral, pharmacological and/or surgical interventions)
12. Details of subject enrollment (including total number of patients treated for the condition of interest during the timespan of study, number of patients evaluated for study, and number of patients who declined participation in study and why)
13. Details of follow-up (including length of follow-up: minimum, range, mean or median; number of subjects lost to follow-up and why; use of statistical techniques, taking into account differing lengths of follow-up).

toms); (2) quantification of symptoms; (3) the clinician's observations (anatomic and functional); (4) quality of life; and (5) socioeconomic measures.

The subject's observations or symptoms should include an overall assessment of the condition and general or specific characteristics, such as quantity, frequency or magnitude of symptoms associated with the condition. Researchers should clearly describe the instrument or method used to assess symptoms. There is a critical need for reliable, validated instruments for symptom assessment in all types of pelvic floor disorders, which may include standardized interviews, questionnaires, symptom diaries, and other techniques for the collection of qualitative and quantitative data. In addition, the extent and significance of overlap between symptoms of different pelvic floor disorders is poorly understood and requires further research. For all conditions research is needed to define categories of improvement after intervention, including determining patient preferences for different states (e.g. if treatment results in resolution of the stress incontinence but also results in the development of urgency).

Researchers should clearly describe their methods, instruments and procedures for reporting and recording clinical observations, and provide reliability data or indicate its absence. As will be discussed in more detail in the section on pelvic organ prolapse, there is a standardized system for the quantification (staging) of pelvic organ prolapse based on physical examination findings that should be used as appropriate for the objectives of individual studies [12]. The usefulness and validity of a simplified technique for screening for pelvic organ prolapse should be investigated. In addition, further research is required to determine the importance and validity of assessment of pelvic muscle function on physical examination. Whether specific pelvic floor defects (sites of connective tissue or fibromuscular damage) can be reliably identified and characterized on physical examination also needs to be determined.

Health-related quality of life is a multidimensional construct designed to measure an individual's perception of the health consequences of a condition and its subsequent treatment. Assessments include physical, psychological and social measures; overall life satisfaction; and perceptions of wellbeing. Although both generic (overall) and condition-specific instruments have been used to measure health-related quality of life in women with pelvic floor disorders [13–15], more research is required, particularly to evaluate the sensitivity of these instruments to change after intervention and to investigate the impact of coexisting conditions. Researchers should define health-related quality of life as it relates to their study, and clearly describe the methods or instruments for its assessment. Whenever possible, researchers should select instruments with published reliability and sensitivity.

Socioeconomic measures should be obtained, particularly to evaluate any difference in economic impact of different interventions in controlled trials. In addition, specific cost-effectiveness analyses may be performed to compare the relative merits of interventions according to the market value of goods and services required to achieve a given health effect, with effectiveness characterized as a specific outcome, such as alleviation of symptoms or the restoration of function.

Pelvic Organ Prolapse

For the purposes of this discussion, pelvic organ prolapse includes anterior vaginal prolapse (previously known as cystocele), apical or uterine prolapse, posterior vaginal prolapse (previously known as rectocele, enterocele, and perineal descent; it does not include rectal prolapse.

There is as yet no large epidemiological study evaluating the natural history of women with asymptomatic prolapse, or the type and frequency of symptoms in women with symptomatic prolapse. Even the association of specific symptoms with physical examination findings of prolapse has not been well studied. Ideally, the clinical definitions of prolapse would include the presence and severity of symptoms, and the distinction between cure and failure after intervention would include the resolution or persistence of such symptoms. However, symptoms could not be included in these definitions until further research provides data on the association between prolapse and symptoms, both before and after intervention, in a large cohort of women.

The definitions of prolapse presented here are based on findings at physical examination. Any current distinction between 'normal' physical examination findings and 'abnormal' findings that constitute prolapse is arbitrary, as data correlating symptoms to physical findings are lacking. Many women after vaginal delivery have some degree of 'prolapse' (i.e. physical examina-

tion changes consistent with less than perfect vaginal support). Although this might be considered 'normal' for parous women, we recommend that until data are available on which to base such a distinction, only the complete absence of prolapse should be considered 'normal'. Further research is necessary to determine the importance of asymptomatic prolapse and its relationship to the subsequent development of symptomatic prolapse. In addition, we recognize that many women who may be categorized as 'anatomic failures' are, in fact, satisfied with their postsurgical results; we anticipate that evidence provided by further research will allow subsequent refinement of these definitions to take into account the relief of symptoms and patient satisfaction, as well as anatomic outcomes.

The definitions of prolapse were not based on specific test results, primarily because of lack of evidence. We recommend that further research be performed to investigate the usefulness of various tests (for example, imaging by X-ray contrast or ultrasound) in determining definitions and outcomes of prolapse.

Stages of prolapse are determined using the standardized system of the International Continence Society [12]. In this system measurements are made at different vaginal sites, providing quantification of prolapse affecting different vaginal segments (anterior and posterior vagina, vaginal apex or cervix) as well as an overall stage of prolapse. Measurements are made in centimeters relative to the hymen as the reference point; negative numbers represent positions above the hymen, and positive numbers represent points beyond or past the hymen.

In general, prolapse is defined as descent of stage I or greater. An optimal anatomic outcome (cure) after intervention is defined as stage 0, or no prolapse. A satisfactory anatomic outcome (improvement) after intervention is defined as stage I. An unsatisfactory anatomic outcome (persistence or recurrence, failed treatment) after intervention is defined as stage II or greater, or no change or worsening from the pre-treatment stage. Specific definitions for individual conditions of prolapse are listed in Table 2.

Enterocele is defined as a cul de sac abnormality containing peritoneum and intra-abdominal contents, and involving the apical, anterior or posterior compartments of the vagina. Enterocele may be a separate entity from apical prolapse. Cure of enterocele should be defined in terms of correction in the anatomic compartment (e.g. vaginal apex or posterior vagina). Further research is needed to investigate different types of enterocele.

Bladder neck position should be described as a continuum (not as a dichotomy of 'normal' versus 'abnormal') using one of a variety of methods, such as the cotton swab test, ultrasound or other methods. Similarly, perineal descent should be described as a continuum (not as a dichotomy) using one of a variety of methods, such as defecography, ultrasound, perineometry or magnetic resonance imaging (MRI). Bladder neck position and perineal position can be measured at rest,

Table 2. Definitions of apical or uterine prolapse, anterior vaginal prolapse and posterior vaginal prolapse

Apical or uterine prolapse

Definition

Descent of the vaginal apex (posthysterectomy) or cervix to within 1 cm of the hymen or lower; stage I or worse by ICS* staging, with point C more than 2 cm lower than TVL† (quantification value for point C at least $-(TVL-3)$ cm or lower)

Optimal anatomic outcome (cure)

No prolapse of the vaginal apex or cervix is demonstrated; stage 0 by ICS staging, with point C between $-TVL$ and $-(TVL-2)$ cm (quantitation value for point C $\leqslant[TVL-2]$ cm)

Satisfactory anatomic outcome (improvement)

Descent of the vaginal apex or cervix to within 1 cm above the hymen; stage I by ICS staging, with point C between 2 cm lower than TVL and 1 cm above the hymen (quantitation value for point C between $-[TVL-2]$ and -1 cm)

Unsatisfactory anatomic outcome (persistence or recurrence, failed treatment)

Descent of the vaginal apex or cervix to 1 cm proximal to the hymen or lower, or no change, or worsening from pre-treatment stage; stage II or worse by ICS staging, with point C -1 cm or lower, or no change or worsening from pre-treatment position

Anterior vaginal prolapse

Definition

Descent of the anterior vagina to within 1 cm of the hymen or lower; stage I or worse by ICS staging, with point Aa or Ba at -2 cm or lower

Optimal anatomic outcome (cure)

No prolapse of the anterior vagina is demonstrated; stage 0 by ICS staging, with points Aa and Ba at -3 cm

Satisfactory anatomic outcome (improvement)

Descent of the anterior vagina to within 1 cm above the hymen; stage I by ICS staging, with point Aa or Ba at -2 cm

Unsatisfactory anatomic outcome (persistence or recurrence, failed treatment)

Descent of the anterior vagina to 1 cm proximal to the hymen or lower, or no change or worsening from pre-treatment stage; stage II or worse by ICS staging, with point Aa or Ba at -1 cm or lower, or no change or worsening from pre-treatment position

Posterior vaginal prolapse

Definition

Descent of the posterior vagina to within 1 cm of the hymen or lower; stage I or worse by ICS staging, with point Ap or Bp at -2 cm or lower

Optimal anatomic outcome (cure)

No prolapse of the posterior vagina is demonstrated; stage 0 by ICS staging, with points Ap and Bp at -3 cm

Satisfactory anatomic outcome (improvement)

Descent of the posterior vagina to within 1 cm above the hymen; stage I by ICS staging, with point Ap or Bp at -2 cm

Unsatisfactory anatomic outcome (persistence or recurrence, failed treatment)

Descent of the posterior vagina to 1 cm proximal to the hymen or lower, or no change or worsening from pre-treatment stage; stage II or worse by ICS staging, with points Ap or Bp at -1 cm or lower, or no change or worsening from pre-treatment position

* ICS, International Continence Society; † TVL, total vaginal length.

Point Aa represents a point on the anterior vagina 3 cm proximal to the external urethral meatus; by definition, its value is -3 cm in the absence of prolapse and has a maximum of +3 cm.

Point Ba represents the most distal extent of prolapse affecting the anterior vagina; by definition, its value is -3 cm in the absence of prolapse and has a maximum positive value of the total vaginal length.

Point C represents the most distal edge of the cervix or vaginal cuff (posthysterectomy).

Point Ap represents a point on the posterior vagina 3 cm proximal to the hymen; by definition, its value is -3 cm in the absence of prolapse and has a maximum of +3 cm.

Point Bp represents the most distal extent of prolapse affecting the posterior vagina; by definition, its value is -3 cm in the absence of prolapse and has a maximum positive value of the total vaginal length

with the Valsalva maneuver (bearing down or straining), or with pelvic muscle contraction. Further research is needed to standardize the methods currently used to measure bladder neck position and perineal position, and to draw clinically meaningful distinctions between normal and abnormal positions.

In addition to the recommendations for minimum data collection for all subjects with pelvic floor disorders, we recommend that the physical examination for research subjects in studies of pelvic organ prolapse include: (1) the use of the standardized quantification system for staging of prolapse [12]; (2) rectovaginal and anal sphincter examination; (3) assessment of the presence or absence of pelvic muscle contraction; and (4) a screening pelvic neurologic examination (which could include one of a variety of methods, such as bulbocavernosus reflex, anal wink response, anal sphincter tone or anal sphincter contraction). As mentioned above, further research is required to determine the usefulness and validity of assessment of pelvic muscle function on physical examination; and to determine the role of testing in defining conditions and response to intervention for pelvic organ prolapse.

Urinary Incontinence and Other Urinary Symptoms

Urinary incontinence may occur as a solitary symptom, as in stress urinary incontinence, or as part of a symptom complex, e.g. when urge urinary incontinence is accompanied by urgency and frequency. The International Continence Society [16] has developed standard definitions and introduced the concept of incontinence as a symptom (e.g. for stress incontinence the patient says she loses urine on coughing), a sign (the patient is seen to leak when coughing during physical examination), and a condition (genuine stress incontinence, when the patient fulfills the definition during urodynamic studies). Therefore, in International Continence Society terms the condition represents a definitive diagnosis and requires the use of urodynamic studies, with measurement of both intravesical and intra-abdominal pressure.

In this section, existing International Continence Society definitions are used except where stated. In general, urinary incontinence of all types is defined as involuntary loss of urine that is both objectively demonstrable and a social or hygienic problem for the patient. The following two sections describe stress and urge urinary incontinence as separate entities; however, the conditions commonly coexist (mixed incontinence). Further research is needed to better define the overlap in conditions, to determine whether it is feasible to distinguish between types of symptoms by questionnaire or voiding diary and, if so, how this can best be quantified.

Stress Urinary Incontinence

The **symptom** of stress urinary incontinence indicates the patient's or caregiver's statement of involuntary loss of urine during physical exertion. The **sign** of stress urinary incontinence is the objective demonstration of loss of urine synchronous with physical exertion. The **condition** of genuine (urodynamic) stress incontinence is the involuntary loss of urine occurring as a result of a rise in intra-abdominal pressure, in the absence of a detrusor contraction (modified from the International Continence Society definition).

Subcategories of stress incontinence are in common clinical and research use, including types based on urethral mobility (hypermobility versus fixed urethral position) and urethral function (commonly measured as urethral pressure or leak-point pressure, and described by the term 'intrinsic sphincter deficiency (ISD)' when abnormal). However, at present there are insufficient data on which to base the valid definition of such subcategories. Further research is needed to define characteristics of normal and abnormal urethral position and function, and to determine how these characteristics relate to the pathophysiology and optimal clinical management of stress incontinence.

Outcome after treatment should be defined in terms of stress urinary incontinence, but also in terms of associated symptoms and unwanted (side) effects resulting from an intervention, after a return to baseline activities and medications. Cure of stress urinary incontinence is defined as: (1) resolution of the stress incontinence symptoms; (2) resolution of the sign (negative full bladder cough stress test, performed under the same conditions as before treatment); and (3) no new symptoms or side effects. New symptoms or side effects should be specifically described and could include new urinary symptoms such as urinary urgency, frequency, urge incontinence, with or without urodynamic changes of detrusor overactivity (detrusor instability); change in sexual function; development or worsening of pelvic organ prolapse; adverse effect on bowel function; onset of urinary tract infections; surgical complications, such as foreign-body reaction to grafts, the development of fistula or diverticula; osteitis or osteomyelitis; neuropathy; and others. In studies using urodynamics after intervention the absence of genuine stress incontinence should be documented.

Failure of treatment of stress urinary incontinence is defined as persistent stress symptoms with the number of incontinent episodes unchanged, or worse, by voiding diary, plus a positive full bladder cough stress test (performed under the same conditions as before treatment), or genuine stress incontinence confirmed by urodynamic studies, with or without new symptoms or side effects.

Between the two extremes of cure and failure we recognize the value of a category for subjects who are improved. Improvement includes persistent stress symptoms but with the number of incontinent episodes decreased by voiding diary, plus a positive full bladder

cough stress test (performed under the same conditions as pre-treatment) or genuine stress incontinence confirmed by urodynamic studies, with or without new symptoms or side effects. However, further research is required before clinically meaningful categories of improvement can be defined. It would be particularly valuable to define levels of improvement considered important to the patient, and to determine how to best measure such a change. For example, if a change in the number of incontinent episodes is an important measure of improvement, is this better quantified as an absolute number of leak episodes after treatment, or as a percentage change from baseline? In addition, when more than one characteristic is used to define an outcome (i.e. symptoms and signs), the characteristics will not be concordant in some situations. Possible categories to describe these situations include patient-observed treatment effect, with absence of stress symptoms and no side effects, but a positive full bladder cough stress test; and provider-observed treatment effect, with persistence of stress symptoms, no side effects and a negative full bladder cough stress test.

Urge Urinary Incontinence

Urge urinary incontinence usually occurs with other lower urinary tract symptoms. Therefore, each symptom is defined as follows. **Frequency** is the statement that the patient voids eight or more times in 24 hours. **Nocturia** is the statement that the patient wakes from sleep in order to pass urine. **Urgency** is the statement that the patient feels a strong need to pass urine for fear of leakage. **Urge urinary incontinence** is the report that the patient has involuntary loss of urine associated with a feeling of urgency (modified from the International Continence Society definition). **Nocturnal enuresis** denotes loss of urine during sleep. The term 'overactive bladder' has been coined to describe symptoms suggestive of detrusor overactivity (detrusor instability), and is defined as urgency and/or urge incontinence, usually occurring with urinary frequency, in the absence of local pathological or metabolic factors (such as urinary tract infection or polyuria with diabetes).

For outcomes related to symptoms, cure is defined as the patient's statement that the symptom(s) is no longer present. In the case of frequency, there are seven or fewer micturitions per 24 hours. Failed treatment is defined as the patient's statement that the symptom(s) is no better or worse, with objective data from a urinary diary. As discussed above, the category of improvement cannot be specifically defined at present and requires further research to define outcomes of value to patients. Improvement could include the patient's statement that the symptom(s) is less frequent or less troublesome with evidence from a urinary diary.

Detrusor overactivity (detrusor instablity and hyperreflexia) is a urodynamic diagnosis characterized by involuntary phasic detrusor contractions during the filling phase of cystometry, which may be spontaneous or provoked, and which the patient cannot completely suppress. The detrusor contractions may be provoked by rapid filling, alterations of posture, coughing, walking, jumping, or other provocative maneuvers. Outcomes for detrusor overactivity should be defined separately for symptoms, as described above, and for urodynamic findings. Cure of detrusor overactivity is defined as the absence of involuntary phasic detrusor contractions on filling cystometry. Failure is defined as unimproved or worsened detrusor overactivity on urodynamics. Again, the definition of improvement cannot be specified but, if used, the method of measurement should be precisely defined.

Minimum Dataset for Urinary Incontinence and Other Urinary Symptoms

In addition to the recommendations for minimum data collection for all subjects with pelvic floor disorders, we recommend that studies of urinary incontinence and other urinary symptoms include: (1) a urinary diary for at least 3 days per episode of data collection, recording and reporting (as a minimum) pad use, urinary incontinence episodes and urinary frequency; (2) physical examination to include (a) screening for pelvic organ prolapse (in some studies, such as surgical studies of stress urinary incontinence, the standardized quantification system for staging of prolapse [12] should be used; (b) rectal examination; (c) assessment of the presence or absence of pelvic muscle contraction; and (d) a screening pelvic neurologic examination (which could include one of a variety of methods, such as bulbocavernosus reflex, anal wink response, anal sphincter tone or anal sphincter contraction); (3) postvoid residual urine volume measurement; (4) testing to evaluate for urinary tract infection; and (5) urodynamic studies to include (a) a full bladder cough stress test to elicit the sign of stress urinary incontinence; and (b) filling cystometry. For surgical studies of stress urinary incontinence, if measures of urethral mobility and function are used the methodology should be specified precisely. Further research is needed to clarify the role of pad tests in quantifying symptom severity and response to treatment; if pad tests are used, the methodology should be described in detail.

Posterior Pelvic Floor Dysfunction (including Fecal Incontinence)

Women with other pelvic floor disorders frequently have coexistent problems with the posterior pelvic floor, which may include fecal incontinence, fecal urgency, constipation, chronic pain (such as levator syndrome or proctalgia fugax), solitary rectal ulcer syndrome and rectal prolapse. These are among the most understudied of all pelvic floor disorders. Because of lack of evidence, our recommendations are much less specific for this group of disorders than for pelvic organ prolapse and

urinary incontinence. There are some accepted definitions for symptoms and conditions of posterior pelvic floor dysfunction, but further research is needed to assess whether they are applicable to the group of women with pelvic floor disorders. Therefore, the following definitions are very broad; we anticipate that future research findings will guide the development of more specific definitions.

Fecal Incontinence

For the purposes of this discussion, fecal incontinence includes incontinence of either feces or gas. Although there is an assumption in the literature that incontinence of formed stool represents a more severe form of fecal incontinence than incontinence of liquid stool (and similarly, that incontinence of liquid stool represents a more severe form of fecal incontinence than incontinence of gas) [17], there are minimal data to support this. We have preserved the distinction between different types of loss (based solely on the patient's description) in our definitions, but further research is required to confirm or refute this. Our definitions of fecal incontinence are based on symptoms. There are many systems that quantify symptoms related to fecal incontinence [18]; however, an internationally agreed scoring and evaluation system does not yet exist. This lack of consensus makes it difficult to compare findings across studies. We identified this need for a standardized system of evaluation and quantification of symptoms (which may include questionnaires, diaries and quality of life assessment) as a high priority for further research in this field. In contrast to urinary incontinence, the objective demonstration of fecal incontinence has not been a component of definitions to date. In addition, as with pelvic organ prolapse, specific test results were not included as part of the definitions (although certain tests may be useful in determining the etiology of different subcategories of fecal incontinence).

A definition for fecal incontinence commonly used in the colorectal literature is 'the inability to defer defecation until a socially acceptable time'. This definition was felt to be deficient for defining fecal incontinence in women with pelvic floor disorders in several respects. First, it does not differentiate between true loss of stool and functional disorders that may compromise the ability to defer defecation but not represent true incontinence, such as diarrhea or fecal urgency. Second, it does not require a negative impact on the patient's lifestyle, which was felt to be an important component of our definition. As with urinary incontinence, the number of episodes of fecal incontinence was felt to be an important indicator of severity but not a component of the definition itself. We recommend that researchers report the number of incontinent episodes by time frame of interest and the character of loss (solid stool, liquid stool, gas). Definitions for fecal incontinence are listed in Table 3.

Table 3. Definitions of fecal incontinence

Incontinence of formed stool
Definition
Recurring episodes of involuntary loss of formed stool that is a social or hygienic problem. The time frame of interest and the character of loss should be specified.
Cure
Patient statement of no involuntary loss of formed stool within the stated time frame.
Improvement
Favorable change based on outcome measures to be developed, including quality of life, frequency of symptoms, consistency of loss, socioeconomic factors, etc.
Persistence/recurrence (failed treatment)
No improvement or worsening of symptoms.
Incontinence of liquid stool
Definition
Recurring episodes of involuntary loss of liquid stool that is a social or hygienic problem. The time frame of interest and the character of loss should be specified.
Cure
Patient statement of no involuntary loss of liquid stool within the stated time frame.
Improvement
Favorable change based on outcome measures to be developed, including quality of life, frequency of symptoms, consistency of loss, socioeconomic factors, etc.
Persistence/recurrence (failed treatment)
No improvement or worsening of symptoms.
Incontinence of gas
Definition
Recurring episodes of involuntary loss of gas that is a social or hygienic problem. The time frame of interest and the character of loss should be specified.
Cure
Patient statement of no involuntary loss of gas within the stated time frame.
Improvement
Favorable change based on outcome measures to be developed, including quality of life, frequency of symptoms, consistency of loss, socioeconomic factors, etc.
Persistence/recurrence (failed treatment)
No improvement or worsening of symptoms.

In defining the impact of interventions on fecal incontinence, cure was defined as complete resolution of the symptom. Failed treatment (persistence or recurrence) was defined as no improvement or a worsening of symptoms. As with the other pelvic floor disorders, improvement could not be specifically defined but could include some favorable change in symptoms that may be based on quality of life measures, frequency of symptoms and consistency of loss. Further research is needed to develop clinically meaningful levels of improvement after intervention.

Constipation

Constipation is a symptom with many different definitions, based on stool frequency, consistency, the need for straining, incomplete emptying, other characteristics, or some combination [19–21]. Without a standard accepted definition of constipation and without evidence that these definitions are applicable to the

population of women with pelvic floor disorders, we recommend that further research be performed before developing such a definition.

Fecal Urgency

Fecal urgency is a symptom rather than a condition. The Rome diagnostic criteria for functional bowel disorders considers fecal urgency to be a supportive symptom for the diagnosis of irritable bowel syndrome, defined as 'having to rush to have a bowel movement' [21]. In parallel to wording related to urinary urgency, we suggest the definition of fecal urgency be 'the patient's statement of overwhelming desire to defecate accompanied by fear of leakage of bowel contents'. However, further research is required to test this or other definitions before recommendations can be made.

Minimum Dataset

In addition to the recommendations for minimum data collection for all subjects with pelvic floor disorders, we recommend that studies of posterior pelvic floor dysfunction include physical examination with (1) screening for pelvic organ prolapse (in some studies, such as surgical studies of fecal incontinence, the standardized quantification system for staging of prolapse [12] should be used); (2) rectal examination; (3) assessment of the presence or absence of pelvic muscle contraction; and (4) a screening pelvic neurologic examination (which could include one of a variety of methods, such as bulbocavernosus reflex, anal wink response, anal sphincter tone or anal sphincter contraction). At present there are insufficient data to make recommendations for minimum testing. Particularly for surgical studies of fecal incontinence, researchers are encouraged to consider imaging of the anal sphincters (e.g. with anal endosonography) and some type of neurophysiologic testing (such as electromyography or other tests). Further research is needed to define the role of testing in the evaluation and management of posterior pelvic floor dysfunction.

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EDITORIAL COMMENT: This is a compilation of opinions regarding the need for standardization of terminology for pelvic floor dysfunction. Some of their definitions may or may not be appropriate, however, we are now in the process of defining what represents prolapse versus normal, and what represents a cure after intervention versus persistence. Hopefully this document will serve as a starting point to allow for further discussions and revisions of these definitions as we study this complex problem.