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Terminology for Bladder Health Research in Women and Girls – PLUS Transdisciplinary Consortium Definitions

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For the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium

Abstract

Aims: To report research terminology and definitions for describing healthy bladder function among women and girls.

Methods: The Prevention of Lower Urinary tract Symptoms (PLUS) Consortium developed research terminology and definitions for elements of healthy bladder function based on existing understanding of storage and emptying functions of the bladder and accepted definitions of lower urinary tract symptoms (LUTS). The novel concept of a bladder “bioregulatory” function was also proposed. Elements of bladder function corresponding to bladder health (BH) and LUTS were developed and refined using an iterative process. A comprehensive reference table structured by bladder function (Storage, Emptying, Bioregulatory) and elements of each function was created to document proposed research terminology and definitions.

Results: The BH research definitions for each bladder function are: 1) *Storage*: The ability to hold urine for a reasonable duration of time and sense bladder fullness without fear of or concern about urgency, discomfort or leakage; 2) *Emptying*: The ability to empty the bladder completely in a timely, efficient, effortless, comfortable manner; and 3) *Bioregulatory*: The bladder barrier protects the individual/host from pathogens, chemicals, and malignancy. Research definitions for 7 Storage, 7 Emptying, and 3 Bioregulatory elements of function are presented. Novel LUTS research definitions were developed when gaps in existing definitions were identified or non-clinical language was desired.

Conclusions: PLUS BH definitions reflect a transdisciplinary approach to standardizing research definitions for elements of bladder function from a perspective of health rather than dysfunction and provide a framework for studying BH in clinical practice, public health promotion and LUTS prevention.

Introduction

Bladder function has been defined primarily through the presence or absence of lower urinary tract symptoms (LUTS) rather than corresponding indices of health. The International Continence Society (ICS) reports on LUTS, the International Urogynecologic Association (IUGA) and ICS joint report on female pelvic floor dysfunction, and the International Children' Continence Society (ICCS) report provide excellent resources for LUTS and pelvic floor dysfunction terminology for women of all ages.[1–7] However, current understanding of bladder function and terminology focus on definitions of bothersome LUTS rather than normal bladder function.[1–7] Furthermore, current validated questionnaires related to bladder function focus primarily on bothersome symptoms of LUTS pathology (e.g. incontinence) rather than the full spectrum of bladder function. A narrow focus on single aspects of dysfunction, rather than a holistic focus on the spectrum of health to dysfunction, has led to challenges with measurement and interpretation for most studies related to LUTS. For example, assuming that the absence of urinary incontinence is an indicator of bladder health may not be accurate because other bladder pathologies (e.g. infections or retention) may exist. In addition, the absence of single or multiple bladder pathologies does not necessarily imply optimal bladder health. We have learned from other areas of medicine that the lack of clinically manifest disease does not always equate to health.[8]

Promotion of optimal bladder function and prevention of LUTS is particularly important for girls and women. Women are at higher risk than men are for specific LUTS such as urinary incontinence and urinary tract infections due to the anatomy and physiology of the female urogenital system, women's hormonal milieu, pregnancy and childbirth, and in many contexts, gendered inequities.[9–12] Moreover, LUTS tend to begin earlier in the life course for women than for men.[10,13] To date, neither bladder health nor normal bladder function(s) have been adequately researched in women or girls. We posit that clear definitions of both health and disease are critical to conducting research that can inform understanding and promotion of optimal bladder function. This premise is consistent with the discipline and tenets of prevention science, which involves the systematic study of potential precursors to both human dysfunction and health.[14,15] To study and promote optimal bladder function, an agreed upon definition of bladder health and healthy bladder functions along with valid and reliable measures of bladder health are necessary prerequisites.

The Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium was established in 2015 with a mission to identify "bladder health" (BH) as a state to preserve and protect; and to expand research in the area of clinical practice, and policies beyond the detection and treatment of LUTS to the promotion and preservation of bladder health and prevention of LUTS in women and in girls from school age through adolesence.[16] The PLUS Research Consortium is comprised of a transdisciplinary network of professionals,

including community advocates, health care professionals with diverse clinical expertise, and scientists representing over 20 disciplines. The details of the consortium's history, process and purpose have been previously reported.[16]

As no research definition for bladder health existed, the first step necessary for the consortium to achieve its goals was to establish a research definition of bladder health (see Lukacz et al. for a description of this process).[17] Consistent with the World Health Organization's definition of health,[18] the PLUS Research Consortium conceptualizes bladder health as *"a complete state of physical, mental and social well-being related to bladder function, and not merely the absence of LUTS,"* with function that *"permits daily activities, adapts to short term physical or environmental stressors, and allows optimal well-being (e.g., travel, exercise, social, occupational or other activities).*[17] This research definition highlights individual function and subjective experiences associated with well-being. Consistent with the tenets of prevention science, the PLUS Research Consortium is applying a life course developmental perspective to planned etiologic research.[19] The objective of this paper is to present the research definitions developed by the PLUS Research Consortium for assessing the spectrum of bladder health, from bladder health to dysfunction across the life course.

Materials and Methods

The process by which the PLUS Consortium developed a research definition of BH has been previously reported.[17] A subgroup of PLUS investigators that included research and clinical experts convened into a Terminology and Conceptual Framework & Models (TCFM) Intellectual Resource Group. After development of the bladder health definition, the fourteen members of TCFM continued to develop and refine specific terminology and definitions for the storage, emptying, and bioregulatory elements of healthy bladder function. Our initial objective was to propose BH research definitions that could be developed, organized, compared and displayed in a similar and parallel fashion to existing ICS defined LUTS.[1–7]

At the outset of this work, a broad search and review of the literature was conducted using PubMed, Ovid Medline and Scopus for current bioregulatory, bladder health, and LUTS terminology or definitions. The search also included the active or current ICS Standardisation and Terminology Reports and Documents (https://www.ics.org/folder/92) and confirmed an absence of published research definitions of bladder health or healthy bladder functions.[20] While "normative data" have been published for certain bladder function measurements in women, the study populations are typically described as "normal", "healthy" or "asymptomatic", all based on the absence of one or more LUTS symptoms.[21–23] However "normal" or "asymptomatic" function based solely on the absence of LUTS may not necessarily equate to healthy function. Thus, the PLUS Research Consortium terms and definitions were developed based on the recognized "two-phase" concept of bladder function (Storage and Emptying) described by Wein et al.[24] Published LUTS definitions provided definable starting points for developing bladder health function definitions.[1–7] Since the proposed BH definitions are for women and girls, the *ICS/IUGA Joint Report on the Terminology for Female Pelvic Floor Dysfunction* and The Standardization of Terminology of Lower Urinary Tract Function in Children and Adolescents: Report from the

Standardisation Committee of the International Children's Continence Society served as the primary basis for the LUTS definitions.[4,7]

The concept of "elements of function" was developed by the TCFM group during BH definition creation to reflect key elements of each function. The elements of storage function were determined to include "capacity" and "continence" during daytime (waking) and nighttime (sleeping) periods; as well as "sensation" of urge and comfort during filling and storage. Emptying functions of the bladder include "initiation," "stream flow" (including speed, character, and continuity), "efficacy" (completeness), and "sensation" (including relief of urge, completeness, and comfort during and after voiding). The elements of storage and emptying functions were compared with accepted definitions of LUTS obtained from published terminology recommended by international organizations.[1–7,20,25] For each element of bladder function, a bladder health definition based on subjective experience was proposed.

The definitions of elements of bladder function corresponding to both BH and LUTS were refined using an iterative process, balancing the needs to be descriptive, clinically relevant and meaningful, while also easy to use and understandable by a lay population, clinicians, and researchers. While the IUGA/ICS definitions for LUTS is the gold standard for current terminology, in order to incorporate a more patient centered language throughout our work, the PLUS consortium has made a few, minor modifications to this terminology. Modifications to published LUTS definitions were suggested by the TCFM when it was thought that a refinement in definition would increase specificity, clarity, or be more patient-centered. The TCFM elected to diverge from typical ICS phrasing of symptom definitions which include the phrase "the complaint of…". While the initial intent of this phrasing was likely to clarify that a symptom is reported by the patient as bothersome, it was felt that use of "complaint" could have a negative connotation. In contrast to LUTS definitions, priority was given to defining BH using positive attributes. Thus, these definitions avoided double negative language such as "denies complaint of…" and used positive phrasing such as "the bladder empties completely with minimal effort" for Emptying – Efficacy.

Finally, the novel concept of a bladder "bioregulatory" function was acknowledged, recognizing that the bladder lining and urine composition may play a role in bladder health and dysfunction.[26] Definitions were proposed for a "Biosis barrier" describing the role of the bladder microbiome in preventing infection, a "chemical or physical barrier" describing the role of the urothelium in prevention of absorption of chemicals, and a "neoplastic barrier" describing the regulated turnover of cells to maintain health and prevent malignancy. Unlike the storage and emptying functions, which can be assessed subjectively, the bioregulatory functions require objective assessment.

Based on the overarching research definition of BH developed by the PLUS Consortium, definitions for elements of BH function were developed to include the perspective of aging and chronic disease (where complete well-being may be unattainable and health is the ability to adapt and self-manage) and allostasis (defined as resilience to short-term physical, social and environmental stressors).[17] Thus, the definitions of BH were developed and structured to be compatible with existing ICS terminology, but also extend beyond ICS terminology with

respect to their emphasis on health across the life course and allostasis in the context of short-term stressors.

An initial table was developed and structured by bladder function (Storage, Emptying, Bioregulatory) and elements of function. The TCFM process of definition development occurred iteratively over 14 months and included pre-meeting preparation and review of circulated documents and current versions of existing and proposed BH and LUTS definitions. Committee members provided comments and suggested edits that were routinely collated and circulated to the group after TCFM leads noted specific issues or items to be discussed during meetings. Discussions of definitions and related issues were conducted until consensus was met. If committee members were not available for web-based or in-person meetings, they provided comments in advance of the meeting or upon review of an updated draft circulated after the meeting. If a new publication including LUTS definitions or terminology was identified in the literature between meetings, the document was circulated to the group for review and the table was annotated with definition(s) for discussion at the next meeting.

Terminology and definitions were circulated to the entire 83 member consortium for comment prior to approval and adoption by the consortium. Agreement on research definitions by the Consortium was reached by consensus. As over a year had passed since initiation of this work, a broad literature search was conducted again in PubMed, Ovid Medline and Scopus for current bioregulatory, bladder health or LUTS terminology or definitions. The search also included the active or current ICS Standardisation And Terminology Reports and Documents to ensure new or updated LUTS terminology was included and to identify if any bioregulatory or BH terminology had been published in the interim.[20] Based on the initial terminology table, a comprehensive reference table of research terminology and definitions was designed for use by the PLUS Research Consortium for development of an instrument(s) to measure bladder health in women and school age and adolescent girls.

Results

Proposed research definitions for subjective experiences of BH in women and girls across the elements of bladder function, along with objective measures of bioregulatory function, are presented in Table 1. These definitions include “overall” definitions of storage, emptying, and bioregulatory functions and seven elements of storage-related definitions, seven elements of emptying-related definitions, and three elements of bioregulatory-related definitions. In accordance with recommendations in the review of terminology by ICS in 2004, “voiding” was used in place of micturition, passing urine or urination in both existing ICS LUTS terminology and newly proposed BH and LUTS definitions.[3] Existing ICS LUTS definitions for elements of bladder function are listed along with the newly proposed BH and LUTS definitions for comparison (definition listed with corresponding reference).[1–7]

Overall Definitions

Overall definitions for elements of bladder function were developed for LUTS and BH. The overarching definition of BH served as the foundation for the sub-component BH definitions

for Storage, Emptying and Bioregulatory. No “overall” definition for the subjective experience of LUTS existed (noted as “new”); therefore definitions were proposed as follows:

- ***BH (Overall)***: A complete state of physical, mental and social well-being *related to bladder function*, and not merely the absence of LUTS. Healthy bladder function does not impact daily activities on a routine basis, is adaptable to short term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).[17]
- ***LUTS (Overall)***: The subjective indicator of bladder dysfunction or change in bladder function as perceived by the patient, caregiver, or partner, which may lead to seeking help from healthcare professionals. (***PLUS modification)***
- Storage Function
  - ***BH Storage (Overall)*:** Ability to hold urine for a reasonable duration of time and sense bladder fullness without fear of or concern about urgency, discomfort, or leakage. Storage function does not impact daily activities on a routine basis, is adaptable to short term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
  - ***LUTS Storage Symptoms (Overall)*:** Bothersome LUTS that occur with filling of the bladder with urine. (***PLUS modification***)
- Emptying Function
  - ***BH Emptying (Overall)***: The ability to empty the bladder completely in a timely, efficient, effortless, comfortable manner. Emptying function does not impact daily activities on a routine basis, is adaptable to short term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
  - ***LUTS Emptying Symptoms (Overall)***:
    - **Voiding symptoms:** A departure from normal sensation or function, experienced during or following the act of voiding.[4] ***(PLUS modification)***
    - Bothersome LUTS that occur during or immediately following bladder emptying of urine. (***PLUS modification***)
- Bioregulatory Function
  - ***BH Bioregulatory Barrier Function (Overall):*** The bladder barrier protects from pathogens, chemicals, and malignancy; is adaptable to short term physical or environmental stressors; and is able to completely recover from disruption of the barrier layer, without long term or persistent sequelae.

- ***LUTS Bioregulatory Barrier Dysfunction (Overall):*** A disruption in the protective barrier of the bladder resulting in LUTS. (***PLUS definition***)

Elements of Storage Function Definitions

- ***BH Capacity/Frequency – Day/Waking:*** A frequency of voiding during waking hours that does not impact daily activities on a routine basis; and is adaptable to short term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Capacity/Frequency – Day/Waking:
  - Voiding frequency during waking hours that occurs more frequently than desired and/or impacts daily activities on a routine basis. (***PLUS definition)***
  - **Increased daytime urinary frequency:** Voiding occurs more frequently during waking hours than deemed normal.[2,4] ***(PLUS modification)***
- ***BH Capacity/ Frequency – Night/Sleeping*:** A frequency of voiding during sleeping hours, due tthe urge tvoid, that allows for optimal sleep quality and is within physiologic age norms; and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Capacity/Frequency – Night/Sleeping:
  - Voiding during sleeping hours occurs more frequently than desired and impacts sleep quality and/or quantity. (***PLUS definition***)
  - **Nocturia**: Interruption of sleep one or more times because of the need tvoid. Each void is preceded and followed by sleep.[4] ***(PLUS modification)***
- BH Continence - Day/Waking:
  - The ability thold urine during waking hours for a reasonable duration of time and throughout daily activities without any leakage of urine. Maintenance of continence does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows a woman tpursue her optimal well-being (e.g. travel, exercise, social, occupational or other activities).
  - At completion of voiding there is continence (i.e. nsubsequent leakage or dribbling of urine).
- LUTS Continence - Day/Waking:
  - **Urinary incontinence (UI)**: Involuntary loss of urine.[2,4] ***(PLUS modification)***

- Types of UI **(*PLUS modification*):**[4]
  - Stress UI: urine loss with physical exertion, sneezing, or coughing
  - Urgency UI: urine loss associated with urgency
  - Postural UI: urine loss with change in body position
  - Mixed UI: urine loss with urgency and alswith physical exertion, sneezing, or coughing *OR* urgency and stress UI
  - Continuous UI: continuous urine loss
  - Insensible UI: urine loss without awareness
  - Coital UI: urine loss with coitus
- Post void dribble (post void leakage): Involuntary passage of urine following the completion of voiding.[4] ***(PLUS modification)***

- BH Continence - Night/Sleeping:
  - The ability thold urine during sleeping hours, without leakage of urine. Maintenance of continence does not impact her own, her partner's or caregiver's sleep or daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows a woman tpursue her optimal well-being (e.g. travel, exercise, social, occupational or other activities).
  - At completion of voiding during sleeping hours there is continence (i.e. nsubsequent leakage or dribbling of urine).
- LUTS Continence - Night/Sleeping:
  - **Nocturnal enuresis:** Involuntary loss of urine that occurs during sleep and is recognized after awakening.[2,4] **(*PLUS modification*)**
  - **Nocturnal urgency incontinence:** Leakage of urine on the way tthe toilet upon waking from sleep due turgency tvoid. (***PLUS definition***)
  - **Nocturnal post void dribble** (post void leakage): Involuntary passage of urine following the completion of voiding during sleeping hours.[4] **(*PLUS modification*)**
- ***BH Sensation – Urge*:** The awareness and sensation of urge and bladder fullness that allows sufficient time tget tthe toilet without fear of leakage; and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Sensation – Urge:
  - **Urinary urgency:** The sudden, compelling desire tpass urine that is difficult tdefer.[4] The urgency may be associated with fear of urine loss

before making it tthe toilet. Despite absence of leakage, this may cause distress or bother, and/or impact daily activities. (***PLUS modification***)

- **Absence of urge:** The lack of sensation at full capacity. (***PLUS definition)***

- ***BH Sensation – Comfort*:** The bladder fills and stores urine with increasing degree of sensation; and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Sensation – (Dis)Comfort:
  - **Bladder pain**: Suprapubic or retropubic pain, pressure, or discomfort related tthe bladder, and usually increasing in degree of sensation with bladder filling. Sensation may persist or be relieved after voiding.[2,4]

Elements of Emptying Function Definitions

- ***BH Voiding Initiation*:** Voiding proceeds when intended and without effort; and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Voiding Initiation:
  - **Hesitancy:** A delay in initiating voiding.[4] **(*PLUS modification*)**
- **BH Stream Flow – Speed:** Voiding occurs in an amount of time that does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Stream Flow – Speed:
  - **Slow stream**: The urinary stream is perceived as slower compared tprevious performance or in comparison with others.[4] ***(PLUS modification)***
- ***BH Stream Flow – Character*:** Voiding occurs in a uniform stream without spraying or splitting; and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Stream Flow – Character:
  - **Spraying (splitting) of urinary stream:** Urine is passed as a spray or split rather than a single discrete stream.[4] ***(PLUS modification)***
- ***BH Stream Flow – Continuity*:** Voiding occurs continuously without interruption and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).

- LUTS Stream Flow – Continuity:
  - **Intermittency:** Urine flow that stops and starts on one or more occasion during voiding.[4]
- ***BH Efficacy*:** The bladder empties completely with minimal effort; and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Efficacy:
  - **Urinary retention**: The inability tvoid completely despite persistent effort in the presence of a full bladder.[4] (***PLUS modification)***
- ***BH Sensation – Urge relief:*** The bladder feels empty and without urinary urge or urgency after voiding; and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Sensation – Urge
  - **Persistent urgency:** Sensation of urinary urge or urgency after voiding. (***PLUS definition)***
  - **Need timmediately re-void**: Sensation that further voiding is necessary soon after passing urine. ***(PLUS modification)***
- ***BH Sensation – Completeness*:** The bladder feels empty at the end of voiding; and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Sensation – Completeness
  - **Feeling of incomplete (bladder) emptying**: Sensation that the bladder is not empty after voiding.[4] ***(PLUS modification)***
  - **Non-neurogenic chronic urinary retention**: An elevated post-void residual of greater than 300 mL that persists for at least 6 months and is documented on twor more separate occasions.[25]
  - **Post void dribble** (post void leakage): Involuntary passage of urine following the completion of voiding.[4] **(*PLUS modification*)**
- ***BH Sensation – Comfort:*** The bladder empties with decreasing degree of sensation; and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities).
- LUTS Sensation – (Dis)comfort:
  - **Dysuria:** Urethral pain, burning or other discomfort during voiding.[4] **(*PLUS modification*)**

Elements of Bioregulatory Function Definitions

- ***BH Biosis Barrier*:** A healthy relationship (symbiosis) between host and bladder microbiota that is adaptable tshort term physical or environmental stressors and is able tcompletely recover from disruption of the microbiome and barrier layer, without long term or persistent sequelae. ***(PLUS definition)***
- ***LUTS Biosis Barrier* - Dysbiosis and/or infection**: Disruption of the symbiotic relationship between host and healthy bladder microbiota. ***(PLUS definition)***
- ***BH Physical/Chemical Barrier*:** The intact urothelium that lines the bladder (basal/intermediate/umbrella cells) provides a barrier between irritating urinary substances and underlying neuromuscular tissue; is adaptable tshort term physical or environmental stressors; and is able tcompletely recover from disruption of the microbiome and barrier layer, without long term or persistent sequelae. ***(PLUS definition)***
- ***LUTS Physical/Chemical Barrier*:** A breakdown in the apical layer of urothelium (‘umbrella cells’) due tdisruption of tight-junction complexes and uroplakins (hexagonal plaques) and/or the sulfated polysaccharide glycosaminoglycan (GAG) layer, allowing passage of toxic and irritating urinary substances through the urothelium or release of neuroactive chemicals stimulating LUTS. ***(PLUS definition)***
- ***BH Neoplastic Barrier*:** The intact urothelium that lines the bladder (basal/intermediate/umbrella cells) sloughs and regenerates in a regulated manner; and is adaptable tshort term physical or environmental stressors; and is able tcompletely recover from disruption of the microbiome and barrier layer, without long term or persistent sequelae.
- ***LUTS Neoplastic Barrier*:** Malignancy that forms in tissues of the bladder. Most bladder cancers are transitional cell carcinomas. Other types include squamous cell carcinoma and adenocarcinoma. ***(PLUS definition)***

Discussion

Bladder function has been primarily defined through the presence or absence of LUTS and functional urodynamic studies. The reliance on urodynamic studies tobjectively assess bladder function arose from clinician dissatisfaction with reliance on reported LUTS symptoms alone.[27] Current standardized terminology tdescribe the lower urinary tract has allowed researchers and clinicians tcommunicate in meaningful ways; however, the current terminology describes bladder dysfunction rather than bladder health.[1–7] Until now there has been little need for terminology about the opposite end of the spectrum tfacilitate research that informs practice, with the goal of bladder health promotion and LUTS prevention. In this manuscript, we present our transdisciplinary research consortium’s proposed terminology for bladder health functions using the International Continence Society’s standardization publications of Lower Urinary Tract Function as a framework.[1–7] The intent of this effort is tpropose research definitions for bladder function from the perspective of health, which will be used for research instrument development within the PLUS Research

Consortium. We dnot intend for these tbe clinical terms until further research supports these definitions. We recognize that, whenever possible, the ICS and IUGA use an evidence-based approach that incorporates a transdisciplinary perspective for developing terminology documents. When supported by evidence, organizations such as ICS and IUGA may wish tconsider adopting and/or adapting some of this proposed terminology in the future. Currently these are for research purposes only and PLUS hopes other researchers can benefit from this transdisciplinary team science work product and approach. We hope this work will spur global exploration of the promotion of bladder health and prevention of LUTS. We anticipate that the language of researchers will need further refinement, informed by use of the terminology and definitions and future research including community engagement. The ultimate goal is for the proposed research definitions tmeet the needs of the stakeholders: women and girls, clinicians, public health practitioners and policy makers.

While large investments have been made in the prevention of other prevalent conditions such as obesity and cardiovascular disease[8,28,29], investment in bladder health and the prevention of LUTS is comparatively small. One reason for this disparity may be that medical specialists in lower urinary tract dysfunction traditionally considered the absence of disease tbe synonymous with bladder health. We posit that clear definitions of both health and disease states are critical tconducting research that will aid in understanding and promoting bladder health. Bladder dysfunction is well represented in the research literature and clinical practice by the dissemination and use of LUTS definitions. In this manuscript, we offer research definitions that correspond twidely recognized bladder functions of storage and emptying; in addition, we propose definitions for more recently recognized aspects of bladder function, which we collectively refer tas the bioregulatory function. This bioregulatory definition is not intended trepresent an exhaustive or comprehensive list of all the biologic functions of the bladder, but rather thighlight the importance of bioregulatory function and acknowledge the role of the urothelium and microbiome in bladder health.[26]

With the introduction of new research terminology, feedback from users will be critical. Homma noted that as LUTS terminology was used, confusion developed among researchers and clinicians when the terms were used as both symptoms and cystometric terms.[30] Clearly, the transdisciplinary science of bladder health is in its nascent stages and the terminology presented in this paper should be viewed as a starting point tcreate a common language with the intent trevise it as knowledge advances. In addition, as others have found, lay persons use different terms and descriptions of function and symptoms than healthcare providers.[31] A balance may need tbe struck between pragmatism, terms people can readily identify with, and professional consensus on the usefulness of the terminology in conducting and interpreting research.[32] We recognize that validation of the language used in the subjective and objective experiences of women and girls by end-users (i.e. women and girls, researchers and clinicians) is critical.

The main strength of this bladder health research terminology framework is that a transdisciplinary group comprised of clinical, health behavior, and research methods experts, in an iterative process, created the proposed definitions. Bladder health research definitions correspond twidely recognized bladder functions of storage and emptying and LUTS symptoms; they additionally correspond tmore recently recognized aspects of bladder

function, which we collectively refer tas bioregulatory function. The literature was reviewed for existing LUTS and bladder health terminology, existing definitions were modified where deemed appropriate, and only in situations where nexisting terminology existed, new definitions were created. [1–7,17]

The limitations tthis approach include the fact that these definitions were developed by a single group from a single country using English Language, and these definitions may not be applicable tclinical or community practice. However, our method is consistent with those described by other organizations developing and standardizing terminology for LUTS. [1–7,20,33] In addition, our interpretation of some bladder function elements, such as “post void dribble,” differs from current description of the “two-phase” concept of bladder function.[24] Our transdisciplinary group struggled with whether this symptom represents a failure of the emptying or storage bladder function and decided tinclude a description under both, as women and girls may identify post void dribble with different functions. Further research in this area is needed tdetermine if our interpretation is supported. Also, some of the components of the definitions we have developed, such as the urinary microbiome or what defines a “short term” stressor, are not yet fully understood. We hope that this work may serve as a foundation upon which bladder health terminology can continue tevolve. Ongoing review, refinement, and definition development by our group and others is not only anticipated, but essential twidespread acceptance and use.

With research definitions of both bladder health and dysfunction, scientists of diverse disciplines will be positioned tconduct rigorous prevention science work. Etiologic studies are needed tidentify risk and protective factors for optimal bladder function across different levels of biology (e.g., cellular function, organ systems) and the social ecology that surrounds individuals (e.g., toileting environments and norms). With results from etiologic research, scientists will be positioned tdevelop and test prevention interventions aimed at modifying risk and protective factors, with the goals of promoting bladder health, preventing LUTS, and moderating major dysfunction due tLUTS.

Conclusions

The bladder health research terminology and definitions presented represent a transdisciplinary approach tstandardizing definitions for different elements of bladder function from a perspective of bladder health. The proposed PLUS bladder health and dysfunction terminology in this paper are for research purposes in the PLUS consortium’s work tbetter understand bladder health. This work provides a framework of bladder function and definitions of BH for research, which may in turn inform clinical practice, public health promotion and LUTS prevention. We dnot expect that these research definitions will be embraced by all members of the medical and scientific community; however, these are the definitions the PLUS Research Consortium is using tfurther our BH promotion and LUTS prevention research agenda. These definitions are currently being used tdevelop novel instruments tmeasure BH across a broad socio-demographic spectrum of women and girls.

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Table 1.

Detailed bladder dysfunction and health table addressing functions as well as symptoms and experiences of the bladder in health and disease.

		Bladder Dysfunction	**Bladder Health (BH)** ***(PLUS definitions)***
		The subjective indicator of a disease or change in condition as perceived by the patient, caregiver, or partner and may lead her tseek help from healthcare professionals. ***(PLUS modification†)***	A complete state of physical, mental and social well-being *related tbladder function*, and not merely the absence of LUTS. Healthy bladder function does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows pursuit of optimal well-being (e.g. travel, exercise, social, occupational or other activities)*.
Bladder Function	**Elements of Function**	**LUTS/Subjective Experience(s)**	**Subjective Experience(s)**
Storage	**Overall**	Bothersome LUTS that occur with filling of the bladder with urine. †	Ability thold urine for a reasonable duration of time and sense bladder fullness without fear of or concern about urgency, discomfort or leakage*
	Capacity/ Frequency – Day/ Waking	a. Voiding frequency during waking hours that occurs more frequently than desired and/or impacts daily activities on a routine basis. ***(PLUS definition)*** b. **Increased daytime urinary frequency:** Voiding occurs more frequently during waking hours than previously deemed normal. †	A frequency of voiding during waking hours that does not impact daily activities on a routine basis*.
	Capacity/ Frequency – Night/ Sleeping	a. Voiding frequency during sleeping hours that occurs more frequently than desired and impacts sleep quality and/or quantity. ***(PLUS definition)*** b. **Nocturia**: Interruption of sleep one or more times because of the need tvoid. Each void is preceded and followed by sleep. †	A frequency of voiding during sleeping hours, due turge tvoid, that allows for optimal sleep quality and is within physiologic age norms*
	Continence -Day/Waking	a. **Urinary incontinence**: Involuntary loss of urine. † b. **Types of UI**† : • Stress UI: urine loss with physical exertion, sneezing, or coughing • Urgency UI: urine loss associated with urgency • Postural UI: urine loss with change in body position • Mixed UI: urine loss with urgency and alswith physical exertion, sneezing, or coughing *OR* urgency and stress UI • Continuous UI: continuous urine loss • Insensible UI: urine loss without awareness • Coital UI: urine loss with coitus c. Post void dribble (post void leakage): Involuntary passage of urine following the completion of voiding. †	a. The ability thold urine during waking hours for a reasonable duration of time and throughout daily activities without any leakage of urine* b. At completion of voiding there is continence (i.e. nsubsequent leakage or dribbling of urine) *
	Continence -Night/Sleeping	a. **Nocturnal enuresis**: Involuntary loss of urine that occurs during sleep and is recognized upon awakening. † b. **Nocturnal urgency incontinence:** Leakage of urine on the way tthe toilet upon waking from sleep due turgency tvoid. ***(PLUS definition)*** c. **Nocturnal post void dribble** (post void leakage): Involuntary passage of urine following the completion of voiding during sleeping hours. †	a. The ability thold urine during sleeping hours, without leakage of urine* b. At completion of voiding during sleeping hours there is continence (i.e. nsubsequent leakage or dribbling of urine) *
	Sensation - Urge	a. **Urinary urgency:** The sudden, compelling desire tpass urine that is difficult tdefer. The urgency may be associated with fear of urine loss before making it tthe toilet. Despite absence of leakage, this may cause distress or bother, and/or impact daily activities. † b. **Absence of urge:** The lack of sensation at full capacity. ***(PLUS definition)***	The awareness and sensation of urge and bladder fullness that allows sufficient time tget tthe toilet facilities without fear of leakage*

		Bladder Dysfunction	Bladder Health (BH) *(PLUS definitions)*
	Sensation - Comfort	**Bladder pain**: Suprapubic or retropubic pain, pressure, or discomfort, related tthe bladder, and usually increasing with bladder filling. Sensation may persist or be relieved after voiding. †	The bladder fills and stores urine with increasing degree of sensation*
Bladder Function	**Elements of Function**	**LUTS Subjective Experience(s)**	**Subjective Experience(s)**
Emptying	**Overall**	a. **Voiding symptoms:** A departure from normal sensation or function, experienced by the woman during or following the act of voiding. † b. Bothersome LUTS that occur during or immediately following bladder emptying of urine. †	The ability tempty the bladder completely in a timely, efficient, effortless, comfortable manner*
	Voiding Initiation	**Hesitancy:** A delay in initiating voiding. †	Voiding proceeds when intended and without effort*
	Stream Flow - Speed	**Slow stream**: The urinary stream is perceived as slower compared tprevious performance or in comparison with others. †	Voiding occurs in an amount of time that does not impact daily activities*
	Stream Flow - Character	**Spraying (splitting) of urinary stream:** Urine is passed as a spray or split rather than a single discrete stream. †	Voiding occurs in a uniform stream without spraying or splitting*
	Stream Flow - Continuity	**Intermittency:** Urine flow that stops and starts on one or more occasions during voiding. †	Voiding occurs continuously without interruption*
	Efficacy	**Urinary retention:** The inability tvoid completely despite persistent effort in the presence of a full bladder. †	The bladder empties completely with minimal effort*
	Sensation – Urge relief	a. **Persistent urgency:** Sensation of urinary urge or urgency after voiding. ***(PLUS definition)*** b. **Need timmediately re-void**: Sensation that further voiding is necessary soon after passing urine. †	The bladder feels empty without urinary urge or urgency after voiding*
	Sensation - Completeness	**a. Feeling of incomplete (bladder) emptying**: Sensation that the bladder is not empty after voiding. † **b. Non-neurogenic chronic urinary retention**: An elevated post-void residual of greater than 300 mL that persists for at least 6 months and is documented on twor more separate occasions.[25] **c. Post void dribble** (post void leakage): Involuntary passage of urine following the completion of voiding. †	The bladder feels empty at the end of voiding*
	Sensation -Comfort	a. **Dysuria**: Urethral pain, burning, or other discomfort during voiding. †	The bladder empties with decreasing degree of sensation*
Biregulatory	**Elements of Function**	**LUTS Objective Experience(s)**	**Bladder Health Objective Experience(s)**
	Overall	A disruption in the protective barrier of the bladder resulting in LUTS. ***(PLUS definition)***	The bladder barrier protects the individual/host from pathogens, chemicals, and malignancy; is adaptable tshort term physical or environmental stressors and is able tcompletely recover from disruption of the barrier layer, without long term or persistent sequelae.
Barrier Function	**Biosis barrier**	**Dysbiosis and/or infection**: Disruption of the symbiotic relationship between host and healthy bladder microbiota. ***(PLUS definition)***	A healthy relationship (symbiosis) between host and bladder microbiota**
	Physical/ Chemical Barrier	A breakdown in the apical layer of urothelium (‘umbrella cells’) due tdisruption of tight-junction complexes and uroplakins (hexagonal plaques) and/or the sulfated polysaccharide glycosaminoglycan (GAG) layer allowing passage of toxic and	The intact urothelium that lines the bladder (basal/ intermediate/umbrella cells) provides a barrier between

		Bladder Dysfunction	Bladder Health (BH) *(PLUS definitions)*
		irritating urinary substances through the urothelium or release of neuroactive chemicals stimulating LUTS. ***(PLUS definition)***	irritating urinary substances and underlying neuromuscular tissue**
	Neoplastic barrier	Malignancy that forms in tissues of the bladder. Most bladder cancers are transitional cell carcinomas. Other types include squamous cell carcinoma and adenocarcinoma. ***(PLUS definition)***	The intact urothelium that lines the bladder (basal/ intermediate/umbrella cells) which sloughs and regenerates in a regulated manner**

Each BH element of function definition for Storage and Emptying is followed with an asterisk (*) that refers tthe qualifying statement: "…**and does not impact daily activities on a routine basis, is adaptable tshort term physical or environmental stressors, and allows a woman tpursue her optimal well-being (e.g. travel, exercise, social, occupational or other activities)**." For the Bioregulatory BH elements of function definitions, each is followed by double asterisks (**) that refers tthe qualifying statement: "…**and is adaptable tshort term physical or environmental stressors and is able tcompletely recover from disruption of the microbiome and barrier layer, without long term or persistent sequelae**." In accordance with the recommendations in the review of terminology by the ICS in 2004, "voiding" was used in place of micturition, passing urine or urination in both existing ICS LUTS terminology and newly proposed BH and LUTS definitions.[3] Definitions with this terminology change are included with other "PLUS modifications" marked with a (†) symbol.