

Terminology for Bladder Health Research – Proposed Definitions for Women and Girls



JL Lowder, MD, MSc; T Bavendam, MD; A Berry, MSN, CRNP, PhD; SS Brady, PhD; CM Fitzgerald, MD, MS; CS Fok, MD, MSPH; PS Goode, MSN, MD; CE Lewis, MD, MSPH; ER Mueller, MD, MSME; DK Newman, DNP, FAAN; MH Palmer, PhD; L Rickey, MPH, MD; A Stapleton, MD; ES Lukacz, MD; **For the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium**



Washington University in St Louis, MO; National Institutes of Health, Bethesda, MD; Children's Hospital of Philadelphia, PA; University of Minnesota, MN; Loyola University, IL; University of Alabama, AL; Birmingham/Atlanta Veterans Affairs Geriatrics Research Center, AL; University of Pennsylvania, PA; University of North Carolina-Chapel Hill, NC; Yale University, CT; University of Washington, WA; University of California San Diego, CA

Introduction

- Bladder function has been defined primarily through the presence or absence of lower urinary tract symptoms (LUTS) rather than corresponding indices of health
- Promotion of optimal bladder function and prevention of LUTS is particularly important for women and girls
 - Women are at higher risk than men are for specific LUTS such as urinary incontinence and urinary tract infections
- To date, neither bladder health nor normal bladder function(s) have been adequately defined in women or girls for research purposes
- 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
 - Expand research:
 - in the area of clinical practice
 - on policies that impact bladder health
 - beyond the detection and treatment of LUTS to the promotion and preservation of bladder health and prevention of LUTS in women and girls¹
- Consistent with the World Health Organization's definition of health, 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)"²
- "Normative data" have been published for certain bladder function measurements in women. However:
 - The study populations are typically described as "normal," "healthy" or "asymptomatic"
 - Descriptions of "health" are based on the absence of one or more LUTS symptoms
 - Absence of LUTS may not necessarily equate to healthy function
- The objective of this paper is to present PLUS Research Consortium research definitions for healthy bladder functions

Methods

- A subgroup of PLUS investigators that included research and clinical experts convened into a Terminology and Conceptual Framework & Models (TCFM) Intellectual Resource Group
 - The process by which the PLUS Research Consortium developed a research definition of BH has been reported²
 - After development of the BH definition, TCFM members continued to develop and refine specific terminology and definitions for elements of healthy bladder function related to storage, emptying, and bioregulatory
- 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 International Continence Society (ICS) defined LUTS^{3,4}
- A broad search and review of the literature was conducted for current bioregulatory, LUTS, and bladder health terminology or definitions
 - The search included the active/current ICS Standardization and Terminology Reports and Documents^{3,4}
 - The search confirmed an absence of published research definitions of bladder health or healthy bladder functions
- Terms and definitions were developed based on the recognized "two-phase" concept of bladder function (Storage and Emptying) described by Wein et al.⁵
- Published LUTS definitions provided definable starting points for developing bladder health function definitions
- Novel concept of bioregulatory function was acknowledged
- Definitions were revised in an iterative process over a 14-month period

Results

- The PLUS research definitions for Bladder Health (BH) in women and girls, across the elements of bladder function are presented
- These definitions include:
 - "overall" definitions of storage, emptying, and bioregulatory functions
 - 7 elements of storage-related definitions
 - 7 elements of emptying-related definitions
 - 3 elements of bioregulatory-related definitions

		Bladder Health (BH) (PLUS definitions)
		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)*.
Bladder Function	Elements of Function	Subjective Experience(s)
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*
	Capacity/ Frequency – Day/Waking	A frequency of voiding during waking hours that does not impact daily activities on a routine basis*.
	Capacity/ Frequency – Night/Sleeping	A frequency of voiding during sleeping hours, due to urge to void, that allows for optimal sleep quality and is within physiologic age norms*
	Continence - Day/Waking	a. The ability to hold 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. no subsequent leakage or dribbling of urine)*
	Continence - Night/Sleeping	a. The ability to hold urine during sleeping hours, without leakage of urine* b. At completion of voiding during sleeping hours there is continence (i.e. no subsequent leakage or dribbling of urine)*
	Sensation - Urge	The awareness and sensation of urge and bladder fullness that allows sufficient time to get to the toilet facilities without fear of leakage*
	Sensation - Comfort	The bladder fills and stores urine with increasing degree of sensation*
Bladder Function	Elements of Function	Subjective Experience(s)
Emptying	Overall	The ability to empty the bladder completely in a timely, efficient, effortless, comfortable manner*
	Voiding Initiation	Voiding proceeds when intended and without effort*
	Stream Flow - Speed	Voiding occurs in an amount of time that does not impact daily activities*
	Stream Flow - Character	Voiding occurs in a uniform stream without spraying or splitting*
	Stream Flow - Continuity	Voiding occurs continuously without interruption*
	Efficacy	The bladder empties completely with minimal effort*
	Sensation – Urge relief	The bladder feels empty without urinary urge or urgency after voiding*
	Sensation - Completeness	The bladder feels empty at the end of voiding*
	Sensation - Comfort	The bladder empties with decreasing degree of sensation*
Bio regulatory	Elements of Function	Bladder Health Objective Experience(s)
	Overall	The bladder barrier protects the individual/host 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.
Barrier Function	Biosis barrier	A healthy relationship (symbiosis) between host and bladder microbiota**
	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**
	Neoplastic barrier	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 to the qualifying statement: "... and does not impact daily activities on a routine basis, is adaptable to short term physical or environmental stressors, and allows a woman to pursue 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 to the qualifying statement: "...and is adaptable to short term physical or environmental stressors and is able to completely 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.

Conclusions

- Proposed bladder health research terminology and definitions:
 - Represent a transdisciplinary approach to standardizing definitions for the elements of bladder function from a perspective of bladder health rather than dysfunction
 - Provide a framework of bladder function and definitions of BH for research to study clinical practice, public health promotion and LUTS prevention
- These definitions are currently being used to develop novel instruments to measure BH across a broad socio-demographic spectrum of women and girls

This study is supported by the National Institutes of Health (NIH) through cooperative agreements (grants U01DK106786, U01DK106853, U01DK106858, U01DK106898, U01DK106893, U01DK106827, U01DK106908, U01DK106892).

References

- Harlow BL, Bavendam TG, Palmer MH, Brubakder L, Burgio KL, Lukacz ES, Miller JM, Mueller ER, Newman DK, Rickey LM, Sutcliffe S, Simons-Morton D. The Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium: A Transdisciplinary Approach Toward Promoting Bladder Health and Preventing Lower Urinary Tract Symptoms in Women Across the Life Course. *J Women's Health* (2017) DOI: 10.1089
- Lukacz ES, Bavendam TG, Berry A, et al. Defining Bladder Health in Women and Girls: Implications for Research, Clinical Practice, and Public Health Promotion. *J Womens Health (Larchmt)*. 2018;27(8). doi:10.1089/jwh.2017.6786
- Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Uilmsten U, van Kerrebroeck P, Victor A, Wein A. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. *Am J Obstet Gynecol*. 2002 Jul;187(1):116-26
- Haylen et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Report on the Terminology for Female Pelvic Floor Dysfunction. (2010) *Neurology and Urology Dynamics* 29:4–20.
- Wein AJ & Barrett DM. Voiding Function and Dysfunction a logical and practical approach. Chicago IL; Year Book Medical, 1988, pp. 114-136.