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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

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Abstract

Lower urinary tract symptoms (LUTS) are highly prevalent in women, and are expected to impose a growing burden to individuals and society as the population ages. The predominance of research related to LUTS has focused on underlying pathology, disease mechanisms, or the efficacy of treatments for women with LUTS. Although this research has been vital for helping to reduce or ameliorate LUTS conditions, it has done little to prevent the onset of LUTS. Health promotion and prevention require an expansion of scientific inquiry beyond the traditional paradigm of studying disease mechanisms and treatment to the creation of an evidence base to support recommendations for bladder health promotion and, in turn, prevention of LUTS. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) introduced the concept of prevention as an important priority for women's urologic research as a prelude to supporting the formation of the Prevention of Lower Urinary Tract Symptoms (PLUS) research consortium. In this article, we introduce the PLUS research consortium to the scientific community; share the innovative paradigms by which the consortium operates; and describe its unique research mission: to identify factors that promote bladder health across the life course and prevent the onset of LUTS in girls and women.

Keywords: lower urinary tract symptoms, urination, bladder, incontinence, urinary tract infection, women's health, social ecology, transdisciplinary, prevention, health promotion

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Introduction

MUCH OF THE RESEARCH related to lower urinary tract symptoms (LUTS) conducted by independent investigators and NIH-funded cooperative research groups have focused on underlying pathology, disease mechanisms, and treatment efficacy in women with LUTS. Although this research is important in helping to reduce or eliminate LUTS conditions, it has done little to prevent the onset of LUTS. With the aging of the population and rising costs of health-care, focusing on treatment, as opposed to prevention, may be unsustainable. The Prevention of Lower Urinary Tract Symptoms (PLUS) research consortium was developed with a novel goal to develop a prevention research agenda through a transdisciplinary scientific initiative.

The consortium recognized that bladder health is a construct—an attribute that can be defined and measured in terms of separate, but related subcomponents.¹ This approach can be divided into three considerations. First, the construct of bladder health is composed of multiple health promoting functions that reflect more than the absence of LUTS. Second, bladder health is influenced by risk and protective factors across different levels of biology, psychology, and social ecology (interpersonal, institutional, community, and societal).² Third, bladder health can only be understood and promoted through the study of diverse populations of girls and women across all stages of life.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) introduced the concept of prevention as an important priority for women's urologic research as a prelude to supporting the formation of a prevention-oriented research consortium to complement the ongoing efforts within the NIDDK aimed at improving the understanding of patients with LUTS through deep phenotyping: the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) and the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP). A request for applications was published in August 2014, and PLUS was funded and initiated in 2015. This research group is composed of seven research centers and one Scientific and Data Coordinating Center (SDCC) to advance the consortium's work (Fig. 1). The Research Centers were selected based on their potential to change current paradigms that hinder development of bladder health promotion efforts with potential for implementation at the population level. The SDCC was selected based on its capacity to support biopsychosocial and social ecological approaches toward bladder health and urinary symptom prevention research.

The purpose of this article is to introduce PLUS to the scientific community, describe its unique research mission to identify factors that promote female bladder health across the life course and prevent the onset of LUTS, and to share the innovative paradigms by which the consortium operates.

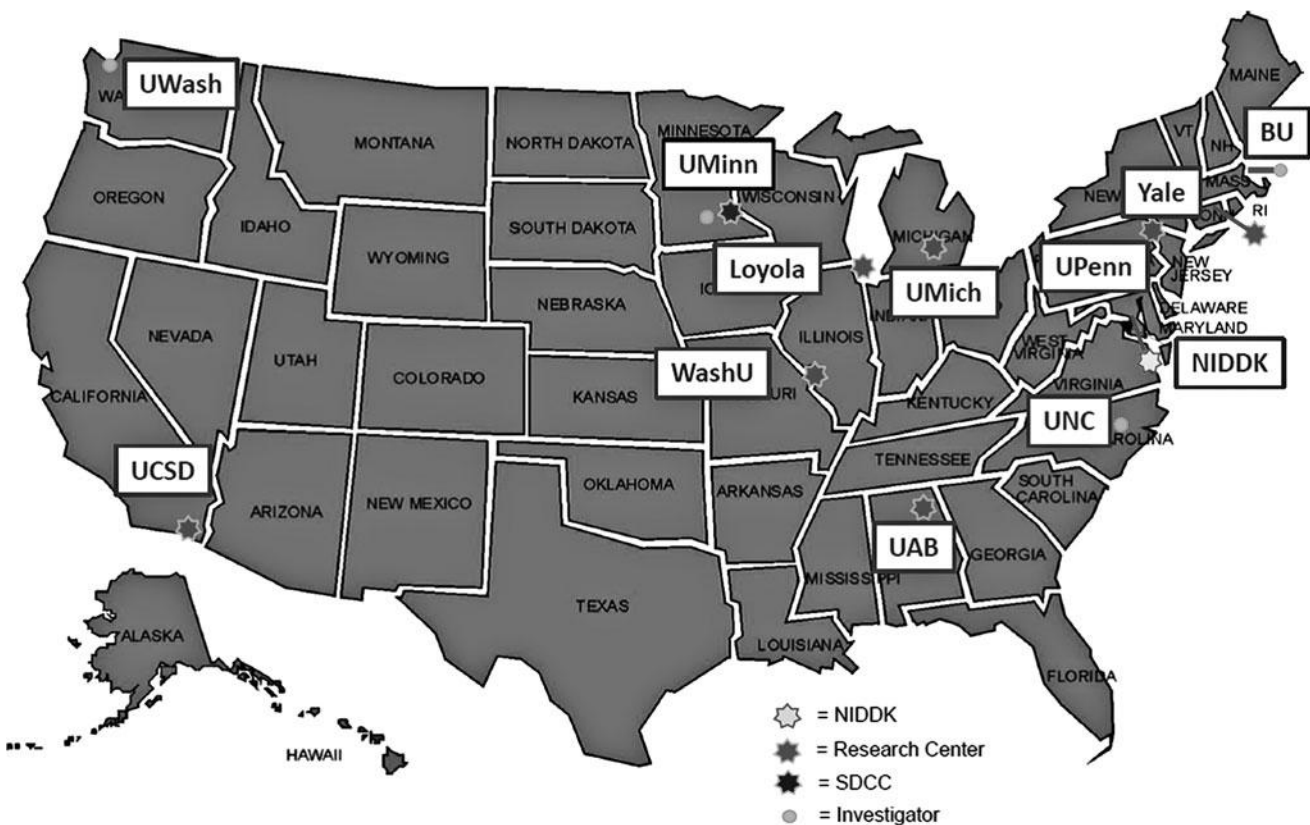


FIG. 1. PLUS research centers, Scientific and Data Coordinating Center, and investigator locations. BU, Boston University; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; PLUS, Prevention of Lower Urinary Tract Symptoms; SDCC, Scientific and Data Coordinating Center; UAB, University of Alabama Birmingham; UCSD, University of California San Diego; UNC, University of North Carolina.

Description and Magnitude of LUTS in Women

The lower urinary tract functions to store urine produced by the kidneys and empty the accumulated urine when appropriate. LUTS include various dysfunctions of the bladder, pelvic floor, and/or specific pathology (*i.e.*, bladder infections).^{3,4} The International Continence Society (ICS) standardized nomenclature divides LUTS into three groups: storage, voiding, and postmicturition symptoms.³ Storage symptoms are experienced as urine accumulates in the bladder and include symptoms such as urinary frequency, urgency, nocturia, and incontinence. Voiding symptoms are experienced during the emptying phase and include symptoms such as abnormalities in voided stream (*e.g.*, hesitancy) and postmicturition symptoms such as postvoid dribbling and the feeling of incomplete emptying.^{3,4} PLUS uses the ICS definitions of LUTS to be inclusive of all symptoms, including pain, associated with lower urinary tract conditions in women.⁴

LUTS are highly prevalent in women. The individual and societal burden from LUTS is expected to increase as the female population ages.^{5,6} Based on population growth and estimated prevalence, LUTS may affect more than 43 million women in the United States over the next 30 years.⁷ In community samples, 73% of women reported at least one storage or voiding symptom, while moderate–severe LUTS were reported by 18% of women 30 years of age and older.⁸ A recent cross-sectional Norwegian study of urinary incontinence (UI) showed that 11.3% of women in their 20's experienced LUTS and these symptoms increased with each decade, with ~30% of women in their 50's and 40% of women in their 80's experiencing LUTS.⁹ The National Health and Nutritional Examination Survey (NHANES) data from 2005 to 2010 showed that 17% of women ≥20 years had experienced UI,¹⁰ with symptoms worsening with age to the extent that nearly 20% of women over 50 years of age reported moderate-to-severe UI.¹¹ Other LUTS evident in women include those associated with interstitial cystitis/bladder pain syndrome reported in 3% and bladder infections, which affect women across the life course, but particularly women over 45 years of age.^{12,13}

The economic impact of LUTS in women and girls is profound. While the overall costs to society has not been determined, the financial cost in the United States of overactive bladder (*i.e.*, urgency, with or without urinary frequency, nocturia, or urgency UI) alone in 2007 in both sexes was determined to be \$65.9 billion per year and projected to be \$82.6 billion per year in 2020.¹⁴ Recurrent bladder infections generate approximately \$2 billion annually in U.S. healthcare costs as a result of outpatient visits, diagnostic tests, and prescriptions.^{15,16} Clearly, LUTS result in considerable individual and societal costs that will increase significantly as the population ages. Indeed, many women, even severely symptomatic women, often delay or do not seek treatment, which could result in loss of productivity and added costs to treatment should symptoms progress. Reasons to delay or not seek care include lack of knowledge about the risks for LUTS, misconceptions about normal aging, and misperceptions about treatment availability and efficacy.¹⁷

It has long been recognized that LUTS can have serious negative impacts on quality of life. Furthermore, LUTS significantly contribute to overall morbidity and are strongly

associated with many chronic medical conditions. Depression, decreased physical activity, obesity, weight gain, and diabetes have all been linked to LUTS and many are likely bidirectional associations.^{18,19} In one study, when women were matched for age, race, and comorbidity index, the presence of LUTS independently predicted increased emergency department visits, hospitalizations, and medical provider visits, as well as decreased work productivity and increased activity impairment.²⁰ These compelling associations highlight the urgent need to develop evidence-based prevention strategies for LUTS and their downstream consequences. By reducing rates of LUTS onset in girls and women, the burden in terms of healthcare costs and decreased quality of life may also be reduced.

The PLUS Research Paradigm

Bladder health promotion and LUTS prevention require an expansion beyond the traditional research paradigm of focusing on disease treatment to developing the evidence base that will lead to recommendations that promote bladder health and inform prevention of LUTS in girls and women. PLUS adopted several processes and approaches to accomplish such a paradigm shift.

A shift from multidisciplinary to transdisciplinary teams

A key component of PLUS is an intentional effort to breakdown traditional scientific silos and work across different disciplines. While *multidisciplinary* approaches utilize experts from different disciplines, the contributions from these experts are used without integration. *Interdisciplinary* research on the other hand integrates experts across different disciplines and conducts its work jointly. *Transdisciplinary* research integrates discipline-specific approaches and extends to generate a fundamentally new aspect to scientific inquiry.²¹

Members of the consortium were selected intentionally to bring expertise in preventive medicine, primary care, nursing, medical sociology, behavioral sciences, epidemiology, and biostatistics, along with adolescent medicine, pediatrics, geriatrics, and female pelvic medicine and reconstructive surgery (urology and urogynecology). To achieve the consortium goals, it was necessary to adopt a transdisciplinary approach that would take full advantage of this breadth of expertise among consortium investigators. Early rapid consensus affirmed our intention to avoid traditional hierarchies; instead the consortium investigators embraced, harnessed, and stimulated the transdisciplinary approach among themselves. During the formative phase of PLUS, senior leadership provided intentional efforts for investigators to learn about each other to learn from each other during subsequent PLUS activities. To facilitate this process, we established a series of web-based educational seminars for all PLUS investigators to promote transdisciplinary thinking, particularly as it relates to our goals of defining bladder health and its potential risk and protective factors.

Filling the gaps in knowledge of risk and protective factors

The historical focus of LUTS research on disease and its treatment has contributed to an inadequate understanding of

several factors that potentially affect LUTS development and progression; and these gaps may have hindered the development of an effective LUTS prevention strategy. For example, there is little evidence about individual behaviors or habits that contribute to LUTS or that promote healthy bladder function, and there are large gaps in our understanding of risk and protective factors for symptom progression. Moreover, most established risk factors have only been studied at the level of the individual (e.g., individual conditions such as obesity, behaviors such as caffeine consumption, characteristics such as age), whereas very little is understood regarding the myriad of risk and protective factors operating at other levels of social ecology (e.g., social and environmental factors).^{2,22} PLUS is committed to developing and broadening this evidence base and encouraging the LUTS research community to look beyond a disease-focused perspective to be inclusive of health promotion and prevention that will ultimately lead to a reduction in incidence and prevalence.

Developing a definition of bladder health

PLUS identified an urgent need at the outset to define the construct of “bladder health” and develop measures to assess bladder health and various degrees of LUTS across the entire life course. As bladder health has never been rigorously defined nor systematically studied, several of the consortium’s preliminary studies will focus on understanding and defining bladder health with the goal of developing tools to measure the bladder health construct. To this end, the consortium worked to develop a preliminary framework for conceptualizing bladder health at different life stages. Three broad aspects of bladder function were adopted as follows: storage, emptying, and bioregulatory. The novel bioregulatory function component encompasses the role of the bladder in preventing systemic disease (e.g., infection and malignancy). The consortium identified knowledge gaps related to “normal” or healthy states after proposing both subjective and objective measures for each of the bladder functions. The details of this process will be forthcoming. In addition to defining bladder health, a fundamental aspect of promoting LUTS prevention is to understand how women view their own bladder and pelvic floor function. PLUS is developing qualitative research protocols to examine girl’s and women’s knowledge, behaviors, and perceptions related to bladder health and LUTS.

Broadening the view: a shift from individual-based biological focus to broader social ecology

Currently, the majority of female LUTS-related research has centered on biological risk factors and medical interventions and has largely focused on the segment of the population with current symptoms of LUTS or the so-called “tip of the iceberg.” These efforts are likely influenced by the ease in defining and describing the array of bladder disorders while the bladder is in a state of illness and the difficulty in defining bladder health and best practices for bladder health. The current scientific evidence about bladder health is largely confined to the bladder’s ability to store and empty urine observed in a clinical setting. Unfortunately, the current literature assumes that the absence of symptoms in a particular area of bladder function (e.g., incontinence) equates to

bladder health. This assumption is problematic when attempting to assess bladder health or LUTS risk factors, because a “no” response to a query about the presence of UI does not infer the absence of other LUTS (e.g., dysuria, difficulty voiding, and so on) nor does it necessarily indicate a state of bladder health.

Understanding bladder health will involve investigating the childhood history and behaviors of girls and women who do and do not have LUTS, including toilet training, daily habits such as voiding behaviors, intake of fluid types and amounts, and lifestyle choices (e.g., smoking, exercise, and so on). Girls and women’s attitudes and beliefs about what practices will promote bladder health are likely influenced by all levels of social ecology.²³ Cultural differences in attitudes and behaviors are also important to explore, as differences among ethnic and racial populations have been documented. For example, in certain cultures, women fear being stigmatized based on having an unclean body and a compromised social identity.²⁴

It has long been recognized in public health that an individual’s health and health behaviors are affected by a variety of contextual settings. These contexts include interpersonal relationships, institutional environments, such as schools and workplaces, community-level factors, such as the built environment and cultural norms, and societal levels factors, including industry influences and health policy. As we broaden our research scope beyond individual biology and behavior, we will improve our ability to understand the mechanisms necessary to maintain bladder health within widely varying contextual settings of social ecology.

This broadened approach allows us to explore environmental factors that may create a significant burden for girls and women to maintain bladder health. Creating foundational knowledge about the role of environmental factors, particularly those involving toilet access, cleanliness and safety, and personal, social, school and occupational barriers, as well as public policy, are important research goals within PLUS.

These environmental based knowledge gaps have been incorporated into the consortium’s conceptual framework, which is being used to identify protective and risk factors for bladder health and LUTS across the life course. PLUS adapted a framework based on that of Glass and McAtee,² to include social ecological, as well as biological factors, which may influence bladder health across the life course. PLUS investigators are identifying factors for further investigation at each level of our conceptual framework, from societal to the individual. Details will be forthcoming in future publications.

Broadening the view: life course perspective

PLUS is committed to studying ways to prevent LUTS across all life stages. This approach assumes that bladder health can be compromised at any stage in the life course, and bladder pathology manifesting in adulthood may begin early in life. Therefore, the importance of identifying protective and risk factors during the early stages of life is evident. This approach is also consistent with health promotion and prevention for other chronic conditions, such as cardiovascular disease and cancer. PLUS’s initial efforts will focus on identifying factors in individuals that can report information for themselves (adolescents through community-dwelling older women), recognizing that factors amenable to intervention in childhood may emerge.

As women develop normally, common day-to-day activities, as well as biological changes, can influence LUTS onset and progression. For example, high impact sports, vigorous activities, and pregnancy are associated with stress incontinence in girls and women during their reproductive years, and the menopausal transition is associated with overactive bladder, urinary tract infections, and UI.¹³ Recent research has shown that older women prone to falls and fractures were also more likely to experience urgency UI,¹³ and a history of involvement in professional sports had a negative impact on current pelvic floor health.²⁵ It is important that all research conducted to explore these risk factors, as well as protective factors, assess temporality and bidirectionality of these associations.

A commitment to involving community stakeholders in prioritizing and building the research initiatives

From the inception of the consortium, PLUS investigators prioritized a strong focus on engaging community stakeholders. The consortium embraces best community engagement practices, which include recommending and overseeing mechanisms for reciprocal communication with a variety of community-based individuals located within our priority ecological settings. A standing committee was formed to promote and oversee the community engagement activities associated with the PLUS research initiatives. Furthermore, PLUS investigators intend to disseminate results of our community engagement methods and progress to the scientific community, so that other consortia may utilize best practices and learn from this novel approach to studying health and promoting disease prevention.

Challenges for the Consortium

The PLUS structure and governance are predicated on flexibility and fluidity, especially as its work evolves. Infrastructure committees were created to address policy and dissemination issues, provide educational forums, and create a conceptual framework and definitions for our work (Fig. 2). In addition, the consortium formed multiple transdisciplinary intellectual resource groups, with members from each research center and the SDCC, with interest and expertise in key topical areas, including prevention science, measurement, study design and analytical methods, database resources, literature assessment, and community engagement. The PLUS Steering Committee (SC), formed by the Principal Investigators (PIs), NIDDK program scientist, and contracted SC Chair, is the decision-making body of the Consortium. A small Executive Committee is composed of two rotating research center PIs, SDCC PIs, SC Chair, and the NIDDK Scientific Officer. This committee facilitates SC work by preparing agendas, promoting ongoing awareness of PLUS concerns (including participation and equity), and interfacing with external entities such as outside investigators and other Consortia. An External Experts Panel appointed by the NIDDK oversees the progress and direction of the consortium.

The adoption of a transdisciplinary approach brought unique opportunities and challenges. PLUS leadership has taken great care to recognize the known complexities of transdisciplinary team building. This process is labor intensive, prone to conflict and miscommunication, and requires preparation, practice, trust, and extensive coordination among coinvestigators working at geographically dispersed sites.^{26,27} We recognized the importance of first determining

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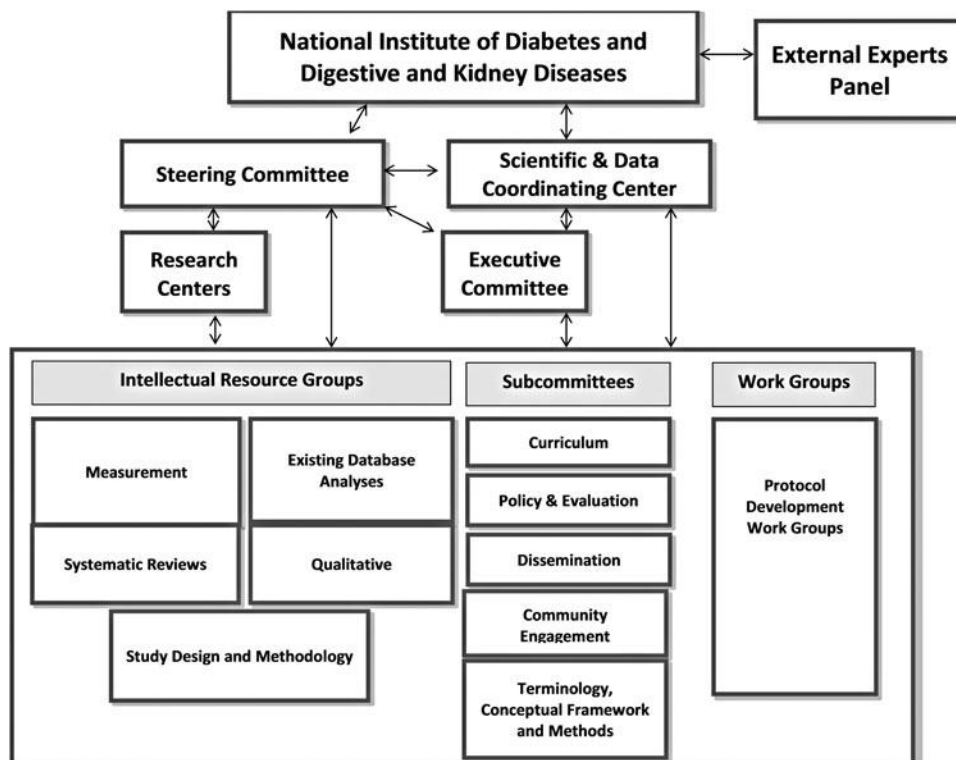


FIG. 2. PLUS organizational structure.

foundational research needs and then using the most appropriate research methodology, while building and maintaining trust and a sense of community within the consortium. The initial work within PLUS differed from a traditional, task-oriented clinical trials network, requiring adjustments for many “task-oriented” researchers.

PLUS investigators rely on core principles that include equity, fairness, and respect to guide structure and governance decisions. The consortium’s investigators uphold the goal of continual assessment of our efforts to include and value the perspectives of all investigators and the expression of all voices. The pragmatic consequences of structure and governance reflect these principles and values that affirm equal opportunity for participation and representation. Being broadly inclusive of all perspectives and making decisions in a timely manner will remain a work in progress.

Our structures and processes will continue to evolve as we balance this inherent tension. We work to identify disconnects in our communications as quickly as possible and often find that there is not as much disagreement as there is terminology confusion arising from how different disciplines use the same terms to mean different things. A professional moderator for periodic in-person meetings assists the consortium members to create transparency, build consensus, and ensure clarity of language and shared decision making. The use of online web-based weekly meetings, task management programs, and integrated website technology to maintain up-to-date and open communication are other keys to our success. In addition, the ability to adapt and remodel into different work groups has facilitated the progress of the consortium. Our choice to adopt a transdisciplinary perspective fosters this collaboration and provides the unique opportunity to address LUTS using a paradigm that integrates biology, psychology, and social ecology. Thus, individual- and associated environmental-level factors can be concurrently evaluated.

Ultimately, achieving this end requires taking advantage of the full depth and breadth of experts’ knowledge from the broad range of disciplines represented. We anticipate over time that PLUS outcomes will include new language, methods, and foundational science that will advance our understanding of bladder health and LUTS prevention.

Concluding Thoughts

Through its transdisciplinary approach, PLUS is creating new conceptual models and paradigms, developing innovative measures, and establishing foundational knowledge for future interventional research on bladder health and LUTS prevention. Together, these efforts will pave the way to improve the quality of life of girls and women across the life course.

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Author Disclosure Statement

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