National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health

Uncovering the Hidden Burden of Benign Genitourinary Conditions

Natcher Conference Center, Building 45
Bethesda, MD
October 7–8, 2019

FINAL MEETING SUMMARY

MONDAY, October 7, 2019

Welcome Remarks

Griffin P. Rodgers, M.D., MACP, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)

Dr. Griffin P. Rodgers welcomed participants to the conference and expressed appreciation to the planning committee for convening this meeting. He explained that the iceberg metaphor—wherein much of the disease burden is subclinical, unreported, or otherwise hidden from view, and only the "tip of the iceberg" is apparent—very much applies to benign genitourinary conditions (BUC), including urinary tract infections (UTIs), urologic chronic pelvic pain syndrome, erectile dysfunction (ED), urinary stone disease, and conditions associated with lower urinary tract symptoms (LUTS).

The NIDDK-sponsored Boston Area Community Health (BACH) Survey, which collected data on urologic symptoms and their effects on daily life in four diverse Boston-area neighborhoods, revealed that many people do not seek care for urologic conditions, thus individuals who present for clinical care represent only the tip of the iceberg. Below the surface, the burden of BUCs extends to include unreported symptoms that are not adequately captured in research or care. The burden of BUCs is not limited to prevalence alone. In fact, BUCs negatively affect quality of life (QOL), including social life and dignity. Yet, for many who seek care from primary care clinicians, a perceived lack of effective and tolerated treatment options and competing clinical priorities often result in these conditions' remaining undocumented and untreated.

Existing epidemiological data suggest that BUCs may play a role in the development of such diseases as obesity, diabetes, depression, and hypertension and may be early manifestations of systemic conditions (for example, ED and cardiovascular disease or nocturia and chronic kidney disease). Yet BUCs are rarely considered in the context of overall health or recognized as potential factors on the causal pathway of research on these conditions. The economic effects of BUCs—which span individual, medical, and societal costs ranging from lost work productivity and absenteeism to purchase of absorbent products—still are not fully quantified. Finally, environmental consequences may include increased incontinence product waste (e.g., diapers) and increased use of antibiotics.

Dr. Rodgers stated the meeting objectives: (1) Determine what data are needed to understand the hidden burden of BUCs. (2) Identify strategies to capture these data in a feasible manner in both clinical and research settings. (3) Identify novel and existing tools to capture the necessary data. Dr. Rodgers again

thanked the meeting planning committee, as well as all the participants who took time from busy schedules to attend the workshop.

Setting the Stage: Meeting Overview and Objectives
Tamara Bavendam, M.D., M.S., NIDDK

Dr. Tamara Bavendam elaborated on the "not-so-hidden" burden of genitourinary (GU) conditions and began by describing her experience focusing on women's urinary conditions, which are underemphasized in the training of urologists. Dr. Bavendam expressed that academic urology departments and federal research programs usually focus on cancer and underprioritize BUCs. She pointed out that vaginal childbirth often has long-term consequences regarding GU conditions and emphasized the importance of holistic care and that a prevention focus is needed to address BUCs.

Dr. Bavendam discussed the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium, established by the NIDDK in 2015, to build a scientific foundation for evidence-based studies to prevent lower urinary tract symptoms (LUTS) and bladder conditions in adolescent and adult women. Conditions associated with LUTS include urinary incontinence, frequent or urgent urination, trouble urinating or urinary retention, and pain associated with lower urinary tract function. Urinary incontinence (UI) and overactive bladder are underemphasized but are correlated with a wide range of related conditions. Depression—which can result from LUTS—contributes to diabetes, obesity, CVD, and decreased mobility. To make progress in this field, researchers need the right kind of data. Patients are not routinely screened for BUCs, which often rely on self-report measures for diagnosis. Current symptom questionnaires are very condition-specific. Stigma limits self-reporting and advocacy. BUCs are often perceived as "normal" QOL conditions and resultingly are assigned lower priority by individuals with BUCs, clinicians, and payers.

Dr. Bavendam noted that the same symptoms can result from different conditions, many of which lack objective measures of diagnosis. Symptoms perceived as QOL conditions include UI, overactive or underactive bladder, prostate inflammation, ED, and nocturia. Bladder infection, interstitial cystitis, and urinary stone disease symptoms are reported first because of the associated pain. Nephrology, urology, and gynecology all need to be combined to properly deconstruct BUCs.

Stigma and lack of screening decrease the recognition of the burden of these conditions. Financial barriers and lack of treatment options also can prevent patients from receiving quality care. Unlike other BUCs, urinary stone disease is viewed seriously by clinicians because it presents with pain and can lead to renal failure. Dr. Bavendam hypothesized that presenting data on the downstream effects of GU conditions can help BUCs be considered serious medical conditions instead of as affecting only QOL. Researchers now need to prioritize the necessary data to support an understanding of the resulting effects of BUCs, ensuring the correct measures of data collection. More research questions need to be asked than in previous studies, which have primarily incorporated questions on UI. Dr. Bavendam concluded that a cadre of committed and persistent federal, professional, and citizen scientists are needed to raise the profile of BUCs.

Raising the Profile of Genitourinary (GU) Conditions
Wanda Jones, Dr.P.H., Office of Research Integrity, U.S. Department of Health and Human Services (HHS)

Dr. Wanda Jones expressed appreciation to Dr. Rodgers for his leadership and support of research that drives needed progress. In 1996, the Agency for Health Care Policy and Research, now the HHS Agency

for Healthcare Research and Quality (AHRQ), released clinical and consumer guidelines on UI. That report estimated that UI affects 10–35 percent of adults, women much more than men, and conveyed that incontinence-related care carries significant cost. Although the 1996 report identified the effects of UI on society, researchers were not receptive to the findings; meanwhile, associated conditions such as diabetes and obesity have only increased. Dr. Jones emphasized that the social isolation effects of incontinence weigh on patient dignity more so than the stigma. Treating UI with a prescription alone simply adds to the polypharmacy of aging. Dr. Jones expressed optimism that moving forward, needed research will ensue in this field. Addressing UI will require multidisciplinary networks and coordinated outreach.

Background in Physiology of Conditions
Richard Lee, M.D., M.B.A., Weill Cornell College of Medicine

Dr. Richard Lee provided an overview of the urinary system in males and females. Dr. Lee emphasized that differences between the male and female anatomy lead to differing problems and outcomes related to BUCs. He indicated that bladder stones usually result from a partial blockage in the lower urinary tract and occur more often in men. Incontinence is common in both sexes, but stress incontinence occurs much more frequently in women because it tends to be a byproduct of childbirth. Dr. Lee noted that a multibillion-dollar industry has developed to treat overactive bladder with medications and devices. In males, prostate problems include enlargement, infection, and inflammation. Male urethral stricture disease is likely underreported; this is relevant to gender reassignment surgery. Dr. Lee explained that innervation to the bladder and bowels is very complex and related across genital, urologic, and intestinal systems. The urinary, bowel, and genital systems should be considered together when addressing innervation problems.

Regarding the pros and cons of specialization in medicine, historically, specialization has served as the foundation for expertise. Increased specialization leads to economies of speed and scale and produces research that is more specific. However, specialization also can lead to the siloing of knowledge and expertise. Silos of knowledge can be broken by establishing cross-functional roles with a high level of collaboration among researchers in a results-oriented environment. Dr. Lee emphasized that meetings like this one are important steps in increasing communication among researchers.

Dr. Lee discussed how several diseases affect the urinary tract. Obesity leads to various urologic problems and complicates surgeries, whereas reducing weight reduces incontinence symptoms. Obesity is a component of a metabolic syndrome that affects multiple systems and exacerbates LUTS. It also might affect carcinogenesis through inflammation. Diabetes impairs wound healing and increases infections. Diabetes also promotes polyuria, ED, renal damage, and bladder dysfunction. Urology affects cognitive impairment because it can lead to social isolation. Additionally, early research indicates that the use of anticholinergics and androgen ablation may lead to dementia. Environmental effects include endocrine disruptors and carcinogenesis of the prostate or the urothelial tract; stone formation is linked to warmer environments. The long-term effects of pregnancy and vaginal delivery in urology are not well understood. Pregnancy increases risk of stress incontinence, pelvic organ prolapse, and potential for kidney stone formation. Because of these reasons, pregnancy can lead to social isolation and has unknown effects on downstream bladder function.

Patient and Caregiver Perspectives
Moderator: Tamara Bavendam, M.D., M.S., NIDDK
Speakers: Christine Loizou, Patient; Mary Worstell, Patient and Caregiver

Dr. Bavendam invited the speakers to share the stories of their personal GU experiences.

Ms. Christine Loizou shared her experience with UI after delivery of her first child and noted that her labor was longer than average. Ms. Loizou recounted her most frightening post-childbirth moments, not realizing that she had a problem; as far as she knew, her experiences could have been normal. She was alarmed by the persistence of the fluids being released from her body, which resulted in substantial use of incontinence products (e.g., adult diapers and pads), but Ms. Loizou felt that the solution was to increase her supply of products at home. Her QOL changed, and even a short walk in her neighborhood became challenging. She emphasized that UI, which was discussed neither before nor after delivery, should be included in conversations about pre- and postpartum health care. Ms. Loizou conducted research on her own about what she was experiencing, without knowing what to investigate, even with access to an obstetrician-gynecologist (OB/GYN) consultation. Her research resulted in an initial appointment with a urologist, after which she saw improvement; however, symptoms remain (e.g., stress UI). Ms. Loizou thanked the meeting organizers and researchers for their efforts.

Discussion

- When asked how long she had been experiencing UI, Ms. Loizou replied that her son is now 19 months old and that her condition has improved over time. Increased emphasis has been placed on such techniques as pelvic floor muscle exercises (e.g., Kegel exercises) prior to and during a second pregnancy.

- Dr. Sonya Brady (University of Minnesota School of Public Health) asked Ms. Loizou what she recommends scientists investigate. Ms. Loizou emphasized the importance of OB/GYNs discussing UI and the potential risks prior to childbirth and what to do if UI occurs. She noted that followup care, teaching physicians to take UI seriously, and communication research are places to start.

- In response to a question on discussions with a urologist about physical therapy, Ms. Loizou explained that her urologist referred her to a physical therapist, who helped her with pelvic floor muscle therapies. She noted that physical therapists who specialize in BUCs are limited.

- Dr. Bernard Harlow (Boston University School of Public Health) asked what could have been done to possibly prevent the childbirth-related UI. Ms. Loizou replied that starting Kegel exercises early may have been helpful and pointed out that being induced into labor might have had an effect. Regarding changes on the health care system level, Ms. Loizou indicated that all the possible outcomes of delivery, including pelvic floor prolapse and UI, should be discussed. The attention to postpartum care is insufficient; the baby's health and the mother's postpartum health should be balanced and weighted equally. Dr. Carolyn Best (American Urological Association) added that she lived with the effects of UI for 2 years after the birth of her two children. After referral to a urologist by her OB/GYN, Dr. Best was happy to report a successful surgery to correct stress UI. However, she was surprised that her doctor did not communicate to her how difficult recovery would be. Dr. Best thanked Ms. Loizou for sharing her story and lauded the NIDDK for convening this meeting.

Ms. Mary Worstell, a public health professional focusing on women and family health, spoke as a patient on the personal cost of BUCs. She places costs associated with bladder health or BUCs into four categories: individual, family-related, health care system (e.g., efficiency and outcomes), and community. For the broad interest of this meeting, she added a fifth category: global. Ms. Worstell described her early experiences with UI, which included taking gymnastics and enduring ridicule from classmates. It was her experience with many painful UTIs that brought bladder health to her attention. Although the cost and impact to her job were not significant, she wrestled with loss of intimate relationships with fear of

pursuing new ones. Guidance was limited on preventing recurrent UTIs. Facts on the necessary urination patterns for adults prone to UTIs (e.g., before and after sex) surfaced only 10 years ago, in 2009.

Ms. Worstell observed that many children experience multiple UTIs with painful and traumatic treatment. Many of her family members, both male and female and of all ages, struggle with urinary problems (e.g., kidney stones) and have benefited from emerging new treatments. The medical and psychological costs can accumulate. Ms. Worstell's bladder health awareness and concern was heightened when a friend was diagnosed with interstitial cystitis, leaving her disabled, homebound, and unable to work. The friend also was affected by mental health issues related to anxiety about severe, chronic pain. Hospital staff sometimes did not understand her friend's urgency for access to bathroom facilities, which might extend past routine procedures for patients with similar conditions. Medical costs have been significant, and other friends are involved in her caregiving.

Ms. Worstell next recounted her experience caring for her mother (now 96 years of age), who was affected by chronic UTIs for more than 40 years. Her mother's medications were expensive, side effects were numerous, and a prior condition (blindness) was accelerated. Alternative treatments, such as probiotics and vitamins, provided relief for a short time, but the condition rebounded—additional treatments were unsuccessful. Having been a caregiver for both her friend and her mother, Ms. Worstell went from viewing BUCs on the individual and family levels to seeing BUCs as a community and global health system issue. The actions to address these issues depend on the shared insights and leadership that emerges from this meeting.

Discussion

- A participant commented on the lack of inclusion of the patient voice on advocacy panels to guide policy and research at the federal level. Dr. Bavendam encouraged reaching out to the various federal groups represented at this meeting and noted the NIDDK's efforts to engage patients in the research process. The Patient-Centered Outcomes Research Institute (PCORI) is a leader in patient-centered research; other agencies also have begun to recognize the importance of patient-centered research.

- The AHRQ representative called attention to two of her agency's initiatives that involve patients in research: a collaboration with the U.S. Food and Drug Administration (FDA) on establishing the correct measures in women's health research and the initiative involving American Urogynecologic Society patients who are developing questions for patients. Also, the Women's Health Planning Initiative conducted a systematic review and has endorsed screening questionnaires that have been effective.

- Dr. Karen Huss explained that most National Institute of Nursing Research (NINR) efforts focus on patient-centered outcomes, families, and caregivers, rather than on specific diseases. The NINR sponsored a 2-day summit in August 2017 titled "The Science of Caregiving: Bringing Voices Together." Further details can be accessed from the NINR website.

LIGHTNING PANEL OF AGENCY ROLES
Moderator: Mary Worstell, Patient and Caregiver

National Institute on Aging (NIA)
Marcel Salive, M.D., M.P.H.

Dr. Marcel Salive provided an overview of the NIA's interests related to urinary issues, which he noted is a major topic of interest. He highlighted NIA resources that address UI and emphasized the importance of awareness

around geriatric interests, noting the need for communication between physicians. The Grants for Early Medical/Surgical Specialists' Transition to Aging Research (commonly called GEMSSTAR) program, geared for new investigators, provides grants for early medical/surgical subspecialists in the transition to aging. Dr. Salive explained that the program funds work on interventions for UI prevention and treatment in older adults. He also highlighted the Paul B. Beeson Emerging Leaders Career Development Award, which aims to foster career development of investigators who bridge the fields of geriatrics and other medical topics. He emphasized the award's interdisciplinary focus. Awardees participate in an annual meeting to aid research development. Dr. Salive encouraged attendees to visit the NIA blog for further information regarding funding opportunities.

NINR
Karen Huss, Ph.D., R.N., ANP-BC, FAAN, FAAAAI, FAHA

Dr. Huss discussed opportunities within the NINR Extramural Research Program in terms of general urinary issues. The NINR's mission is to promote and improve the health of individuals, families, and communities. The prevalence of GU conditions, as well as their relationship to other medical conditions and burden on patients, makes them relevant to the mission of NINR. Dr. Huss next reviewed previous NINR funding opportunities for patients with various medical conditions relevant to urology. One initiative, the Tübingen Lifestyle Intervention Program, aims to teach women low-risk self-management practices related to preventing UI and is one of NINR's innovative programs.

The NINR's strategic plan is based on symptom science, wellness, self-management, and end-of-life and palliative care. Its work spans two crosscutting areas: (1) innovation and technology and (2) career development and training for young scientists. Although the NINR does not focus on a specific disease or condition, its goal is to improve QOL for individuals. She discussed the concept of self-management for individuals with chronic conditions, and she emphasized the importance of promoting health and functional well-being.

NIDDK
Ziya Kirkali, M.D.

Dr. Ziya Kirkali discussed urology networks established by the NIDDK. The first, the Multidisciplinary Approach to the Study of Chronic Pelvic Pain Research Network, carries out deep phenotyping of patients with urologic chronic pelvic pain syndromes. The second, the Symptoms of Lower Urinary Tract Dysfunction Research Network, identifies and describes subtypes of patients with lower urinary tract dysfunction. The organization also focuses on disseminating data and sharing resources. The third, the Prevention of Lower Urinary Tract Symptoms Research Consortium, focuses on promoting bladder health. The fourth, the Urinary Stone Disease Research Network, is currently conducting research on behavioral interventions with smart water bottles and economic incentives for prevention of stone recurrence, as well as a second study to understand and mitigate stent-associated pain and urinary symptoms.

Dr. Kirkali informed attendees that the NIDDK maintains a repository of data from supported studies and biospecimens, which are available for use. He also highlighted the NIDDK Urologic Diseases in America (UDA) compendium as a resource for more information.

AHRQ
Arlene Bierman, M.D., M.S.

Dr. Arlene Bierman stated that the focus of the AHRQ is to improve quality and outcomes of care delivery and to increase evidence at the point of care. The Agency focuses on improving ambulatory care and health care transitions. The Affordable Care Act mandated dissemination of evidence-based practice. AHRQ has a two-step process to determine funding allocations for research. A research investigator can nominate a topic for dissemination and implementation based on the strength of evidence, impact on population, and gaps in practice.

Dr. Bierman discussed the balance between these elements across topics. AHRQ has received a request for UI research; Dr. Bierman noted the lack of evidence on how to implement this topic in practice. She identified shared decision-making, clinical decision support, and patient-reported outcome measures as important components of the AHRQ. She discussed the development of an authoring tool to help users create clinical decision support.

U.S. Environmental Protection Agency (EPA)
David Meyer, Ph.D.

Dr. David Meyer stated that he was invited to speak on environmental factors related to urologic issues but explained that this topic is not currently on the radar of the EPA. He added that topics of EPA focus must be related to access to clean water, air, or land. Although the effect is relatively tangential, evidence supports a relationship between urology and the environment. Dr. Meyer discussed the requirement for Congressional mandates in pursuing topics of study and the need to focus on specific states (e.g., common retirement states, such as Florida) when considering this issue. He emphasized the need for sound science to precipitate action and stated that although this topic represents a new area of interest for EPA, it constitutes a compelling story.

Health Resources and Services Administration (HRSA)
Joan Weiss, Ph.D., R.N., CRNP

Dr. Joan Weiss provided an overview of programs in HRSA that address GU conditions, which are focused primarily on UI. The Geriatrics Workforce Enhancement Program (GWEP) is aimed at improving health-based outcomes for older adults by maximizing patient and family engagement and integrating geriatrics in primary care. The GWEP works to enhance coordination between academia, primary care practices, and community-based organizations to better meet the needs of older patients and promotes workforce training, clinical training environment improvements, program evaluation, and intervention dissemination. Dr. Weiss emphasized the importance of symptom identification, diagnoses, and treatment options. She also spoke on the HRSA Career Development Program, which helps junior faculty become academic geriatric specialists. Dr. Weiss stated that many participating faculty members in this program are addressing GU conditions.

Office of Women's Health (OWH), HHS
Dorothy Fink, M.D.

Dr. Dorothy Fink began by conveying that as an endocrinologist, she is struck by the overlap between many conditions associated with aging; she spoke specifically on the relationship between osteoporosis and hypercalciuria. She discussed the importance of transforming research on GU conditions to public health policy. Dr. Fink highlighted the Coordinating Committee on Women's Health, noting the need for collaboration among organizations. She emphasized that the OWH is charged with facilitating the dissemination of information to the public and challenged attendees to think about how to promote research findings and effect changes in health care and treatment.

Office of Research on Women's Health (ORWH), NIH
Lisa Begg, Dr.P.H., R.N.

Dr. Lisa Begg provided an overview of the ORWH, noting that its mission is consistent with that of the NIH. The ORWH's strategic plan includes five goals: (1) to advance rigorous research that is relevant to the health of women, (2) to develop methods and leverage data sources to consider sex and gender influences that enhance research for the health of women, (3) to enhance dissemination and implementation of evidence to improve the health of women, (4) to promote training and careers to develop a well-trained, diverse, and robust workforce to advance science for the health of women, and (5) to improve evaluation of research that is relevant to the health of women. Dr. Begg highlighted several funding opportunities, including Building Interdisciplinary Research

Careers in Women's Health (BIRCWH), which focuses on career development for junior faculty. The program supports approximately 60 new scholars each year.

The ORWH is committed to collecting data on understudied, underreported, and underrepresented populations. Dr. Begg noted that although the program is small, it provided nearly $3 million in fiscal year 2018 for 15 projects. The ORWH also is committed to understanding sex and gender influences on health and disease at every level. The biannual Report of the Advisory Committee on Research on Women's Health: Fiscal Years 2017–2018 is now available on the ORWH website.

Eunice Kennedy Shriver **National Institute of Child Health and Human Development (NICHD)**
Donna Mazloomdoost, M.D.

Dr. Donna Mazloomdoost provided an overview of the NICHD priorities and funding opportunities. The NICHD leads research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. Each branch has identified research gaps and strategic priorities, but the NICHD possesses the flexibility to fund projects that align best with its priorities or a stated public health emergency.

Dr. Mazloomdoost represents the Gynecologic Health and Disease Branch (GHDB), which supports basic, translational, and clinical research programs related to gynecologic health throughout the reproductive lifespan. Her work includes studies of pelvic floor disorders, and she noted that the NICHD funds many clinical multicenter trials related to pelvic floor disorders. Dr. Mazloomdoost stated that several of the GHDB research priorities are inclusive of urinary studies, and she directed attendees to the NICHD website for current funding opportunities.

Discussion

- Ms. Worstell highlighted major themes, which included outcomes of care, care prevention, self-management, programs and research, community education, comorbidity, systematic reviews, shared decision-making, clinical decision support, tangential connections with other conditions, geriatric training, career development, impact of menopause and hormone therapy, and sex and gender influence on health disparity. She emphasized the wide diversity of activities among federal agencies represented at the panel.

- Dr. Margot Damaser (Lerner Research Institute, Cleveland Clinic) commented on the need for experts on methodology and big data, as well as environmental burden related to GU conditions. She asked if funding opportunities for interdisciplinary research on this topic are available.

- Dr. Susan Zieman (NIA) stated that the NIA is interested in supporting specialized scientists in aging research. She spoke of NIDDK Interagency Coordinating Committees, and she emphasized that the NIA does not focus on a single disease, but any health problems associated with aging. The NIA is interested in the development of transdisciplinary infrastructure.

- Dr. Bierman conveyed the importance of having real-world evidence and putting it into practice, noting the AHRQ's strong interdisciplinary focus.

- Dr. Begg stated that the ORWH works across the NIH; she encouraged people to approach ORWH, as well as NIH Institutes and Centers (ICs), to ask if they would consider pursuing an area outside their usual research. The NIDDK Urology Interagency Coordinating Committee will discuss this topic.

- Dr. Leslee Subak (Stanford University School of Medicine) stated the importance of communication between agencies and academic researchers. She proposed that the NIH focus on interdisciplinary networks and other activities within the broader research community.

- Dr. Bernard Harlow (Boston University School of Public Health) highlighted the need for senior mentorship awards related to women's urological health. Dr. C. Neill Epperson (University of Colorado) agreed, commenting on the difficulty for senior leaders to mentor the next generation of investigators. Dr. Huss replied that the NINR has a funding mechanism to support senior research and mentorship. Another participant highlighted mechanisms offered by other ICs.

- Dr. Zieman highlighted the Clinician-Scientists Transdisciplinary Aging Research program, which aims to transition clinical junior and senior scientists to aging research. Ms. Gail Hunt (National Alliance for Caregiving) stated that the Patient-Centered Outcomes Research Institute funds investigator-initiated grants in multidisciplinary research.

How Do We Conceptualize the Hidden Burden?
Sonya Brady, Ph.D., University of Minnesota School of Public Health

Dr. Brady presented a conceptual framework for considering upstream determinants and downstream consequences of GU conditions. She explained that individuals are embedded in a social ecology; although public health typically focuses on how social ecology influences health, the purpose of this meeting is to address how health influences social ecology.

The social ecological model explains how multiple levels of influence (i.e., individual, interpersonal, institutional, community, society/public policy) create risks/barriers and protective/facilitating factors that contribute to an individual's health, health behaviors and environmental context. Individual characteristics include knowledge, beliefs, genetics, physiology, and behavior. Primary interpersonal groups (e.g., family, friends, partners) help to shape an individual's identity and may provide social support. Organizational structures (e.g., schools, worksites, churches) operate within a formal identity and may create rules or customs that affect health and health behavior. Communities are tied by a shared identity and exist within social norms that influence behavior. At the societal level, social norms are applied more broadly and may be tied to policies and laws that regulate health behaviors. Dr. Brady explained that environments with protective factors foster opportunities for health and mitigate the effects of risk factors. In contrast, environments with risk factors impose constraints on health.

The PLUS Research Consortium adapted Thomas Glass and Matthew McAtee's conceptual framework for public health to address bladder health and prevention research. Dr. Brady explained that PLUS is based on the concept that both social and biological science, as well as a life-course perspective, are necessary to understand health and disease. An individual's health at any point in time is a cumulative result of a lifetime of exposures. She emphasized the use of the social ecological model as a tool for studies of health.

Dr. Brady noted that the social ecological model also embraces reciprocal determinism, the concept that not only does the social environment influence a person's health and behavior, but a person's health and behavior also influences the social environment. She reiterated that the purpose of this meeting is to address the latter component of reciprocal determinism: how bladder health influences social ecology. She used the PLUS adaptation of the Glass/McAtee model to explain that BUCs may impose constraints on health and social ecology. These conditions also may express and exacerbate biological risks, because they impose constraints on self and social ecology. This effect can become cyclical, leading to the development of comorbid conditions, a microbiome response, and alterations to the hormonal environment. Dr. Brady emphasized that because of the complexity of interactions between factors, a single study or initiative cannot address all issues within the

framework sufficiently. However, this meeting represents an opportunity to begin to conceptualize the downstream consequences of GU conditions and to develop a pathway to advance this area of research.

Reference

1. Glass TA, McAtee MJ. Behavioral science at the crossroads in public health: Extending horizons, envisioning the future. *Soc Sci Med*. 2006; Vol 62(7): 1650–71.

PANEL: COMPONENTS OF BURDEN

Moderator and Introduction: Siobhan Sutcliffe, Ph.D., Sc.M., M.H.S., Washington University School of Medicine in St. Louis

Prevalence of GU Conditions

Brian Matlaga, M.D., M.P.H., Johns Hopkins University

Dr. Brian Matlaga described the UDA, an NIDDK-funded project aimed at developing compendia on the burden of urologic conditions for discussions on policymaking and funding priorities. He focused his presentation on three prevalent conditions: UI, kidney stones, and benign prostate hyperplasia (BPH). Data were obtained through Medicare and the National Health and Nutrition Examination Survey (NHANES).

Dr. Matlaga first addressed UI, noting that more than half of women experience some degree of incontinence. The disorder's prevalence has increased over time. A sharp decline in surgical interventions for UI treatment occurred in 2010, likely due to a U.S. Food and Drug Administration (FDA) warning regarding mesh implantation, which also may have influenced clinical practices. As a result, spending on the treatment of UI decreased. Dr. Matlaga presented the results of a longitudinal analysis showing that reoperations are frequent among surgical therapies.

Dr. Matlaga next discussed kidney stones. The prevalence of kidney stones is equivalent between men and women, and prevalence has increased over time. He spoke on imaging approaches; computed tomography (CT) scans represent the most common procedure but may pose safety risks to patients because of the potential for recurrence. Dr. Matlaga discussed alternative approaches to CT scans (e.g., ultrasounds). He conveyed that surgical interventions for this condition are increasing because of increased endoscopic treatment (i.e., ureteroscopy). Likely as a result, Medicare expenditures are increasing. The most common prescription for kidney stones is an opioid agonist, which is a concern in the context of the addiction epidemic in the United States. A longitudinal analysis demonstrated that repeated surgical procedures are common, although the determinants for this statistic are unclear.

Dr. Matlaga noted that the prevalence of BPH has increased over time, but surgical interventions have declined. He explained that the decline likely is driven by the development of minimally invasive therapies. However, because some of these interventions are ineffective, other procedures may become more common. Dr. Matlaga mentioned that other treatments, such as alpha blockers, are under development. He also discussed the social dynamics of treatment; patients with private insurance are more likely to rely on newer therapies.

Dr. Matlaga concluded by reviewing the implications for treatment of the three disorders. Because UI displays increasing prevalence and decreasing interventions, an unmet need may exist in the treatment of patients with UI. Kidney stones offer an opportunity for improvement to the care process, both in terms of imaging and prescribed medications. Patients with BPH experience a gap in surgical therapy options because of lack of efficacy in available treatments.

Methodologic Challenges of Understanding Economic Burden
Todd Wagner, Ph.D., Stanford University

Dr. Todd Wagner discussed the methodologic challenges involved in understanding economic burden. He noted that he chaired the Economics Committee at the 6th International Consultation on Incontinence (ICI), held in Tokyo, Japan, in September 2016 and has benefited from the input of experts in the field, some of whom are present at today's meeting. Dr. Wagner reviewed existing knowledge regarding incontinence, emphasizing that the effects of incontinence are myriad. Effective treatments exist but vary in their cost and outcomes. Care providers often are constrained by resource limitation. Generally, many professional societies, such as ICI, recommend cost-effectiveness analysis (CEA) for assessing the value of a treatment if one treatment is more effective but more expensive than another. Dr. Wagner discussed the CEA challenges associated with measuring outcomes in ways that are meaningful to patients, highlighting the importance of the time horizon, because costs and values are likely to change over time. He also emphasized that perceptions of value differ among the patient, provider, and society. As a result, some programs may be effective at one level but not at the decision-making level.

Although progress has been made in the past decade, the CEA models remain highly sophisticated; thus, a thorough review of the model is difficult. The level of uncertainty, in particular, presents a challenge. Furthermore, a wide variation exists in "costs" of treatment based on modality and skills, as well as in patient adherence to treatment procedures, especially for behavioral therapy. Dr. Wagner described his role in the Treatment of Uncontrolled Lupus via the Interferon Pathway (TULIP) trial, in which he worked to determine the trial's per-participant cost. He found that the program was not self-sustaining, because the cost of the program was greater than participants were willing to pay. In contrast, an online video the team developed was sustainable, but garnered poor adherence.

Regarding surgery for stress UI, Dr. Wagner discussed the complexity of determining the value difference between close substitutes for treatment. Small sample size and lack of endpoint data beyond 12 months limit statistical power, and few studies compare all available treatments, making analysis of benefits difficult. In addition, it may be hard to capture and quantify costs related to such factors as employment, productivity, and effects on families and caregivers—translating to fertile territory for health economics. He emphasized that health shocks, which are unexpected and significant events (e.g., cancer or trauma), provide opportunities to quantify economic outcomes of health events. Unlike health shocks, GU conditions often develop more gradually. Patient acclimation and normalization of UI often lead to underreporting of the disorder, which represents a challenge in terms of availability of databases for performing cost-effectiveness analyses.

References

1. Ettner SL, Huang D, Evans E, et al. Benefit-cost in the California treatment outcome project: Does substance abuse treatment "pay for itself"? *Health Serv Res* 2006; Vol 41(1):192–213.
2. Humphreys K, Wagner TH, Gage M. If substance use disorder treatment more than offsets its costs, why don't more medical centers want to provide it? A budget impact analysis in the Veterans Health Administration. *J Subst Abuse Treat* 2011; Vol 41(3):243–51.

Quality of Life and Social Impacts
Christine Bradway, Ph.D., R.N., CRNP, FAAN, University of Pennsylvania

Dr. Christine Bradway drew on her perspective as a researcher and clinician, as well as evidence from the literature, to discuss QOL and social impacts related to UI. She defined health-related quality of life (HRQoL) as aspects of an individual's perception of their position in life that can be shown clearly to affect physical and mental health. She emphasized the social effects of UI, which include suffering, decreased self-esteem, affected relationships, and embarrassment.

A wide array of quantitative tools exist for measuring HRQoL. In an analytical study, the contributing effects of potential non-biologic factors (e.g., culture, anxiety, assertiveness) were assessed along the UI treatment pathway. Dr. Bradway noted a gap in QOL data for informal caregivers of women. Additional areas requiring further study include determinations of anxiety and depression in multiethnic populations, as well as cognitive appraisals.

Dr. Bradway stated that she believes in multi- and mixed method approaches (i.e., the integration of qualitative and quantitative measures) in assessing HRQoL and stressed the importance of considering both types of data. She discussed qualitative understandings of HRQoL and social impacts, highlighting evidence suggesting a substantial effect of urologic disorders on sexuality in both men and women. She presented perspectives from patients, noting the importance of integrating the gathered information into a unified model. In a meta-synthesis, researchers found that effects of UI on intimacy lead to feelings of fear, shame, blame, and guilt.

In a meta-synthesis, Dr. Bradway identified five primary themes surrounding men's experiences post-prostatectomy: facing a life-changing situation, experiencing changes and their effects, striving to manage and adjust, coping with perceptions of masculinity, and anticipating the future.

She reviewed the development of a meta-ethnography surrounding women with chronic pelvic pain. The model revealed a culture of secrecy surrounding the disorder; women often struggle to determine whether their pain is "normal." Dr. Bradway suggested that these models be used by other researchers.

Dr. Bradway identified topics requiring further study. These included knowledge gaps on "hidden" populations (e.g., men, LGBTQ patients, multiethnic patients, caregivers) and the characterization of GU sub-types. She spoke on the need to evaluate the effectiveness of professional education of providers and caregivers in decreasing burden, and she discussed the importance of language in encouraging patient engagement. She also emphasized the potential importance of electronic health records in driving practice. She concluded by acknowledging that some individuals with GU conditions report high QOL despite their condition and may represent opportunities to understand resilience.

Environmental Burden
David Meyer, Ph.D., EPA

Dr. Meyer discussed the framing of environmental questions around BUCs. He presented the fundamental objectives of environmental protection: (1) to minimize damage to human life, (2) to minimize damage to ecological systems, and (3) to minimize depletion of natural resources. Dr. Meyer explained that common questions relating to environmental protection involve chemical harm and resources for sustainability. Key tools for addressing these questions include life-cycle assessments and risk assessments.

Life-cycle assessments consider a product's impacts along its life cycle from cradle to grave, including source materials, manufacture, transport, use, and disposal. Dr. Meyer explained that the product life cycle provides a broader understanding of environmental impact and helps to avoid burden shifting. Life-cycle analysis relies on environmental impact modeling, which considers the causal chain from stressors (e.g., contaminants) to midpoints (e.g., toxicity) to endpoints (e.g., disease), with ultimate emphasis on damage to human and ecological health.

GU treatment can create issues across the life cycle because of material and energy use. Dr. Meyer highlighted GU treatments and remedies that impart environmental effects: the use of pharmaceuticals, increased water consumption, changes to diet, surgical and device interventions, waste and wastewater treatments, and diapers and pads to manage incontinence. For example, not only does pharmaceutical production tend to be resource-intensive, but pharmaceuticals and their metabolites can end up in surface water, and traditional wastewater treatment does not effectively remove these chemicals.

Dr. Meyer discussed the balance between human quality of life and environmental burdens. He stated that the ability to minimize waste generation as part of treatment protocols is important for promoting human and environmental health while conserving natural resources. He concluded his presentation by affirming the importance of integrated decision-making; environmental impacts represent one of many factors in the treatment of BUCs.

Increased Risk of Comorbid Conditions
Ted Johnson, M.D., Emory University School of Medicine

Dr. Johnson described counts, couplets, and clusters surrounding chronic conditions that are comorbid to GU conditions. He explained that the majority of Centers for Medicare and Medicaid Services' (CMS) Medicare beneficiaries have at least two chronic conditions, and individuals with multiple chronic conditions account for a disproportionate amount of Medicare spending. In addition, multimorbidity has been associated with poor outcomes, including mortality and hospitalization.

Chronic conditions can be grouped into concordant, unrelated, and discordant couplets. In concordant couplets, management strategies for the individual's conditions are aligned. In unrelated couplets, management strategies for an individual's conditions do not affect one another. In discordant couplets, management strategies for the individual's conditions contradict one another. The presence of discordant couplets is associated with an increased morbidity risk. Dr. Johnson discussed his research on the synergy between the effects of nocturia and insomnia. He stated the need for the development of behavioral techniques that consider both conditions simultaneously.

Dr. Johnson explained that clusters of chronic conditions are informed by quantitative analyses of symptoms. Using NHANES data, he examined patterns of 12 chronic health conditions in 3,800 women with UI. Five clusters emerged: (1) patients with none of the 12 conditions, (2) younger individuals with cardiovascular disease risk, (3) asthma-predominant patients, (4) older individuals with cardiovascular disease, and (5) patients with multiple chronic conditions. Overall, prevalent comorbid conditions included arthritis, asthma, diabetes, and hypertension, but rates of these conditions—as well as age, BMI, and type and severity of UI—varied across clusters. Dr. Johnson hypothesized that a mechanistic relationship may exist between the asthma and UI in the asthma-predominant cluster.

Reference

1. Markland AD, Vaughan CP, Okosun IS, et al. Cluster Analysis of Multiple Chronic Conditions Associated with Urinary Incontinence among Women in the USA. *BJU International* 2018; Vol 122(6):1041–8.

Discussion

- A participant asked about the temporal relationship between comorbidity and bladder-related issues. Dr. Johnson replied that his initial analyses were cross-sectional, so this question has not yet been addressed; however, he agreed that it requires further study.

- Dr. Zieman stated the need for discussions regarding disparities in diagnosis and treatment of GU conditions. Ms. Jenna Norton (NIDDK, NIH) noted that the issue will be discussed during the prevalence breakout session.

- Dr. Lona Mody (University of Michigan) conveyed that costs for urinary-related interventions at nursing homes are borne by the nursing homes, but the cost savings achieved through a decrease in hospital readmissions are realized by other parties. She asked how facilities might be incentivized to take on the costs of providing this care when they will not see the economic benefits. Dr. Wagner agreed that the

issue is complex; he stated that the CMS is struggling to determine effective approaches for incentivizing various providers.

- Dr. Daniel Shoskes (Cleveland Clinic) noted that retrospective analyses often rely on data extracted from billing codes or self-recalled diagnoses. He asked what criteria are used in analyzing the available data. Dr. Wagner stated the importance of considering the context of data, noting that larger data sets often allow greater precision in analysis. Dr. Matlaga explained that evidence varies by condition; investigators should analyze the best available data.

- Dr. Holly Kramer (Loyola University Chicago) raised an issue regarding nomenclature; she discussed issues regarding the use of the term "benign" to describe bladder dysfunction. She stated the need for standardized definitions within the field. Attendees also discussed the need to differentiate and define symptoms, syndromes, diseases, and conditions. Dr. Bavendam clarified that the NIDDK uses the term "benign" to mean non-cancerous to distinguish the NIDDK mission of research on non-cancerous GU conditions from the National Cancer Institute mission of research on cancers of the GU tract.

- In response to a question regarding comorbidity of obesity, Dr. Johnson clarified that obesity differs from the model's other conditions; measure of obesity is continuous, while the other conditions are characterized dichotomously. Another attendee stated that the relationship between obesity and GU conditions speaks to the complexity of this issue and highlights the need for complex models.

- A participant asked whether the reported decline in prevalence of UI might reflect a decrease in reporting and diagnosis, possibly resulting from the decrease in surgical options. Dr. Matlaga agreed that the issue merits further investigation. In a response to a question about consumer product information, Dr. Matlaga underscored the need to help patients with decision making.

- In response to a question about data on younger women, Dr. Johnson clarified that most of the data sets were not age-restricted. He noted the importance of studying changes in comorbidity over time. Dr. Bavendam stated that almost no studies of women under 30 years of age exist, but investigators are beginning to focus attention on younger individuals.

- In response to a comment, Dr. Meyer explained that the EPA examines risk across the life cycle for humans, as well as examining the risks of products. He explained that the EPA uses comparative tools to determine the best way to minimize impacts. Dr. Meyer clarified that the EPA does not possess the data necessary to directly quantify the waste generated from disposal of pads or diapers in the United States. Estimates are based on sales data.

- Dr. Annemarie Dowling-Castronovo (Wagner College Evelyn L. Spiro School of Nursing) asked about healthy bladder behavior skills. Dr. Matlaga affirmed the need to evaluate first the efficacy of therapies for specific levels of GU conditions, as well as the opportunity cost of pursuing behavioral intervention rather than therapeutic treatment.

- Dr. Melissa Constantine (University of Minnesota) asked about the link between incontinence and institutional care. Dr. Wagner stated that issues exist regarding causality, as investigators must control for multiple conditions. Dr. Bradway underscored the importance of mixed-methods approaches to account for multiple factors. Dr. Johnson stated that the treatment of GU conditions may help delay institutionalization.

Charge to Breakout Groups
Jenna Norton, M.P.H., NIDDK

The breakout groups were charged to determine what is needed to measure burden across each burden domain, including prevalence, QOL, economic costs, the environment, and comorbid conditions. Participants attended one of five breakout groups.

BREAKOUT DISCUSSIONS: What Do We Measure across Each Burden Domain?

Prevalence—Emphasize Underreported Conditions and Underrepresented People
Moderators: Lisa Begg, Dr.P.H., R.N., ORWH
Siobhan Sutcliffe, Ph.D., Sc.M., M.H.S., Washington School of Medicine in St. Louis

Quality of Life—Social Impacts on Patients and Caregivers
Moderators: Joan Weiss, Ph.D., R.N., CRNP, HRSA
Christine Bradway, Ph.D., R.N., ORNP, FAAN, University of Pennsylvania

Economic Costs
Moderators: Todd Wagner, Ph.D., Stanford University
Michelle Kim, M.D., Ph.D., Partners HealthCare

Environmental Burdens
Moderators: David Meyer, Ph.D., EPA
Jim Hokanson, Ph.D., Duke University

Comorbid Conditions Impacted by Benign Urologic Conditions
Moderators: Arlene Bierman, M.D., M.S., AHRQ
Ted Johnson, M.D., Emory University School of Medicine

TUESDAY, October 8, 2019

Reports from Breakout Sessions

Ms. Norton invited the breakout group moderators to report the results of their discussions.

Breakout Group 1: Prevalence—Emphasize Underreported Conditions and Underrepresented People

Dr. Siobhan Sutcliffe reported the Prevalence Group discussion. The group identified recurrent UTIs in men, asymptomatic bacteriuria, and urogenic bladder as three underreported conditions. The group discussed special populations and high-risk groups, including American Indians (AI) and Alaska Natives (AN), Asians, Pacific Islanders, Hispanics, and transgender individuals (because of hormone effects). The group also discussed postpartum conditions and UI and recognized that much is known about prevalence, but not about the risks or the role of cytokines and inflammation.

Dr. Sutcliffe explained that the discussion next focused on prevalence in rural areas and the timeliness of receiving health care services, especially for such vulnerable groups as persons with dementia and those with disabilities. Regarding representation in surveys that capture national and regional prevalence estimates, participants noted that the questionnaire excludes institutionalized individuals, such as the military, prisoners, and nursing home residents. Other challenges in estimating prevalence and combining survey data include the lack of clear definitions for some conditions. The group identified that training in epidemiology research and methods could be enhanced, as well as support for clinicians conducting research.

Discussion

- A participant asked how well the severity of the impacts of GU conditions is understood. Dr. Sutcliffe pointed out that the group's discussions focused on prevalence, rather than disease severity. A participant emphasized that research is needed in high-risk and underrepresented groups (e.g., AI/AN and Pacific Islanders), but data are lacking.

Breakout Group 2: Quality of Life—Social Impacts on Patients and Caregivers

Dr. Weiss reported that the group focused on addressing six key questions, which she summarized. The group agreed on prioritizing the need to capture QOL indicators; developing a short, concise, comprehensive instrument of burden; addressing shame; and not normalizing GU conditions. Clustering GU conditions with other factors and conditions, such as goals and dementia, developing new treatments, and addressing prevention ranked high on the group's list of priorities. Other data needs included treatments (targeted and traditional), prevention, QOL indicators related to sleep, burden surrogate, and cost.

Dr. Weiss pointed out that the group's discussion of QOL aspects not being adequately or accurately defined in underrepresented groups overlapped with similar discussion reported by the Prevalence Group. The Quality of Life Group considered that social media could potentially play a role in reducing shame among the younger generations. The group discussed the positive and negative aspects of using urinary catheters and noted that most of the evidence focuses on the negative aspects; however, some patients prefer catheters for the independence of going out socially. The group also identified that QOL data are not being captured because of a lack of representative billing codes in the electronic health records. In addition, education on the importance of QOL measures will be essential at all levels—including clinicians, graduate medical schools, and residency. QOL health literacy for health care professionals, as well as patients and families, should be considered. A key message to increase awareness about QOL and its impact is the loss of wages and work productivity.

After discussions about the key challenges of accurate measurement of QOL aspects in clinical and research settings, the group determined that measurements, by nature, are not fully accurate. Because of under-reporting and -diagnosis, the International Classification of Diseases, 10th Revision (ICD 10) codes do not accurately capture GU conditions, except for in the case of kidney stone disease. Under-reporting may be a result of GU conditions' being normalized, but no GU condition should be normalized at any age. It also was pointed out that incontinence can be related to sexual violence.

To determine how these challenges can be addressed to capture the necessary data, Dr. Weiss conveyed the need for a campaign to improve GU conditions-associated QOL that centers on saving and preserving dignity. The group discussed such strategies as connecting with others interested in this topic by leveraging pragmatic clinical trial databases—for example, the NIH Collaboratory, Health Care Systems Research Network, and the National Patient-Centered Clinical Research Network.

The group discussed ways to engage key stakeholder communities in research to generate meaningful data. They proposed engaging pharmaceutical companies, other NIH ICs and federal partners, CMS, Kaiser Permanente and other private care providers. A review of the existing QOL activities and initiatives of the key stakeholders would be one place to start.

The group next discussed the highest priority data. The preliminary list includes developing a short, comprehensive instrument on GU conditions for data collection, establishing GU friendly communities, and establishing GU health care systems.

Discussion

- A participant observed during the Day 1 discussions that the group most affected by GU conditions—women—were not included as stakeholders and noted that these patients would be the ones to best address the most important questions regarding QOL measurements.

- Participants discussed alternative data resources, including shared experiences. Google Analytics and other Google resources can assist in data collection by providing search term information, because individuals may feel more comfortable searching for information on GU conditions privately than raising them in clinical settings. For example, Google Trends provides added granularity of data by region and time and can be used to compare search patterns for different GU conditions. Social media could be a powerful tool if patients are willing to share their experiences on those platforms. A certain level of knowledge is necessary to share your GU experience without feeling shame.

Breakout Group 3: Economic Costs

Dr. Michelle Kim reported the economic cost deliberations. Discussions focused on the burden of cost to the caregiver and how to estimate those costs, touching on the labor market employment effects. The caregiver takes time off from work, purchases supplies for the patient, and cares for patient's other needs. The group discussed how gender affects cost and noted that in general, women are the primary caregivers. Having multiple BUCs can compound the cost to caregivers if the patient is leaving home for residency in a long-term care facility.

Dr. Todd Wagner said that the group next focused on patient cost and discussed the costs that individuals face. Out-of-pocket expenses can be significant and often produce a tension between patients and their insurers. Although social isolation cost is part of the burden if patients are not able to leave their home, Dr. Wagner remarked on the difficulty in estimating those costs unless they are connected to the labor market and loss of work. The group noted that costs are underreported in data sets, which also poses a challenge to economists' estimations because the use of self-reported data is questionable. Dr. Kim called attention to coding issues for BUC conditions related to hospital admissions that affect cost estimates.

Dr. Wagner explained that even having the ideal data set and perfect patient-level costs does not negate the fact that no other entity (e.g., insurers) wants to cover these costs—incentives exist for accountable care organizations, but they are modest. Estimating costs from long-term outcomes using clinical trial data can be robust, but treatments change rapidly, thereby affecting investments in this area. The group discussed how prevention might be a better focus that could lead to cost savings, but funders interested in investing would be needed. Dr. Wagner recounted the final discussion on a collaborative care model and GU team-based approach that could be implemented when people at risk are identified. The challenge would be in financing such a team; one option the group discussed was engaging the CMS.

Discussion

- Dr. Bavendam observed that the current economic cost of incontinence is still being extrapolated from 1998 data and noted that updated estimates would be helpful, but seems complicated and costly to get. Dr. Wagner explained that the group discussed performing a cost of illness study, which would be one way to update the data. Dr. Kim added that obtaining proprietary data from incontinence product developers (i.e., vendors) is another option the group discussed.

- Dr. Robert Star (NIDDK) commented that the urology community could consider reaching out to the vendors to suggest participating in clinical trials only when the time to follow-up is appropriate.

- A participant asked about the use of existing evidence from studies of positive outcomes to influence costs. Dr. Wagner pointed out that women participating in the TULIP intervention group were not willing to incur costs independent of insurance. In general, people are spending more on sanitary products than on education about their condition.

Breakout Group 4: Environmental Burdens

Dr. Jim Hokanson reported that the group divided their discussion into environmental impacts related to coping and related to treatment. For coping, incontinence products or diaper usage (paper waste) was the major focus of the discussion, and several points were made. Comparatively, adult diapers are larger and are worn longer than children's diapers. Ideas to evaluate the environmental impact included contacting the major vendors on the amount of product they generate and asking patients about usage, although data accuracy is a concern. Uptake in such treatments as neuromodulation (e.g., Botox®) is low in UI patients, suggesting a true baseline measure of environmental impact. Fecal incontinence related to pelvic floor muscle weakness is another component of diaper usage in adults. Frequent bathroom visits and toilet flushes result in increased water usage. Color-coding water-conserving, dual-flush toilet buttons (small versus large volume) could be considered. Exploring gender-specific UI products and catheters for retention might be helpful.

Regarding treatment, Dr. Hokanson summarized that medications, particularly antibiotics, whether excreted from the body or discarded unused, could potentially impact the environment but would need to be weighed against antibiotic use in farming—which likely has substantially greater impacts. Indirectly, water-soluble medications can have an impact on the food chain/supply. Sewage epidemiology can be considered as an impact measure. Dr. Hokanson noted that the group also discussed surgical disposables; data on usage could be obtained from the doctor.

Discussion

- A participant pointed out that Medicaid covers the cost of adult diapers and asked about similar coverage with Medicare when coupled with a diagnosis. Another participant noted that extracting Medicare data from the Veterans Affairs Consumer Expenditure survey and U.S. Bureau of Economic Analysis consumer tracking reports might be applicable.

- One participant commented on the indirect effects of antibiotic use affecting multi-drug-resistant individuals, suggesting an environmental impact. He also noted unnecessary use of antibiotics for a common cold, including the side effects, and wondered whether this meeting could prompt a call for antibiotic behavior change with a supporting environmental argument. Dr. Meyer responded that environmental researchers are in the early stages of tracking the number of antibiotic substances that can be detected in water sources globally. Some water analyses show that as many as 160 antibiotics and their degradation products are present in rivers and streams, but the analytical methods still are being optimized. It will be up to the states to determine a local or regional impact. EPA will respond and assist the states, but would be addressing the issue on a national level.

Breakout Group 5: Comorbid Conditions Impacted by Benign Urologic Conditions

Dr. Johnson summarized the group deliberations. The group first focused on framing their discussions to ensure capturing the impact in women and men, across the life span, and across all ages. The intent is to concentrate on diverse experiences, encompassing a variety of BUCs, with and without comorbidities. Dr. Johnson noted that the group spent time discussing several topics, including hidden burden, comorbidities and GU symptoms; leveraging impact; and getting usable information into electronic health records. Several potential areas of hidden burden were identified, including before and at first contact with the health system; upon receiving a first treatment; evaluating response to treatment; and receiving treatment for other conditions driving GU symptoms.

Regarding comorbidities, Dr. Johnson indicated that the group recognized that many people with GU do not have comorbid conditions and that questions related to the GU/comorbidities relationship would need to be answered. Discussions also touched on examining concordance/discordance, developing comorbidity guidelines, and clustering.

Dr. Johnson highlighted suggestions for leveraging impact: Embed questions on lower urinary symptoms into studies and clinical trials. Link to other conditions because of the prognostic significance of GU symptoms. Link GU outcomes as a motivator to other conditions. Match the treatment to the GU condition. Drive new solutions by fostering new partnerships with groups interested in GU conditions. Examine QOL questionnaires and review the appropriate measures.

The group also discussed ways to get the needed information into the electronic health records and agreed that the existing material is likely insufficient in its current state. Dr. Bierman elaborated on the types of studies needed for investigating comorbidity and GU: population health/epidemiological, clinical, and practice-based/health systems–based.

Discussion

- When asked about ways to benefit from existing big data for assessing GU conditions across the lifespan, Dr. Bierman noted the ongoing population health initiatives that are collecting data across the spectrum, including the NIH *All of Us* and the CMS-Centers for Disease Control and Prevention (CDC) Million Hearts. She explained that data quality is an issue and noted how enhancing existing data sets would be helpful.

- A participant commented on the success in educating primary care physicians about lower urinary tract symptoms (LUTS), the screening methods, treatments, and QOL burden at her academic institution. Dr. Bierman agreed that educating primary care physicians about the available resources bridges gaps in knowledge and also the health care communities. Dr. Christine Liu (Boston University School of Medicine) suggested advocating for training and building in resources from the base (i.e., ground level). Another participant pointed out an untapped resource: school nurses, who are tuned in to public health and are knowledgeable on fecal incontinence, as well as bathroom health, habits, and access in children. School nurses may have innovative ideas that can be leveraged. Dr. Bierman called attention to the U.S. Preventive Services Task Force that makes evidence-based recommendations about clinical and preventative services in children, adolescents, and adults. She advocated for increased funding to support prevention clinical trials.

- In response to a question on when to introduce an animal model for mechanistic studies, Dr. Johnson noted that the comorbid condition breakout group may not be the best one to address this topic. He acknowledged that disease-specific animal models would be useful to study bladder voiding patterns and behaviors that affect humans.

Patient Comment
Stephen Chanock, Patient

Dr. Stephen Chanock spoke on his experience with BPH, which he identified as understudied and underfunded. He explained that he is interested in the genetics of BPH, because the condition runs in his family. Dr. Chanock conveyed that he has experienced multiple bouts of prostatitis and, as a result, has faced difficulties with urination, including nocturia, urgency, and blockage.

As his symptoms progressed, Dr. Chanock turned to Dr. John Pahira, the director of MedStar Georgetown University Hospital's Center for Kidney Stone Disease and Lithotripsy Unit. He was prescribed Flomax® (tamsulosin), an alpha-blocker used to treat BPH in men. When his condition did not improve sufficiently, Dr. Chanock opted to receive a UroLift® treatment, which involves the use of implants to open the obstructed pathway. Dr. Chanock noted that although he initially experienced unpleasant complications, he has responded well to the treatment and no longer requires medication for BPH. He emphasized the positive impact of the procedure on his QOL.

Dr. Chanock recounted his interactions with other men with BPH, explaining that the condition has created a "quiet epidemic." He stated that he was disconcerted by the amount of misinformation available to the public. He underscored the NIH's potential for expanding the body of knowledge on BPH. Dr. Chanock also spoke on the need for improved screening to differentiate between prostate cancer and BPH, as men with these conditions undergo extensive, unnecessary, and painful tests.

Discussion

- Dr. Harlow commented that women are diagnosed with conditions (e.g., endometriosis, fibroids) that are similarly stigmatizing; he noted that stigmatized conditions often receive less attention from the NIH. He emphasized the importance for men to speak publicly on stigmatized conditions. Dr. Chanock stated that he plans to write a published piece on his personal experience.

- Dr. Chanock stated he wishes he had begun to address his condition 3 or 4 years earlier, because his condition had begun to affect his ability to travel and to engage in routine activities.

PANEL: MEASURING UROLOGIC CONDITIONS IN DIVERSE SPECIALTY RESEARCH
Moderator and Introduction: Margot Damaser, Ph.D., Cleveland Clinic

Obesity and Diabetes
Leslee Subak, M.D., Stanford University School of Medicine

Dr. Leslee Subak spoke on the striking relationship between obesity, diabetes, and GU conditions. She posed the question of whether GU conditions reflect a cause or effect of obesity, noting that different causal pathways may exist. A large body of literature exists regarding GU conditions. Dr. Subak discussed the need for ancillary studies to add measures to existing research. Ancillary studies necessitate identification of studies, collaboration, limits to participant burden, and funding.

Dr. Subak reviewed the incorporation of UI measures in large epidemiologic studies, explaining that the additions, which involved the use of simple survey questions, resulted from conversations among investigators. She spoke on ancillary studies performed in clinical trials for hormone therapy, the Women's Health Initiative, and the Heart and Estrogen/progestin Replacement Study. The researchers characterized types and severities of UI. Ancillary studies also have been performed within obesity and diabetes studies, including the Diabetes Prevention Program (DPP), Action for Health in Diabetes

(LookAHEAD), and Epidemiology of Diabetes Interventions and Complications (EDIC). The DPP trial showed that weight loss can help to reduce UI. In the LookAHEAD trial, UI was the most prevalent complication of diabetes.

Dr. Subak emphasized the value of compiling large data sets of health information in studies. Prevalence is a useful measure but is difficult to estimate because of the lack of a standardized definition. Brown, et al. (2006) developed and validated a three-question measure for urinary incontinence—the 3IQ—which was found to be reproducible and showed acceptable accuracy for classification of incontinence type.

Dr. Subak concluded her talk by providing real-world examples that depict the relationship between GU symptoms and weight management. She underscored the value of promoting awareness of GU conditions, reiterating the importance of urinary function to overall health.

References

1. Thom D. Variation in Estimates of Urinary Incontinence Prevalence in the Community: Effects of Differences in Definition, Population Characteristics, and Study Type. *Journal of the American Geriatrics Society* 1998; Vol 46(4):473–80.
2. West DS, Gorin AA, Subak LL. A Motivation-Focused Weight Loss Maintenance Program is an Effective Alternative to a Skill-Based Approach. *International Journal of Obesity* 2011; Vol 35(2):259–69.
3. Brown JS, Bradley CS, Subak LL, et al. The Sensitivity and Specificity of a Simple Test to Distinguish Between Urge and Stress Urinary Incontinence. *Annals Internal Med* 2006; Vol 144(1):715–23.

Opening the Conversation about Erectile Dysfunction in Patients with Diabetes
Nicole Ehrhardt, M.D., The George Washington University Medical Faculty Associates

Dr. Nicole Ehrhardt conveyed the complexity of diabetes, noting multiple levels of contributing factors and barriers to care and self-management. Dr. Ehrhardt discussed the need for greater attention toward urologic conditions when treating individuals with diabetes.

Of all comorbid medical conditions, diabetes imparts the greatest risk of ED. A survey identified impotence as one of the top three priorities among individuals with diabetes. In addition, ED is associated with increased risks for coronary heart disease, stroke, and all-cause mortality. Glycemic control improves ED; this effect motivates patients to manage their blood sugar. Glycemic control may improve cardiovascular health. Dr. Ehrhardt stressed the need to use existing data to partner with patients to improve their diabetes, GU complications, and cardiovascular outcomes.

References

1. Khatana SA, Taveira TH, Miner MM, Eaton CB, Wu WC. Does Cardiovascular Risk Reduction Alleviate Erectile Dysfunction in Men With Type II Diabetes Mellitus? *International Journal of Impotence Research* 2008; Vol 20(5):501–6.
2. Rance J, Phillips C, Davies S, et al. How Much of a Priority Is Treating Erectile Dysfunction? A Study of Patients' Perceptions. *Diabetic Medicine* 2003; Vol 20(3):205–9.
3. Yaman O, Akand M, Gursoy A, Erdogan MF, Anafarta K. The Effect of Diabetes Mellitus Treatment and Good Glycemic Control on the Erectile Function in Men with Diabetes Mellitus-Induced Erectile Dysfunction: A Pilot Study. *The Journal of Sexual Medicine* 2006; Vol 3(2):344–8.

Cardiology
Jason Lazar, M.D., The State University of New York Downtown Medical Center

Dr. Jason Lazar discussed the relationship between urological and cardiovascular dysfunction, explaining that nocturia is a presenting symptom that is prevalent among cardiology patients. LUTS and nocturia are relevant to nearly all major cardiovascular risk factors. A particularly striking relationship exists between nocturia and hypertension.

Dr. Lazar conveyed that the relationship between the urinary and cardiovascular systems creates profound complications, as hypertension is prevalent among older adults. Dr. Lazar recognized the work of the late Dr. Ronald G. Victor, who found that nocturia was higher in individuals with untreated high blood pressure. Dr. Lazar challenged the effect of thiazide diuretics on nocturia, even though diuretics are listed commonly as a contributing factor to the disorder.

The association between hypertension and nocturia is well established, but the mechanistic explanation is unknown. Traditionally, hypertension was considered a systemic disease. Dr. Lazar proposed that hypertension is a biomarker of vascular disease. He highlighted four studies showing nocturia as a subclinical symptom of vascular problems, with or without hypertension. He conveyed that nocturia is predictive of cardiovascular events in younger men and mortality in older men.

Dr. Lazar stated that increased brain natriuretic peptide (BNP) levels during sleep promote urine output. However, BNP is released in response to increased ventricular and arterial tension. He proposed that the elevation of BNP may be a mechanism for dealing with volume overload. He spoke on the importance of decision-making in terms of medical therapy for individuals with nocturia.

Dietary sodium is a stimulus for BNP release, and sodium uptake contributes to increased urination. Dr. Lazar spoke on the application of this knowledge to motivate patients to decrease their dietary salt intakes. He has used sodium restriction effectively to treat nocturia. He proposed that many of his patients experience volume overload; thus, edema may not accurately represent extracellular fluid. Dr. Lazar suggested that sleep disruption associated with nocturia may worsen cardiovascular disease and congestive heart failure. He concluded by challenging attendees to question their assumptions regarding nocturia and cardiovascular health.

Mental Health
C. Neill Epperson, M.D., University of Colorado

Dr. C. Neill Epperson, a psychiatrist, has spent 20 years studying the effects of hormones in the brain. She stated that her career mission is based on the centrality of the brain with regards all other areas of health. Dr. Epperson explained that severe LUTS increases the risk of clinical depression and anxiety. She emphasized also the strong connection between the bladder and brain. Diseases of these systems are likely to affect one another. She noted that this connection is particularly important for postpartum women but is present across the lifespan.

Approximately 38 percent of the population will report two or more adverse childhood experiences, and adverse childhood experiences increase the risk of physical and mental illness. In a study, Dr. Epperson demonstrated a significant relationship between adverse childhood experiences and LUTS in perimenopausal women. She identified physical abuse, emotional neglect, parental divorce, and domestic violence as factors influencing LUTS. Dr. Epperson noted that nocturia was most bothersome symptom and was greater in individuals with two or more adverse childhood experiences.

Dr. Epperson stated that negative affective measures appear to be related to LUTS. One potential mechanism is a blunted cortisol response. She emphasized the importance of mental health treatment for individuals with bladder disorders. Treatment of both systems simultaneously may lead to better outcomes.

Geriatrics
Lona Mody, M.D., University of Michigan

Dr. Lona Mody conveyed that throughout her career, she has employed several methodologies to reduce urinary catheter complications in older adults. Priority areas are based on the perspectives of patients, nurses, and caregivers. Dr. Mody outlined geriatricians' major priorities: function, cognition, avoidance of harm, healthy aging and QOL, patient preferences, understanding resiliencies, and a team approach.

Although she is a patient-oriented clinical researcher, Dr. Mody's work spans the spectrum of basic science and policy. She collaborates with researchers with expertise in microbiologic, molecular, and genomic approaches to inform her clinical studies. She collaborates also with policy and practice experts to implement her clinical methods to a broader population.

Dr. Mody is working to reduce urinary catheter–associated complications in older adults. Patients with implanted devices—feeding tubes, urinary catheters, or both—show an increased risk of UTI. The patients were infected by multi-drug-resistant organisms (MDROs), which are difficult to treat. The risk of MDRO infection was greater in patients with urinary catheters than in those with feeding tubes.

Dr. Mody carried out simple interventions across nursing home residences, training providers to use gowns and gloves when treating high-risk patients. The practices resulted in a reduction of infections. An economic evaluation demonstrated that savings from readmission counter the additional care costs, but these savings are not realized by the nursing homes that bear the cost of the interventions.

These practices have been applied to multiple nursing homes across the United States; catheter-associated UTI rates declined significantly in these facilities. Other researchers have reported similar results.
Dr. Mody affirmed the importance of considering clinical research within the context of a network, and she underscored the value of collaboration between hospitals and nursing homes. She noted that teamwork, communication, simplicity, and thorough investigative work are critical to the success of research aimed at policy change.

References

1. Mody L, Krein SL, Saint S, et al. A Targeted Infection Prevention Intervention in Nursing Home Residents with Indwelling Devices: A Randomized Clinical Trial. *JAMA Internal Medicine* 2015; Vol 175(5):714–723.
2. Saint S, Greene MT, Krein SL, et al. A Program to Prevent Catheter-associated Urinary Tract Infection in Acute Care. *New England Journal of Medicine* 2016; Vol 374:2111–19.
3. Wang J, Foxman B, Mody L, Snitkin ES. Network of Microbial and Antibiotic Interactions Drive Colonization and Infection with Multidrug-Resistant Organisms. *PNAS* 2017; Vol 114(39):10467–72.
4. Wang L, Lansing B, Symons K, et al. Infection Rate and Colonization with Antibiotic-Resistant Organisms in Skilled Nursing Facility Residents with Indwelling Devices. *European Journal of Clinical Microbiology & Infectious Diseases* 2012; Vol 31(8):1797–1804.

Discussion

- In response to a question about patient reporting and predictability of nocturia, Dr. Lazar stated that some patients report consistent symptoms, while others report variation. In his opinion, Dr. Lazar said that patients likely cross a salt sensitivity "threshold" in which sodium overload results in increased nocturia.

- Dr. Margot Damaser asked panelists and attendees to identify fields whose representation would have added value to the panel. Suggested medical fields were orthopedics, general surgery, neurology, gastroenterology, immunology, microbiology, and pediatrics. Other suggested representatives were payers, product developers, tobacco cessation experts, communicators, companies involved in electronic health records, and marriage and family counselors.

Measurement Science and Application in Benign GU Conditions
Melissa Constantine, Ph.D., University of Minnesota

Dr. Constantine declared that research questions must be defined succinctly to provide a conceptual definition that determines the measurement procedures. She presented a multidimensional model of bladder health, whose primary components are storage, emptying, and psychosocial factors. Each primary component is subdivided into secondary and tertiary subcomponents for a robust deconstruction into specific items that can be measured or reported.

Dr. Constantine emphasized that all measurements contain error. Researchers should examine the potential sources of error and attempt to minimize each source at all stages of the research design. This rigorous approach strengthens confidence in the measurements and increases the internal reliability of the study. Multi-item operationalization strengthens the study rigor by testing and refining multiple metrics to answer a question. For example, researchers can propose 20 questions to gauge how well a patient is coping with symptoms; eventually the researchers can reduce these to three key questions that gauge the metric. Dr. Constantine continued that a multi-trait, multi-method matrix of measurement that incorporates multiple data sources produces a gold standard of validity. Data sources include patients, providers, medical records, and objective tests.

Regarding issues related to GU measurement, Dr. Constantine pointed out that a patient's decision to seek care depends on self-perceptions of health. She expressed that care-seeking should begin when a patient is still relatively healthy. Patients are less likely to seek care while still coping, but treatments are less likely to succeed for patients who begin care only when they can no longer cope with their worsening condition. Researchers should consider populations along the full spectrum of bladder health, instead of focusing on patients at urology clinics who have the worst symptoms.

Mapping the Path Forward as a Group
Tamara Bavendam, M.D., M.S., NIDDK
Jenna Norton, M.P.H., NIDDK
Sonya Brady, Ph.D., University of Minnesota School of Public Health
Margo Damaser, Ph.D., Cleveland Clinic

Dr. Brady explained that the afternoon's discussions would focus on ways of conceptualizing the hidden burden of GU conditions, which impact numerous aspects of society. She reminded attendees that

Dr. Bavendam had described both upstream contributors (e.g., diabetes, obesity, cognitive impairment) and downstream consequences (e.g., product use, decreased activity, obesity) of GU conditions.

Dr. Brady spoke on the importance of leveraging studies to gain a greater understanding of the prevalence of GU conditions. A brief measure of GU conditions is necessary to encourage reporting in studies. She asked participants to work in small groups to create a short list of questions to identify GU conditions. She also asked that they identify a single question that could be used to identify individuals requiring further screening. Dr. Brady asked the participants to note the challenges they encountered in developing questions.

Table 1 (Trigger Question)

- Does anything about your bladder or pelvis bother you?

Comments/Solutions

- Incorporate a visual tool, such as a check list or diagram, where people could mark the location of their problem.
- Patients are not always aware of the specific location of the bladder or pelvis in the body; others may not be concerned.

Table 2 (Three Questions)

- Do you pee or leak when you don't want to? Does it bother you?
- Do you have trouble peeing? Does it bother you?
- Do you have any pain when you pee? Does it bother you?

Table 3 (Economics Questions)

- What are the out-of-pocket costs, impact to labor markets, caregiver costs, and costs of leisure activities?

Table 4

- What is normal and what is expected for a given age?
- What might a person expect from treatment?

Recommendations

- Ask people to compare their health relative to others in their age group.
- Evaluate what is realistic in terms of treatment outcomes for a specific age group to generate realistic treatment options.

Table 5

Recommendations

- Use visuals to relay the message (e.g., show a picture of someone running to the bathroom).

Table 6

- How are people going to interpret different terms (e.g., urinary or anatomy)?
- Do you have problems with urination or having sex?

Table 7

- Have you passed or been told you had a kidney stone?

Comments
- Distinguish between sex and bladder questions.
- There are three domains to these types of questions: stones, bladder storage and emptying, and sexual functions.

Discussion

Participants discussed conversation trigger questions, in general. In discussion the following points were made:

- The trigger question should invoke a yes or no answer.
- Consider addressing health literacy issues with patients early.
- The Patient Perception of Bladder Conditions is a general screening question for UI. There are six response categories (continuum of self-perceived severity) followed by two in-depth questions. Data revealed that about half of women who reported no problem actually have some form of LUTS, suggesting that a single question would not be beneficial.
- The question timeframe should vary by condition, but also depends on how the information is being used. One year seems reasonable.
- Problems like kidney stones and UTIs are cyclical, so it would be difficult to choose an optimal time to ask a question.
- The aim is to determine the GU burden in non-urological studies in a given population.
- Some companies, such as Tonic Health, specialize in integrating patient-facing questionnaires in waiting rooms.

Dr. Brady asked whether all the impacts of GU conditions were being captured in the existing framework. In discussion the following points were made:

- Caregiver impact can be more explicitly indicated in the social impact section of the framework.
- Broaden the genetic substrate to include genomics and other ’omics.
- Interpersonal relationships, such as one-on-one relationships with providers, and health care systems can be highlighted. Spouses or partners and families can be considered separately and individually.
- Given the demographic changes in the United States leading to a larger number of older adults who will eventually experience some of these conditions, planning should be focused on mobility and resources for communities.
- Dr. Brady summarized that specific information about the impact of GU conditions should be emphasized. Once the impact is determined, persons in positions of power (e.g., policy makers) need to react and respond thoughtfully in providing opportunities, not constraints, for individuals experiencing these conditions.

Ms. Norton presented a model depicting how inflection points along the pathway from healthy bladder to symptoms to treatment and/or compensatory behaviors impact the burden across domains (e.g., QOL, society, the environment, comorbid conditions). She suggested that researchers may be able use the inflection points to understand the significant burdens imposed by GU conditions. Ms. Norton invited attendees to provide feedback on the model.

Discussion

- Ms. Norton agreed with the suggestion that some compensatory behaviors may not impart negative effects but clarified that patients who seek compensatory behaviors outside of the health system may lack the benefits of medical care. Self-management, in contrast, occurs after consultations with a provider. Another suggestion was to consider self-management and compensation in the context of the environment.

- A participant affirmed the importance of increasing and reducing protective and risk factors, respectively, at the first inflection point (i.e., at the beginning). He suggested that this strategy will help reduce the downstream effects of burden.

- Another participant pointed out that comorbid conditions create complications because of their complexity. A third participant emphasized the importance of capturing myriad improvements downstream from early behavior or risk factor changes.

Ms. Norton moved the discussion to ways that personas, which are fictional but realistic characters, may be used to illustrate an individual's disease trajectory and conceptualize the burden of GU conditions. Personas humanize discussions around health care and can help people who do not know people with GU conditions understand the impacts of the conditions. This concept may be used to reduce the stigma surrounding GU conditions and to capture diversity among patients. The personas could be used in context of the inflection points to show how the burden of a GU condition might change by following different pathways along the model.

Discussion

- A participant suggested that personas may be more impactful if they were based on real-life patients, with identifying details omitted for privacy. Ms. Norton noted that in her experience, personas have resonated even when based on fictional people and noted that creating personas from stories gathered from multiple individuals can allow one persona to capture multiple issues. She noted the potential difficulty of obtaining real-life stories that meet all necessary criteria.

- Ms. Norton emphasized the interdisciplinary value of personas, noting that they can be used to inform clinicians, public health officials, and educators.

Dr. Damaser asked participants to consider how their participation in the workshop has impacted how they will conduct their research, practice, and advocacy. She shared that participating in the workshop increased her desire to collaborate with other investigators to translate basic research into clinical studies and practice. She emphasized the importance of defining burden to determine outcome measures.

Discussion

- A participant stated that she intends to consider LUTS as a disease, rather than a symptom. She emphasized the importance of defining diseases to encourage individuals to seek treatment.

- Another participant stated that her clinic releases two questions on a different topic each year. She intends to bring forward questions related to GU conditions to that forum.

- Dr. Jill Huppert (AHRQ) stated that she is seeking help to implement nonsurgical interventions for UI in women. She noted that she plans to use resources provided by speakers in drafting her plan. Another attendee stated she plans to review and improve the PCORI portfolio in this area.

- A participant noted that he was motivated by Dr. Lazar's presentation to discuss with his team the inclusion of nocturia as a risk factor for heart failure. Another participant discussed plans to convey the discussed concepts with his team and to pursue collaborations with other attendees.

Ms. Norton closed the Mapping the Path Forward discussion with steps for how the group could move forward as a whole. She suggested developing one or more manuscript(s) based on the workshop's discussions, as well as creating personas to exemplify different types of GU conditions. She invited attendees interested in either the manuscript or the personas to contact her. Dr. Bavendam emphasized the importance of disseminating the discussed concepts to a broad audience. Ms. Norton also noted the possibility of working together to develop and add a GU supplement to AHRQ's Medical Expenditures Panel Survey (MEPS). She concluded by encouraging participants to leverage the connections they have made over the past 2 days.

Discussion

- A participant pointed out that the CDC website lacks information on GU conditions.

- Dr. Salive pointed out that the NIA-sponsored Health and Retirement Study includes questions related to incontinence. He suggested that additional data regarding GU conditions be added to the study.

- Dr. Bavendam commented that NIDDK R01 grants can be used for ancillary studies.

- Another participant suggested Healthy People might present another opportunity for bringing focus to GU conditions.

Closing Remarks

Dr. Bavendam thanked organizers, speakers, and attendees for their participation in the workshop. She stated her confidence that the workshop has initiated future progress for the field.

Adjournment

Dr. Bavendam adjourned the meeting.