

Urology Interagency Coordinating Committee Meeting

Urology Community Partnerships for Research

Hybrid Meeting June 25, 2024

Meeting Summary

Welcome and Introductions

Jenna Norton, Ph.D., M.P.H., Program Director, Division of Kidney, Urologic, and Hematologic Diseases (KUH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)

Dr. Jenna Norton welcomed attendees to the meeting of the NIDDK Urology Interagency Coordinating Committee (UICC). She explained that the UICC was mandated by Congress to encourage cooperation, communication, and collaboration across federal agencies involved in benign urology research, care, and public health activities. The goal of the UICC is to improve coordination of the federal response to urologic conditions. Dr. Norton invited the participants to introduce themselves.

Opening Remarks

Robert Star, M.D., Director, KUH, NIDDK, NIH

Dr. Robert Star explained that the purpose of the meeting was to consider ways to enhance innovations in urologic health. He emphasized that the meeting participants should be attentive to one another's ideas and perspectives and noted that the well-being of patients should always be the top priority. Dr. Star acknowledged that budget constraints might limit the implementation of the many new and exciting concepts in the field. Outcomes of current and future investments in urologic research must be maximized, and a consensus message should be used to educate interested parties about the importance of this research.

Snapshot of Urology Research at NIDDK

Ziya Kirkali, M.D., Program Director, KUH, NIDDK, NIH

Dr. Ziya Kirkali provided an overview of benign urologic research at NIH and NIDDK. This research focuses on the development, function, and structure of the genitourinary (GU) tract; GU repair after injury; and such conditions as benign prostatic hyperplasia (BPH), chronic prostatitis/chronic pelvic pain syndrome, erectile dysfunction, interstitial cystitis/bladder pain syndrome (IC/BPS), lower urinary tract symptoms (LUTS), overactive bladder (OAB), underactive bladder, urinary incontinence, urinary stone disease, urinary tract infections (UTIs) and other infections, and urologic chronic pelvic pain syndrome (UCPPS). Urologic research applications are submitted to more than a dozen NIH institutes, centers, and offices (ICOs); NIDDK and the National Cancer Institute receive most of these submissions and are the primary sponsors of urologic research at NIH. Dr. Kirkali presented a graph of extramural funds awarded annually by KUH. Total KUH funding has increased steadily from \$383 million in 2014 to \$508 million in 2023. In fiscal year 2023 (FY23), approximately 70 percent of the awards supported kidney-related research, and urology and hematology research each received about

15 percent of the total. Almost 60 percent of the urology funding supported investigator-initiated grants (R01). A quarter of the urology funding was awarded to U01 initiatives and research consortia (16 percent) and training grants (9 percent), and the additional funding supported small business grants (8 percent), Urologic Disease Centers (5 percent), and other mechanisms.

NIDDK supports several consortia involved in urologic research and care (including the <u>Multidisciplinary</u> <u>Approach to the Study of Chronic Pelvic Pain [MAPP] Research Network, Prevention of Lower Urinary</u> <u>Tract Symptoms [PLUS] Research Consortium, Symptoms of Lower Urinary Tract Dysfunction Research Network [LURN], and Urinary Stone Disease Research Network [USDRN]</u>), as well as <u>Urologic</u> <u>Diseases in America</u> [a urologic epidemiology contract]).

NIDDK supports the <u>Collaborating for the Advancement of Interdisciplinary Research in Benign Urology</u> (<u>CAIRIBU</u>) program, a community of U54 O'Brien Urology Centers, the P20 Exploratory Centers for Interdisciplinary Research in Benign Urology, and the Multidisciplinary K12 Urologic Research (or KURe) and Urological Epidemiology (or KEpi) Institutional Research Career Development Programs. KUH training and career development mechanisms are available to support early stage researchers at multiple levels, including high school and undergraduate studies (R25 awards), graduate and medical school (F30 and F31 awards), postdoctoral studies (F32 and K01 awards), and junior faculty (K01, K08, and K23 awards). Bridge funding, institutional training awards, and a loan repayment program are also available. In FY22, KUH supported 482 trainees and scholars.

Dr. Kirkali reiterated Dr. Star's introductory remarks about including patients during all stages of research and emphasized that NIDDK purposefully centers the patient voice in its programs and activities. He reviewed proposals for future initiatives to address key gaps in urological research and care.

- Towards a Personalized Approach to BPH/LUTS: Connecting Molecular Pathology to Lower Urinary Tract Symptoms: This initiative would aim to understand differential patient responses to BPH/LUTS therapy and apply personalized solutions to address this group of burdensome and costly illnesses. The goal is to comprehensively assess clinical BPH/LUTS phenotypes by leveraging LURN resources to collect and interrogate biological samples from men with obstructed BPH/LUTS who require therapy. Deep clinical phenotyping of this cohort (including bladder and prostate biopsies) will enable subgrouping based on biological characteristics and help inform the selection of targeted interventions.
- <u>Clinical Trials to Inform Management of Urologic Chronic Pelvic Pain Syndrome Study</u> (<u>COMPASS</u>): COMPASS would conduct state-of-the-art clinical trials for UCPPS that overcome the limitations of past studies by identifying and enriching for phenotypic subgroups, selecting personalized interventions, and implementing improved measures and innovative trial designs. The expanded evidence base of insights into patient phenotypes and associated clinical outcomes from the MAPP Research Network and the broader field will be incorporated in COMPASS study designs.
- <u>PheNOtyping Women at Risk for Lower Urinary Tract Symptoms (NO-LUTS)</u>: The NO-LUTS initiative would extend the work of the PLUS consortium by employing updated clinical phenotyping tools to collect population-based data that will provide important information about bladder health in women across the lifespan—with a focus on perimenopause, a key transition for bladder health. The NO-LUTS longitudinal cohort study will identify potential risk and protective factors for LUTS and provide a new evidence base for individualized prevention and treatment strategies.

• <u>Management of Asymptomatic Renal Stones (MARS)</u>: The MARS study would address whether interventions (i.e., ureteroscopy or high-energy shock wave lithotripsy) lead to improved outcomes compared with active surveillance in people with asymptomatic renal stones. MARS would implement an artificial intelligence (AI)/machine learning (ML) approach to using multidimensional data to identify best management options for individuals with different characteristics and identify optimal follow-up strategies for active surveillance of people with asymptomatic renal stones.

Dr. Kirkali informed the meeting participants that NIDDK will be celebrating its 75th anniversary in 2025 and added that details of anniversary events will be shared in the future.

Future Urology Research and Activities across Federal Agencies *Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)*

Candace Tingen, Ph.D., NICHD

Dr. Candace Tingen began her presentation by emphasizing the importance of co-operative funding and collaboration between ICOs. She pointed out that research related to reproductive-age women—including urogynecology—is a focus of the Gynecologic Health and Disease Branch at NICHD. NICHD sponsors the <u>Pelvic Floor Disorders Network</u> of investigators studying uterine and pelvic floor prolapse and accompanying side effects. NICHD also has a gynecology pain portfolio that might overlap with urological pain—for example, when endometriosis affects the bladder. In March 2024, the Biden Administration announced a new executive order to expand upon the established White House Initiative on Women's Health Research. In response to the executive order, NIH has pledged to launch an NIH-wide effort to close gaps in women's health research across the lifespan (e.g., the impact of perimenopause and menopause on heart health, brain health, and bone health). This coordinated NIH-wide effort will be co-chaired by the NIH Office of the Director, the Office of Research on Women's Health, and institute directors from the National Institute on Aging (NIA); National Heart, Lung, and Blood Institute; National Institute on Drug Abuse; NICHD; and National Institute on Arthritis, Musculoskeletal and Skin Diseases. Dr. Tingen remarked on the success of NICHD small business awards in supporting the development of medical devices related to urogynecology.

Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)

Roger Wiederhorn, M.D., FDA

Dr. Roger Wiederhorn described the FDA's efforts to establish a drug development plan for IC/BPS, which has been a challenge to define, diagnose, and treat. Classic IC was described in 1918 as bladder pain related to bladder filling and a cytoscopic bladder lesion. The original NIDDK criteria for IC did not include all patients with similar symptoms. Currently, these criteria have been expanded to define BPS/IC (bladder pain syndrome/interstitial cystitis) designation. The patients with BPS/IC are a heterogenous population. The etiology and pathogenesis of IC/BPS are not understood, and patient populations and diagnostics vary worldwide. No new drugs have been authorized for this indication since Elmiron was approved in 1996. Cytoscopies do not always reveal inflammation or pathology in patients with IC/BPS, and the understanding of this condition has relied on expert opinion. Worldwide harmonization has coalesced around clinical definitions of Hunner's lesion and non-Hunner's BPS/IC. The current European and U.S. clinical definitions include chronic pain or discomfort related to the bladder, accompanying urinary symptoms, and the exclusion of other diseases or disorders with similar presentations.

In response to an advisory committee recommendation, the FDA published *Interstitial Cystitis/Bladder Pain Syndrome: Establishing Drug Development Programs for Treatment*, a draft guidance for industry, in December 2019. An updated version was published in June 2023. The document suggested enrollment criteria (e.g., bladder pain or discomfort with accompanying LUTS lasting longer than 6 months, endpoints of sufficient severity to observe clinically meaningful improvement with a drug, rigorous evaluation to exclude other conditions, special circumstances for Hunner's lesions); effectiveness endpoints for IC/BPS trials (e.g., ideal treatment should improve both bladder pain/discomfort and LUTS); and the inclusion of patient-reported outcomes (e.g., the development of fit-for-purpose instruments was encouraged). The guidance recommended two randomized, double-blind, placebo-controlled studies lasting longer than 6 months to adequately assess the outcomes because of intermittent flares. Sponsors should prespecify how to handle flares and prespecify the use of rescue medications in the trial protocol.

National Institute on Aging

Alexis Bakos, Ph.D., M.P.H., RN, NIA

Dr. Alexis Bakos presented an overview of urology research supported by NIA. Overall, NIA's area of focus spans basic, translational, clinical, and behavioral research in all areas that affect older adults. Most of NIA's current urology portfolio consists of large grants (R01 awards), but NIA accepts small grant applications (e.g., R03 and R21 awards) and career development applications (i.e., K awards). Additionally, NIA funds the Society for Pelvic Research conference grant and has discussed diversity supplement programs to increase diversity in the pelvic research community. Dr. Bakos noted that Congress designated NIA the lead NIH institute for palliative care in its FY24 appropriations budget. Dr. Bakos clarified that, contrary to popular belief, palliative care encompasses more than end-of-life care. She explained that palliative care ideally should begin at the time of diagnosis of any serious or life-threatening illness but can be offered at any stage of the disease trajectory. The congressional report language encourages NIA to implement an NIH-wide strategy to expand and intensify national research programs in palliative care across the lifespan. The funding will support career development activities for urologists to assess and address basic palliative-care needs, as well as studies that investigate how integration of palliative care affects patient outcomes.

Agency for Healthcare Research and Quality (AHRQ)

Lionel Bañez, M.D., AHRQ

Dr. Lionel Bañez provided an overview of AHRQ's ongoing systematic review of the medical management of kidney stones. The mission of AHRQ is to produce evidence to improve health care and make it more accessible, equitable, and affordable. AHRQ works with the U.S. Department of Health and Human Services and other partners to ensure that the evidence is understood and used effectively through efforts like the Evidence-based Practice Center (EPC) Program. The EPC-produced evidence reports are designed to serve as a trustworthy source of independent and unbiased information to inform evidencebased decisions for clinical guidelines, health policies, research funding opportunities, and medical coverage. The American Urological Association (AUA) nominated the topic on medical management of kidney stones, with the goal of updating related clinical practice guidelines that were last published in 2014. The systematic review-which was funded by the Patient-Centered Outcomes Research Institute (or PCORI) and initiated in May 2024-will cover several key questions regarding the assessment and treatment of kidney stones. A detailed preliminary scope of the review is available online, and the public comment period on the draft key questions concluded on June 19, 2024. Next steps include developing the protocol for conducting the systematic review, which involves soliciting unpublished data from the public and performing the review, including authoring of a draft evidence report that will be subject to peer and public review. The draft report will be available for a 45-day public comment period in early summer 2025. The final report is expected in September 2025. Dr. Bañez explained that organizations can submit topics to AHRQ, which will prioritize them for review. He shared several funding opportunities: AHRQ Health Services Research Projects (R01) (PA-24-154), AHRQ Small Health Services Research

Grant Program (R03) (<u>PA-24-155</u>), and AHRQ Health Services Research Demonstration and Dissemination Grants (R18) (<u>PA-24-156</u>).

Discussion

• The meeting participants discussed ways to integrate urology research into the umbrellas of larger research programs (e.g., Alzheimer's disease, cancer, obesity) with NIA and other ICOs to increase the opportunities for funding. Dr. Star emphasized the need for organizations and investigators to contact NIH program officers for information about pay lines and best fits for their research applications. Dr. Bakos encouraged researchers to contact more than one NIH ICO per project.

American Urogynecologic Society (AUGS)

Catherine Bradley, M.D., MSCE

Dr. Catherine Bradley explained that AUGS is a nonprofit organization representing professionals dedicated to treating female pelvic floor disorders. AUGS membership currently comprises more than 2,000 practicing physicians, nurse practitioners, physical therapists, nurses and health care professionals, and researchers from many disciplines around the globe. Pelvic floor disorders-including bladder and pelvic floor pain, fecal incontinence, LUTS, pelvic organ prolapse, recurrent UTIs, and sexual health issues—are common, embarrassing, and often debilitating. These disorders exert profound emotional, economic, and societal effects and serve as a burden on the health care system. Dr. Bradley shared the results of a recent study showing that 75 percent of NIH funding supports diseases that primarily affect men. NIH funding for pelvic floor disorders decreased by 30 percent between 2009 and 2019. In FY17-FY19, 10 percent of NIH's research budget was dedicated to women's health research; of that total, almost 80 percent was allocated to studies of contraception and pregnancy. AUGS recognized the importance of evaluating the health conditions women face throughout their lives, including conditions that become more prevalent in the post-reproductive years. To address this gap, AUGS developed the National Urogynecology Research Agenda, which was published in 2023 and overseen by an AUGS scientific committee, developed by more than 50 writers across 9 content areas, reviewed by NIH-funded AUGS members, and supported by 14 societies and patient organizations. Through this effort, six research priorities were identified, including the following:

- LUTS: Conditions categorized as LUTS include stress urinary incontinence, OAB, urgency urinary incontinence, and failure to empty. The report recommends characterizing LUTS phenotypes and investigating their associations with treatment responsiveness, evaluating the potential synergy of combined therapies, improving the understanding of how pregnancy and the peripartum period lead to LUTS, examining predisposing factors (e.g., genetics, family history, neurologic symptoms, pelvic floor muscle function, labor, route of delivery), and evaluating the optimization of existing treatments and novel approaches.
- **IC/BPS:** IC/BPS is a group of diseases with multifactorial (e.g., allergic, autoimmune, immune, neuroendocrine) etiology that affect women five times more than men, are associated with poor quality of life, and result in a massive economic burden. Research priorities identified in the report include developing biomarkers for accurate diagnosis, comparing the effectiveness of different treatments using standardized outcome measures, improving the understanding of connections between IC/BPS and mental health issues, and examining the effects of the bladder microbiome on IC/BPS pathogenesis.
- **Recurrent UTIs:** Recurrent UTIs are the most common infection in adults. They primarily affect women and exert a large health care burden. The current limited understanding of the role of

bladder microbiome in GU health has been a barrier to distinguishing between symptomatic UTIs and healthy bladder flora. The report recommends characterizing healthy and diseased bladder states, investigating patient-centered outcomes and disparities in UTI care, and developing a point-of-care test to rapidly and accurately diagnose UTIs and distinguish UTIs from other causes of frequent and painful urination.

AUA Office of Research

Steven Kaplan, M.D.

Dr. Steven Kaplan announced that Dr. Henry Lai will be replacing him as AUA's Research Council Chair. He reviewed recent AUA activities, including sponsorship of the 2024 <u>Innovation Nexus</u> <u>Conference</u> to expand the involvement of innovators and ignite discovery in urology. AUA plans to host an <u>Innovation Nexus Boot Camp</u> in September 2024. The boot camp will enable the mentorship and collaboration that is required to develop a healthy research ecosystem. Dr. Kaplan noted that AUA's Research Education, Conferences and Communications Committee identified several research education needs, especially related to the acquisition of research funding and clinical trial design and setup. The Committee also noted a strong desire for an AUA collaborative network, specifically in oncology. AUA's Research Grants and Investigator Support Committee Task Force identified several gaps in urologic research, including understanding social and environmental drivers of urologic health and the strategies that can improve and sustain urologic health for underserved patient populations; whether precision medicine approaches can be applied to bladder dysfunction; how material and tissue engineering can be used to improve patient outcomes; whether a better fundamental understanding of fibrosis can be used to prevent and treat diseases of the genitourinary tract; and whether a urine-based, lab-on-a-chip technology can be developed to provide better detection and reduce the burden of common urologic diseases.

Dr. Kaplan summarized AUA research funding in 2023. Approximately \$1.3 million was awarded to 27 continuing and 34 new early career investigators (i.e., 14 medical students, 6 residents, 13 postdoctoral fellow, and 1 early career faculty member). Grantees included 17 new female awardees and 9 awardees from groups that are underrepresented in the field of medicine. Funding sources included endowments, partnerships with industry and nonprofit organizations, and draw-down funds. Dr. Kaplan highlighted the range of <u>Urology Care Foundation Research Grants</u> and noted that the upcoming letter-of-intent deadline for the Rising Stars award is July 2, 2024.

Research on Calculus Kinetics (R.O.C.K.) Society

Nicole Miller, M.D., and Kristina Penniston, Ph.D.

Drs. Nicole Miller and Kristina Penniston reviewed R.O.C.K. Society research priorities. Dr. Miller explained that the goal of the R.O.C.K. Society is to support research on the basic mechanisms involved in the formation of urinary calculi. Members are scientists and clinicians from diverse fields who are elected based on their contributions to urolithiasis research. Urinary stone disease is a common problem, and its incidence is rising in women and in Black adults and children. The presentation of urinary stone disease varies from highly symptomatic, frequent, and recurrent to asymptomatic and one-time stone formation. Disparities in the treatment and management of urinary stone disease have been identified, and the disease is a risk factor for chronic kidney disease.

Dr. Penniston noted that the etiology of stone formation is multifactorial, with input from genetic, anatomical, metabolic, hormonal, and environmental inputs. Underlying comorbidities and certain medications also contribute to urinary stone disease. Dr. Penniston reviewed basic needs in urolithiasis research, including mechanisms underlying stone formation, attachment, and migration in the kidney; genetic and epigenetic factors that contribute to stone formation; factors that affect the composition of different stones; and the effects of microbial, dietary, and environmental influences and interactions. Clinical research needs in risk assessment include improving on the 24-hour urine collection method as

the primary risk and diagnostic tool; investigating the inclusion of nonurinary risk factors and biomarkers in the overall risk profile; developing more effective algorithms for patient phenotyping and noninvasive techniques for assessing stones *in vivo*; and advancing accurate tools to assess dietary patterns. Clinical research needs in the area of therapeutics include optimizing patient uptake and adherence to recommendations, developing strategies for personalized nutrition therapy, testing methods to optimize uptake and use of up-to-date stone prevention recommendations and guidelines, investigating urinary alkalinization strategies and whether urinary acidification is effective in struvite stone prevention, and determining whether existing drugs can be repurposed for stone prevention. Dr. Penniston emphasized "big picture" research needs, especially strategic support for multi-institutional and interdisciplinary research teams (particularly those including M.D.–Ph.D. collaborations and community–investigator partnerships) and funding for investigators proposing novel clinical study designs.

Society for Basic Urologic Research (SBUR)

William Ricke, Ph.D.

Dr. William Ricke discussed aspects of BPH research prioritized by SBUR. He reviewed different classifications of urethral obstruction, including hyperplasia due to BPH nodules (treated with 5α -reductase inhibitors) and pressure from smooth muscle contraction (treated with α -blocker therapy) or fibrosis (possible treatment with antifibrotic agents). He noted that precision medicine presents a major opportunity in urologic research. AI approaches and advanced imaging techniques and omics will be required to stratify patients based on phenotype, develop new biomarkers, and identify relevant cell types and new molecular targets. Dr. Ricke emphasized that the effort to better understand the anatomical, cellular, and molecular mechanisms underlying BPH will require support for a new generation of diverse researchers who must be identified early and supported throughout their careers. Societies and nonprofit organizations will be necessary to promote awareness of BPH; consortiums, portals, and biorepositories will be needed to combine efforts to tackle common problems and improve translational BPH science. Dr. Ricke highlighted recent efforts to develop mouse models of the effects of diet and exercise, including studies demonstrating that dietary restriction and increased exercise results in decreased urinary frequency in older mice.

Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) *A. Lenore Ackerman, M.D., and Christopher J. Chermansky, M.D.*

Dr. Christopher Chermansky provided an overview of SUFU. The mission of SUFU is to optimize the care of women, men, and children with lower urinary tract dysfunction and/or pelvic floor disorders through education, research, and involvement in health care policy. SUFU research areas of interest include female pelvic floor disorders, neurourology, and lower urinary tract dysfunction. SUFU also fosters interdisciplinary dialogue and communication, promotes the development of young scientists, and supports scientific, educational, and professional activities through publications, meetings, and activities. SUFU membership currently includes 438 active members, 93 affiliate members, and 53 senior members. Of 584 total members, 543 reside within the United States. The SUFU Research Network (SURN) is a collaborative entity of SUFU members that promotes and conducts high-quality multicenter clinical studies related to SUFU areas of interest, provides access to research opportunities and mentorship for interested SUFU members, and fosters research and the development of future clinical trials. One SURN study evaluated antibiotic use and UTI rates for patients with idiopathic OAB receiving onabotulinum toxin A. The second study described outcomes of surgical management of female urethral stricture disease. SURN has published four manuscripts based on these studies. Finally, SUFU has partnered with AUA to put forth joint guidelines for the diagnosis and treatment of idiopathic OAB, the surgical treatment of female SUI, and the management of neurogenic lower urinary tract dysfunction.

Dr. A. Lenore Ackerman reviewed SUFU research priorities in the areas of foundational research (e.g., understanding the causes of functional urologic disorders, gaining insights into UTIs), translational research (e.g., phenotyping subtypes of common LUTS, defining the interplay of urologic conditions with other comorbidities, identifying biomarkers of urologic diseases), and clinical research (e.g., defining the early events in urinary disease progression to facilitate earlier interventions, identifying populations at highest risk of symptomatic deterioration before the damage becomes irreversible, standardizing condition-specific clinical research outcome measures for the evaluation of novel therapeutic approaches, investigating multimodal and multidisciplinary therapy/treatment approaches for functional urinary conditions). SUFU also acknowledges that developing the clinical urologic research workforce is essential for these efforts. Support for the careers of existing and future urologists studying NIDDK - prioritized conditions is an essential need, as is enhanced inclusion of urologic clinicians in foundational research to inform models of disease

Discussion

- In response to a question about which NIH institutes fund chronic infectious disease research, Dr. Chris Mullins answered that both NIDDK and the National Institute of Allergy and Infectious Diseases (NIAID) fund these research programs. NIDDK supports projects that investigate clinical aspects of these diseases, and NIAID funds investigations that focus on the pathological agent. Dr. Mullins acknowledged that the separation between these two categories cannot always be well defined.
- The group discussed positive and negative aspects of research programs that overlap multiple ICOs. Dr. Star shared the example of hematology, which experienced success with funding after being embedded within multiple NIH institutes. Dr. Tracey Rankin noted that NIH's goal is to find the best scientific home for a project based on the programmatic expertise of the different ICOs.
- Dr. Shannon Givens asked about common patient and caregiver misconceptions about bladder issues in pregnant women. She commented on the difficulty of distinguishing between abnormal bladder symptoms and symptoms that are a result of the standard physiological changes that occur during pregnancy. Dr. Bradley emphasized that patients must determine which symptoms are abnormal and whether symptoms are manageable. She noted that certain symptoms during pregnancy might be predictive of increased disease risk that does not resolve after childbirth.
- Dr. Debbie Gipson asked about unique pressures on urologists that might be leading to their departure from the workforce. Dr. Ackerman described the reduced income and apparent productivity loss experienced by clinicians who perform research in urology. She noted that participation in a study section can lead to losses that total thousands of dollars. Urologists are unlikely to suffer from extreme financial challenges, but they often must manage significant medical debt.

General Discussion

• Ms. Jennifer Solomon explained that the Health Resources and Services Administration's Geriatrics Workforce Enhancement Program (GWEP) aims to educate and train health and supportive care workforces to care for older adults through interdisciplinary collaborations with community, academic, and primary care partners. She noted GWEP activities related to urinary incontinence, including 2-page briefs for any clinician working with older adults, education on nonsurgical management of urinary incontinence and pelvic and physical therapy interventions in older adults, and webinars on urological issues in older adults. One GWEP session trained 50

residents on matters of incontinence. The program's next project will expand into Tribal, underserved, and rural communities.

- Dr. Norton commented on the common needs and concepts across the presentations, an indication of the strong consensus on areas where efforts should begin.
- The group discussed possible approaches for addressing the urology workforce challenge, including adding bridge funding or instituting funding requirements to incorporate clinicians on research teams or within NIH portfolios. Dr. Star suggested that the meeting participants identify smaller areas of success in urology research and workforce development and identify common elements that have contributed to that success. Dr. Ackerman noted that partnerships with industry might be a path forward; however, without sufficient foundational research, it will be difficult to attract attention from biomedical and pharmaceutical companies. Another participant suggested that a co-investigator model, in which clinicians partner with other researchers who have more availability for grant-writing and research activities, might be part of the solution. Dr. Star remarked that positions could be established to translate between research and the clinic, enabling more efficient efforts in both areas.
- The group discussed the need to shift pathological definitions in urology from being symptombased to being phenotype-based. For this to occur, phenotype criteria for different conditions must be standardized.
- Ms. Claudia King shared the Interstitial Cystitis Association's research priorities, including research that would elucidate the role of compromised bladder blood flow and bladder inflammation in provoking central sensitization. Studies to assess psychosocial factors associated with inflammation and central sensitization, as well as rigorous randomized control trials to assess the effectiveness of psychosocial interventions, are recommended. The best methods to help patients manage external stressors that cause symptom flares should be identified. Clinicians should determine how to best disseminate, implement, and sustain evidence-based recommendations for IC. Challenges with food and allergens should be conducted to ascertain their roles in compromised bladder function. Prospective, randomized, double-blind clinical trials of fulguration and cyclosporine should be conducted to determine whether the results are caused by the treatment or by patient expectations.
- Mr. Steve Bain, a patient of the Stone Center at Vancouver General Hospital, expressed interest in AI tools for diagnosing and suggesting treatments and lifestyle changes to address kidney and urological conditions. Mr. Bain has experience with AI-related research; he believes that powerful AI tools will be possible with appropriate data sets. Based on his experience with recurrent kidney stones, more information about his condition and treatment and prevention options would have been beneficial.

Adjournment

Dr. Norton thanked the attendees for their participation. The federal employees were excused, and representatives from the organizations continued their discussions in a closed session.

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