

National Institute of Diabetes and Digestive and Kidney Diseases
Urology Interagency Coordinating Committee Meeting
Urology Community Partnerships for Research

June 25, 2024
11:00 a.m. – 4:00 p.m.)
(Federal Attendees excused at 2 p.m.)

Building 45 (Natcher), Room D, National Institutes of Health
9000 Rockville Pike, Bethesda, MD

SUMMARY FROM PARTICIPATING UROLOGY ORGANIZATIONS AND SOCIETIES

Opening remarks were made by Robert Star, M.D., Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK/NIH and Ziya Kirkali, M.D., also of the NIDDK/NIH.

Dr. Star noted that the NIDDK celebrates its 75th anniversary this year. He said this UICC meeting, as with those before it, was convened in order to foster a more organized response to non-malignant (so-called “benign”) urology research needs. He shared financial data illustrating that urology research funding is not keeping pace with needs, particularly those that are needed to advance science sufficiently to make innovations in urologic health. “I’ve never seen a time like this,” he said while describing NIDDK’s relatively flat budget amidst significant biomedical inflation. Given this challenge, he invited participants to discuss how best to invest in future research to advance urologic health.

Dr. Star shared “concept clearances” from the NIDDK Advisory Council, approved in a May 2024 meeting (available at <https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/concept-clearances>).

- He highlighted prior and ongoing concepts that focused on “[Precision BPH](#),” Phenotyping Women at Risk for Lower Urinary Tract Symptoms ([NO-LUTS](#)), and clinical trials related to chronic pelvic pain syndrome ([COMPASS](#))
- Among new “concept clearances” he cited initiatives aimed at Management of Asymptomatic Renal Stones ([MARS](#)), the [ReKINDLE](#) opportunity (focused on rejuvenating the developmental biology field while also attracting new investigators to urology research), a new opportunity for planning grants to strengthen community-engaged research (details [HERE](#)), and innovative approaches to capitalizing on advances in data science as they relate to urology research (details [HERE](#)).

Dr. Kirkali reviewed the current landscape of urology research at NIDDK and highlighted the contributions of consortia such as MAPP, PLUS, LURN, and USDRN. He also confirmed continuation of:

- George M. O’Brien Urology Cooperative Research Centers and the Urology Centers (CAIRIBU) Interactions Core (details [HERE](#))
- K12 Urological Epidemiologic Institutional Career Development Programs (KUroEpi)

Dr. Kirkali provided more information on the concepts that may represent future funding initiatives in this area (Precision BPH, NO-LUTS, COMPASS and MARS).

Comments from leaders and representatives of several other NIH institutes and federal agencies as well as other NIDDK Program Officers were heard. These included: Candace Tingen, PhD (Eunice Kennedy Shriver National Institute of Child Health and Human Development); Roger Wiederhorn, MD (Center for Drug Evaluation and Research, US Food and Drug Administration); Alexis Bakos, PhD, MPH, RN (National Institute on Aging); Lionel Bañez, MD (Agency for Healthcare Research and Quality); Mark Wilson, MD, PhD (Veterans Health Administration); Kevin Abbott, MD, MPH (KUH Program Director who oversees the Urologic Diseases of America project); and Daniel Gossett, PhD (KUH Program Director who oversees the SBIR & STTR programs).

Invited urology organizations and societies then took turns identifying knowledge gaps and research needs.

- **American Urogynecologic Society (AUGS)** – Catherine Bradley, MD, MSCE
- **American Urological Association (AUA) Research Office** – Steven Kaplan, MD
- **Research on Calculus Kinetics (ROCK) Society** – Kristina Penniston, PhD, RDN, Nicole Miller, MD

- **Society for Basic Urologic Research (SBUR)** – William Ricke, PhD
- **Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)** – Lenny Ackerman, MD, PhD, Christopher Chermansky, MD
- **Society of Genitourinary Reconstructive Surgeons (GURS)** – Bradley Erickson, MD
- **Endourological Society** – Ben Chew, MD, MSc
- **Interstitial Cystitis Association (ICA)** – Laura Santurri, PhD, MPH

A statement from the **Sexual Medicine Society of North America (SMSNA)** was made available to us, but a representative from SMSNA was not there. Additionally, 2 patients with interstitial cystitis and 1 with recurrent kidney stones provided their thoughts and perspectives virtually.

NIDDK Program Officers and other federal attendees then left the meeting. Dr. Kirkali had previously asked Cate Bradley and Kris Penniston to chair the remainder of the meeting. Thus, representatives from the various organizations – in-person and online – and invited patient representatives continued to talk.

The broad outline for our meeting was to: (1) review the UICC meeting and provide comments to NIDDK Program Officers; (2) identify common research needs and themes across all areas; and (3) identify ways to move forward from this meeting. Ben Chew, Kris Penniston, and Cate Bradley took notes.

COMMENTS ON THE UICC MEETING AND SUGGESTIONS TO NIDDK PROGRAM OFFICERS

- All welcomed this forum as a way to assemble the full breadth of genitourinary/urology organizations and societies. Some of us had not met before; many had not previously participated in UICC meetings. All agreed this forum should continue, if not coordinated by the NIDDK then via other mechanisms. **All agreed on importance of close relationships with NIDDK KUH Program Directors and hearing directly from them.** We hope NIDDK continues to organize or at least support these types of meetings.
- Many of us are exploring ways to include patients in our research agendas and certainly in clinical studies. As such, the inclusion of patient representatives was most welcomed. **We appreciate anything the NIDDK can do to help us continue and expand these initiatives in the future.**
- Many had not previously heard about recent KUH “concept clearances” presented by Dr. Star, so good to hear about them here and better understand the process of developing new funding initiatives. **Communication to investigators and organizations about what is available through current opportunities and about what’s on the horizon is most welcome.** We appreciated the insights and perspectives shared, especially related to funding challenges and research priorities.
- We welcome the opportunity to more regularly communicate our research needs and ideas with KUH directors. We realize the “concept clearances” that came out of the May 2024 (and prior) KUH meeting were likely informed by investigators within our research community, but there may not be agreement about priorities.
- We appreciated the presence of other NIH institute reps and the information they shared. Many of the urologic diseases we study are multifactorial and/or present differently throughout the lifespan and among different sub-populations. We were encouraged by comments articulated by Drs. Tingen and Bakos related to the potential for **“crossover” funding, “dual assignment” funding, and co-funding as we recognize these as mechanisms may be able to stimulate new interdisciplinary and collaborative research.** There was discussion about how this might help to support research that spans the interests of multiple institutes, such as research on the urinary microbiota and on aging in the lower urinary tract.
- The group discussed that NIDDK no longer supports clinical R21 awards but does support them for basic science research. However, these smaller awards, which used to be less burdensome (largely due to the need for preliminary data), now appear to require data in order to get funded. Has this affected the number of urology research applications that are submitted? The need for seed money to get initial data was stressed. **We therefore hope that NIDDK will continue to support R21 or other small grant mechanisms that do not require preliminary data.**
- The above may also stimulate more urologists, urogynecologists, and other clinician-scientists in this area to write grants. **Currently, there are few incentives for urologists to devote significant time for research.** This is particularly true where departmental and/or institutional support and encouragement is lacking. Another disincentive relates to the low odds of getting funded, which will become even more of a problem if the current funding situation doesn’t improve and if smaller grant mechanisms, such as the R21, are not supported.
- **Need funding and infrastructural support (organizational, statistical) for large networks of investigators to track patients, harmonize and centralize data, and analyze results.** Investigators

cannot afford this on their own. One investigator noted that the AUA charged \$150,000/year for statistical support for a project.

- There was support for working on a **conference grant to discuss an approach to study a common pathophysiological process** (e.g., fibrosis, urobiome) across multiple different UTDs

RESEARCH NEEDS IN UROLOGY

NEEDS ARTICULATED BY PATIENTS

- **Better pain control.** Patients tell us that pain management from physicians is typically poor. Patients are frequently treated as “drug seeking.” This applies to numerous urologic conditions, notably IC and kidney stones. Untreated pain can have serious downstream effects on health and on QOL.
- **Low access to the appropriate urology/urogyn experts.** One patient flies from Florida to Houston to get appropriate IC care, which is time-consuming and costly. Disability for IC is frequently not covered.
- **Low uniformity with respect to how some conditions, such as IC, are treated.** How can more urologists be motivated to treat IC? How can research advances be better translated to the clinic? How can the uptake of recent research findings by providers be improved?
- **Hidden burden, lack of respect for those with “benign” urologic conditions.** You’re a “warrior” if you have cancer. But if you have incontinence, erectile dysfunction, or pelvic/bladder pain, you are belittled or told “it’s all in your head.”
- **Under-reporting of benign urologic/GU conditions drives less funding for research.** Cancer is always better funded, despite that it is treatable in many cases, whereas many suffer from LUTS and other urologic issues for their entire lives.
- **Patients need more and better information about their conditions.** Patients want to know “What is going on in my body?” “What can I do to mitigate symptoms or prevent recurrence?” In order to provide patients with answers, more research is needed on pathophysiology. Yet, funding for our research is anything but increasing.

NEEDS OF UROLOGY AND GENITOURINARY INVESTIGATORS AND ORGANIZATIONS

- Specific research needs were articulated by each invited organization (SEE ATTACHED)
- **Common needs were identified**
 - Agree to use the term “*urinary tract dysfunction*” (UTD) vs. “benign” or “non-malignant” to describe functional (and reconstructive) urologic disorders
 - Need to agree on definitions and standardized terminology for UTD-related sequelae
 - Increased public awareness of the rising incidence and debilitating effects of UTDs is needed
 - Need to address stigma of many UTDs, which in turn may address their under-reported nature, their relative invisibility, and lack of research funding
 - Novel clinical approaches to study these complex, multifactorial, and heterogeneous conditions are needed
 - Novel and standardized research approaches to phenotyping patients and studying treatment responsiveness are needed; would benefit from partnering with experts in phenotyping and study design
 - Nearly all UTDs are understudied with respect to women; this needs to be addressed
 - Many diagnostic gaps and needs for most all UTDs; non-invasive diagnostic technologies used in other health conditions – including *in vivo* imaging – may be transferrable to UTDs
 - Impact on mental health, QOL, psycho-social functioning, and stress is under-studied; presents opportunities to partners with experts in those areas
 - Inadequate funding for pathogenesis in nearly all areas
 - Patient-centered outcomes need to be identified, standardized, and utilized across all UTDs and in clinical research trials
 - Social and environmental drivers of urologic health – opportunity for interdisciplinary research
 - Develop evidence and best practices for transitional care of patients with various UTDs from childhood to adulthood to geriatric to palliative life stages
 - UTDs among cancer survivors is understudied and may be untapped area for research funding

COMMON RESEARCH QUESTIONS AND CHALLENGES

- **Influence of microbiota** – gut, urinary tract, etc. – on UTD etiology, progression, and expression and as related to host-microbe interactions

- **Influence of fibrosis** across all UTDs
- **Phenotyping** (molecular, metabolic, anatomic, histologic, treatment-based, etc.) as a way to gain new insights into pathophysiology, disease expression and symptoms, and treatment responsiveness across all UTDs. Need common approach we all use in our specific areas! Need training, education.
- **Providing resources for and supporting the development** of a diverse and committed urologic clinician-scientist cohort to participate in and lead future UTD research

DELIVERABLES AND FUTURE PLANS

1. Written feedback about the UICC meeting to NIDDK KUH - DONE
2. “White paper” or opinion piece articulating the research areas that require more attention and funding (the “national research agenda” from AUGS was suggested as a model); could be jointly published in >1 journal
3. Paper on preserving and growing the clinical urology workforce
4. Conference grant to discuss an approach to study a common pathophysiological process (e.g., fibrosis, urobiome) across multiple different UTDs
5. Continue this dialogue among urology/genitourinary organizations and societies (perhaps in virtual meetings, conferences, symposia at society or organizational meetings), focusing on:
 - Refinement of shared research areas and priorities
 - Interdisciplinary basic and translational research collaborations to study common pathophysiological processes across UTDs
 - Interdisciplinary clinical studies involving investigators and patients from multiple different UTDs
 - Building community partnerships for research and advocacy