

National Diabetes and Digestive and Kidney Diseases (NIDDK) Advisory Council Meeting

Division of Kidney, Urologic, and Hematologic Diseases Advisory Subcouncil Meeting May 8, 2024

Advisory Council KUH Subcommittee Members:

Dr. Mark Nelson (University of Vermont)
Dr. Keith Norris (University of California at Los Angeles)
Dr. Aylin R. Rodan (University of Utah)
Dr. Kathleen Sakamoto (Stanford University)
Dr. Ian Stewart (ex-Officio, USAF; Walter Reed National Military Medical Center)
Dr. Claire Yang (University of Washington)

NIH/NIDDK/KUH Staff:

Dr. Kevin Abbott	Dr. Susan Mendley
Dr. Eric Brunskill	Dr. Chris Mullins
Dr. Kevin Chan	Dr. Deepak Nihalani
Ms. Dee Doherty	Dr. Jenna Norton
Ms. Emily Duggan	Dr. Afshin Parsa
Dr. Gregory Germino	Ms. Aretina Perry-Jones
Dr. Debbie Gipson	Dr. Matt Portnoy
Ms. Shannon Givens-Bradley	Dr. Tracy Rankin
Dr. Daniel Gossett	Mr. David Robinson
Dr. Raquel Greer	Dr. Cindy Roy
Dr. Shilpa Hattangadi	Dr. Anna Sadusky
Dr. Jason Hoffert	Dr. Ivonne Schulman
Ms. Kayla Hurd	Ms. Aliecia Shepherd
Dr. Chris Ketchum	Dr. Robert Star
Dr. Paul Kimmel	Mr. Jonathan Teinor
Dr. Ziya Kirkali	Dr. Ken Wilkins
Dr. Karl Malik	

Welcome and Introductions

Dr. Star welcomed council members and attendees to the 225th KUH subcouncil meeting. Dr. Star welcomed Dr. Claire Yang as an Ad Hoc Advisory Council Member and Ms. Kayla Hurd as a new Program Analyst for KUH. Dr. Nelson led the motion to approve the meeting minutes from January subcouncil.

Upcoming Meetings and Workshops

Dr. Star noted several upcoming meetings and workshops and commented that this information is available on the ECB for future reference.

KUH Initiative Presentations

Dr. Star noted that NIDDK received a flat budget, and with escalating costs, it will necessitate cuts.

KUH staff members presented the following initiatives, followed by feedback from Councilors:

- Patient Science and Post-Dialysis Fatigue (Chan): Dr. Norris noted that this is a helpful initiative to support research that impacts patients and commented that he is supportive of including biomarkers and gene expression in this effort. Dr. Rodan echoed Dr. Norris' comments that this is important research for patients and noted that identifying biomarker pathways may help develop an intervention.
- Matching for Kidney Precision Therapeutics (MAP-IT) (Gipson): Dr. Rodan commented that this initiative advances the successes of KPMP to the next phase and queried if it is possible to collaborate with large laboratories and industry in terms of therapeutics/interventions. Dr. Gipson noted there is opportunity to collaborate with laboratories, both centrally and locally, as well as with industry in terms of developing therapeutics. Currently, within the NIDDK portfolio, extramural investigators partner with industry to develop or (from industry) provide assays, therapeutics, and data sharing within ancillary studies, as well as for scientific collaboration. Dr. Norris noted that the development of novel therapeutics as well as precision analytes look at different pathways using a precision medicine approach such as lifestyle. Dr. Gipson noted that this could be considered as an intervention (drug, device, behavioral modification). In addition, she offered that a national precision trials program could be available to a diverse community that may not typically have access to clinical trials. Dr. Stewart commented that new interventions, such as SGLT-2 inhibitors could decrease "event rates" and the need for precision therapeutics. Dr. Gipson noted that SGLT-2 inhibitors are generally targeted toward the final common stages of CKD to slow kidney disease progression and decrease cardiovascular events. However, kidney precision therapeutics are intended to address early disease in order to prevent moderate to severe kidney failure by targeting the etiology or unique active disease processes. As with all therapies, there are non-responders to therapies who need additional assessment of how they are different and the development of novel treatment approaches for these resistant subgroups as well. These approaches may be considered additive.
- Chronic Kidney Disease of Uncertain Etiology (CKDu) in Agricultural Communities (CURE) Consortium (Mendley): Dr. Rodan queried the plan for referral for those with CKDu. Dr. Mendley noted that there are resources within countries for participants with CKD, hypertension, and diabetes mellitus. Dr. Norris commented that this is important condition to understand and added that novel insights that will from this study, and of particular interest, the effects of climate change on kidney disease.
- Interventions to Improve Outcomes After AKI: COPE AKI (Schulman): Dr. Rodan queried if any modifications have been made to boost slow enrollment. Dr. Schulman noted the group is in the process of obtaining IRB approval and has decreased the number of patient-reported outcome questions from 40 to 10 minutes, shortened the informed consent form, developed a consent form in Spanish, and now, Research Coordinators meet to establish best practices. Dr. Norris queried if the satellite sites are in the health system. Dr. Schulman noted that they are and added the following updates:
 - Johns Hopkins University has expanded to its Bayview Medical Center
 - Yale has expanded to its St. Raphael Yale New Haven Hospital Saint Raphael Campus
 - Vanderbilt is adding their Nashville Veterans Affairs Medical Center (NVAMC)
 - University of Alabama at Birmingham has expanded locally

- Cleveland Clinic, Ohio is expanding to the Cleveland Clinic in Weston, Florida

Dr. Schulman commented this will boost general enrollment as well as recruitment numbers for Hispanic and African American participants.

- Phosphate Binders in Children with CKD (FIT4KID) (Gipson): Counselors expressed continued support for this initiative.
- A trial of transplanting Hepatitis C-viremic kidneys into Hepatitis C-Negative kidney recipients (THINKER-NEXT) (Mendley): Dr. Norris noted this initiative is a good use of initiative funds to increase the number of healthy kidneys and added that this is a cost effective trial.
- Management of Asymptomatic Renal Stones (MARS) (Kirkali): Dr. Rodan commented that this is an important study and queried if various medical interventions are being considered for patients who are identified with small stones. Dr. Kirkali noted medical interventions in the surveillance arm may dilute the intervention effect. Dr. Yang commented that this is a large problem to address and emphasized the importance of including the patients that choose not to be randomized as prior surgical patients often do not wish to elect for surgery again. Collecting data on this effort would be important and impactful.
- George M. O'Brien Urology Centers (Nihalani): Dr. Nelson noted that this program is successful and outreach efforts with Dr. Penniston have been integral to the Consortium. He also added that the groups are very interactive and CAIRIBU meetings are stimulating and attract junior investigators. He commented that this is a great investment from NIDDK. However, he noted some collaboration issues in the past, where one of the kidney stone group (Mayo clinic) has had a difficult time interacting with other stone sites. Dr. Mullins noted that KUH staff is working with the center investigators on how to optimize collaborations across funded sites. Dr. Yang emphasized the efforts of this group to recruit new and young PIs as urology research is not as visible in graduate programs as cancer and neuroscience. Dr. Nelson echoed this comment.
- Re-competition of Institutional Career Development for Epidemiology of Urologic Diseases (UroEpi) (Abbott): Counselors expressed continued support for this initiative.
- Rekindle: Revisiting Embryogenesis in Kidney Development, Initiating New Directions, Launching ESIs and promoting Diverse perspectives (Brunskill): Dr. Rodan expressed support for this effort as kidney development research is important for young and older populations with congenital abnormalities. Kidney developmental biologists have expressed concern that kidney development biology grants are not being funded and suggested advertising this opportunity widely.
- KUH Predoctoral to Postdoctoral Fellow Transition Award (F99/K00) (Hattangadi): Dr. Yang queried that if someone is enrolled in a postdoctoral program and transitioning into a K, U, or H fields, what other incentives aside from financial are available, particularly from a mentorship standpoint. Dr. Hattangadi noted that students have to identify a K,U, or H mentor for this effort prior to applying to the program. Additionally, the U2C/TL1 program pairs students with mentors of all different backgrounds. Dr. Yang suggested reaching out to large scale meetings to advertise these programs. Dr. Hattangadi

commented that staff have contacted diverse organizations in science as well that provide outreach to African American and Hispanic students. Dr. Nelson noted including graduate students in this effort is helpful.

- Innovative Science ACcelerator Program (Maric-Bilkan): Dr. Rodan expressed strong support for this program and queried how many applicants have graduated into a traditional R01 as a result. Dr. Maric-Bilkan noted the first ISAC awardee just received an R01 and added that this type of science is difficult to fund through traditional peer review. Dr. Norris queried if this is more like an R21 or pioneer award; Dr. Maric-Bilkan noted that staff think of this in terms of a small pioneer award. Dr. Nelson commented that the R21 has become a mini R01 and expressed enthusiasm for this program. Dr. Germino queried how many proposals were able to complete their hypothesis; Dr. Maric-Bilkan noted that the program is still only a couple of years old, but final outcomes are being tracked. Dr. Rankin noted that providing seed funding for risky projects results in a high fail rate; however, there is still a need to fund “risky” science.
- Development of Catalytic Tools and Technologies for Kidney, Urologic, and Hematologic Diseases (Gossett): Dr. Norris commented that this project and ISAC might be connected to provide investigators with tool development resources. Dr. Star noted that staff provide recommendations to applicants about what funding opportunities or programs are most appropriate for their research. Dr. Gossett noted an upcoming workshop on kidney engineering that leverages the ISAC structure to join several communities. Dr. Ketchum noted that this may also recruit investigators from outside KUH. Dr. Rodan expressed support for this program. Dr. Star emphasized that interested grantees may reach out to program staff for support.

KUH Closed Session

Dr. Star commented on the importance of confidentiality during closed session. Council members approved several closed business items.