

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

### **Division of Kidney, Urologic, and Hematologic Diseases Advisory Subcouncil Meeting January 27, 2022**

#### **Advisory Council KUH Subcommittee Members:**

Dr. Iain Drummond (Mount Desert Island Biological Laboratory)  
Ms. Dawn Edwards (American Association of Kidney Patients)  
Dr. Mark Nelson (University of Vermont)  
Dr. Keith Norris (University of California at Los Angeles)  
Dr. David Penson (Vanderbilt University)  
Dr. Kathleen Sakamoto (Stanford University)  
Dr. Ian Stewart (Commissioned Corps of the US Public Health Service)

#### **NIH/NIDDK/KUH Staff:**

Dr. Kevin Abbott	Dr. Deepak Nihalani
Dr. Julie Barthold	Dr. Jenna Norton
Dr. Eric Brunskill	Dr. Van Nguyen
Dr. Kevin Chan	Mr. Matt Oldham
Ms. Dee Doherty	Dr. Afshin Parsa
Dr. Patrick Donohue	Ms. Aretina Perry-Jones
Ms. Emily Duggan	Mr. Robert Pike
Dr. Greg Germino	Dr. Tracy Rankin
Ms. Shannon Givens-Bradley	Mr. David Robinson
Dr. Daniel Gossett	Dr. Cindy Roy
Dr. Raquel Greer	Dr. Anna Sadusky
Dr. Xiaodu Guo	Dr. Ivonne Schulman
Dr. Shilpa Hattangadi	Ms. Neha Shah
Dr. Jason Hoffert	Ms. Aliecia Shepherd
Dr. Chris Ketchum	Dr. Victoria Spruance
Dr. Paul Kimmel	Dr. Robert Star
Dr. Ziya Kirkali	Mr. Jonathan Teinor
Dr. Susan Mendley	Dr. Ken Wilkins
Dr. Chris Mullins	

#### **Welcome and Introductions**

Dr. Star welcomed council members and attendees to the 218<sup>th</sup> KUH subcouncil meeting. Dr. Star welcomed Dr. Raquel Greer, a new KUH Program Director, to oversee health disparities research within kidney disease. Additionally, Dr. Star also formally welcomed Dr. Keith Norris and Ms. Dawn Edwards as councilors. Ms. Edwards and Dr. Penson led the motion to approve the meeting minutes from September subcouncil.

#### **Upcoming Meetings and Workshops**

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

## **Consortia Management Board (CMB) and External Expert Panel (EEP) Updates**

Mr. Teinor detailed the list of KUH CMB and EEP meetings and provided a list of the following upcoming CMB and EEP meetings:

### CMBs

- Chronic Kidney Disease Biomarkers Consortium (CKD BioCon II)
- Hematology Centers
- Kidney Precision Medicine Project (KPMP)
- New England Research Institutes Underactive Bladder Project
- Polycystic Kidney Disease Research Resource Consortium (PKD RRC)
- (Re)Building a Kidney (RBK) Consortium
- United States Renal Data System (USRDS)
- Urology O'Brien Centers
- Urologic Diseases in America (UDA)

### EEPs

- Chronic Kidney Disease in Children (CKiD) Study
- Chronic Renal Insufficiency Cohort (CRIC) Study
- Kidney O'Brien Centers

### Meetings convened since September 2021:

- Urology O'Brien Centers CMB
- (Re)Building a Kidney (RBK) CMB
- Kidney Precision Medicine Project (KPMP) EEP
- NERI - Underactive Bladder CMB
- Polycystic Kidney Disease-RRC CMB
- United States Renal Data System (USRDS) CMB

### Upcoming Meetings

- UDA CMB - Monday, March 14, 2022
- eCare CMB - April 11, 2022
- GUDMAP4 CMB - May 3-4, 2022

## **FY21 Portfolio Analysis**

Dr. Ketchum provided an overview of the 2021 KUH portfolio and noted several observations:

- KUH total awarded dollars were up in 2021 (an R01 "success" story). However, average total costs per R01 award remain low and more ESI and diversity candidates are needed.
- The kidney applicant pool is expanding, resulting in more submitted applications and total dollar awards.
- The urology applicant pool is relatively flat, but investigators continue to submit more applications, also resulting in more total dollars. The urology portfolio contains many multiple PI (MPI) R01 awards.
- While the hematology portfolio gained dollars in 2021, this portfolio is still losing investigators and applications (mostly to NCI and HL). Hematology applications are primary focused on basic research in R01s, with fewer investigators who are MDs.

Dr. Ketchum remarked that total awarded dollars are flat for NIDDK but have increased in KUH by approximately 5%. Total awarded dollars within KUH increased by 5% for kidney and hematology and by 7% for urology.

Dr. Nelson commented on the need to recruit graduate students before these students transition to industry. Dr. Penson noted graduate students on PhD track in urology are often recruited into the oncology field; however, he emphasized that benign urologic disease is also a critical area of study. Dr. Spruance noted that the urology program's new focus on neurourology has helped recruit investigators and well as the F99/K00 mechanism, which is designed to attract investigators from other fields. She also emphasized the need for the R25 mechanism and institutional network awards, as this investment will increase the number junior investigators. Dr. Sakamoto suggested more translational project RFAs designed to recruit MDs and MD/PhDs. Dr. Star noted that staff will present training information for discussion on a yearly basis. Dr. Norris noted a large number of minority investigators at the post-doctoral level that are not retained in research and remarked on the need to rethink how to construct "on ramps" for these investigators.

Dr. Ketchum emphasized that NIDDK is a payline driven institute that follows the science and added that more applications result in more awards and more funds for KUH programs. In FY21, NIDDK and KUH competing R01 applications rose slightly but are trending downward for FY22. Awarded NIDDK competing R01 awards are flat, however, numbers for KUH have increased, Both NIDDK and KUH competing R01 award total cost averages are increasing by approximately 4%.

Dr. Ketchum noted ESI competing applications are trending downward for KUH, particularly for urology and hematology, which highlights pipeline concerns. KUH ESI success rates for FY21 is at 29%. Dr. Penson commented on clinical versus research efforts based on PI salaries and noted that K awards do not provide enough salary support. Dr. Rankin noted this salary was raised 2-3 years ago but added that raising this cap will remove funds from another pool. Dr. Norris commented that only the wealthy institutions can support the gaps at either K or R mechanism level. Dr. Penson suggested a different mechanism for surgical and medical students than for PhD students and noted a K award is needed to pay for the research portion, but not protected time. Dr. Penson echoed Dr. Norris's comments and added that there are disparities amongst institutions as well. Dr. Norris noted the K award is geared toward training efforts; however, some investigators need more research support to obtain preliminary data, narrow their training focus, and establish partnerships with other investigators.

Dr. Ketchum noted that urology R01 Team Science awards have increased significantly, noting that success rates from MPI are similar to individual R01 success rates.

In FY20, NIDDK spent \$205M (about 10% of its budget) on Minority Health, including intramural research. According to RCDC coding, KUH spent \$39M (or 9%). In terms of underrepresented scientists, the NIH funded ~1K Black investigators in FY20 (representing only 2.4% of the total pool of RPG investigators). Dr. Ketchum commented that public data from NIH RePORT is available at [https://report.nih.gov/sites/report/files/docs/NIH\\_Principal\\_Investigators\\_by\\_Gender\\_Race\\_Ethnicity\\_and\\_Disability\\_2016-2020\\_02\\_23\\_2021\\_PDF.pdf](https://report.nih.gov/sites/report/files/docs/NIH_Principal_Investigators_by_Gender_Race_Ethnicity_and_Disability_2016-2020_02_23_2021_PDF.pdf). Dr. Ketchum noted that data on underrepresented investigators is limiting; however, a new Executive Order was issued in January 2021 on "Establishing an Equitable Data Working Group" to address that many Federal datasets are not disaggregated by race, ethnicity, disability, or other key demographic variables. This

Order will mandate that datasets collect this key demographic information to help address disparities and enhance support for underserved communities.

### **United States Renal Data System (USRDS) Presentation**

Dr. Abbott introduced Dr. Johansen, the lead PI for the USRDS, who discussed several aims of this study, including to:

- examine the impact of COVID-19 on the ESRD and CKD populations,
- document the extent of vulnerability of the ESRD population in general,
- examine differences in impact based on treatment modality and race/ethnicity, and
- generate data that could be used to guide infection control and policy decisions.

Dr. Johansen displayed a summary of key findings in advance:

- 2020 showed an unprecedented decline in the total population (prevalence) of end stage renal disease (ESRD; dialysis and transplant combined).
- Since prevalence is the combination of new people starting on ESRD plus people who already have ESRD minus those who died, the relative contribution of delayed initiation of ESKD therapy vs increased mortality, both of which occurred, is difficult to determine.
- The onset of COVID was associated with a significant increase in rates of hospitalization and death among ESKD patients.
- Patients with ESRD had a significantly higher rate of COVID infection, COVID hospitalization rate, and COVID associated death rate compared to the general population.

Dr. Johansen remarked that USRDS uses data from CMS and private payers (Optum Clinformatics) to describe the ESRD and CKD populations and monitor important outcomes. Typically, there is an ~18-month lag in data used to enumerate and study these populations. Dr. Johansen emphasized the following findings:

- Black patients on dialysis had a higher rate of hospitalizations earlier (in the pandemic, first wave) than other populations, yet rates for the Hispanic population were also higher than average.
- Hemodialysis patients had higher hospitalization rates than peritoneal dialysis patients.
- Older patients were initially more likely to be hospitalized, but as the year went on, younger Black and Hispanic populations were more likely to be hospitalized.
- Hospitalization rates among patients on dialysis were approximately 40 times higher than in the general population.
- Rates of COVID hospitalization were high among transplant patients
- AKI was common in CKD patients during COVID hospitalization.
- A large increase in mortality for the ESRD over recent years as well as a large dip in incidence of ESRD early in the pandemic.
- High impact publications supported, extended, and disseminated important observations with a report of the first ever shrinkage of the ESRD population.
- In 2021, the Annual Data Report highlighted the cumulative impact of COVID-19 in 2020:
  - Diagnosis: 7.7% CKD, 15.8% dialysis, 9.4% transplant
  - Deaths: 18% higher for patients on dialysis, 19% for transplant recipients

In January 2022, a joint statement from the National Kidney Foundation and the American Society of Nephrology was published stating: “According to data from the US Renal Data System, 15.8% of all patients on dialysis in the United States had contracted COVID-19 as of the

end of 2020. During the winter 2020 wave, weekly deaths due to COVID-19 peaked at nearly 20% and annual mortality during 2020 was 18% higher than in 2019.”

In closing, Dr. Johansen thanked her team and NIDDK staff for the opportunity to present.

Meeting participants offered the following feedback:

- Dr. Star noted the importance of creating and maintaining a database with the appropriate denominators to show COVID’s impact across the U.S.
- Dr. Norris queried what strategies are being used to disseminate this data to the KUH research community. Dr. Johansen noted the team is focused on interpreting and publishing findings in journals, and she noted a recent partnership with CJASN on USRDS insights. Dr. Johansen also remarked that the team provides data to journalists as well.
- Ms. Edwards commented on the importance of educating patients about home dialysis options, particularly among black and brown communities.
- Dr. Stewart commented that the home dialysis option would impact patients with comorbidities who find travel difficult and queried if there are plans to get data from patients who received COVID vaccines. Dr. Johansen noted that the Annual Data Report was not adjusted for the COVID vaccine. However, there are codes for comorbidities. Dr. Johansen emphasized that the team relies on claims data to see patient-related events, so there is a big gap.
- Dr. Drummond noted a risk factor for COVID is interferon levels and a reduction on patient immune system functions and commented that this may affect patients using home dialysis. Dr. Johansen noted the team was able to compare home dialysis patients with healthier “in Center” people without comorbidities.
- Dr. Star noted this was a challenging year for the USRDS as CMS data was provided late in the year and queried if there are plans to phenotype the “long hauler” COVID population for EHR data. Dr. Johansen noted that data is being released on this topic and added that the team is using the N3C website to explore this data.
- Ms. Edwards queried if the National Kidney Foundation submitted a request for dialysis patients to be prioritized and asked if these patients will receive prioritization in the future. Dr. Johansen commented that, based on research findings, this group should be elevated to receive prioritization in the future. Ms. Edwards emphasized the importance of this action to advance kidney care and get more patients into home therapies.
- Dr. Mendley queried if COVID treatments are available for dialysis patients. Dr. Johansen noted she believed dialysis patients were not given the vaccine (in the timeframe presented, 2020) as it was not approved at the time.
- Dr. Star cited Dr. Gibbon’s talk on health disparities by geographic areas. Dr. Johansen noted the ESRD database contains updated zip codes and commented that disparity information can be tracked. Dr. Abbott noted more residential address are available and can be completed.
- Dr. Star queried if USRDS investigators were interested in any other data sources. Dr. Johansen noted access to the National Death Index, Medicare data, and Medicare advantage data (although there is a 1-year lag) would be helpful. She noted the team would also like access to view vaccine booster information and “long hauler” COVID issues.
- Dr. Norton commented that a discussion on this topic will be held during the next NIDDK KICC meeting.

## **KUH Closed Session**

Dr. Star commented on the importance of confidentiality during closed session. Council members approved a special council review and two restorations.