



National Institute of  
Diabetes and Digestive  
and Kidney Diseases

## **Kidney Interagency Coordinating Committee Meeting**

Natcher Conference Center, Room D  
National Institutes of Health  
Bethesda, MD  
and Virtual

March 15, 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)*

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

Dr. Jenna Norton welcomed members and attendees to the NIDDK Kidney Interagency Coordinating Committee (KICC) meeting, which involved both in-person and virtual attendance. She reminded participants that the KICC was mandated by Congress in 1987 to encourage cooperation, communication, and collaboration among all federal agencies engaged in kidney research and related activities. This mandate was in recognition of the need for better coordination of the federal response to chronic kidney disease (CKD). The objective remains to convene an active group of federal professionals working to address CKD. The KICC aims to foster engaged discussion, solicit feedback on plans and ideas, and make a notable change in kidney disease. The federal response to CKD among agencies is multifaceted, interconnected, and encompasses public education and outreach; surveillance; professional education and outreach; delivery of and payment for CKD care; research; quality improvement; and evidence of therapy's efficacy. Through KICC, NIDDK aims to foster discussion about bringing these many facets of CKD together.

Dr. Robert Star also welcomed the participants and noted that he looks forward to the discussions.

Dr. Norton reviewed the agenda and invited attendees to introduce themselves.

#### **Follow-up from October 2023 Meeting**

*Jenna Norton, Ph.D., M.P.H., Program Director, KUH, NIDDK, NIH*

Dr. Norton explained that NIDDK wants to acknowledge the concerns raised during the October 2023 KICC meeting regarding the U.S. Preventive Services Task Force's (USPSTF) CKD screening research plan. KUH /NIDDK has initiated discussions both with NIH colleagues who are representatives on the USPSTF and with Agency for Healthcare Research and Quality (AHRQ) staff who support USPSTF. Some key literature has been shared to inform USPSTF's analysis, ensuring that it is monitoring the nuances of this topic. Discussions are ongoing, and the next meeting between NIH and AHRQ staff will occur in April 2024.

## **Around the Table**

Dr. Norton invited members to provide their updates and announcements. Ms. Sharon Pearce acknowledged National Kidney Month in March and the 2024 World Kidney Day that was commemorated on March 14, 2024.

### ***Centers for Medicare & Medicaid Services (CMS)***

Dr. Abigail Ryan called attention to the Calendar Year 2025 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) proposed rule for renal analysis that will be released for public comment this June. She encouraged participants to provide their comments and also to respond to the upcoming requests for information regarding the 2025 ESRD PPS.

### ***U.S. Department of Veterans Affairs (VA)***

Dr. Anne Utech reported that the VA's Nutrition and Food Services celebrates National Nutrition Month® in March and joined the Academy of Nutrition and Dietetics to commemorate Registered Dietitian Nutritionist Day on March 13, 2024; Nutrition and Dietetics Technician, Registered Day was on March 14, 2024. This year's theme—Beyond the Table—speaks to an all-of-government approach in terms of how food choices affect sustainability and health. Dr. Utech noted that this is the time to act on behalf of patients and their nutritional health and that the VA Nutrition and Food Services is actively implementing the [Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health](#). The VA is taking this charge by responding to nine different nutritional commitments, and its nutritional services have been expanded virtually, resulting in an 18 percent increase in clinical encounters and a 34 percent increase in VA Video Connect services.

Dr. Susan Crowley announced that the VA is continuing to expand its TeleNephrology program and will be providing CKD care to veterans residing in Samoa. A major challenge is indicating a specific date of the patient visit, due to differences in time zones. Dr. Crowley also noted that the VA, in partnership with the U.S. Department of Defense (DoD), is in the process of revising its CKD guidelines, with consideration to the Kidney Disease: Improving Global Outcomes clinical practice guidelines. The VA is taking a slightly different approach this cycle and is developing these guidelines collaboratively with the primary care community. Primary care and nephrology colleagues from the VA and DoD are serving as co-chairs on a panel of experts and have begun convening meetings. Other agencies participating in the federal response to CKD will have the opportunity to comment.

### **Key Findings: A Scientific Workshop on Post-dialysis Fatigue (PDF)**

*Kevin Chan, M.D., M.S., Program Director, KUH, NIDDK, NIH*

Dr. Kevin Chan explained that nephrologists may use various measurements and clinical metrics to determine how well their patients are responding to treatment. Dialysis patients, however, report not feeling well even though their measurements are within the acceptable ranges, suggesting that other factors are involved. Some measured outcomes (e.g., dialysis adequacy, hemoglobin) are visible and the values may be deemed normal by a clinician. Unmeasured, hidden outcomes related to how patients feel that can be quantified are not being captured. NIDDK has the onus to work through these unmeasured outcomes with scientific discoveries, developing instruments and tools that other federal agencies can use in the mission of public service.

One unmeasured, hidden outcome is PDF, which is an iatrogenic, debilitating fatigue from the dialysis treatment and is experienced by 50 percent to 85 percent of hemodialysis patients. This syndrome begins during hemodialysis, intensifies throughout the hemodialysis session, and lasts for many hours after treatment has ended. No diagnostic criteria or laboratory/radiological tests exist, and the exact cause is unknown. PDF has been acknowledged for decades, but little progress has been made to address it. On May

22–23, 2023, NIDDK convened a [Scientific Workshop on Post-Dialysis Fatigue](#) that concluded with a call to action.

Dr. Chan reported on the workshop proceedings. He noted that Ms. Dawn Edwards, a patient and kidney disease advocate who was a panelist during the workshop, described how she experiences PDF.

Ms. Edwards, a high-performing employee and leader in the U.S. Postal Service prior to dialysis, explained that after dialysis she is too debilitated to speak and becomes incapacitated. NIDDK partnered with patients and the American Association of Kidney Patients (AAKP) to host a PDF workshop that brought together multiple diverse stakeholders to discuss this overlooked complication of dialysis treatment and how best to advance this research area. NIDDK co-designed the workshop with patients and AAKP to ensure that scientific presentations included separate language that explained science to the patient and that it provided a safe space for patients to share their fatigue experience. The goals of the workshop were to understand what PDF feels like, identify the immediate knowledge gaps that impede progress in the field, and identify the science that can address these knowledge gaps.

In response to an AAKP survey that asked what term best described their fatigue after dialysis treatment, patients answered “zapped out,” “foggy,” or “washed out.” The common theme was debilitation, which goes beyond feeling tired and fatigued. When asked about the duration of PDF after treatment, the majority of patients reported that they were unable to perform any other activities throughout that day, and others reported fatigue well into the following day. When asked to specify what they were unable to do after a dialysis treatment that they could do before a treatment, 50 percent of patients responded that they could not work full time, and the majority had difficulty with physical chores and cognition. Many reported the inability to experience joy in watching their children or grandchildren.

Dr. Chan highlighted several recommendations that emerged from the workshop:

- **Establish a case definition** that leads to a standardized diagnostic criteria for post-dialysis fatigue that provides medical credibility, serves as a basis for establishing International Classification of Diseases (ICD) and Current Procedural Terminology codes, and facilitates quantification of benefits and treatment coverage.
- **Develop a post-dialysis fatigue outcome** that captures the voice of patients and meets regulatory standards for the U.S. Food and Drug Administration and CMS.
- **Uncover the mediators and biological mechanisms** that drive post-dialysis fatigue in terms of treatment characteristics, the time course, and pathophysiology.
- **Establish a patient science and post-dialysis fatigue forum**, thus creating a safe environment for patient-partnered research that embeds the voice of patients into scientific instruments, outcomes, and models. These tools could provide a scientific platform for future clinical trials and drug development. The forum could empower patients to rename post-dialysis fatigue and use a diagnostic term that better conveys what they feel.

In closing, Dr. Chan reiterated that PDF is a common and debilitating side effect of dialysis and that little scientific progress has been made on understanding or mitigating it, even though the field has known about patients’ experience for decades. Initial scientific goals include developing a case definition and diagnostic instrument, establishing a PDF outcome, and understanding the mediators and biological mechanisms.

## Questions and Discussion

Dr. Norton opened the discussion. Questions were provided to frame the discussion.

*What are your reactions to the recommendations that came out of the workshop? Is there anything you might add, amend, or clarify?*

- Dr. Robert Nee asked about any differences in home hemodialysis versus conventional 3-times-a-week treatments and the prevalence of PDF. Dr. Chan noted that some clinical trials have evaluated frequent hemodialysis and nocturnal hemodialysis and observational studies have investigated home hemodialysis, including technology by NxStage Medical, Inc. The results showed that these forms of dialysis offer an improvement in the time to recover over conventional hemodialysis, but more robust tools are needed to quantify this improvement.
- Dr. Susan Ziemann highlighted that the National Institute on Aging (NIA) has been studying fatigue and fatiguability in older adults for nearly 15 years and wondered whether this cohort could serve as a comparator group to identify specific inflammasomes that might be related. Dr. Paul Kimmel agreed that inflammasome activation could be a potential hypothesis for PDF.
- Dr. Ziemann asked whether any risk factors for PDF had been identified. Dr. Chan explained that chronic fatigue has become more prevalent since the advent of Long COVID and that similar syndromes may overlap in symptoms. Regarding risk factors, he noted one hypothesis is that postural orthostatic tachycardia syndrome (POTS) and PDF are similar because of a dysautonomia. Observational studies have shown that if blood pressure drops during dialysis and patients become dizzy, then the post-dialysis fatigue worsens. A gentler dialysis scheme, such as nocturnal hemodialysis, could alleviate these symptoms. Dr. Kenneth Wilkins directed participants to the [NIH POTS health information webpage](#). He also noted that syndromes similar to POTS were discussed during the workshop and that further details can be accessed in the [workshop executive summary](#).
- Dr. Crowley commented that other illnesses, such as multiple sclerosis, are characterized by overwhelming fatigue that can be severely disabling. She speculated about any lessons learned from the neurology field that might provide insight into the pathogenesis of PDF and therapeutic options. Dr. Chan noted that experts in treating chronic fatigue syndrome who attended the workshop highlighted parallels with PDF and referenced supportive exercise as one method to alleviate symptoms. These experts also called attention to the different phenotypes of fatigue and responses to interventions. Dr. Chan added that clinical therapies are being developed but currently are limited.
- Dr. Star pointed out that research related to COVID-19 has linked muscle energetic defects to long-term effects, suggesting a role for biological endpoints. He conveyed that NIDDK's intention in convening external experts studying similar disorders to PDF is to learn from one another and advance research. Understanding the causes and onset of PDF can help to unravel other disorders. Dr. Chan added that Dr. Robert Haley at The University of Texas Southwestern Medical Center discussed Gulf War Illness during the workshop and described a case definition, phenotypes, and gene expression changes. This provides NIDDK with another blueprint for investigating PDF.
- Mr. Paul Conway expressed AAKP's appreciation for having worked with NIH on this workshop. He commented that AAKP is trying to raise awareness about the true cost of kidney disease to individuals and taxpayers. Patients are receiving life-saving treatments, but those treatments leave them too tired to continue working (part time or full time) in any meaningful capacity. Their inability to work has implications for the disability policies of the U.S. Department of Labor and Social Security Administration, as well as for general employment practices. Furthermore, their

doctors must recognize these effects when considering a patient's quality of life. AAKP observes that this approach focuses on the whole person, which is missing from many good intentions and programs. Mr. Conway remarked that NIH has taken a serious path forward and is trying to focus on the overall impact of disease.

- Mr. Matthew Johnson asked whether any differences in PDF were observed with changes to the dialysis frequency—for example, from three times a week to short daily dialysis or nocturnal dialysis. Dr. Chan called attention to the NIH/NIDDK [Frequent Hemodialysis Network \(FHN\) Daily Trial](#) and the data that have been published. The FHN Daily Trial revealed a significant difference in recovery time between dialysis received six times per week and the traditional three-times-per-week dialysis protocol.
- When asked about fatigue levels associated with peritoneal dialysis versus hemodialysis, Dr. Chan noted that data for this comparison are limited. He speculated that what the technician does during the procedure and, to a lesser extent, the actual frequency of dialysis are related to the effects. Patients participating in the workshop reported dreading the dialysis crash that happens when their blood pressure rapidly decreases and they become symptomatic.
- Dr. Norton pointed out that the FHN Daily Trial evaluated dialysis recovery time as a secondary outcome that is suspected to be related to PDF but is not diagnostic. PDF lacks a medical definition.
- Dr. Kevin Abbott noted that the Comparison of High-Dose Hemodiafiltration With High-Flux Hemodialysis (CONVINCE) trial has an ancillary aim of assessing fatigue and recovery time in a series of questionnaires. These data likely will be published soon.
- Dr. Debbie Gipson commented that major goals of this effort are to begin defining the case, building a new assessment measure, and bringing data to clarify what PDF is and how it occurs, as well as whom it affects and to what degree. The aim is to move from observational studies and indirect approaches to a method that directly addresses these questions. Dr. Norton added that the answers to these questions begin with understanding PDF and having robust definitions and knowledge to inform research. Assessing the current information will benefit patients, who do not want to wait 20 years for the research to provide solutions.
- Dr. Zieman noted that research has revealed that the mitochondrial and biochemical activity switching in peripheral skeletal muscle that occurs as a person ages has been linked to changes in oxygen and nutrient extraction from arterial blood (A-V O<sub>2</sub> difference), which has been more strongly associated with decreased exercise tolerance in heart failure with preserved ejection fraction. This age-related change in skeletal muscle tissue is also associated with fatigue. She noted that the aging research community has worked to find definitions to establish an ICD code for fatigue and fatigability.
- Dr. Vanessa Marshall asked whether discussions about PDF had addressed populations that experience health disparities, in particular, intersectionality and social determinants of health. Dr. Chan explained that the workshop discussions did touch on social determinants of health but that the patients participating in this workshop considered PDF a physiological phenomenon and thought that conversations on social factors at this stage would be too distracting. He added that the observational data have not shown that a particular race, ethnicity, or underrepresented group is more affected by PDF. Aging, which has accompanying comorbidities, has been shown to be associated with the severity of PDF. Dr. Norton echoed Dr. Chan's statements that feedback from the patient community was clear. They saw social determinants of health as a distraction from focusing on what they consider the primary problem: dialysis itself and the mode of delivery.

- Mr. Richard Knight pointed out that one challenge confronting patients is that dialysis is done through a business model, which patients have to adhere to. The business model is not attuned to the patient, and a more individualized approach is needed, one that considers age as a factor. Many patients, including Mr. Knight, are able to leave dialysis and resume their activities (e.g., sports, work), and other patients cannot return to normal routines. Mr. Knight speculated that—using existing technology but with different approaches—the field can make some adjustments to the model.
- Dr. Abbott highlighted emerging research that reveals that cancer-related studies investigating muscle atrophy and fatigue found abnormal proteins that were specifically toxic to myosin fibrils in certain cancers.
- Dr. Nahed El Kassar noted that anemia affects fatigue, which has effects on physical and cognitive function. She emphasized the importance of correlating the hemoglobin level to what dialysis patients experience. In addition, Dr. El Kassar explained that anemia is identified in 17 percent of patients older than age 65, in an average of 27 percent patients at age 80, and in as many as 40 percent of patients residing in nursing homes. Anemia affects oxygen levels and mitochondrial function and can explain cellular function and fatigue. She further noted that anemia in older patients can be due to nutritional deficiencies, and she emphasized assessing their functioning. She highlighted [“Fatigability as a Predictor of Subclinical and Clinical Anemia in Well-Functioning Older Adults,”](#) which reports on findings from the Baltimore Longitudinal Study of Aging that might be relevant to this topic. Dr. El Kassar also called attention to [“Explaining the ‘Unexplained Anemia in Older Adults’: From Pathophysiology to Clinical Practice”](#)—an NIA workshop that will be held on April 9–10, 2024, both in person and virtually.

*What opportunities exist for federal agency partners to address post-dialysis fatigue and the issues raised during the workshop and this discussion?*

- Dr. Andrew Narva asked why the workshop was not titled post- “hemodialysis” fatigue, which seems more appropriate. Dr. Chan noted that patients switching to other modalities also experience fatigue and that PDF already has been discussed in the medical and scientific literature. Dr. Norton explained that patients have noted that “fatigue” does not capture the diversity of symptoms they experience. She emphasized the importance of not limiting or narrowing this topic.
- Dr. Chan reminded participants that a basic definition of PDF has yet to be determined and that PDF is a term that physicians coined but is sufficient for today’s discussions. The workshop revealed parallels with other diseases, such as chronic fatigue syndrome. Physicians and patients expressed concern about the stigma linked to such terms, which studies have shown affects patients’ ability to get treatment. In 2015, the National Academies of Sciences, Engineering, and Medicine (National Academies) recommended that myalgic encephalomyelitis/chronic fatigue syndrome be renamed to systemic exertion intolerance disease and be assigned a new ICD code. The National Academies report [“Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness”](#) prompted this action. Dr. Chan commented that these terms are not just naming side effects or complications of treatment. The symptoms affect many aspects of people’s lives, create inequities in wealth and the workforce, and impede the ability to participate in the community.
- Ms. Pearce noted that the National Kidney Foundation is reviewing how to build quality measures that more fully address the patient’s lived experience and is exploring how to make the CMS ESRD Quality Incentive Program (QIP) more patient-centric. She speculated that achieving the latter may require developing new measures and incorporating some of the definitions discussed in the workshop. It is unclear whether new measures are a priority from a care delivery standpoint,

especially given that the QIP does not provide incentives for this type of work. She emphasized that additional policy efforts in this area could be beneficial for patients.

- Dr. Narva emphasized educating patients about their treatment options. He noted that discussing this PDF phenomenon, or the lack of it, is a routine component of many nephrologists' approach to educating their patients about treatment modalities.
- In response to a question from Dr. Nee about patients who have received a kidney transplant and their experiences with prolonged fatigue, Dr. Chan noted that this patient population has many reasons to have generalized fatigue. Patients describe and identify PDF as an acute phenomenon that is debilitating and has strong temporal association with dialysis treatment.
- Dr. Norton agreed that some nephrologists have shared decision-making conversations with patients and discuss PDF. Conversely, she noted that many individuals who crash into dialysis have not had those conversations or made any informed choice about the dialysis modality they receive. Ensuring that individuals have the opportunity to make informed choices about their dialysis modality—with consideration of PDF as a potential outcome if they choose hemodialysis—would be an improvement. Dr. Chan added that in clinical practice guidelines, PDF is not one of the indicators for considering a modality switch.
- Dr. El Kassar commented on anemia and hemoglobin levels during dialysis and asked the nephrologists about physiological effects that could explain PDF. Dr. Chan clarified that the dialysis process involves three steps: removing fluids, changing electrolytes, and removing toxins. He also noted that the target hemoglobin range is 9–12 g/dL. Dr. Abbott noted that hemoglobin levels are not routinely monitored as a metric of dialysis. Dr. James Oliver added that metabolite shifts are occurring between the extracellular/intravascular space and the dialysis machine and also between the intracellular and extracellular spaces.
- Dr. Jodi Smith asked whether the workshop highlighted data on children experiencing PDF. She advocated for including children's and parents' voices in this conversation. Dr. Gipson explained that this initiative allows input across the life span and can be inclusive of children. No data were presented during the workshop that represented the pediatric perspective, which reflects an informational gap to be addressed.
- In response to a question from Dr. Zieman about learning from patients who do not experience PDF, Dr. Chan noted that 6 percent of patients who responded to the AAKP survey reported not having experienced PDF.
- Mr. Knight emphasized addressing dialysis in a holistic manner, rather than in isolation. More than 30 percent of patients crash into dialysis and are told that they need to stop working. Some patients can function to varying degrees, and they should be allowed to determine their abilities in consultation with their nephrologists. He reiterated individualizing dialysis, as opposed to applying a business model. Many patients will be able to work and function and have a better quality of life, which is the ultimate objective.
- Mr. Conway noted that kidney patients who are started on dialysis in the emergency room have never had a choice because their disease was not known to them. He remarked that for patients who have landed on dialysis before receiving a diagnosis—who have lost their jobs, who are dependent, who live on disability, and who have watched their financial security diminish—it is essential that the United States consider the whole person—as well as the taxpayer—in the larger ecosystem of kidney care.

## ***Summary***

Dr. Star summarized that he observed tremendous interest in this topic, both in the biological and clinical aspects of PDF and in the patients and their ability to return to work and other normal activities. PDF spans all the areas that NIH is interested in advancing in terms of promoting and using biology to promote health. NIDDK intends to begin addressing PDF. Dr. Chan, on behalf of KUH, has proposed an initiative to NIDDK leadership, and the institute anticipates that Congress will assist this effort. The next 2 years will be challenging, and KUH is reviewing other ways to initiate work. Dr. Star emphasized the importance of ensuring that the scientific component is rigorous and accurate. Participants with additional suggestions can contact Drs. Chan, Norton, or Star.

## **Adjournment**

Dr. Norton thanked the attendees for their participation and adjourned the meeting. The next KICC meeting will be held on September 20, 2024.



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