Kidney Health Initiative Expands Offerings

T he Kidney Health Initiative (KHI) is a public-private partnership founded in September 2012 by the American Society of Nephrology and the U.S. Food and Drug Administration (FDA). Since its inception, KHI has steadily increased its membership to more than 70 member organizations. KHI advances its mission through a portfolio of innovative, collaborative, and member-driven projects. The collaborative will complete six of its 13 initial projects by the end of 2015:

• Pharmacokinetics in Patients Receiving Continuous Renal Replacement Therapy
• Outcome Measures in Lupus Nephritis
• Promoting Kidney Health and Innovative Treatments for Kidney Disease: Barriers and Potential Solutions
• Pragmatic Trials in Dialysis: Challenges and Opportunities
• Regulatory Policies and Positions Affecting Device Approval in the US: Tools to Assess the Process and Foster Device Development for Patients with Kidney Disease
• Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease

Innovation in kidney disease is substantially lagging behind other specialty areas, despite the enormous toll that chronic kidney disease and end-stage kidney disease exacts on its patients. No one stakeholder—be it regulatory, payer, industry, patients, or health professionals—has the capability and resources to reverse this approximately 60-year trend. Rather, the diverse membership of KHI, including members from each of the critical stakeholders, is in an excellent position to pose solutions to these critical barriers and serve as a platform for their implementation.

The KHI “Promoting Kidney Health and Innovative Treatments for Kidney Disease: Barriers and Potential Solutions” workgroup helps frame the strategic priorities that will stimulate innovation in kidney disease and identifies several transformative initiatives to support. Please look for their publication in the coming months. KHI hosted a workshop titled “Understanding Patients’ Preferences: Stimulating Medical Device Development in Kidney Disease” in August 2015. The workshop was organized by the KHI “Workshop to Elucidate Role of Patient Preferences in Support of CDRH Regulatory Actions in Kidney Disease” workgroup, and balanced education with small group breakout discussions, allowing patients to share their ideas directly with the FDA, scientists, doctors, nurses, and technicians. The KHI workshop was attended by more than 100 participants including over 50 patients, care partners, and family members.

“KHI’s early progress gives kidney patients hope for a better tomorrow and emphasizes that real advances can be made through a collaborative approach that brings together all the stakeholders in the kidney space,” observed Prabir Roy-Chaudhury, MD, PhD, FASN, who co-chairs the KHI Board of Directors along with Patrick Archdeacon, MD, a medical officer in the Office of Medical Policy with the Center for Drug Evaluation and Research (CDER) at the FDA.

To advance efforts to improve patient safety and promote the development of therapies for diseases that affect the kidneys, KHI established a Patient and Family Partnership Council (PFPC) in 2015. PFPC has worked closely with the KHI Board of Directors, interacting, advising, and making recommendations on KHI member proposals, projects, and efforts so that patient involvement is meaningful and effective.

The KHI membership thanks the KHI Board of Directors for their leadership and service. In particular, the membership recognizes four leaders who are stepping off the KHI Board of Directors at the end of 2015:

• Nancy M. Gallagher, RN, CNN
• Kristine Kuus, PhD
• Sam M. Pederson

KHI would also like to recognize the new members of the KHI Board of Directors who will begin serving in 2016:

• Paul T. Conway
• Wendy St. Peter, PharmD
• Roberta L. Wager, MSN, RN
• Alexander S. Yezzi, MD

To obtain additional information or to discuss KHI, the initiative’s projects, or the KHI PFPC, please contact the KHI staff at KHI@asn-online.org.

Findings

Directed Kidney Donors Would Consider Kidney Paired Donation

More than 90 percent of directed living kidney donors and recipients would be willing to participate in kidney paired donation (KPD) programs, reports a survey study in *Transplantation*. The researchers surveyed 222 directed living kidney donors and their recipients treated at one Canadian center between 2001 and 2009. Respondents were asked whether they would have been willing to participate in KPD programs if that opportunity had been available at the time of their donation. The impact of various types of incentives, monetary and otherwise, was assessed as well.

Eighty-six donors responded to the survey: a rate of 42 percent. Of the responding donors, 93 percent said they would have been willing to participate in a KPD program. Most donors said they would be more willing if offered reimbursement for lost wages and travel. However, cash payments—up to $50,000—had little effect. Donors were also more willing to participate if there was some advantage to the recipient, such as a younger donor or a better HLA match. Willingness decreased with delays longer than 3 months or need for the donor to travel.

The researchers also approached 38 recipients during follow-up visits, all of whom participated. Ninety-two percent said they would have been willing to participate in a KPD program.

Kidney paired donation programs are an emerging approach to increase living donor transplantation among patients who have a willing but incompatible donor. If compatible living donors and recipients were to participate, the number of KPD transplants could be doubled.

A large majority of both directed donors and recipients would be willing to participate in KPD programs, the survey suggests. Participation might be increased by reimbursement for costs and increasing the efficiency of KPD, although not by cash incentives. The researchers note, “The finding that compatible donors and their recipients may be more willing to participate in KPD in exchange for a better kidney highlights the need for education and transparency in order to ensure compatible donors and recipients are adequately informed before engaging in KPD” [Hendren E, et al. Willingness of directed living donors and their recipients to participate in kidney paired donation programs. *Transplantation* 2015; 99:1894–1899].

Donor Hypothermia Reduces Delayed Graft Function

In deceased organ donors, initiating a period of mild hypothermia reduces the rate of delayed kidney function after transplantation, concludes a trial in the *New England Journal of Medicine*. After declaration of death according to neurologic criteria, deceased organ donors in two donation service areas were assigned to hypothermia, 34° to 35° C, or normothermia, 36.5° to 37.5° C. The temperature protocols began as soon as donation was authorized and continued until the patient left the intensive care unit for organ recovery. The main outcome of interest was the rate of delayed graft function, defined as need for dialysis in the first week after kidney transplant.

The study was terminated early when interim analysis showed the “overwhelming efficacy” of hypothermia. At that time, 370 deceased donors had been enrolled and 572 patients had received a kidney transplant.

Delayed graft function occurred in 28 percent of patients receiving kidneys from donors assigned to hypothermia versus 39 percent for recipients of kidneys from the normothermia group. On multivariable analysis, the odds ratio for delayed graft function with organs from the normothermia group was 0.62. The benefit of hypothermia was greater in renal grafts from expanded-criteria donors and other high-risk subgroups.

Delayed graft function occurs in up to half of recipients of kidneys from deceased donors. This trial found that inducing mild therapeutic hypothermia in the donor after declaration of death reduces the risk of delayed function after kidney transplantation. The improvement in clinical outcomes may be most pronounced in recipients of kidneys from the highest-risk donors [Niemann CU, et al. Therapeutic hypothermia in deceased organ donors and kidney-graft function. *N Engl J Med* 2015; 373:405–414].

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