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Special Report

Stimulating Patient Engagement in Medical Device Development in Kidney Disease: A Report of a Kidney Health Initiative Workshop

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New technologies challenge current dialysis treatment paradigms as devices become smaller, more portable, and increasingly used outside the dialysis clinic. It is unclear how patients will view this care transition, and it will be important to consider patient and care partner perspectives during all aspects of development for novel dialysis therapies, from design and clinical trials to regulatory approval. To gain insight into this area, the Kidney Health Initiative, a public-private partnership between the American Society of Nephrology, the US Food and Drug Administration, and nearly 80 member organizations and companies dedicated to enhancing patient safety and fostering innovation in kidney disease, convened a workshop of patients, care partners, and other kidney community stakeholders. The workshop included background presentations followed by focused small group discussions in 3 areas (device design, clinical trials, and regulatory approval). Participants explored how to involve patients throughout the life cycle of a medical device, including discussions of how patients can influence device design, assist in the planning and implementation of clinical trials, and provide input to affect regulatory decisions. Patients were engaged in the workshop discussion and interested in sharing their perspectives, but they recommended additional efforts around education, communication, and outreach in these areas.

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More than 14% of Americans have chronic kidney disease and more than 600,000 of these individuals have end-stage renal disease (ESRD), with 400,000 dependent on hemodialysis (HD).[1] Individuals with kidney disease have greater morbidity and mortality and poorer quality of life compared with individuals without kidney disease.[1,2] Technological innovation could potentially improve care and quality of life for individuals with ESRD. However, there has been a relative lack of innovation in this area. The kidney community lags behind other medicine subspecialties in conducting randomized controlled trials and research funding and as a result also lags in innovative drug and device development.[3,4]

In an effort to foster innovation and new product development, the American Society of Nephrology (ASN) and the US Food and Drug Administration (FDA) partnered to form the Kidney Health Initiative (KHI) in 2012. The mission of KHI is 2-fold: "to advance scientific understanding of the kidney health and patient safety implications of new and existing medical products and foster development of therapies for diseases and conditions that affect the kidney by creating a collaborative environment, in which the FDA and the greater kidney community can interact to optimize evaluation of drugs, devices, biologics, and food products."[5,p1615] Members of KHI may submit project proposals focusing on kidney-related topics ranging from product safety to community engagement, all positioned to drive collaboration and innovation in the kidney community.[5]

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The FDA Center for Devices and Radiological Health (CDRH) regulates medical devices, including ESRD devices such as HD and peritoneal dialysis systems, hemodialyzers, and vascular access devices. In an attempt to spur innovation in this product area, CDRH announced the "Innovation Challenge: End-Stage Renal Disease" in 2012.[6] Investigators submitted novel devices, including wearable and implantable dialysis systems, at various stages of development. However, patient perspectives on these innovative devices were lacking. To fill this void, CDRH proposed a KHI project to stimulate ideas for expanded patient input into the device development process. We describe the resultant workshop content and received stakeholder input on barriers and solutions to incorporating patient perspectives into product development and regulatory decision making for novel devices.

APPROACH

KHI formed a workshop planning committee, which included representatives from academia, industry, patient groups, professional associations, and the FDA (Table 1). The objectives of the workshop were to introduce product development concepts to patients and care partners, stimulate their participation in product development, and brainstorm best practices to allow participation in product development. Early on, the committee identified a lack of stakeholder familiarity with device regulatory and development pathways as a critical barrier. To provide education and thus promote meaningful engagement at the planned workshop, the group developed an animated video to generate interest in the topic and then held a webinar to provide critical background information to potential workshop participants.[7] Additional information on the progression of the project can be found in Box 1.

The workshop was open to the public and was promoted via kidney disease advocacy groups, ESRD Networks, professional societies, and KHI member organizations. Travel grants (n = 43) were awarded to patients and care partners to facilitate attendance. To encourage a diverse range of participants, grants were purposefully distributed based on commitment to collaboration (personal statement, webinar attendance, etc), demographics (region of country and age), and kidney disease status (current dialysis modality, transplant recipient, etc). Additionally, special accommodations were made with the hotel, transportation services, and local dialysis clinics to facilitate workshop attendance.

The workshop included introductory content, as well as plenary sessions designed to provide key information about specific stages of product development. These were followed by breakout sessions in which attendants were preassigned to one of 4 focus groups. Group assignment was loosely stratified by kidney disease status, patient/care partner status, and professional background to ensure a range of experiences in each group. Focus

Table 1. Kidney Health Initiative Project Work Group Members

Name	Affiliation
Workgroup co-chairs	
Dolph Chianchiano, JD, MPA	National Kidney Foundation; member, KHI Board of Directors
Frank P. Hurst, MD, FASN	CDRH, FDA
Work group members	
Deborah J. Brouwer-Maier, RN, CNN	Fresenius Medical Care, North America
Celeste Castillo Lee†	Patient advocate, Vasculitis Foundation; former program manager, Patient and Family Centered Care at University of Michigan Health System; member, KHI Board of Directors; Chair, KHI Patient and Family Partnership Council
Diana Clynes	American Association of Kidney Patients
Maria Ferris, MD, MPH, PhD	University of North Carolina, Chapel Hill; liaison for American Society of Pediatric Nephrologists
Jennifer E. Flythe, MD, MPH	University of North Carolina Kidney Center
Terri Hill, BSHA, RN, CNN	Fresenius Medical Care, North America
Martin Ho, MS	CDRH, FDA
Carolyn Y. Neuland, PhD	CDRH, FDA; member, KHI Board of Directors
Lillian Pryor, MSN, RN, CNN	Fresenius Medical Care, North America; liaison for American Nephrology Nurses' Association
Bradley Roynon, RAC	Baxter Healthcare Corporation
Melissa Threlkeld, MHA, FACHE	Patient advocate, Austin, TX
Linda Upchurch, MBA, MHA	NxStage Medical, Inc

Abbreviations: CDRH, Center for Devices and Radiological Health; FDA, US Food and Drug Administration; KHI, Kidney Health Initiative.

†Deceased.