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.

INDEX WORDS: End-stage renal disease (ESRD); dialysis; patient engagement; patient preference; patient satisfaction; patient choice; patient experience; patient-centered care; chronic kidney disease (CKD); technological innovation; medical device; product development; renal failure; workshop.

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 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

INDEX WORDS: End-stage renal disease (ESRD); dialysis; patient engagement; patient preference; patient satisfaction; patient choice; patient experience; patient-centered care; chronic kidney disease (CKD); technological innovation; medical device; product development; renal failure; workshop.
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. 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. 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

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<td>Workgroup co-chairs</td>
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<tr>
<td>Dolph Chianchiano, JD, MPA</td>
<td>National Kidney Foundation; member, KHI Board of Directors</td>
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<td>Frank P. Hurst, MD, FASN</td>
<td>CDRH, FDA</td>
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<td>Work group members</td>
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<tr>
<td>Deborah J. Brouwer-Maier, RN</td>
<td>Fresenius Medical Care, North America</td>
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<tr>
<td>Celeste Castillo Lee</td>
<td>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</td>
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<tr>
<td>Diana Clynes</td>
<td>American Association of Kidney Patients</td>
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<tr>
<td>Maria Ferris, MD, MPH</td>
<td>University of North Carolina, Chapel Hill; liaison for American Society of Pediatric Nephrologists</td>
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<td>Jennifer E. Flythe, MD, MPH</td>
<td>University of North Carolina Kidney Center</td>
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<td>Terri Hill, BSHA, RN, CNN</td>
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<td>Martin Ho, MS</td>
<td>CDRH, FDA</td>
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<td>Carolyn Y. Neuland, PhD</td>
<td>CDRH, FDA; member, KHI Board of Directors</td>
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<td>Lillian Pryor, MSN, RN, CNN</td>
<td>Fresenius Medical Care, North America; liaison for American Nephrology Nurses’ Association</td>
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<td>Bradley Roynon, RAC</td>
<td>Baxter Healthcare Corporation</td>
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<td>Melissa Threlkeld, MHA, FACHE</td>
<td>Patient advocate, Austin, TX</td>
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<td>Linda Upchurch, MBA, MHA</td>
<td>NxStage Medical, Inc</td>
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**Table 1. Kidney Health Initiative Project Work Group Members**

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

1Deceased.
Box 1. Progression of Project

A: Project Submission
KHI developed an inclusive and transparent project submission process in which KHI members submit project proposals via an online portal.

B: Project Endorsement
Proposals are reviewed by the KHI Board of Directors and evaluated based on the proposal’s ability to meet the KHI mission, make a lasting impact, and outline a deliverable that is feasible before endorsed as an official KHI project.

C: Work Group Formation
Once a project is endorsed, multidisciplinary work groups are formed through an open process by which an application to serve as a work group member is posted on the KHI website.

D: Video Development
The work group developed and released a short animated video to engage patients and encourage them to attend educational webinars held in April 2015. The video has been viewed more than 1,800 times (https://www.youtube.com/watch?v=HfpxO30y84).

E: Webinars
The webinars educated patients on the device development process, the role of the FDA (CDRH), and the CDRH Patient Preferences Initiative in order to provide critical background information to potential workshop participants.

F: Workshop
The work group hosted a workshop titled “Understanding Patients’ Preferences: Stimulating Medical Device Development in Kidney Disease” in August 2015. The objectives were to introduce product development concepts to patients and care partners, stimulate their participation in product development, and brainstorm on best practices to allow participation in product development.

Table 2. Discussion Questions for Workshop Breakout Sessions

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<tr>
<th>Session</th>
<th>Discussion Questions</th>
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| Session 1: How can patients and care partners assist in the development and design of a new medical device? | 1. In ESRD care, what are some gaps that new devices may help?  
2. What technologies are in need of improvement?  
3. How can device developers obtain input from patients and care partners for design issues?  
4. What function or components of medical devices are important to patients and care partners? |
| Session 2: How can patients and care partners help ensure the success of future clinical trials? | 1. Why do some people choose to participate or not to participate in clinical trials?  
2. How can we increase patient involvement in clinical trials?  
3. What study factors are most important to patients and care partners?  
4. What are some ways patients and care partners can help in the design of a clinical trial?  
5. Are current PROs adequate? Are we measuring the right information during a trial?  
6. Can we assess patient preferences during clinical trials? |
| Session 3: How can patients and care partners help with the decision to make a new device available as well as improve a device once it is on the market? | 1. How should patients and care partners participate in the FDA process to “approve” a new medical device? What problems could arise?  
2. Who should collect the patient preference information?  
3. What is benefit vs risk and how do patients and care partners think about these topics?  
4. Using the idea of benefit/risk and a medical device label, how will patients determine what medical device is right for them? |

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

Overview

The workshop was held August 12 to 13, 2015, in Baltimore, MD. There were 109 attendees, including 49 patients and 11 care partners. Among the patients, 40 self-identified as having ESRD (in-center HD, n = 12; home HD, n = 8; peritoneal dialysis, n = 8; and transplant recipient, n = 12). There were also individuals who self-identified as having chronic kidney disease (n = 5) or rare kidney disease (n = 4). Other participants included nephrologists, scientists, and nurses, as well as representatives from government, industry, and nonprofit organizations. A list of faculty is provided in Item S1 (available as online supplementary material).

The workshop began with a discussion of the ongoing transformation of the health care system from a paternalistic environment dominated by health care professionals to a more patient-centric environment valuing patient-provider partnerships. In today’s health care environment, patients are encouraged to access medical information and take more active roles in their health care. Such an environment creates opportunities for patients to be strong advocates for driving new therapeutic advances. A provider and patient partnership brokered by the Multiple Myeloma Research Foundation was highlighted as a successful effort by another disease group that resulted in new therapeutic advances.

FDA/CDRH Patient Initiatives Overview

As part of the introduction, representatives from the CDRH provided an overview of recent initiatives to incorporate patient perspectives into the device approval process. In 2013, the CDRH launched the Patient Preference Initiative, which aims to develop a systematic approach to eliciting, measuring, and incorporating information about patient preferences throughout the device life cycle. Additionally, the CDRH has developed guidance for patient involvement in regulatory decision making and recently announced the formation of a Patient Engagement Advisory Committee, which will provide further patient perspectives on FDA policies. In parallel, there has been growing emphasis on incorporating patient-reported outcomes (PROs) into device studies, reinforcing the importance of PROs in the regulatory process. The CDRH has also partnered with the Medical Device Innovation Consortium, a public-private partnership focused on medical device regulatory science, to develop a framework for incorporating preference data throughout the device development cycle and a catalog of valid scientific methods for evaluating patient perspectives in the regulatory context.

Innovation Forum

To help frame development concepts, an Industry Innovation Forum was held during the workshop to showcase ESRD devices at varying stages of development (Table 3) and highlight how such devices might benefit from patient input. The session was intended to promote discussions among device developers and stakeholders and generate patient interest in being involved in the development process. The presenters commented on the value of patient feedback and stressed the importance of patient participation at each development phase. The rest of the conference focused on opportunities for patient involvement in specific aspects of the device development and approval process.

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<thead>
<tr>
<th>Company/Organization Name</th>
<th>Product</th>
<th>Website</th>
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<tr>
<td>The Kidney Project, University of California San Francisco</td>
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<td>Nx2me Connected Health</td>
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<td>Humacyte Inc</td>
<td>GORE ACUSEAL Vascular Graft</td>
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<td>Humacyl HAV (human acellular vessel)</td>
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<td>PAK1 (project designation name, may change at market entry)</td>
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Session 1: How Can Patients and Care Partners Assist in the Development and Design of a New Medical Device?

Overview

Patient advocacy takes many forms, ranging from calls for policy change to simply speaking up regarding health care needs. Although patients have not traditionally been involved in the design and development of medical devices, they are uniquely positioned to play a key role. This session explored these concepts because patients are keenly aware of unmet needs or technologies that are in need of improvement. For novel devices, companies and patients can work collaboratively to ensure that the final designs and labeling are patient centric.

Engaging Patients in the Development of Medical Devices

One of the products demonstrated in the Innovation Forum was a connected health platform used with home HD. The ideation stage of development was initiated in part in response to patient input regarding a desire to automate flow sheets and assist in troubleshooting alarms. Incorporating a user guide into the platform further supported patients, easing their transition to the home environment. After initial design of this platform, patients reviewed and tested the product, identifying opportunities to improve subsequent iterations. The patient input was critical to the advancement of the product.

Determining Acceptable Benefits and Risks of Emerging Therapies: A Patient Community’s Approach

A case study from a patient community was presented as an example of successful patient engagement in product development. To encourage innovation in an area of unmet need, the Parent Project Muscular Dystrophy group conducted research to determine how patients and care partners weigh potential benefits and risks of treatment. The results were intriguing in that patients were willing to tolerate substantial risk in exchange for modest benefit. This disease community used their findings to develop and submit to the FDA a draft guidance document for developing drugs for the treatment of Duchenne muscular dystrophy.13

Prioritizing Patient Preferences

The Dutch Kidney Foundation and the Dutch Kidney Patient Association have worked together to encourage incorporation of patient preferences into the device design process for novel therapies. As an example, the initial concept for a new wearable HD system changed when developers learned that many patients would actually prefer night-time treatments with freedom from the device during the day versus a continuous wearable device. This critical feedback informed ongoing work on the development of a compact home dialysis device as part of their NeoKidney initiative.14

Patient Feedback From Breakout Session 1: Device Design

Patients expressed interest in participating in the design process, and many made suggestions about how to improve existing technologies. Ideas included an emphasis on automation, connectivity, and enhanced self-care. Examples included increased machine portability, automatic transmission of treatment data, remote monitoring to decrease office visits, and point-of-care testing for monthly laboratory tests. Some attendees pointed out that many patients (and some providers) may not be aware of existing technologies and suggested greater opportunities for education, as well as improved communication among patients, clinicians, and developers. The optimal solution for this knowledge gap was unclear, but suggested options included online device user forums, a feedback “clearing house,” and patient advisory boards for manufacturers. It was noted that electronic communication is not an option for everyone and that telephone, mail, and in-person focus groups should also be used. Many thought that companies should broaden engagement with patients, but noted barriers to this process, including health care privacy rules. The groups also expressed a need to develop guidelines for developers to interact with patients regarding design questions. Participants also expressed the need for greater kidney disease education in general as a means to help engage patients in the process of improving technologies. Peer support groups and patient mentorship programs were identified as other means to increase patient education and engagement.

Session 2: How Can Patients and Care Partners Help Ensure the Success of Future Clinical Trials?

Overview

Nephrology trials face many challenges related to research design and patient recruitment. Kidney disease is often silent until later stages, and the lack of overt symptoms may cause patients to miss eligibility windows. Additionally, many kidney diseases progress slowly, requiring lengthy trials that are less attractive to participants. Kidney trials may also be less appealing because they typically center on mortality and biochemical changes rather than patient-oriented outcomes (eg, symptoms and quality of life). This session explored platforms for patient engagement in research, existing PRO measures, and ideas for increasing patient involvement.
Patient-Informed Clinical Trials

Improved research infrastructure via patient and investigator networks and greater focus on patient-centered outcomes are 2 strategies to address nephrology research challenges. For example, patient-powered social research networks such as those facilitated by the web-based platform PatientsLikeMe may be beneficial. These networks, which bring patients together to share information and experiences, have been used successfully in other disease states to identify and notify patients about clinical trial eligibility, as well as provide a rich data source to guide PRO development. However, as of the date of the workshop, no web-based dedicated kidney patient forums have been created despite their potential to identify and recruit participants, as well as foster research aligned with patient goals.

PRO Instruments in Dialysis: Are We Measuring the Right Outcomes?

One potential strategy to increase patient interest in clinical trial participation is to focus on trial outcomes that are most important to patients. This session was designed to give participants a high-level overview and examples of PRO measures that have been used in prior dialysis clinical trials. To facilitate information accessibility, the session focused on PROs measuring quality of life and symptom burden, but acknowledged that there are numerous other types of PROs, such as patient experience of care. Speakers suggested that patient participation in all aspects of PRO development and testing is needed to ensure that measures align with patient priorities. The subsequent focus group sessions explored patient and care partner perceptions of existing recognized PROs such as the Kidney Disease Quality of Life (KDQOL) survey.

Patient and Care Partner Engagement in Clinical Research

The Patient-Centered Outcomes Research Institute (PCORI) includes “Engagement” as one of their core program initiatives and believes in including patients and other stakeholders in the research process, from topic selection through dissemination and implementation of results. Part of this effort includes the Patient-Centered Clinical Research Network (PCORNet), which is an initiative to increase patient engagement through the creation of disease group-specific networks of patients, family members, and stakeholders (Patient-Powered Research Networks). In working with these networks, researchers have learned the importance of educating patients and care partners about basic research tenets and best practices to facilitate effective collaboration in the development and design of networks, registries, clinical trials, and research projects.

Patient Feedback From Breakout Session 2: Clinical Trials

Patients frequently cited lack of knowledge about available clinical trials as a barrier to participation. Suggestions for trial publicity included notifications via professional/patient organizations, dialysis providers, ESRD Networks, and clinic bulletin boards. Attendees noted that the recruiter is important, citing a better chance of participation if asked by their physician or another trusted provider. Patients also expressed interest in participating in study planning stages, suggesting that “patient-endorsed” trials might foster community interest. Patients also voiced a need for more patient-centric outcome measures. Some observed that existing PROs, which are intended to capture quality of life, do not always do so. Several participants noted personal experience with low KDQOL scores, yet self-reported their overall quality of life as very good. Others expressed frustration that trial findings (either positive or negative) are not communicated to trial participants or the greater patient community, noting that this was essential to reassure patients that study participation was worthwhile. A few patients thought that placebo-controlled trial designs were a deterrent because they were reluctant to receive the placebo, seeing no potential benefit. The importance of trial convenience, including time commitment, travel, and the ease and frequency of follow-up visits, was noted as an important factor affecting participation. Additional barriers included lengthy and confusing consent processes (often with the most junior member of the team), narrow selection criteria, and privacy concerns. Incentives were discussed and included compensation for time and loss of income, expense reimbursement, the ability to keep devices after trial completion, and being a patient consultant for the company after device approval. Important intangible incentives for participation included the potential future availability of a device that improves treatment convenience (reduced time, portability, emergency backup, and affordability).

Session 3: How Can Patients and Care Partners Help With the Decision to Make a New Device Available, as Well as Improve a Device Once It Is on the Market?

Overview

This session highlighted examples and opportunities for patients to participate in the regulatory decision-making process, ranging from patient testimony at an advisory panel meeting to participating in complex preference surveys to evaluate benefit-risk trade-offs. After approval, continued patient participation in the postmarket phase also provides critical real-world feedback, which can be used to improve product performance and safety.
**The Patient Voice and the FDA**

The FDA has existing opportunities for patient engagement. The FDA Patient Network website provides FDA-related information for patients, including a patient network newsletter, a patient-comment portal, and public meeting notifications. Patient-focused education regarding clinical trials and webinars led by FDA experts can also be found on the website. The FDA also has a Patient Representative Program, which incorporates patient voices into advisory committee discussions and includes over 200 patient representatives across over 300 diseases and conditions. Of note, many meetings are open for public comment so that patients can still participate, even if they are not advisory panel members.

**FDA Regulatory Decision Making: Obesity Study as a Potential Tool**

In addition to evaluating the safety and efficacy of a device, CDRH considers patient viewpoints when making benefit-risk determinations for device approvals. As an example, this session described how, in an effort to better understand how to quantify patient preferences in the context of a regulatory decision, a scientific survey related to weight-loss devices was conducted in a population of patients with obesity. The study provided quantitative information related to patient-focused trade-offs among effectiveness, safety, and other attributes of weight-loss devices. It also allowed the creation of a decision tool used to calculate both the minimum acceptable benefit that patients would require for a given treatment and the maximum tolerable risk. This study showed how patient preference science could be used in the regulatory context and helped facilitate the first new obesity device approval since 2007.

**Patient Impact in the Postmarket Phase**

Although clinical trials provide initial data on benefits and risks of new products, subsequent data for product monitoring are also important. Postmarket surveillance systems are used to update benefit-risk information, but these systems are limited by under-reporting in that users may not report adverse events as they occur. Although it is part of the FDA’s mission to monitor safety and effectiveness, all stakeholders, including providers and patients, must recognize the importance of safety reporting. These reported “real-world experiences” could help inform future product precautions or risk modification strategies. Having reliable and meaningful postmarket information about device safety, effectiveness, and quality is key for informing care, enhancing device performance, and improving patient outcomes.

**Patient Feedback From Breakout Session 3: Regulatory Decision/Postmarket**

Patients cited the biggest barrier for patient participation in the regulatory process as lack of awareness about opportunities, including those listed on the FDA Patient Network website. The group recommended that the FDA focus on educational outreach by creating a portal where patients could access information on treatment options, benefit-risk analyses, available devices, and adverse event reporting. The importance of plain language was also noted. To transmit information from patients and care partners to the FDA, participants suggested on-site FDA meetings, patient advocacy group meetings, and virtual contact via an online forum. The group again focused on education as a way to increase patient and care partner participation in the regulatory process.

The challenge of labeling devices to reflect patient-specific benefit-risk was also discussed. It was noted that patients have highly individualized ideas of what increases quality of life, what decreases burden, and the trade-off that is acceptable. For this reason, it was mentioned that patient preference information used to guide regulatory decisions should be collected by experts in patient preference science and validated in a separate group.

**SUMMARY**

During the focused sessions, patients expressed interest in participating in the device development process, but they recommended additional efforts around education, communication, and outreach to improve participation in these areas. In addition to increased opportunities for patient education on device development and regulatory processes, it was suggested that there should be more opportunities for education about kidney diseases in general. Several educational resources already exist for patients with kidney disease, but improved publicity of such resources may be of benefit. Alternatively, a “1-stop shop” for kidney disease education could link existing tools to improve use. Increased access to such tools may enhance patient activation, empowering patients to ask questions and become more involved in treatment plan selection, as well as become more involved in the device development process. Enhanced peer mentoring was also identified as a means to facilitate education. Some existing peer mentoring programs are informal and clinic based, but there are also formal programs available.

Regarding communication, stakeholders acknowledged numerous challenges that exist in current communication paradigms. In general, these include barriers to communication between patients and other stakeholders (clinicians, academia, payers, regulators, and industry) in clinical and nonclinical environments.
Fortunately, existing communication barriers are slowly being taken down in the clinical environment as medicine shifts toward a patient-centered clinical approach that encourages clinicians to truly listen to patients. As noted, improving educational resources could encourage more patients to speak out, facilitating more effective health care partnerships. Communication between patients and nonclinical stakeholders such as regulatory personnel raises unique challenges. Due to limitations placed on patient data collected at the federal level, government agencies face additional barriers to soliciting patient input. Similarly, device developers have voiced concerns about interacting with patients to obtain feedback at early stages because of the perceived off-label promotion of those products. Although there are some recommendations in place for products approved for investigational use, guidance is lacking for products earlier in development. Investigators may also be concerned that contacting patients directly may be in conflict with current health care privacy laws.

Privacy concerns could potentially be alleviated if patient feedback was solicited outside the clinical environment via an intermediary. Creating communication “hubs” would allow 2-way communication and provide a place for stakeholders to partner with patients. These hubs could also be a clearinghouse for kidney-related educational resources. Currently, there is no comprehensive source for information about advocacy groups, clinical trials, and new products. Similarly, there is no forum in which patients and developers could freely engage and communicate about device and clinical trial design. Potential options for communication hubs include dialysis clinics, regional ESRD Networks, online forums, or national patient organizations.

Outreach to patients without access to electronic communication was cited as important. Options to enhance patient outreach included dissemination of information through ESRD Networks or various channels in dialysis organizations/clinics (social workers, nurses, etc). Patient organizations could play a role as well. For example, KHI’s newly formed Patient and Family Partnership Council, which includes members from multiple kidney patient organizations, intends to work closely with patient organizations to provide strategic guidance to KHI and its industry members regarding strategies to address the education and communication barriers identified during the workshop.

Our workshop, to our knowledge the first of its kind, is an important step toward enhancing patient engagement in the device development process. However, our report has limitations. First, participants may not reflect the general ESRD population. We purposefully directed travel grants and stratified focus groups, but recognize that individuals with substantial comorbid conditions were excluded due to inability to travel. Additionally, we used loosely stratified focus groups and did not seek to apply exhaustive rigorous qualitative methods in our analysis of the results. Presented results summarize and highlight the most important concepts identified by workshop participants.

Going forward, we believe that each stakeholder can have a unique role in improving patient input in the development and regulatory process. For example, device companies could partner with patient groups to solicit patient input during the design phase, as well as during the clinical trial stage, to ensure that devices and trials are patient centric. Organizations such as KHI and the Patient and Family Partnership Council could potentially facilitate these relationships as an intermediary. Regulators can develop additional mechanisms to seek feedback from patients to help determine areas of unmet need and provide clear recommendations to the development community as to how patient perspectives can be used to enhance the regulatory process.

In conclusion, the workshop demonstrated that patients and care partners are generally interested in the device development and regulatory process but lack knowledge about potential opportunities for involvement. The workshop generated interest among patients and provided ideas and momentum to realize the goal of greater patient engagement in all aspects of the product development process. Areas of focus going forward will involve improved communication and education. Additionally, outreach efforts to engage hard-to-reach patients to ensure appropriate representation from all patients with ESRD is critical. Similarly, future efforts should expand to include the entire spectrum of kidney disease, including chronic kidney disease and transplantation.

ACKNOWLEDGEMENTS

We dedicate this article to the memory of coauthor Celeste Castillo Lee, who died while the manuscript was under revision. Celeste was a tireless patient and care partner advocate whose efforts have done much to raise the profile of patient engagement and patient- and family-centered care. For additional information on Celeste’s legacy, please refer to https://www.asn-online.org/khi/patients.aspx?ID=6.

The authors would like to thank Melissa West and Ryan Murray for their valuable contributions to this manuscript and the overall project. Without their tireless efforts, the workshop would not have been possible.

The views and opinions expressed in this publication are those of the authors and do not necessarily reflect the official policies of any KHI member organization, the US Department of Veterans Affairs, or the US Department of Health and Human Services, nor does any mention of trade names, commercial practices, or organization imply endorsement by the US Government.

Support: This work was supported by the KHI, a public-private partnership between the ASN, the FDA, and nearly 80 member organizations and companies to enhance patient safety and foster innovation in kidney disease. KHI funds were used to defray costs incurred during the project management support, workshop costs, and travel grants provided to more than 40 patients or care
partners. However, there was no honorarium to KHI work group members or speakers. KHI makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the members of the work group. More information on KHI, the work group, and the conflict-of-interest policy can be found on the KHI website. Dr Flythe is supported by National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health (grant K23 DK109401).

Financial Disclosure: Mr Chianchiano has a consultancy agreement with the National Kidney Foundation. Ms Upehrich is employed by N/Stage Medical, Inc. Ms Hill is employed by Fresenius Medical Care, North America. Drs Hurst, Fisher, and Neuland are employed by the FDA. Dr Flythe has received speaking honoraria (Dialysis Clinic, Inc; Renal Ventures; American Renal Associates; ASN; National Kidney Foundation; multiple universities; and Baxter) and research funding for studies unrelated to this project from the Renal Research Institute, a subsidiary of Fresenius Medical Care, North America. To the best of Dr Hurst’s knowledge, Ms Lee had no relevant financial interests.

Peer Review: Evaluated by 2 external peer reviewers, an Associate Editor, and Deputy Editor Berns.

SUPPLEMENTARY MATERIAL

Item S1: Faculty list.

Note: The supplementary material accompanying this article (http://dx.doi.org/10.1053/j.ajkd.2017.03.013) is available at www.ajkd.org

REFERENCES


