Understanding Patients’ Preference: Stimulating Medical Device Development in Kidney Disease – Workshop Overview
Held August 12-13, 2015
Federal Drug Administration’s (FDA) Center for Devices and Radiological Health’s (CDRH) Vision

“Patients in the U.S. have access to high-quality, safe and effective medical devices of public health importance first in the world.”
Patients Can Help FDA/CDRH Make Decisions
Patient Preferences

Patient Preferences is defined as the relative desirability or acceptability of features that differ among alternative diagnostic or therapeutic strategies. **In short** patient preferences refer to the patient’s evaluation of health outcomes provided by a certain health care choice.

Even Shorter: What risks are we (patients) willing to take for possible benefits of a new drug and medical device?
Past Approval

FDA’s decisions mostly considered whether or not a device was beneficial and safe. The devices that were approved had a high level of benefit and a low level of risk for most patients.

It is now understood that some patients are willing to tolerate more risk, especially when treatment options are limited.
Approval Today
The FDA considers some of the following questions:

- How much do patients value a treatment?
- Does the treatment improve the patient’s overall Quality of Life?
- How do patients weigh the potential benefits and risks of treatment?
Overview of Patient Preferences Initiative

In 2013, the FDA’s Center for Devices and Radiological Health (CDRH) began to explore new ways to identify and incorporate the patient voice into decision-making on medical devices. This new effort was called the Patient Preference Initiative.

Today, in addition to the usual assessments of benefit and safety, CDRH will also consider how patients will view a particular device in terms of benefit and risk and use that information to inform approval decisions.

In addition to the Patient Preferences Initiative, the FDA is reaching out to patients and asking for their input through:
- FDA Patient Network
- FDA Website
- Patient Representative Program
- Patient Centered Meetings
We need your help…What do patients want?
Why Patients’ Preferences are Important

• Patients and care partners experience life with medical devices every day or nearly every day.

• Yet, as new medical devices are being designed or tested, we, patients, are often not asked what we like or will work best for us.

• The Kidney Health Initiative brought together patients, care partners, scientists, doctors, nurses, technicians, and companies…

• To ask and hear what is important to patients, and to think about how those ideas can be measured and used by the companies that are developing new or improving existing medical devices.
Patient Preference KHI Workshop
Overview

• Wednesday, August 12 – Thursday, August 13, 2015

• Hilton Baltimore BWI Airport, Linthicum Heights, MD

• Over 100 individuals attended, including 60 patients, care partners and family members

“I think this workshop was revolutionary. I hope it will be the beginning of opening a robust dialogue for patient input in all phases of device development into the future.” – Melissa T., Patient & Participant
Geographic Breakdown of Workshop Attendees
Stakeholder Type Breakdown of Workshop Attendees

- Patient: 49
- Government: 13
- Nephrologist: 5
- Nurse: 4
- Non-profit / Foundation: 5
- Care partner / Family member: 11
- Industry: 11
- Other: 5

Legend:
- Patient
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- Other
KHI Workshop Program Overview

The keynote speakers for the workshop included:

• Paul T. Conway *(Kidney Transplant Recipient, President of the American Association of Kidney Patients)*

• Robert Califf, MD *(Deputy Commissioner of Medical Products and Tobacco, FDA)*

Presentations throughout the workshop touched on the need for active patient participation and asked how patients and care partners could:

• Assist in developing new medical devices?

• Ensure the success of future clinical research?

• Help with the decision to make a new device available as well as improve a device once it’s on the market

***Due to the high level of interest, KHI uploaded archived presentations to the workshop’s page in the Patients Info section of the KHI website: http://www.asn-online.org/khi/patients.aspx?ID=3***
New Innovative Devices or Those on the Horizon
Our Innovation Forum invited several medical device companies and academic investigators to show how incorporating patient preferences could be included in their product development. Innovative devices for peritoneal dialysis, hemodialysis and home hemodialysis that were discussed included:

Emerging HUMACYL™ Profile

Wearable Artificial Kidney
Hear the Voices of Patients & Attendees

• “It was a good mix of people—patients, industry, FDA, doctors.” – Niki H., Industry

• “Thought, effort and resources put into making the entire experience patient-friendly and patient-centered, with the structured facilitation to collect patient perspectives in a way that can readily inform policy and process changes, innovation, and delivery in a way that improves the situation for patients” – Kathryn O., FDA

• “I appreciated having first hand contact with experts in the field. This will improve my son's care and quality of daily life.” – Bobbie R., Family Member

• “What I liked most about the meeting was everything! The selection of speakers, sessions, and content was extremely engaging. You got the opportunity to hear from everyone in the process of your care.” – Thelma B., Patient

• “I have never been asked before about what was important to me, and how my life could be improved while on dialysis. I have had end stage renal disease for 33 years and was on dialysis in 1983 and am back on in 2015 and the quality of my life is the same. Finally, we [patients] are at the table”. Celeste L., Patient
Next Steps for Attendees

✓ Complete a workshop evaluation form, so that KHI can improve future patient-centric workshops

☐ Share information from the workshop with your community [fellow patients back home at their local dialysis clinics or patient groups or churches or community groups] (on-going)

☐ Review the meeting’s Executive Summary, once it is distributed in late 2015/early 2016 and let us know if we got it right!

☐ Sign up for KHI’s mailing list to stay involved and updated on patient preference activities and information by emailing KHI staff at KHI@asn-online.org (on-going)
What You Can Expect From Us?

Next Steps for KHI Workgroup

• Complete and distribute the meeting’s Executive Summary to the workshop attendees and broader kidney community in late 2015/early 2016

• Develop two parallel white papers by February 2016 that focus on:
  1) patient engagement exercise and lessons learned and;
  2) content that was shared and strategies for moving the patient preference concept forward

• Assess industry’s perspective on the workshop and determine what additional activities can support their efforts to include patients’ preference in medical device development
Next Steps for KHI Patient and Family Partnership Council

Additional opportunities have been identified and will be discussed with the KHI Patient and Family Partnership Council (PFPC). Such opportunities include:

- Assessing the development of an online patient community
- Partnering with the dialysis organizations to support product development
- Notifying the Centers for Medicare and Medicaid Services of the workshop and the attendees’ interest in its attendance at future conversations or workshops
Additional Resources

The following links were highlighted as additional resources at the workshop:

- FDA Patient Network: http://www.fda.gov/ForPatients/About/default.html


- American Association of Kidney Patients: https://www.aakp.org/education/resourcelibrary.html

- National Kidney Foundation – Clinical Trials: https://www.kidney.org/patients/resources_ClinicalTrials


- PatientsLikeMe: https://www.patientslikeme.com/

- PCORnet, the National Patient-Centered Clinical Research Network: http://pcornet.org/