Developing Efficient and Effective Regulatory Pathways for Patient Centered Device Innovation

Prabir Roy-Chaudhury MD, PhD, FRCP (Edin)
University of Arizona Health Sciences and SAVAHCS

Disclosures

- Consultant/Advisory Board: WL Gore, Medtronic, BD Bard, Cormedix, Humacyte, Akebia, Relypsa, Cylerus, Vascular Therapies
- Grant/Research Support: NIH, VA, NSF
- Clinical Trial Support: Bayer, Akebia, Vascular Therapies, Cormedix

Outline

- Poor Value in ESRD and Vascular Access Care
- Patient Centered Device Innovation
- Innovative regulatory initiatives in this area

Poor Value in Vascular Access Care

Poor Value = Bad Outcomes 50-60% patency at 1 year

Cost 1.5b/year

Without any mention of quality of life

How can we break this cycle?

Break the cycle through patient-centered innovation

- Innovation (discovery or process of care) that targets the issues that are important to the PATIENT
- Not what is important to the physician, payor, regulator or to industry
The things that are important to patients are often very different from the things that are important to the other stakeholder groups.

**Patient Bias**
- Ability to travel
- Dialysis free time
- Washed out post dialysis
- Death/Mortality
- Hospitalization
- Drop in blood pressure

**Physician Bias**
- How do we develop new therapies that address the issues that patients feel are important?

**Patient Focused Drug Development**
- Patient Drug User Fee Act (PDUFA V)
- FDA committed to holding 24 disease area specific meetings with individual patients and patient groups

**MDIC patient centered benefit-risk project**
- Medical Device Innovation Consortium (MDIC) is very interested in Patient Preferences and Risk-Benefit analyses
- Catalog of Patient Preference Assessment Methods
- Agenda for Future Research in Patient Preferences

**Patient preferences for renal devices**
- Patient’s tolerance for “risk” varies tremendously
- Patients on home hemodialysis may sacrifice some degree of safety with regard to vascular access for an improved (more independent) quality of life
- From the FDA/EMA/PMDA viewpoint there needs to be a way to get insight into how patients perceive the risk/benefit ratio for a specific product
- Incorporated into the regulatory pathway
- The tools for this do not exist...

**Patient preferences workshop**
- How can patients and care partners assist in the development of a new medical device?
- How can patients and care partners help ensure the success of future clinical trials?
- How can patients and care partners help with the decision to make a new device available as well as improve it once it is on the market?
Involving patients in innovation

KHI project on clinical trial endpoints for vascular access

KHI vascular access end points: What they can do...

- Creates a more well defined product development pathway for vascular access
- Catalyst to enhance INTEREST, INNOVATION and INVESTMENT in this field
- Develop better therapies for our patients with vascular access dysfunction