ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Kidney News

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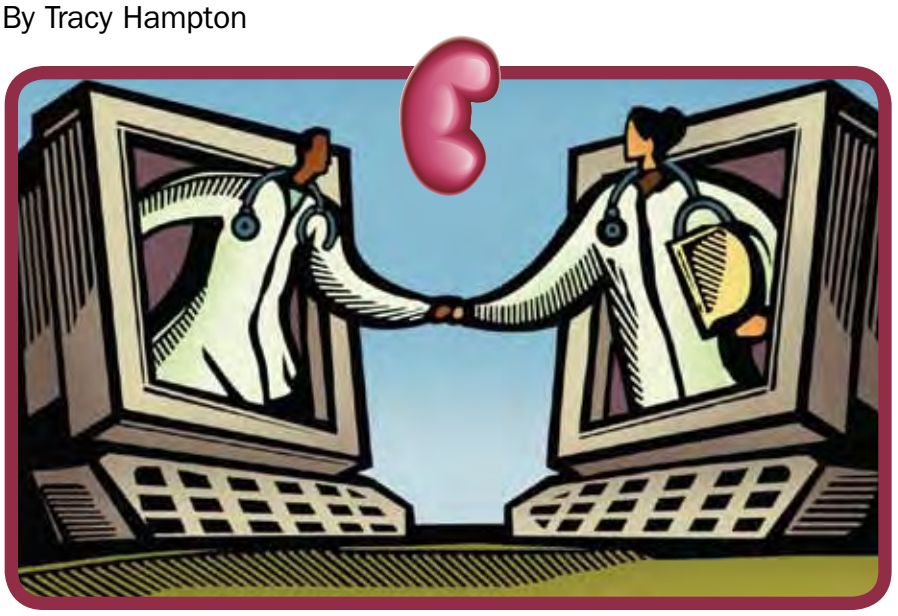
Primary Care Physicians and Nephrologists Favor Collaboration in Kidney Disease Care

By Tracy Hampton



Collaboration between primary care physicians (PCPs) and nephrologists in the care of patients with chronic kidney disease (CKD) is widely advocated, but how do these clinicians prefer to collaborate? That was the focus of recent research on CKD care (Diamantidis CJ et al. Primary Care-Specialist Collaboration in the Care of Patients with Chronic Kidney Disease. *Clin J Am Soc Nephrol*, February 2011).

"We were able to highlight how primary care providers and nephrologists differ on certain aspects of the care of patients with chronic kidney disease," said first author Clarissa Jonas Diamantidis, MD, of the University of Maryland Medical Systems. "We were also able to identify potential barriers to collaboration among primary care providers and nephrologists."

Nephrologists versus PCPs

Communication between PCPs and specialists in the care of patients with chronic illnesses has been linked with improved clinical outcomes, but collaborative care models for CKD across the United States have been limited.

"There are examples of successful multidisciplinary CKD teams including PCPs, nephrologists, nurses, pharmacists, social workers, and dieticians, but we have a long way to go in the U.S. to develop and test these models of care and determine if they are

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Researchers, FDA, and Industry Convene with NIH to Address Acute Kidney Injury

By Rachel Shaffer

Novel interventions and therapeutic agents being developed by academia and the pharmaceutical industry hold promise for the prevention and treatment of acute kidney injury (AKI). But questions about the design of clinical trials for these agents must be addressed before nephrologists can begin to study the therapies—and bring them to patients.

Nephrology researchers and clinicians met with National Institute of Diabetes, Digestive and Kidney Disease (NIDDK) staff, industry representatives, and Food and Drug Administration (FDA) officials in December at the "AKI Clinical Trial Design Workshop," organized and hosted by the NIDDK.

AKI is a common condition associated with high mortality, increased morbidity, and increased risk of chronic kidney disease acceleration to end stage renal disease (ESRD). A highly complex condition, AKI can be caused by one or multiple factors including trauma, compromised blood flow to the kidneys, and infections or nephrotoxins (including therapeutic agents) in the bloodstream.

Besides volume administration and renal replacement therapies, existing

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Acute Kidney Injury

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strategies to reduce the morbidity and mortality of patients with AKI are inconclusive or generally not effective. The workshop provided a unique forum for stakeholders across the AKI treatment spectrum—from basic researchers to industry and regulators—to brainstorm potential new therapeutic compounds, drug targets, and optimal clinical trial designs for AKI.

"Not only did this workshop help us in the nephrology research community better understand what the FDA and industry need and want from us, it sets the stage for more communication in the future—which will hopefully translate to more treatments reaching AKI patients faster," said Paul Palevsky, MD, who assisted in organizing the workshop.

A well-designed clinical trial with appropriate endpoints is necessary for successful translation of a therapy from the bench to the bedside. Trials must meet not only researchers' scientific and methodological standards, but also those of industry (which would make the product available to patients) and the FDA (which must approve the drug). Workshop participants debated where to set clinical endpoints—or a composite endpoint—that could be shared and recognized as acceptable by researchers, the FDA, and industry, in a manner widely agreed as open and transparent. Industry representatives also discussed the limitations, needs, and barriers they face.

"Everyone understood that we cannot continue to work in silos but rather progress depends upon cooperation among the stakeholders," said Mark Okusa, MD, chief of the division of nephrology and director, Center for Immunity, Inflammation and Regenerative Medicine at the University of Virginia in Charlottesville. "This highlighted the necessity of collaboration—and an important role for the NIH Public Private Partnership Program in facilitating these interactions."

National Institutes of Health (NIH) Public Private Partnership Program (PPP) staff also participated in the workshop. The PPP facilitates collaborations between the NIH and other organizations including professional societies, industry members, and academic institutions to improve public health though research. The PPP also provides mechanisms by which AKI researchers and industry members at the workshop could identify shared areas of interest and conduct studies that NIH might not otherwise be able to support (see sidebar).

Among the most important issues facing clinical trial design is identifying approaches to mitigate the financial challenges NIH and industry face in conducting the trials. One potential solution workshop participants identified is to pool similar placebo-treated patients from different Phase II studies into a large protected database available for determination of event rates and other parameters. Such information is essential to the design and implementation of appropriately powered Phase III studies.

The workshop was in part the result of conversations between the NIDDK and the ASN AKI Advisory Group.

"ASN was an important force in convincing NIH that we have important tools and therapies to examine," said NIDDK Acute Kidney Injury Program Director Paul Kimmel, MD, FASN, in his opening remarks. "This [workshop] was a direct result of ASN dialogue with NIDDK."

"The AKI Advisory Group was challenged by NIH staff to delineate up-and-coming therapies for AKI that would provide the stimulus for—and benefit from—a workshop to facilitate interactions between an array of AKI stakeholders," said Bruce Molitoris, MD, FASN, chair of the nephrology division at Indiana University School of Medicine and ASN's AKI Advisory Group Council Liaison. "The NIH then worked diligently to deliver an outstanding meeting based on an environment of understanding, cooperation and respect. Participants left exhausted and exhilarated."

Public-Private Partnerships

In an effort to foster better working relationships between government and industry, the National Institutes of Health (NIH) initiated a program on public-private partnerships (PPP) in 2005. Housed under the Office of Science Policy, the PPP works to "facilitate collaborations that improve the public health through biomedical research."

Although the research benefits of the collaboration of NIH with private industry are well established, at times structuring these partnerships has proven cumbersome. The PPP acts as a central coordinator helping to aid communication, establishing a set objective for the partnership, and organizing the parameters of the collaboration.

An example of a recent collaboration facilitated by the PPP is the Biomarkers Consortium, consisting of the NIH, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, as well as private industry and nonprofit advocacy groups. The project works to speed the identification, testing, and regulatory acceptance of biomarkers. The existence of the PPP allowed the diverse stakeholders involved in the biomarkers consortium to work collectively toward a shared goal of advancing patient health through new diagnostic tools, technologies, and treatments.