U.S. Department of Health and Human Services
National Institutes of Health

KICC News

A quarterly newsletter by the National Kidney Disease Education Program | Issue #3 | Summer 2007

This Issue: Improving CKD Test | June KICC Meeting Summary | Upcoming FDA Advisory Meeting

Improving a Key Test for CKD

NKDEP is working with laboratory professionals worldwide to improve the accuracy of serum creatinine measurements, which are critical to the diagnosis of CKD.

Historically, creatinine determinations have not been standardized, resulting in significant differences in results reported to providers, depending on the lab and method used. The Creatinine Standardization Program aims to eliminate this inter-laboratory variability and yield more accurate measurements of serum creatinine. This in turn will enable more accurate and reliable estimates of glomerular filtration rate (GFR).

The Program provides information to help manufacturers, clinical laboratories, and others in the laboratory community recalibrate their serum creatinine measurement methods. It also supports manufacturers' efforts to encourage their laboratory clients to use a revised GFR estimating equation once they have recalibrated their methods.

Since the Program was launched early last year by the NKDEP's Laboratory Working Group (LWG), laboratory professionals throughout the US as well as equipment manufacturers have become active participants. The LWG has sponsored symposia explaining the initiative at leading clinical chemistry conferences.

For more information, please visit: www.nkdep.nih.gov/labprofessionals/index.htm.

Federal Agencies Discuss CKD at KICC Meeting

The Kidney Interagency Coordinating Committee (KICC) held its annual meeting in Bethesda, MD, on June 14. The two-and-a-half hour meeting brought together representatives from more than a dozen Federal agencies to share information on their programs and activities related to CKD. In his welcome to the participants, Dr. Andrew Narva, NKDEP Director, explained that KICC's purpose is to encourage cooperation, communication, and collaboration among all federal agencies involved in kidney research and other activities. Presentations by representatives from NIDDK, AHRQ, CDC, CMS, FDA, HRSA, IHS, and the VA sparked discussion on how agencies can work together more effectively.

Participants identified the following areas for potential collaboration:

- responding to pressing issues, such as EPO;
- planning for the development of the kidney disease chapter of Healthy People 2020;
- developing health care performance measures;
- creating models of care for improved care of CKD; and
- increasing use of available interventions to slow CKD progression.

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KICC Meeting (continued)

Dr. Robert Star, Acting Director of NIDDK's Kidney, Urologic, and Hematologic Diseases division, asked for areas of clinical research that NIDDK should consider in future planning. Participants recommended the following areas: early stages of CKD, precursors, factors that predict progression, and transition between CKD and dialysis. The KICC meeting summary is available on NKDEP's website: *www.nkdep.nih.gov*. *For more information on the meeting, please contact Elisa Gladstone at gladstonee@extra.niddk.nih.gov.*

Please send your story ideas for future issues of *KICC News* to Elisa Gladstone at GladstoneE@extra.niddk.nih.gov.

FDA to Hold Public Advisory Meeting on ESAs

In March 2007, FDA released a Public Health Advisory on the life-threatening side-effects of erythropoiesis-stimulating agents (ESAs). As part of its response to this issue, FDA will be holding a public advisory committee meeting on September 11, 2007 in Gaithersburg, MD. Open to the public, the meeting will be attended by the Cardiovascular and Renal Drugs Advisory Committee and the Drug and Safety and Risk Management Advisory Committee.

ESAs, such as Aranesp, Epogen, and Procrit, are used to stimulate the bone marrow to make more red blood cells and are FDA approved for various uses, including the treatment of anemia in chronic kidney disease and endstage renal disease. However, study results show that patients with chronic kidney disease had an increased number of deaths and of non-fatal heart attacks, strokes, heart failure, and blood clots when ESAs were adjusted to maintain higher red blood cell levels.

The primary purpose of the meeting will be to discuss updated information regarding the risks and benefits of ESAs in relation to anemia and chronic kidney disease. In the meantime, the FDA and Amgen, the manufacturer of these products, and Ortho Biotech Products, L.P, a distributor of Procrit, have agreed to change the labeling for Aranesp, Epogen, and Procrit to reflect the new safety information and to provide additional instructions for their use. *For more information, please contact Mimi Phan at mimi.phan@fda.hhs.gov.*