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KICC News

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This Issue: **Revised ESA Labeling Approved** | **'07 USRDS Data Highlights** | **CDC Advances Surveillance System**

FDA Approves Revised Labeling for ESAs

On November 8, 2007, the U.S. Food & Drug Administration (FDA) granted approval to revised labeling for erythropoiesis-stimulating agents (ESAs), Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa) and Procrit® (epoetin alfa). Most of the labeling changes pertain to use of the drugs in the treatment of anemia due to chronic renal failure (CRF) or the anemia due to cancer chemotherapy and incorporate recommendations from two FDA advisory committees that met earlier this year. The major revisions relating to use of ESAs in the treatment of the anemia due to CRF are summarized below.

A revised warning statement notes that patients experienced greater risks for death and serious cardiovascular events when administered ESAs to target higher versus lower hemoglobin levels (13.5 vs 11.3 g/dL; 14 vs 10 g/dL) in two clinical studies. The warning also states that patients with an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular events and mortality than other patients.

The dosing recommendations for anemic patients with CRF have been revised to recommend individualization of dosing to maintain hemoglobin levels within the range of 10 - 12 g/dL and adjustment of dosing if patients experience hemoglobin excursions outside this range. The revised dosing recommendations also describe dose adjustment procedures for patients who have insufficient responses to ESAs ("hypo-responders").

The clinical experience section of the Epogen® and Procrit® label was updated to describe improved exercise tolerance and physical functioning for anemic patients with CRF who were treated with an ESA to increase hemoglobin levels from approximately 7 g/dL to 11 g/dL. This experience from a randomized, blinded clinical study replaces the description of various outcomes found in a non-randomized, unblinded clinical study. *For more information regarding evolving safety issues with ESAs, please visit www.fda.gov/cder/drug/infopage/RHE/default.htm.*

NIDDK Releases USRDS 2007 Annual Data Report

The United States Renal Data System's (USRDS) nineteenth Annual Data Report (ADR) is now available. Funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the annual report is the most comprehensive report of kidney failure-related data. New to the ADR is a chapter focused on a timely area of concern related to the public health of the kidney disease population. In this edition, this Emerging Issues chapter looks in detail at the mortality during the first year of end-stage renal disease (ESRD) treatment—an area of particular concern, as it has changed little over the past decade. Other topics include projected ESRD counts and costs through 2020, and data on the care and outcomes of patients affected by Hurricane Katrina. Some highlights from this year's ADR include:

- The overall ESRD incident rate has flattened out during the past several years, rising only 2.8 percent since 2000 to

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USRDS (continued)

reach 347 per million population. Increased use of ACE inhibitors and ARBs, better glycemic control in diabetic patients, and better control of blood pressure may be contributing to this stabilization.

- The rate for patients beginning therapy on hemodialysis has risen 4.1 percent, while the rate for transplant patients has grown 17.5 percent.
- In 2005, total ESRD costs reached $32 billion—1.6 percent of the nearly $2 trillion spend by the United States on healthcare that year.
- Among whites in the general Medicare population, 6.4 percent have CKD and their care accounts for 20 percent of expenditures. But among African Americans, 9.2 percent have chronic kidney disease (CKD), and their costs account for nearly 30 percent of overall expenditures.

For ordering information, visit *www.usrds.org*. *For more information on USRDS data, contact Paul Eggers at paul.eggers@nih.hhs.gov.*

NIDDK Website Features Health Information in Spanish

NIDDK has launched a new portal to feature Spanish-language materials and resources about kidney and urologic diseases on its website.

The National Kidney and Urologic Diseases Information Clearinghouse has 18 kidney and urologic publications in Spanish and will be adding more in the future, including one-page fact sheets that are part of the NIDDK's Awareness and Prevention series. The portal is now available at *www.kidney-espanol.niddk.nih.gov*.

CDC Advances Development of CKD Surveillance System

The Centers for Disease Control and Prevention is collaborating with partners at the Johns Hopkins University and the University of Michigan to develop and establish a surveillance system for CKD prior to end-stage renal disease. This activity entails identifying and analyzing data from a variety of currently existing data sources as well as developing measures for CKD surveillance. Progress to date includes:

1. Developing a protocol for CKD surveillance;
2. Identifying, with input from an Advisory Board, six broad topics relevant to CKD surveillance and several possible measures within each topic;
3. Identifying potential data sources;
4. Investigating surveillance system attributes of key data sources using a standardized instrument. These attributes include representativeness, acceptability, data availability, data quality, defined denominator, feasibility, sensitivity and positive predictive value, flexibility, stability, and timeliness; and
5. Obtaining data from selected sources for analysis.

This system would function seamlessly with other kidney-related surveillance efforts, such as the USRDS and the National Diabetes Surveillance System. The goals are to assess the magnitude of CKD and its risk factors in the United States, monitor national trends, and identify disparities, to promote early diagnosis and improve outcomes and quality of life for those living with CKD. *For more information, please contact Desmond Williams at dewilliams@cdc.gov.*

Please send your story ideas for future issues of *KICC News* to NKDEP at nkdep@info.niddk.nih.gov.