

## Kidney Disease

## Research Updates

National Kidney and Urologic Diseases Information Clearinghouse

Spring/Summer 2008

## Urinary Tract Stones Pose Challenges for Researchers

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) hosted a 2-day symposium recently to share information about potential research on and treatment for urolithiasis, a growing and increasingly expensive health problem in the United States.

Urolithiasis—the formation of stones in the urinary tract—costs the health care system more than \$2 billion annually, according to Yair Lotan, M.D., a symposium speaker and assistant professor in the department of urology at the University of Texas Southwestern Medical Center at Dallas.

The incidence of urolithiasis peaks between the ages of 20 and 60. A promising strategy for reducing health care costs related to urolithiasis, Lotan said, might be promoting primary and secondary prevention strategies through education of high-risk populations.

Identifying appropriate medical expulsive therapies—administering muscle relaxants to hasten the expulsion of stones without surgical intervention—and educating patients and practitioners about them could help decrease costs of stone therapy.

Lotan said 10 percent of people with urolithiasis will have a recurrence of stones within 1 year, 35 to 50 percent within 5 years, and 50 percent or more by 10 years. According to Lotan, improvements in the medical management of people who form recurrent stones are needed, including better guidelines, the use of medical expulsive therapies, and the timing of surgery.



Lithotripters are used to break up kidney stones.

### Treatments for Urolithiasis

The most common treatment for urolithiasis is extracorporeal shock wave lithotripsy, according to Christopher Saigal, M.D., M.P.H., associate

**URINARY TRACT STONES**, continued on page 2

### Inside This Issue

Kidney Disease Worsens Substantially in Some African Americans Despite Hypertension Therapy	3
NIH Panel: Effective Treatment for Sickle Cell Disease Underutilized	4
NIDDK Publications Win NIH Plain Language Awards	6
NKUDIC Answers Nearly 9,000 Queries in 2007	7
UITN Aims to Improve Quality of Life for Those with Urinary Incontinence	8
Featured in the NIDDK Reference Collection	9



**NIDDK**  
NATIONAL INSTITUTE OF  
DIABETES AND DIGESTIVE  
AND KIDNEY DISEASES

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### URINARY TRACT STONES, from page 1

professor in the department of urology at the David Geffen School of Medicine, University of California, Los Angeles.

However, lithotripsy results in a higher rate of stone recurrence, depending on the size and location of the stone, compared with other treatments.

Other options for treating stones include dietary therapy, medication, and surgery.

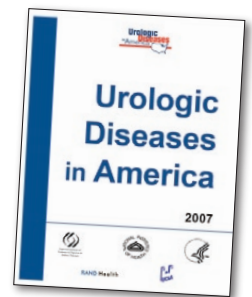
Researchers, clinicians, and industry representatives who attended the meeting identified several areas of study for potential NIDDK research funding, including

- adjuvant therapy clinical trials
- improved stone removal technology
- development of a lithotripter rating system
- creation of a stone registry

Robert A. Star, M.D., director of the NIDDK's Division of Kidney, Urologic, and Hematologic Diseases, suggested several funding methods for urolithiasis research. For example, the

NIDDK has a new funding mechanism for investigator-initiated, modest-sized trials. The U34/U01 funding mechanism supports the implementation phase and the full-scale trial. Star also suggested collaborating with the Department of Veterans Affairs for large trials and partnering with the pharmaceutical industry.

The NIDDK's *Urologic Diseases in America Compendium* includes a chapter about urolithiasis and is available at [www.kidney.niddk.nih.gov/statistics/uda/index.htm](http://www.kidney.niddk.nih.gov/statistics/uda/index.htm). For more information about NIDDK research and funding, go to [www2.niddk.nih.gov/Research](http://www2.niddk.nih.gov/Research). ■



### Kidney Disease Research Updates



*Kidney Disease Research Updates*, an email newsletter, is sent to subscribers by the National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC). The newsletter features news about kidney disease, special events, patient and professional meetings, and new publications available from the NKUDIC and other organizations.

If you would like to subscribe, go to <http://catalog.niddk.nih.gov/newsletter.cfm>. You can read or download a PDF version of the newsletter at [www.kidney.niddk.nih.gov/about/newsletter.htm](http://www.kidney.niddk.nih.gov/about/newsletter.htm).

### Executive Editor: Andrew S. Narva, M.D., F.A.C.P.

Dr. Narva is the director of the National Kidney Disease Education Program (NKDEP) within the National Institute of Diabetes and Digestive and Kidney Diseases. Dr. Narva, a graduate of Harvard Medical School and board-certified in internal medicine and nephrology, served with the Indian Health Service before joining the NKDEP. He also was a member of the National Kidney and Urologic Diseases Advisory Board, the Renal Community Council of the U.S. Renal Data System, the Medical Review Board of End-Stage Renal Disease Network 15, and the National Kidney Foundation's Minority Outreach Committee, which he chaired.



## Kidney Disease Worsens Substantially in Some African Americans Despite Hypertension Therapy



“Despite these sobering results, blood pressure control is still vital in kidney disease and in many other diseases.”

Elias Zerhouni, M.D.  
NIH Director

The largest and longest study of chronic kidney disease (CKD) in African Americans found that the disease worsened substantially in about 25 percent of participants, despite very good blood pressure control and the use of kidney-protecting medications. Participants lost either 50 percent of their kidney function or reached kidney failure, according to the National Institutes of Health (NIH) study, which was published in the April 28, 2008, *Archives of Internal Medicine*.

The study also found that about one-third of the participants experienced a slow decline in kidney function—about what is generally observed with aging.

The African American Study of Kidney Disease and Hypertension (AASK) observed about 750 African Americans on recommended therapy for CKD from 2002 to 2007. Participants for this cohort study were initially recruited in 1995 for the AASK Clinical Trial, which found in 2001 that an angiotensin-converting enzyme (ACE) inhibitor medication protected the kidneys better than two other classes of blood pressure drugs. During the cohort study, nearly nine out of 10 participants were taking an ACE inhibitor or an angiotensin receptor blocking drug, and average blood pressure was close to the national guidelines for high blood pressure in people with CKD.

“Despite these sobering results, blood pressure control is still vital in kidney disease and in many other diseases,” said NIH Director Elias Zerhouni, M.D. “But this research clearly signals the importance of preventing kidney disease, better understanding causes, and finding better ways to manage it in the 26 million Americans who already have it.”

Uncontrolled high blood pressure, an increase in the number of people with diabetes, and the aging of the U.S. population mean more people than ever are getting and living with kidney problems. About 13 percent of the U.S. population, up from 10 percent in 1994, now have CKD. In 2005, more than 485,000 people were on chronic dialysis or had a kidney transplant for kidney failure, costing Medicare, private insurers, and patients \$32 billion.

The AASK Clinical Trial and AASK cohort study were conducted at 21 U.S. medical centers and funded by the National Institute of Diabetes and Digestive and Kidney Diseases since 1994. Additional support was provided by the NIH National Center on Minority Health and Health Disparities and by King Pharmaceuticals.

For more information about kidney disease, visit the National Kidney and Urologic Diseases Information Clearinghouse at [www.kidney.niddk.nih.gov](http://www.kidney.niddk.nih.gov). ■

## Effective Treatment for Sickle Cell Disease is Underutilized, NIH Panel Finds

An independent panel convened by the National Institutes of Health (NIH) concluded that hydroxyurea, an effective drug for treating pain and complications from sickle cell disease, is being underused and that its use should be increased among adults and teenagers with the illness.



Sickle cell disease affects an estimated 50,000 to 100,000 people in the United States and is most common among families from Africa, the Caribbean, Central or South America, India, the Mediterranean, and Saudi Arabia.

The panel, which met for 3 days as part of the NIH Consensus Development Program process, stopped short of advocating the drug's use in children, noting that evidence of its efficacy in this population is not as strong as in adults but that emerging data are positive.

"The compelling benefits of hydroxyurea warrant increased adoption of this drug as a frontline therapy in adults with sickle cell disease," said Otis Brawley, M.D., the panel chair and Professor of Hematology, Oncology, Medicine, and Epidemiology at Emory University.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Director Griffin P. Rodgers, M.D., M.A.C.P., a pre-eminent expert in sickle cell disease and the first hematologist to head the NIDDK, set the stage for the consensus development conference with introductory remarks. The NIDDK, which funds research on sickle cell and other blood diseases, was one of the co-sponsors of the consensus development conference.

"At present, hydroxyurea is the major medical modality with proven efficacy in patients with frequent symptoms related to sickle cell disease, although there is increasing evidence that hydroxyurea is prescribed to only a fraction of patients who may benefit from it," said Rodgers. While gene therapy for sickle cell disease may eventually supplant the need for hydroxyurea treatment by correcting the underlying genetic defect that causes this disease, curative gene therapy has proven to be an "elusive therapeutic holy grail," according to Rodgers. However,

"current genomic studies should provide more insights on directing strategies to resolve the therapeutic challenges of sickle cell disease."

### Safety Concerns

Patient and health care provider concerns about the safety and side effects of hydroxyurea, an anti-cancer drug approved by the U.S. Food and Drug Administration in 1998 to treat adults with sickle cell anemia, have hindered its use despite evidence that the drug's benefits outweigh the risks for adults with the disease. Side effects of the drug include possible lower sperm count in men; increased risk of bleeding, infection, and malignancies; and the potential for birth defects in babies born of women who take the drug during pregnancy.

Sickle cell anemia is a form of sickle cell disease, an inherited blood disorder that causes red blood cells to lose oxygen and become crescent- or sickle-shaped. The misshapen cells clump together and stick to blood vessel walls, restricting blood flow to limbs and vital organs and causing acute pain and permanent damage to the bones, brain, eyes, heart, lungs, kidneys, liver, and spleen.

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**SICKLE CELL,**

continued on page 5



## NIDDK Welcomes Four New Advisory Council Members

U.S. Department of Health and Human Services Secretary Michael O. Leavitt appointed four new members to the Advisory Council of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The Advisory Council guides the NIDDK's discussion of broad science policy issues and provides second-level review of funding requests. The new members, who will serve 4-year terms, are

**David M. Altshuler, M.D., Ph.D.**, professor of genetics and medicine at Harvard Medical School, member of the Diabetes Unit and Department of Molecular Biology at Massachusetts General Hospital, and director of the Program in Medical and Population Genetics at the Whitehead Institute/Massachusetts Institute of Technology Center for Genome Research in Boston. Altshuler serves on the Diabetes, Endocrinology, and Metabolic Diseases Subcommittee.

**Nancy C. Andrews, M.D., Ph.D.**, dean and vice chancellor of Academic Affairs at Duke University School of Medicine in Durham, NC. She is an internationally renowned researcher in pediatric hematology and oncology and the only woman to lead one of the nation's top 10 medical schools. Andrews serves on the Kidney, Urologic, and Hematologic Diseases Subcommittee.

**James W. Freston, M.D., Ph.D.**, the Boehringer Ingelheim Chair of Clinical Pharmacology and professor emeritus at the University of Connecticut School of Medicine at Farmington. Appointed to the NIDDK Advisory Council last year for a 1-year term, Freston has been reappointed this year for a 4-year term. He continues to serve on the Digestive Diseases and Nutrition Subcommittee.

**James P. Schlicht, M.P.A.**, executive vice president and chief government affairs and advocacy officer at the American Diabetes Association (ADA). He is directly responsible for management of all advocacy and government affairs functions and the formulation, adoption, strategic development, and implementation of all ADA public policy positions. Schlicht serves on the Diabetes, Endocrinology, and Metabolic Diseases Subcommittee. ■



Pictured with NIDDK Director Griffin P. Rodgers, M.D., M.A.C.P. (center), are (from left) Nancy C. Andrews, M.D., Ph.D.; James P. Schlicht, M.P.A.; James W. Freston, M.D., Ph.D.; and David M. Altshuler, M.D., Ph.D. Photo credit: Michael Spencer, NIH.

### SICKLE CELL, from page 4

The NIH created the Consensus Development Program in 1977 to impartially judge controversial topics in medicine and public health. The panel's statement on hydroxyurea is not a policy statement of the NIH or the Federal Government. For a copy of the panel's complete consensus statement, go to [www.consensus.nih.gov](http://www.consensus.nih.gov). ■

The NIDDK recently produced two publications related to sickle cell disease and the A1C test for diabetes: *For People of African, Mediterranean, or Southeast Asian Heritage: Important Information about Diabetes Blood Tests* and *Sickle Cell Trait and Other Hemoglobinopathies and Diabetes: Important Information for Physicians*. These publications are available through the NIDDK's National Diabetes Information Clearinghouse at [www.diabetes.niddk.nih.gov](http://www.diabetes.niddk.nih.gov).





## Star Named Director of Kidney, Urologic, and Hematologic Research

**N**ational Institute of Diabetes and Digestive and Kidney Diseases Director Griffin P. Rodgers, M.D., M.A.C.P., has named Robert A. Star, M.D., director of the Division of Kidney, Urologic, and Hematologic Diseases (KUH). Star, who has been acting director of the extramural research division since September 2006, oversees a \$400 million grants and contracts program.

Star was a postdoctoral fellow at the National Institutes of Health (NIH) in the mid-1980s before joining the faculty at the University of Texas Southwestern Medical Center at Dallas. In 1999, he returned to the NIH as a senior scientific adviser for kidney disease and to run a laboratory studying acute kidney injury. In 2002, he became senior adviser for clinical research in the NIH Office of Science Policy and Planning.

“Dr. Star is an exemplary and creative physician-scientist, leader, and manager,” said Rodgers. “He rolls up his sleeves, steps up to tough issues,

and attracts problem-solving, talented scientists from within, as well as outside, the NIH to craft solutions.”

Star graduated *summa cum laude* in applied mathematics from Harvard College and *cum laude* from the Harvard Medical School–Massachusetts Institute of Technology Joint Program in Health Sciences and Technology. He did his internship and residency in internal medicine at Michael Reese Hospital in Chicago. ■

## NIDDK Publications Win NIH Plain Language Awards

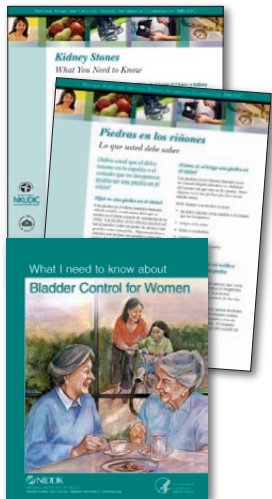
**T**he National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) received recognition in this year’s National Institutes of Health (NIH) Plain Language Awards Competition.

The NIDDK Awareness and Prevention Series was honored with a gold award and the easy-to-read booklet *What I need to know about Bladder Control for Women* won a bronze. An awards ceremony was held at the NIH campus in Bethesda, MD, on April 15.

The NIDDK Awareness and Prevention Series, created for health fairs and similar events, presents brief overviews in English and Spanish of common health problems in a colorful, two-page format. Designed for people not yet diagnosed with diabetes or digestive, kidney, or urologic disorders, the handouts encourage readers to seek further information from the NIDDK or their health care provider.

The *What I need to know about Bladder Control for Women* booklet explains treatments and techniques for managing urinary incontinence and helps women prepare to speak with their doctors about the problem.

The NIH created the Plain Language Awards to promote the NIH Plain Language Initiative, established in response to a 1998 White House memorandum calling for all Federal Government writing to be in an easy-to-read format. The booklet and Awareness and Prevention Series publications can be downloaded or ordered through the NIDDK website at [www.niddk.nih.gov](http://www.niddk.nih.gov). ■

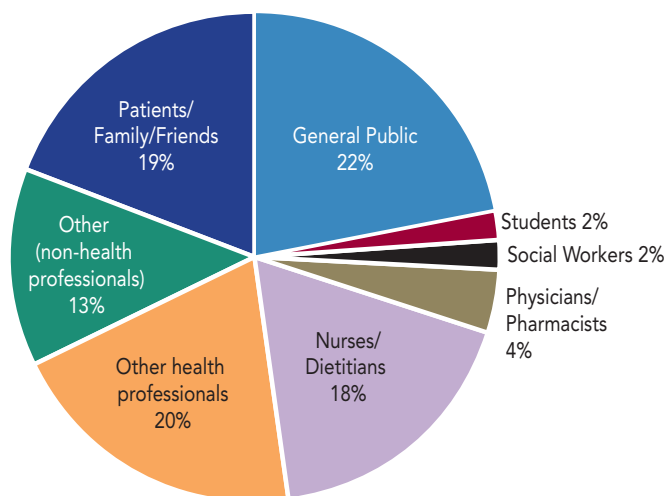


## NKUDIC Answers Nearly 9,000 Queries in 2007

The National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC) responded to 8,859 requests for information during calendar year 2007. While the percentage of inquiries that came from patients, their families, or friends fell by half from 2006—to 19 percent—inquiries from the general public increased 3 percent, according to Kathy Kranzfelder, director of the Clearinghouse. Kranzfelder presented a Clearinghouse update at the National Institute of Diabetes and Digestive and Kidney Diseases' (NIDDK's) annual NKUDIC Coordinating Panel Meeting in March.

“What’s more impressive is traffic to our website, which essentially represents self-service inquiry response,” said Kranzfelder. “In 2007, an average of 25,000 to 30,000 visitors would come to the NIDDK’s kidney and urologic topics each *day*.”

Forty-four percent of the 8,859 “traditional” requests for information came from health professionals. The breakdown of NKUDIC customers in 2007 is depicted in the graph below.



The majority of information requests—4,856—came through online orders. The other most popular ways to request Clearinghouse information were via email messages (1,851); phone calls (1,482); letters (451); and faxes (94).

The NKUDIC inventory includes 208 publication titles. Last year, the Clearinghouse produced 12 new publications and updated 20 existing resources. The NKUDIC distributed 309,710 publications in 2007, including fact sheets, booklets, reports, journal reprints, and materials from patient and professional organizations. The most popular NKUDIC publications in hard copy were

- *Kidney Failure: Choosing a Treatment That’s Right for You*
- *Your Kidneys and How They Work*
- *Interstitial Cystitis/Painful Bladder Syndrome*
- *What I need to know about Bladder Control for Women*

### NIDDK Reference Collection

The number of visitors to the NIDDK Reference Collection last year increased to more than 510,000 from more than 310,000 in 2006. The NIDDK Reference Collection is a free, online database of educational materials not typically referenced in other databases. The most popular kidney and urology search topics were renal artery stenosis, pediatric kidney disease, urinary incontinence in men, and kidney stones. Reference Collection materials and all of the NKUDIC’s other resources are available at [www.kidney.niddk.nih.gov](http://www.kidney.niddk.nih.gov). ■

## UITN Aims to Improve Quality of Life for Those with Urinary Incontinence

Attendees at the National Kidney and Urologic Diseases Information Clearinghouse Coordinating Panel Meeting learned about the benefits of multicenter trials and the activities of the Urinary Incontinence Treatment Network (UITN), a group of gynecologists and urogynecologists conducting urinary incontinence research supported by the National Institute of Diabetes and Digestive and Kidney Diseases in collaboration with the National Institute of Child Health and Human Development.

Specific goals of the UITN are high-impact clinical research; better prevention, evaluation, and management of urinary incontinence; and an improved quality of life for adults with this disorder, with a focus on women.

Some advantages of multisite studies are that they allow protocols to be completed in less time, enable pooling of multidisciplinary expertise, and yield more generalizable results, according to Holly E. Richter, Ph.D., M.D., professor and division director, Women's Pelvic Medicine and Reconstructive Surgery, Kirklin Clinic, University of Alabama at Birmingham. In addition, developed definitions can be used in subsequent networks and trials, and the use of common, standardized measures provides the potential to analyze data across studies.

### Rectifying Problems

The UITN was created in 2000 to address some of the problems with urinary incontinence studies, according to Richter, such as poorly defined enrollment criteria and outcome measures, low rates and short-term follow-up, small sample size, and a lack of comparator groups.

Specific goals of the UITN are high-impact clinical research; better prevention, evaluation, and management of urinary incontinence; and an improved quality of life for adults with this disorder, with a focus on women. The network, which consists of nine clinical continence treatment centers and a biostatistical coordinating center, is involved in several studies, including the

- Stress Incontinence Surgical Treatment Efficacy Trial (SISTER), a randomized trial

comparing 24-month outcomes of the Burch urethropexy compared with the autologous rectus fascial sling for the treatment of stress urinary incontinence (SUI)

- Behavior Enhances Drug Reduction of Incontinence (BE-DRI) trial, a randomized trial to determine whether combining antimuscarinic drug therapy with supervised behavioral training, compared with drug therapy alone, improves the ability of women with urge incontinence to achieve clinically important reductions in incontinence episodes and to sustain these improvements after discontinuing medication
- Trial of Mid-Urethral Slings (TOMUS), a randomized trial comparing the outcomes of a retropubic versus transobturator mid-urethral sling procedure for treatment of SUI

Richter suggested that for future trials and studies, researchers should consider addressing prevention of urinary incontinence and the addition of basic science considerations.

For more information about the UITN, visit [www.uitn.net](http://www.uitn.net). For an easy-to-read booklet about urinary incontinence in women entitled *What I need to know about Bladder Control for Women*, go to [www.kidney.niddd.nih.gov/kudiseases/pubs/bcw\\_ez/index.htm](http://www.kidney.niddd.nih.gov/kudiseases/pubs/bcw_ez/index.htm).





## Featured in the NIDDK Reference Collection

### Diabetes and Chronic Kidney Disease

“Blessing in Disguise,” an article from a journal for patients with chronic kidney disease (CKD), shares the story of one woman’s lifelong experience with diabetes and CKD. The woman, Susanne, is 61 years old, was diagnosed with diabetes at age 13, and has been living with CKD for 30 years. She briefly discusses her history, including childhood and pregnancy, focusing on the positive aspects of having to focus on her health when her kidneys began to fail. At age 57, she began exercising, volunteering at the gym, and educating other women about the benefits of exercise and a sensible diet. She reports that her kidneys are now holding steady at 35 percent function, which she credits to exercising, eating properly, and maintaining a positive attitude. The article includes two, full-color photographs of Susanne exercising and with her grandchildren. “Blessing in Disguise” appears in the June/July 2007 issue of *Kidney Beginnings*. Past issues of *Kidney Beginnings* are available from the American Association of Kidney Patients at 3505 East Frontage Road, Suite 315, Tampa, FL 33607, 1-800-749-2257, 813-636-8122, [info@aakp.org](mailto:info@aakp.org), [www.aakp.org/newsletters/KB-The-Magazine](http://www.aakp.org/newsletters/KB-The-Magazine).

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Reference Collection is a free, online database that helps health care professionals, health educators, patients, and the general public find educational materials not typically referenced in most databases. To find more kidney disease resources, visit [www.catalog.niddk.nih.gov/resources](http://www.catalog.niddk.nih.gov/resources). ■

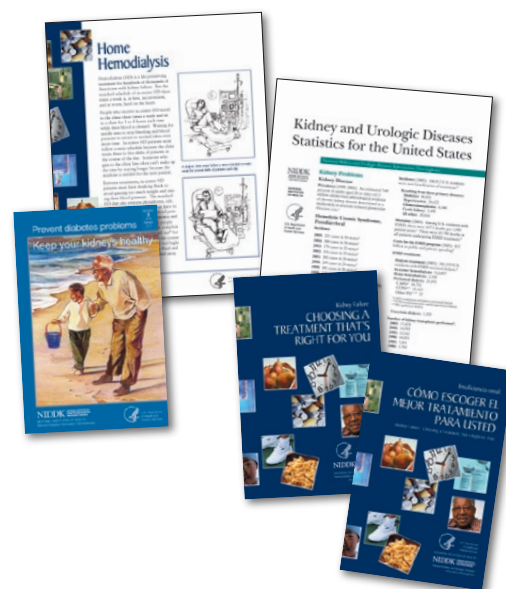
## Additional Resources

### Updated Publications

The National Kidney and Urologic Diseases Information Clearinghouse has updated the following publications:

- *Home Hemodialysis*
- *Insuficiencia renal: Cómo escoger el tratamiento que más le conviene (Kidney Failure: Choosing a Treatment That’s Right for You)*
- *Kidney and Urologic Diseases Statistics for the United States*
- *Kidney Failure: Choosing a Treatment That’s Right for You*
- *Prevent diabetes problems: Keep your kidneys healthy*

These publications are available at [www.kidney.niddk.nih.gov/kudiseases/a-z.asp](http://www.kidney.niddk.nih.gov/kudiseases/a-z.asp).



**ADDITIONAL RESOURCES,**  
continued on page 10



**ADDITIONAL RESOURCES**, from page 9

## New Interactive Tools

New to the Interactive Health Education Tools section of the National Institute of Diabetes and Digestive and Kidney Diseases website are

### Podcasts

- Chronic Kidney Disease–Cardiovascular Disease Link
- Many People Are Unaware They Have Chronic Kidney Disease

### Vodcasts

- Exploring the Link between Kidney and Cardiovascular Disease

The website's interactive tools section consolidates all the tools and resources about kidney

disease from the National Institutes of Health and the National Library of Medicine. To access these resources, visit [www.kidney.niddk.nih.gov/resources/HealthTools](http://www.kidney.niddk.nih.gov/resources/HealthTools).

## Chronic Kidney Disease

The National Kidney Disease Education Program, along with the American Society of Nephrology, has developed a slide presentation about improving patient outcomes for chronic kidney disease (CKD) in the primary care setting. The slides feature the latest data from the *U.S. Renal Data System Annual Data Report* and outline the role primary care professionals can play in detecting and treating CKD. For a copy of the slides, go to [www.nkdep.nih.gov](http://www.nkdep.nih.gov). ■

## Upcoming Meetings, Workshops, and Conferences

The National Institute of Diabetes and Digestive and Kidney Diseases will exhibit at the following upcoming conferences:

### American Academy of Family Physicians Scientific Assembly

September 17 to 21 in San Diego.  
For more information, go to [www.aafp.org/online/en/home/cme/aafpcourses/conferences/assembly.html](http://www.aafp.org/online/en/home/cme/aafpcourses/conferences/assembly.html).

### American Academy of Pediatrics 2008 National Conference and Exhibition

October 10 to 14 in Boston.  
For more information, go to [www.aapexperience.org](http://www.aapexperience.org).

### American Dietetic Association Food and Nutrition Conference and Expo

October 25 to 28 in Chicago.  
For more information, go to [www.eatright.org/cps/rde/xchg/ada/hs.xsl/events.html](http://www.eatright.org/cps/rde/xchg/ada/hs.xsl/events.html).

### American Society of Nephrology Renal Week

November 4 to 9 in Philadelphia.  
For more information, go to [www.asn-online.org/education\\_and\\_meetings/renal\\_week](http://www.asn-online.org/education_and_meetings/renal_week).

### American Academy of Nursing 35th Annual Meeting and Conference

November 6 to 8 in Scottsdale, AZ.  
For more information, go to [www.aannet.org/i4a/pages/index.cfm?pageid=3577](http://www.aannet.org/i4a/pages/index.cfm?pageid=3577).

### American Society of Hematology 50th Annual Meeting and Exposition

December 6 to 9 in San Francisco.  
For more information, go to [www.hematology.org/meetings/2008/index.cfm](http://www.hematology.org/meetings/2008/index.cfm). ■