ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Renal Week Edition

Kidney News

November 2010 | Vol. 2, Number 11

Pay for Performance on the Way: ASN Aims to Improve the Inevitable

By Rachel Shaffer

The Medicare End-Stage Renal Disease (ESRD) program will implement the first-ever pay-for-performance system in the entire Medicare system on January 1, 2012. Before the Affordable Care Act is fully implemented, the nephrology community will play a leading role in piloting this model for health reform.

Prior to rolling out this groundbreaking payment system—entitled the Quality Incentive Program (or QIP)—the Centers for Medicare and Medicaid Services (CMS) issued a QIP Proposed Rule in July and solicited public comment. Released alongside the agency's final rule on ESRD bundled payments, the QIP Proposed Rule outlined CMS's conceptual model for the program.

Under the QIP, CMS will tie facilities' payments to care quality standards. Facilities that fail to achieve specified performance scores for quality of dialysis care will see payment reductions of up to two percent. The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 mandated CMS to institute both bundled payments and a pay-for-performance program for ESRD care. While MIPPA outlined the key aspects of the pay-for-performance program, it left many details to be finalized by CMS.

Given the unprecedented nature of the QIP, ASN formed a QIP Task Force to analyze the proposed rule and, with the support of the ASN Public Policy Board and President Sharon Anderson, MD, FASN, submitted a detailed comment letter on behalf of the society. Foremost among the concerns articulated in ASN's letter was the preservation of equitable patient access to optimal quality dialysis care and all related services.

ASN responds

ASN's comment letter to CMS emphasized the society's strong support for CMS's goal of monitoring the quality of care provided to patients with ESRD. In the context of a novel bundled payment environment, evaluation of quality and unencumbered access to dialysis services and prescribed medications will be of utmost importance. However, given the scientific evidence currently available, the society has reservations about some aspects of the proposed regulations, the letter noted. As the first pay-for-performance program in Medicare, the QIP is fundamentally an experiment—an experiment in a realm of medicine for which nephrologists are still developing evidence-based guidelines for patient management. As such, ASN offered the following overarching suggestions regarding the QIP:

1. Because of limited evidence supporting the QIP measures, the three finalized measures should be subject to replacement by new measures when scientifically validated performance

Continued on page 4

Inside

RENAL WEEK SCIENTIFIC SESSIONS

26 THURSDAY

New Insights, Surprises, and Lessons about the Pathogenesis for Cystic Fibrosis Pigs

State-of-the-Art Lecture: Michael J. Welsh

CKD-MBD: The Bone-Gut-Kidney Connection

Jack W. Coburn Endowed Lectureship: Keith A. Hruska

TGF–β and microRNAs in Diabetic Nephropathy

Barry M. Brenner Endowed Lectureship: Rama Natarajan

28 FRIDAY

Mapping Genes for Complex Traits Using the Canine System

State-of-the-Art Lecture: Elaine A. Ostrander

Denver Health: A Model for Health Care and Health Care Reform

Christopher R. Blagg Endowed Lectureship in Renal Disease and Public Policy: Patricia A. Gabow

30 SATURDAY

From Data to Knowledge to Wisdom: Improving Practice and Policy in the 21st Century

State-of-the-Art Lecture: Harlan M. Krumholz

Biologic Memory in Acute Renal Failure

Robert W. Schrier Endowed Lectureship: Richard Zager

32 SUNDAY

Blocking IL-1β in Auto-inflammatory Diseases

State-of-the-Art Lecture: Charles A. Dinarello

JAMES D.
Age: 56
Time on dialysis: 6 mo.
Lateral abdominal

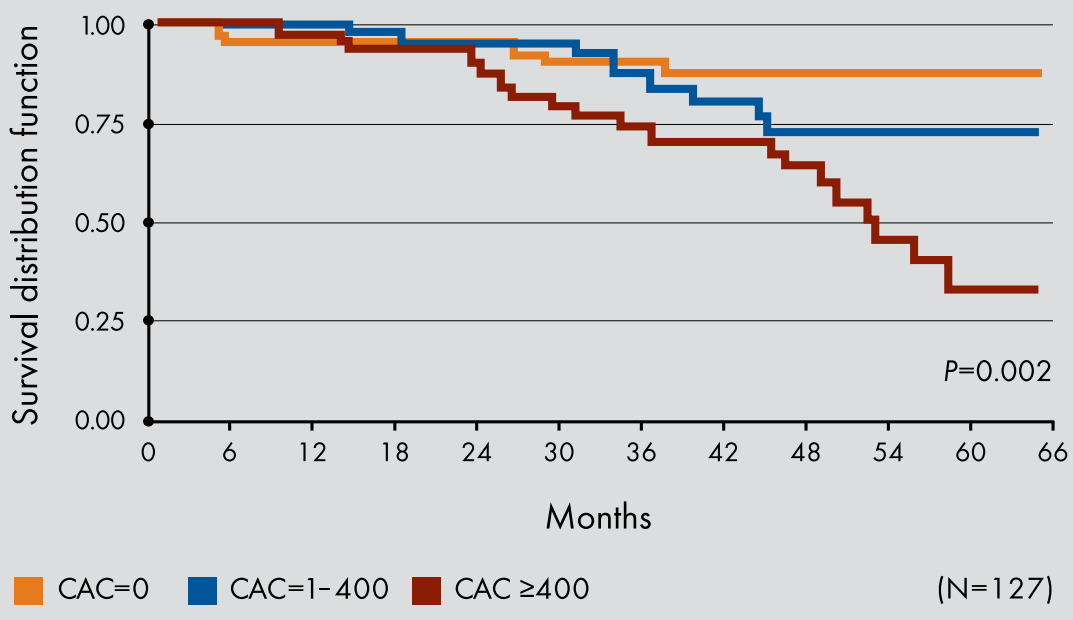
Ca^{+2}ution

64% of new dialysis patients[1] and 83% of prevalent dialysis patients[2] have been shown to have calcification.

2009 KDIGO guidelines[3] for CKD-MBD state:

The presence and severity of cardiovascular calcification strongly predict cardiovascular morbidity and mortality in patients with CKD.

A study by Block *et al* evaluated adjusted survival by baseline coronary artery calcification (CAC) score[4]*



*Multivariable adjusted (age, race, gender, diabetes).
P value represents significance across all 3 groups.

KDIGO suggests restricting calcium dose in the presence of[3]:

- **Persistent/ recurrent hypercalcemia†**
- **Arterial calcification**
- **Persistently low PTH levels**
- **Adynamic bone disease**

†KDIGO recommendation.

References: 1. Spiegel DM, Raggi P, Mehta R, et al. Coronary and aortic calcifications in patients new to dialysis. *Hemodialysis Int.* 2004;8:265-272. **2.** Raggi P, Boulay A, Chasan-Taber S, et al. Cardiac calcification in adult hemodialysis patients: a link between end-stage renal disease and cardiovascular disease? *J Am Coll Cardiol.* 2002;39:695-701. **3.** Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease–mineral and bone disorder (CKD–MBD). *Kidney Int.* 2009;76(suppl 113):S1-S130. **4.** Block GA, Raggi P, Bellasi A, Kooienga L, Spiegel DM. Mortality effect of coronary calcification and phosphate binder choice in incident hemodialysis patients. *Kidney Int.* 2007;71:438-441.

genzyme

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Kidney News

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Pay for Performance

Continued from page 1

targets are developed.
2. The QIP should be redesigned to account for facility-level differences in case-mix.
3. In the interim, careful monitoring in as close to real-time as possible will be crucial to the success of the QIP by minimizing adverse unintended consequences, including compromises in access to care.

Limitations of quality measures

As mandated by MIPPA, CMS will adjust dialysis facilities' payments based on their performance, with the first payment reductions beginning January 1, 2012—with a reduction of up to 2 percent for facilities that do not meet or exceed the standards. To determine payment reductions, CMS proposed calculating a performance score for each facility, based on three quality measures. CMS finalized the three quality measures that facilities will be measured against during the first year of the QIP in the ESRD Final Rule:

- Hemodialysis sdequacy: percentage of Medicare patients with an average urea reduction ratio (URR) of 65 percent or more
- Anemia management: controlled anemia, as shown in two measures:
  - The Medicare percentage of patients at a facility whose hemoglobin levels were <10 g/dL
  - The percentage of Medicare patients at a facility whose hemoglobin levels were >12 g/dL

Facilities already report these three measures to CMS as part of the dialysis facility compare. CMS further proposes to weight the total performance score for each facility such that the percentage of Medicare patients with hemoglobin less than 10 g/dL makes up 50 percent of the score, and the other hemoglobin measure and the hemodialysis adequacy measure each comprise 25 percent of the score. Facilities whose scores do not meet or exceed performance standard would see payment reductions ranging from 0.5 percent to 2 percent of total payments (Figure 1).

Although these three quality measures have been finalized, ASN took the opportunity to call attention to the limitations of the scientific evidence upon which the measures are based. In general, ASN conveyed concerns that incentivizing providers to achieve performance targets that have not been scientifically validated could potentially lead to unintended consequences for patients. For instance, had the current QIP been in place several years ago, with the hemoglobin targets promulgated in clinical practice guidelines at that time (pre-CREATE, CHOIR, and TREAT), performance-based payment may have prompted excess deaths instead of improving patient care.

While acknowledging that CMS is mandated by MIPPA to implement a QIP—and therefore must select quality measures based on currently available information—ASN emphasized that it is important for CMS to recognize the scarcity of scientifically validated performance targets and create opportunities to change and replace these QIP measures in the future as new, more robust evidence becomes available. Nonetheless, the society noted that these three measures—particularly the proposed weighted 10 g/dL hemoglobin measure—seem reasonable at this time, until they can be revised with better scientific evidence.

Case-mix adjustors: a vital addition to the QIP

ASN also conveyed that the quality measures selected may penalize facilities with a large percentage of patients in whom it can be difficult to achieve the specified outcomes. In certain areas of the country, particularly in regions with socioeconomically or medically disadvantaged patients, it is difficult to achieve the most desirable intermediate quality metrics despite the best efforts of nephrologists.

Defining quality based on intermediate quality metrics does not take into account variation between compliance level and vascular access across patient populations, nor does it necessarily reflect the efforts of nephrologists and other providers to provide high-quality care. So ASN strongly encouraged CMS to implement case-mix adjustments when calculating performance scores. Case-mix adjustment is vital to preserving equal access to nephrology care for all patients, regardless of geographic location or socioeconomic status—which must be a foremost goal for the agency under the QIP, ASN said. Besides instituting case-mix adjustors, CMS should also establish mechanisms to monitor patient access patterns before the January 1, 2012, QIP start date.

ASN also noted that quality data from facilities with few patients may be skewed owing to the small sample size, negatively (or positively) affecting their overall performance score. The letter stated that CMS should consider removal of statistical outliers more than a certain number of standard deviations from the mean in all facilities (small or large) in either direction, in order to achieve a better sense of overall performance—and moderate the focus on a single absolute threshold score.

Performance standards

CMS proposes two potential performance standards—the baselines against which facilities will be judged—during the first year of the QIP. CMS would compare facilities' data during the performance period to the lesser of the two following standards:

Continued on page 6

IN DEVELOPMENT

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Pay for Performance

Continued from page 4

1. the facilities' own performance on each measure during 2007, or
2. the national performance rates of all dialysis providers (calculated from 2008 data)

CMS proposes judging facilities against the most lenient of the standards according to facility-specific data. A facility that performed worse than the national average in 2008 would be held to a lower performance standard (its own performance on each measure during 2007) than a facility whose performance in 2007 was better than or equal to the national average in 2008 (which would be held to the 2008 national average). The 2008 national performance rates (percentage of Medicare patients who had the following average values) for each measure are shown here:

- hemodialysis adequacy: 96 percent
- hemoglobin <10 g/dL: 2 percent
- hemoglobin >12 g/dL: 26 percent

Given the variability of patient characteristics across regions and facilities, ASN commented that it is most reasonable to compare facilities to their own patient population, rather than a national average. Supporting CMS's proposal to hold facilities accountable to standards specific to their patient populations, the society noted that the goal of the QIP should not be to rank dialysis units based on performance standards, but rather to bring every unit up to its highest level of function.

ASN also expressed concern regarding CMS's proposal that floors for the performance standards will never be lower than those set for the previous year (i.e., never lower than the performance rates shown earlier), and urged CMS to establish a formal way to evaluate the appropriateness of these metrics—leaving open the option to change the floors in light of new evidence.

Performance period

With payment reductions set to begin January 1, 2012, CMS said the performance period—the period from which CMS will examine providers' data to establish payment reductions—must occur before then to allow time to collect, review, and calculate the performance scores that will determine the extent of each facility's reductions. CMS proposes establishing the performance period as the entire calendar year of 2010, reasoning that it needs a full year (all of 2011) to calculate applicable payment reductions—which will go into effect on January 1, 2012. Under this proposal, providers would see payment reductions in 2012 (the payment consequence year) for care provided during 2010 (the performance period). See Figure 2 for a timeline.

ASN expressed concern that many facilities may not be aware that the care they provide today will be evaluated—and potentially subject to payment reductions—two years from now. Were CMS to finalize the proposed performance standards, facilities would be penalized for patient results that were largely (or wholly) recorded prior to the finalization of the QIP. ASN is concerned that CMS would set a precedent of creating ex post facto regulations and strongly urged the agency to reconsider this proposal. ASN proposed that CMS instead make the first half of 2011 the performance period—assuming the agency publishes the final rule in 2010—and conduct data processing during the final six months of 2011.

Public reporting

Each facility must post information regarding performance under the QIP, as mandated by MIPPA. The information must also be made available to the public through a CMS-maintained website. In the proposed rule, CMS suggests that each facility would share data that shows how well the facility's total performance score, and scores on each of the three measures, compares to the national total performance score average.

ASN conveyed its appreciation for CMS's commitment to transparency and openness in the provision of dialysis care. But the society also noted that executing public reporting programs in a way that is both accurate and meaningful from a patient perspective is challenging. CMS notes that it will provide "appropriate comparisons of providers and facilities to the national average with respect to such scores." ASN suggested that developing methods of meaningful comparison for patients is an activity that would best be conducted collaboratively between the agency and the nephrology community.

ASN encouraged the agency to work with the renal community to obtain a better understanding of stakeholder needs and adjust the public reporting system accordingly, including case-mix adjustors.

Future measures

CMS notes that it will be developing measures that "reflect performance goals widely recognized by the ESRD medical community as demonstrating high quality care." While recognizing that CMS is bound by MIPPA to develop more measures, ASN noted that in the absence of hard study outcomes (rather than observational or patient-reported outcomes) it is difficult to identify quality metrics certain to reflect, and improve, the quality of care.

ASN suggested that CMS consider supporting efforts to generate necessary evidence in this arena. The Children's Oncology Group (COG) offers one such potential model of improving care over time. In the COG, every child with cancer is entered into a protocol and, through studying which patients do better over time, survival rates have improved. While translation of this model to the ESRD environment is neither direct nor problem-free, the approach may warrant consideration as a cost-effective method to generate evidence, ASN said.

Next Steps

CMS staff will review public comments submitted to the agency and will likely release a final rule on the QIP before the close of 2010. Many of the concerns ASN conveyed in December 2009 to CMS regarding its ESRD Bundling Proposed Rule were addressed in the final ESRD bundling rule released this summer, and ASN looks forward to a similar outcome for the QIP program. ASN will continue working with the agency as it shapes the final rule and addresses how this new pay-for-performance system will be updated in future years.

Please visit ASN's policy webpage for ASN's complete comments on the QIP Proposed Rule as well as more information about the new bundled payment system and pay-for-performance proposals.

Figure 1

Summary of proposed scoring methodology

1. Measure Performance Scores

- Performance scores will range from 0 to 30 points, based on three measures:
  - o Hgb <10 g/dL
  - o Hgb >12 g/dL
  - o URR >65%
- 10 total possible points are awarded per measure
- 2 points subtracted for every 1.0% below the performance standard

2. Total Weighted Performance Score

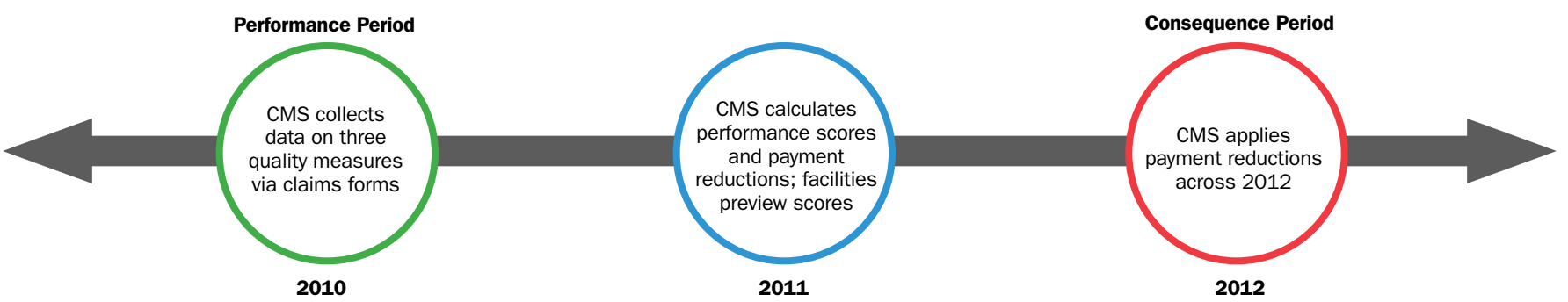
- Measured performance scores are weighted, then summed to create a total performance score:
  - o Hgb <10 g/dL: 50% (of total score)
  - o Hgb >12 g/dL: 25%
  - o URR >65%: 25%

Points Awarded (per measure)	Proposed Model
10	Performance Standard
8	-1%
6	-2%
4	-3%
2	-4%
0	-5%

For more detailed information on CMS's proposed scoring, please visit ASN's public policy website.

Figure 2

Timeline of proposed performance period and payment reductions



ASN in Review

ASN's Yearlong Effort to Lead the Fight Against Kidney Disease

Leaders, volunteers, and staff at the American Society of Nephrology (ASN) work throughout the year to support agendas and goals important to all members of ASN and to the global kidney community. Here we highlight some of ASN's achievements in 2010.

In JANUARY, ASN:

- **Releases new logo.** The new logo and tagline "Leading the Fight Against Kidney Disease" embody ASN's ever more active role in advancing clinical care, research, education, and public policy. The revamped visual identity is the culmination of an effort initiated in 2008 with a survey of members and other stakeholders to evaluate how the Society could better present its goals and achievements.
- **Expands distance learning opportunities.** For the first time, ASN provides the complete board review course and update (BRCU) online, including all 2009 course audio and slides/materials and the opportunity for continuing medical education (CME) credits.
- **Launches the monthly edition of *ASN Kidney News*.** ASN provides expanded information for the kidney community by moving *ASN Kidney News* to monthly publication.
- **Leads the U.S. nephrology community's response to the devastating January 12 earthquake.** The Society convened daily conference calls in collaboration with other organizations to identify and respond to needs for medications, supplies, and volunteers in Haiti. Among the groups working together: the Kidney Community Emergency Response (KCER) Coalition, the International Society of Nephrology, the National Kidney Foundation, the Sociedad Latino-Americana de Nefrologia e Hipertension, dialysis providers, and industry as well as the U.S. Departments of State and Health and Human Services.

In FEBRUARY, ASN:

- **Begins twice-monthly podcast episodes.** Topics addressed in 2010 include the fellowship/residency experience, the Origins of Renal Physiology course, the intersection of medicine and literature, immunosuppressive drug coverage, chronic kidney disease and the urban poor, and writing for scientific journals.
- **Convenes Renal WeekEnds.** In six regional meetings, ASN brings together expert faculty who condense and present highlights in acute kidney injury, transplantation, hypertension, ESRD, parenchymal disorders, and clinical nephrology from ASN Renal Week 2009.
- **Improves processes for members.** ASN rebuilds its member directory to prompt users to update their data, expand member privacy options, and allow members to automatically download member contact information via vCards.

In MARCH, ASN:

- **Testifies at a crucial CMS hearing on ESAs.** ASN testifies at the first Centers for Medicare and Medicaid Services (CMS) Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting regarding use of erythropoeisis stimulating agents (ESAs) to treat anemia related to kidney disease. Information presented by ASN Public Policy Board member Wolfgang Winkelmayer, MD, ScD, FASN, helps influence future regulations and policies. In October, Dr. Winkelmayer testifies on ASN's behalf at the Food and Drug Administration Cardiovascular and Renal Drug Advisory Commit-

Continued on page 8

ASN congratulates 2010 grant recipients

ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

Since 1996, ASN has awarded nearly 200 research grants to advance members' careers and lead the fight against kidney disease. ASN congratulates these recipients on their successful efforts to extend knowledge and improve patient care. More information on the ASN grants program is available at www.asn-online.org/grants_and_funding/.

Carl Gottschalk Research Scholar Grant

Vivek Bhalla, MD, FASN, *Molecular mechanisms of salt-sensitive hypertension in insulin resistance*

David M. Charytan, MD, *Microvascular density in the hearts of individuals with and without CKD: invasive and non-invasive studies*

Paolo Fiorina, MD, PhD, *B7.1 on podocytes: a new therapeutic target for diabetic nephropathy*

Akio Kobayashi, PhD, *Genetic regulation of nephron progenitor cells*

Vladimir Pech, MD, *The role of HCO3- in ENaC regulation*

Timo M. Rieg, MD, *Role of big conductance K channels in K secretion*

Simone Sanna-Cherchi, MD, *Search for rare structural variants in kidney and urinary tract malformations*

John Merrill Grant in Transplantation

Joshua D. Mezrich, MD, *The aryl hydrocarbon receptor as a novel target to direct T-cell differentiation and transplant tolerance*

Norman Siegel Research Scholar Grant

Massimo Attanasio, MD, *Role of GLIS2 in the development of cystic kidney disease*

M. James Scherbenske Grant

Melissa A. Cadnapaphornchai, MD, *Effect of statin therapy on disease progression in children with autosomal dominant polycystic kidney disease*

Mary E. Choi, MD, *TGF-beta signaling in the kidney*

Leonidas Tsiokas, PhD, *Regulation of calcium signaling by the PKD2 gene product*

Student Scholar Grant

Narae Ko, *Role of SLC26 transporters in proximal tubule oxalate transport*

Dhruti Patel, *Investigation of inflammatory processes causing left ventricular hypertrophy and cardiac fibrosis in CKD using a novel mouse model*

Krupa Patel, *Use of NSAIDs as an indicator of patient safety in chronic kidney disease*

Shannon Nees, *Genetics of congenital anomalies of the kidney and urinary tract*

Stacy Rosenberg, *Nephric lineage-specific function of HDAC 1 and HDAC 2*

Ryan Reichert, *Real time Analysis of cAMP changes in PKD*

Amy Zhang, *Stroke risk in non-dialysis anemic CKD patients treated with ESAs: a national case-control study*

ASN in Review

Continued from page 7

tee Meeting on darbepoetin.

- **Nominates members for ESRD panel.** CMS selects five members nominated by ASN to serve on the Clinical Technical Expert Panel on end stage renal disease.
- **Coordinates successful World Kidney Day events.** ASN leaders and staff visit nearly 50 congressional offices to urge legislators to address health disparities, fund research, and support important transplant legislation.

In APRIL, ASN:

- **Participates in NIDDK Network of Minority Research Investigators Workshop**. ASN President Sharon Anderson, MD, FASN, presents an address on *How to Develop a National Reputation*.
- **Improves its grants process.** ASN completely restructures its grants submission process, enabling a much improved submission process for applicants and significantly enhancing the efficiency of processing and tracking applications.

- **Provides grants to medical students and established investigators.** Seven medical students receive ASN Student Scholar Grants, and ASN awards three James M. Scherbenske grants to established investigators.

In MAY, ASN:

- **Advocates for sustainable growth rate (SGR) changes to improve reimbursements and sustain high quality patient care.** ASN successfully urges Congress to postpone SGR cuts. ASN continues to press Congress to replace the flawed formula.
- **Continues expanding distance learning opportunities.** ASN Renal WeekEnds 2010 are available online, including all audio, slides, and materials plus the opportunity for CME credits.
- **Increases focus on geriatric care.** ASN, the National Institute on Aging, and the Association of Specialty Professors (ASP) hold a joint Conference on Acute Kidney Injury in the Elderly. ASN continues to advocate for greater attention to geriatrics-related issues in kidney disease.

In JUNE, ASN:

- **Appoints new editor-in-chief.** Capping a search process initiated in 2009, ASN appoints Gary Curhan, MD, ScD, FASN, as the new Editor-in-Chief of the *Clinical Journal of the American Society of Nephrology (CJASN)* to succeed founding editor William Bennett, MD, FASN, starting in January 2011.
- **Processes 4515 abstracts submitted for presentation at Renal Week 2010.** In the lead-up to the largest and most important kidney meeting in the world, thousands of contributors submit the results of important new studies for presentation at ASN's annual meeting.
- **Increases awareness of chronic kidney disease.** ASN ensures kidney disease is on the radar screen of HHS's Multiple Chronic Conditions Strategic Initiative. Noticing that the initial draft of the initiative did not include mention of chronic kidney disease or end stage renal disease, ASN provides critical feedback recommending their inclusion.
- **Garners recognition for its journals.** Thomson Scientific releases new impact factor rankings. *JASN* maintains the highest rating in the field (7.689), and *CJASN* continues its impressive upward trajectory (4.844).
- **Broadens collaboration with NIDDK.** ASN and the National Institute of Diabetes and Digestive and Kidney Diseases initiate monthly discussions between NIDDK staff, ASN staff, and ASN Research Task Force members to discuss advances in kidney research through collaboration between NIDDK and ASN.
- **Improves communications to members.** ASN transitions from twice-monthly issues of Renal Express to shorter, more focused e-mails, to improve timeliness and focus in communicating items of interest to members.

In JULY, ASN

- **Purchases office space.** On behalf of its members, ASN takes advantage of low commercial real estate prices, low interest rates, and favorable incentives from the District of Columbia (DC) government to obtain newly renovated space that will allow the Society to grow and to continue to accomplish its mission.
- **Provides additional comment on ESAs:** CMS continues to review its coverage of ESAs because of emerging safety concerns. ASN builds on its March comments on existing evidence regarding the effects of ESAs on health outcomes in adult patients with chronic kidney disease (both predialysis and dialysis).
- **Testifies at FDA hearing.** Public Policy Board Chair Thomas Hostetter, MD, FASN, testifies on behalf of ASN members on the implications of the Risk Evaluation and Mitigation Strategy (REMS) program for care of patients with dialysis.
- **Releases a *NephSAP* issue on Clinical Pharmacology.** NephSAP continues to build on its sustained excellence as a venue for continuing education, presenting a special issue focusing on Clinical Pharmacology for the Practicing Nephrologist.
- **Launches its Facebook page.** ASN's facebook page provides a forum for participants to stay informed and comment about advocacy and public policy, educational opportunities, breaking news, current research, grant funding, and ASN services.
- **Releases its first film, commemorating the 20th anniversary of *JASN*.** ASN launches a YouTube channel (Kidney Tube) and commemorates the 20th anniversary of the *Journal of the American Society of Nephrology (JASN)* with a filmed interview of all four editors of the journal since its inception.
- **Expands options for Renal Week planning.** ASN revamps the annual meeting itinerary builder to include a range of new features and download options.
- **Plans ASN Annual Meeting.** The ASN Program Committee meets to select and schedule 477 oral (free communication) abstract presentations and organize 3067 poster sessions for Renal Week 2010.

In AUGUST, ASN:

- **Meets the 12,000-member milestone.** More than 12,000 members now contribute to ASN and its fight against kidney disease. More than 200 members volunteer to fill 62 available positions on one of the Society's 31 committees, advisory groups, and other panels.
- **In her role as ASN President, Dr. Anderson** leads the members of ASN Council in a three-day meeting to discuss how ASN will set priorities to ensure it helps members address and resolve the most important issues and challenges in kidney care over the next five years.
- **Assists with NIDDK strategic goals.** ASN submits nominees for new planning committees to the Division of Kidney, Urologic, and Hematologic Diseases (KUH) at NIDDK in their strategic planning process.
- **Supports travel to Renal Week.** ASN provides travel support to 267 established and young investigators, fellows, residents, and medical students.

In SEPTEMBER, ASN:

- **Pens a guidance letter on remaining areas of concern in the ESRD Bundled Payment System.** The ESRD bundled payment system will monumentally impact the practice of nephrology and patient care. While many of the concerns ASN conveyed in 2009 were addressed in the Final Rule, the ASN ESRD Task Force identifies additional points of concern and submits to CMS a letter of guidance.
- **Submits suggestions for the proposed Quality Improvement Program (QIP).** Besides influencing patient care practices, QIP—the first-ever pay-for-performance program in Medicare—will serve as a model for other areas of medical practice. An ASN task force analyzes the QIP Proposed Rule and submits a comment letter to CMS outlining the Society's insights about various elements of the proposal.
- **Advocates for changes to the standards of the Health Insurance Portability and Accountability Act (HIPPA).** ASN supports HHS proposals that adjust HIPAA standards to ease the collection of data for research while continuing to protect patients' health information.
- **Begins planning for ASN Renal Week 2011, which will take place November 8–13 in Philadelphia.** For the first time ever, ASN invites members to recommend topics for early programs, clinical nephrology courses, and basic and clinical science symposia. Also, for the first time, the ASN Program and Postgraduate Education Committees meet together to initiate the planning process.

- **Updates its online course offering.** ASN provides the complete board review course and update (BRCU) online for 2010, including audio and slides/materials presented at the 2010 meeting, as well as awards and the opportunity for CME credits.

In OCTOBER, ASN:

- **Receives recognition for new logo.** *PR News* recognizes ASN as a finalist for a major award for successful rebranding initiatives; other finalists include Kimberly Clark and Shell.
- **Expands its association with Women in Nephrology.** ASN continues to expand its collaboration with Women in Nephrology, providing support for a website redesign and providing member support services for this important organization.
- **Continues to ensure transparency in relationships with commercial interests.** ASN launches a Conflict of Interest Management Committee, charged with managing conflicts of interest to ensure the ethical conduct of ASN affairs, and serving as a resource to advise leadership related to potential organizational conflicts. The society continues its leadership role in this area by adding news updates, articles, and policy statements to its Conflict of Interest Initiative website (http://www.asn-online.org/coi/).
- **Finalizes annual meeting, with new offerings for 2010.** Two new early programs will be offered (Assessing and Managing Acid-Base Disorders and Polycystic Kidney Disease), as well as an expanded professional development seminar, new abstract category (bioengineering and informatics), a fellows' lounge, and a medical student and resident program.
- **Enhances services for Renal Week press briefings.** ASN offers media training for those presenting their work to the media during Renal Week.

In NOVEMBER, ASN:

- **Hosts the largest and most important kidney meeting in the world.** ASN presents the most important scientific and medical advances, the premier educational opportunities, and essential professional networking opportunities in Denver. Highlights include: Epithelial Transport and Cell Biology, Renal Immunology and Transplantation, New Insights into Glomerular Structure and Function, and Kidney Development and Stem Cells.

- **Holds a summit on increasing interest in nephrology careers.** Concerned that the number of graduates of U.S. medical schools who select nephrology has dropped approximately 25 percent since 2005, ASN holds a summit during ASN Renal Week 2010. Program directors, division chiefs, other academic leaders, and physicians-in-training discuss the recommendations of the ASN Task Force on Increasing Interest in Nephrology Careers and plan next steps to address this potential crisis in the nephrology workforce.
- **Launches new websites for *CJASN* and *JASN*.** New features include expanded search options, reference links, and options for personalizing the reader's experience.

In DECEMBER, ASN:

- **Launches an important new online learning opportunity.** ASN captures approximately 300 hours of Renal Week educational content, including several early programs, basic and clinical science symposia, clinical nephrology conferences, educational symposia, and plenary sessions available to registered participants without charge as added value to their learning experience at Renal Week.

Renal Week 2010

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President's Address

Health Care Policy, Strategic Planning, Disaster Relief in 2010

By Sharon Anderson, MD, FASN

Sharon Anderson, MD

There have been significant changes to health care policy this year, especially for nephrologists. Do you see the practice of nephrology changing as a result?

I believe this is an opportunity for nephrologists. The medical profession in general has not always been as accountable as it can be. In nephrology, specifically, we suffer from a relative lack of good strong clinical evidence backing what we do. Recent policy changes present us the opportunity to assess the areas in which we have good evidence of best practices and identify the areas where we need to do better. Importantly, ASN can help the Centers for Medicare and Medicaid Services (CMS) and other public bodies identify the best practices and performance measures that will ensure the safest and highest quality care for our patients.

We are fortunate that nephrology in general, and ASN in particular, are at the forefront of the discussion. ASN has been very active in discussions with Congress, CMS, and other players. Nephrologists can and should point out to policymakers those areas in which a proposed performance measure has not been shown to make a difference in survival, morbidity, or mortality.

In the next few years, nephrology will lead the way in identifying the strength of the evidence and places where the evidence should not be arbitrarily applied to a given clinical problem. Many specialists outside of nephrology will look to our field to learn more about how to incorporate these policy changes into high- quality delivery of care.

You led the society in a strategic planning initiative that will be discussed in more detail in our December issue. Why did you think this effort was important and what do you think the leaders accomplished as a result?

ASN has experienced astonishing growth in 44 years. Recently, this growth has been exponential; ASN has continued its traditional position as a leading purveyor of quality educational material, and vastly broadened the scope and methodology delivering that education. In the past few years, we have gone from publishing one journal to producing four major publications and we're developing new methods to communicate beyond print. Most striking, we have made a serious investment in grants and public policy, ensuring that ASN's voice is heard when Congress and other policymakers are considering legislation that affects our practice and our patients.

However, no society has endless resources or endless energy. As ASN's reach has grown, more and more opportunities come our way. I'm a big fan of the hedgehog concept put forward by Jim Collins in *Good to Great*. His idea was that truly great organizations figure out three things: what they can be the very best at doing, what they're passionate about, and what they can afford to do. The sweet spot is in the center of all three. I felt ASN might be in danger of going in more directions than it can sustain, and needed to develop a clear set of core activities and priorities for the immediate future. Those activities that fit nicely in the hedgehog concept should continue full force. Other ideas, even the most attractive ones, might need to be considered peripheral or put on a wish list of things to do later. We devoted a full three-day Council meeting to strategic planning in August. Council leaders and staff members completed a lot of work in advance, focusing closely on the society's major areas of endeavor, including education, communications (and publications), policy, grants, and workforce. We developed a list of the major goals that should remain at the forefront, and we look forward to releasing the full strategic plan in the near future. The process helped give ASN a clear road map for future progress.

ASN played a significant role in responding to the disaster in Haiti. What did the leaders learn from this experience about what ASN can do to help in future disaster relief efforts?

The story really starts five years earlier when Hurricane Katrina devastated New Orleans. In my opinion, the nephrology community was ill equipped to deal with such an unprecedented disaster. Heroic efforts were made by many individual nephrologists and individual groups to try to get dialysis patients to functioning dialysis units. But the lack of coordination and communication served as a wake-up call for nephrology. In the intervening years, it's been exciting to see the development of the Kidney Community Emergency Response Coalition (KCER), an organization that brings together public agencies, kidney societies, dialysis organizations, and industry groups to build an infrastructure to help kidney professionals better respond to future disasters. KCER met at ASN Renal Week in November 2009.

Two months later, the earthquake struck Haiti. Because of the infrastructure now in place, the nephrology community was able to respond much more rapidly and effectively to events in Haiti. I'd like to single out ASN member Dr. Didier Portilla who really took the lead on the society's behalf. In collaboration with the International Society of Nephrology (ISN), Doctors without Borders, the Sociedad Latinoamericana de Nefrologia e Hypertension (SLANH), and the Society of Nephrology of the Dominican Republic, we were really able to do some amazing things to help deliver personnel, resources and equipment to Haiti. It was the first time this specific group had come together for disaster relief—the complexities were enormous. But the lessons learned will benefit disaster victims in the future.

This year ASN chose a new editor for *CJASN*. This journal has made impressive progress in its first term. Can you comment on that and how you envision the future of the journal under the leadership of Dr. Curhan?

It's amazing and gratifying to see the growth and maturation of *CJASN* during its first term and under the leadership of its first editor, Dr. William Bennett. Some people were skeptical as to whether we really needed another clinical nephrology journal; I was one of them. We were proved wrong. *CJASN* has turned into a terrific journal growing by leaps and bounds. It will be exciting to see the new directions in which Dr. Curhan will take this journal. We were thrilled he was chosen for this role. He brings tremendous talents and skills to this endeavor. The new team has great ideas about moving the journal to its next level and communicating the content in different ways. The world has gone way beyond print journals and while we have made some inroads, such as our podcasts, which are quite popular, we've only begun to scratch the surface of electronic media and other ways of getting the word out.

What were the biggest challenges planning this year's annual meeting, and what are you most excited about on the program?

It is daunting to consider you have just one year to put together a huge, comprehensive, and diverse meeting. The challenge is to make sure that the meeting has the highest quality topics and enough diversity in the program to appeal to the diverse membership. Under the leadership of Dr. David Ellison, the program committee has done a spectacular job, and everyone is going to be very pleased with the program. While there are too many exciting aspects to count, one highlight is a special symposium honoring the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which is celebrating its 60th anniversary this year. The symposium will highlight some of the best research sponsored by NIDDK, and we're very proud to be able to honor this institute. I'm also very excited about the selection of plenary lectures: topics range from lessons in cystic fibrosis to mapping genes for complex traits in canines to inflammation and its importance in kidney disease to improving practice and policy in the 21st century. This will be a very exciting and dynamic annual meeting.

Continued on page 14

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1. Go AS, Chertow GM, Fan D, McCulloch CE, Hsu C. Chronic kidney disease and the risks of death, cardiovascular events, and hospitalization. *N Engl J Med.* 2004;351(13):1296-1305.

TAK-00306

President's Address

Continued from page 12

ASN purchased a building under your leadership. Why?

This is a really exciting development for our society. ASN has outgrown its current space, and the lease was due to expire next year. For the past few years, ASN Council members had been debating whether to lease or buy space. This year, all the stars aligned in favor of purchasing space. ASN was able to take advantage of very low real estate prices, historically low interest rates, and very favorable incentives from the District of Columbia government. All of this allowed the society to obtain newly renovated space at a highly attractive price, comparable to or slightly lower than leasing new space. The building has a great view of the Washington monument and Jefferson Memorial; we're excited about moving in and pleased that the space will allow ASN to grow and continue to accomplish its mission.

You have now served on ASN Council for six years. How has that experience shaped your perspective on the role of professional societies in serving members and others?

Serving on Council six years has been a terrific experience. The five years prior to becoming president enable the president to begin the job with a fair amount of knowledge and understanding about the society and its members' needs. Serving for this time period has made me think a lot about all nephrologists and how ASN might best serve all of our members. Society members range from academic researchers to full-time clinicians to everything in between. We need to continue to recognize the challenges of successfully addressing the needs of all these professionals.

We are particularly challenged with respect to fully understanding the aspirations, goals, and needs of our younger members. As with any professional society, by the time you get to leadership you have been in the business for a while. The environment for people entering the profession now is very different from the environment my fellow Council members and I entered a couple of decades ago. Leaders in nephrology need to improve our ability to identify the professional needs of our younger people. ASN has been expanding the participation of younger members in our various committees, advisory boards, and task forces and we need to continue to find ways to mobilize the interest and talents of our younger members.

In addition, medical practice in the United States, especially in the generations preceding mine, was pretty much the business of white males. The picture of our society in general and of our profession has really changed. Women now make up about one third of the fellows in nephrology, and nephrology ranks 13th among 35 other specialties in the United States in the number of African Americans. But we need more women and minorities in positions of leadership. ASN needs to expand its efforts to diversify its leaders and make sure nephrology as a career appeals to the widest range of candidates. That starts with getting younger people involved in our advisory groups, task forces, and committees; learning from them; and helping to groom them for leadership roles.

What have you had to put on the back burner during your term as ASN President?

Sometimes it feels like just about everything else. This has been a marvelous, once-in-a-lifetime experience, but it is hard to sustain energy and all the other aspects of your professional and personal life with so much else going on. I am very grateful to my staff and co-workers who have been able to keep the home ship running while I am working on ASN duties. I am also looking forward to being past president; I plan to sit back and watch ASN continue to evolve and grow under the able leadership of my good friend Joe Bonventre.

Sharon Anderson, MD, FASN, is vice chair for clinical affairs in the Department of Medicine at Oregon Health and Science University, and chief of medicine at the Portland VA Medical Center.

President-elect's Address

Public policy, nephrology workforce, aging population warrant attention in 2011

By Joseph Bonventre

Joseph Bonventre

What do you see as the biggest challenges for nephrologists today and in the near future?

Nephrologists will be dealing with the burden of kidney disease in an aging population, and doing this in a fiscally constrained environment and with an increasingly complicated health care delivery system.

Why do you think health care delivery will be more complicated?

The need to control costs may force individual physicians to develop relationships with institutions at which more of the health care might be concentrated, or practicing nephrologists may need to band together in new ways and develop relationships with primary care providers. There may also be challenges in the ways in which dialysis organizations will interface with nephrologists and the health care delivery system.

Some people have compared the Affordable Care Act (PL 111-148) to the health reforms in Massachusetts. From your perspective, how has hospital care in the Bay State changed as a result of reform efforts?

Health care reform in Massachusetts has resulted in some redistribution of care among institutions. Institutions that have traditionally provided care to the indigent now operate in less predictable environments. Since everyone has insurance, individuals have more choices in the selection of the institutions they choose for their care.

Additionally, health care reform has placed a premium on the availability of primary care physicians. In Massachusetts, with so many academic institutions and the resulting emphasis on subspecialty care, there has been a real shortage of primary care physicians.

You've mentioned the increasing rate of kidney disease, aging of the population, and strained financial structures as challenges. Do you think those things combine with the focus on primary care physicians to increase the demand for nephrologists in the future?

Recently, one of the health care systems in this area ran a pilot program that instituted automatic alerts for primary care physicians. The primary care physician was alerted when a patient's renal function was not normal. I'm told that that resulted in an eightfold increase in the number of referrals to the nephrology practice at that organization. Increasing awareness of kidney problems aided by information technology and other means, together with the increasing access to care, will increase referrals and the need for nephrologists.

How can ASN help nephrologists address these challenges?

ASN can support busy physicians, help them keep up to date with medical knowledge, and advocate for nephrologists and kidney scientists in the public policy arena. Providing increased access to information in a readily digestible way will become more and more critical as patient loads increase.

ASN must also find ways to enhance the attractiveness and awareness of nephrology as a career choice as well as increase public awareness of kidney disease. We will need the support of the public to help affect policy issues that are becoming more and more important to providing good care to kidney patients.

When you meet with medical students and talk about their career options, how do you portray nephrology as a career?

Nephrology, more than most subspecialties, is a career in which students can apply the broad knowledge base they're developing in internal medicine and complement that with a detailed knowledge of a fascinating organ that is functionally diverse and ultimately responsible for regulating the internal milieu. These students can address the growing need to carry forward and find new therapies for a disease that affects 8–10 percent of the world's population, and is the major risk factor for cardiovascular disease.

You have been involved with the ASN Grants Review Committee for several years. Could you describe your perspective of ASN's role in that arena?

ASN plays a critical role in supporting investigators at an early stage in their research careers. This support makes a statement to the community that this is a priority, and a statement to applicants that ASN cares about them, cares about the future of nephrology, and supports a vibrant clinical science and research effort. While a minority of the membership receives the awards, these grants support the academic roots of the discipline. Ultimately, everyone benefits from nurturing these young investigators. Individuals who are studying the kidney, physician scientists, and clinicians all look to organizations like ASN to advance knowledge and improve care of patients.

Within the context of public awareness, you led efforts to rebrand ASN with a new logo and tagline. Why did you think that was important?

Things have changed dramatically since ASN was started in 1966. It seemed to me and other members of the ASN Council that the logo had not kept up with changes in society, medical care, academics, and the way hospitals are run. After surveying a number of internal and external constituents, we found that ASN was considered highly professional and extremely solid in providing education and publications, but wasn't felt to be innovative or forward looking. The Council enthusiastically supported the change of logo and development of a tagline that would build on the strengths and project the work ASN is doing to meet future challenges and prepare the membership for that future.

When did you first attend the ASN annual meeting?

In 1981. The ASN meeting was not then the primary meeting for the kidney community. The best science was presented at clinical meetings in Atlantic City, and the FASEB meeting was still strong in the basic science arena. ASN's annual meeting was somewhat secondary in the context of presenting the absolute best data. Over the years, that has changed dramatically, and ASN has become the premier meeting in the world for presenting state-of-the-art science and clinical synthesis.

How has the annual meeting changed?

In addition to now attracting the best science in the field, it has gotten much bigger. That has its good points and also presents some challenges—ASN has to maintain an element of the small meeting appeal within the context of the larger meeting. Program committees over the years have worked hard on this and made significant progress, and ASN should continue to focus on those challenges.

Why did you choose Mark D. Okusa, MD, FASN, to chair the program committee for 2011?

Mark is an outstanding investigator whose work I'm familiar with because our areas of study overlap. He is very attentive to detail and has made a number of important contributions to the ASN in multiple contexts. In making those contributions, he displayed characteristics that I felt important in someone I would work closely with on such an important project. Mark is a practicing nephrologist who leads the Renal Division at the University of Virginia and has a great deal of insight into the

Continued on page 16

Providing [physicians] increased access to information in a readily digestible way will become more and more critical as patient loads increase.

President-elect's Address

Continued from page 15

needs of the practicing nephrologist as well as the clinical and basic investigator. Mark is a very personable individual, and I'm very happy he chose to accept this responsibility. He is already working very hard on the 2011 program and I'm looking forward to a great meeting.

You have served as a Council member for four years and as president-elect for a fifth year. During this time what has surprised you the most about ASN as an organization?

The overall complexity of the society surprised me, and I was pleasantly surprised by the enthusiasm on the part of the staff and Council members to work to move things forward on many different fronts. I knew something about the complexity and I expected ASN to be effective and provide outstanding educational opportunities, with the annual meeting the jewel in the crown. But the culture of change, and the expectation that change would make a positive impact, surprised me.

You also serve on the Board of Directors of the National Space Biomedical Research Institute (NSBRI). What does this organization do and what have you learned serving on its board?

In 1988, I was a founding member of the Board of Directors of this organization, which I helped to put together as an interdisciplinary and interinstitutional organization. My interest in medicine goes back to a college summer when I attended a NASA-funded space biology research institute program that was held at the Ames Research Center in Mountain view, Calif., and the Brain Research Institute at UCLA.

NSBRI is a partnership between NASA and the academic and industrial communities. Its goal is to advance biomedical research to rnsure safe and prolonged space travel for humans, and it focuses on developing effective technology and measures to reduce the risk of space travel. The organization plays a critical role in the development of measures to mitigate risk to astronauts to ensure safety in a future trip to Mars with humans on board.

I've learned a lot about the intricacies of putting together an organization that spans government, academia, and industry and learned a great deal about the challenges of extended space travel. I've also learned about the widespread advantages of space research, which produces critically important advances for life on earth. It's also been interesting to see the increasing openness of the space program. At one point it was very competitive country to country; there are now international meetings where scientists from Russia, China, France, and the United States are gathering to talk about space travel and to share their experiences.

How does the increasingly global aspect of space research compare with biomedical research?

One of the critically interesting and important features of biomedical research today is its nature as a global enterprise. Potentially, scientific and medical research relationships could be built upon to overcome other political issues that feed nationalistic tendencies and separate countries. Scientists take a very straightforward approach to biomedical research. Scientific discoveries and collaboratives override national boundaries.

As you think about serving as ASN President next year, what priorities or strategic initiatives do you consider most important?

ASN should take a more proactive role in the public forum. In the context of public policy, ASN has done this effectively, especially given that it has not always been a priority for the Society. The organization will serve its membership and kidney patients most effectively if the general population learns more about the importance and prevalence of kidney disease. The other major issue of critical importance is the health care workforce. It's critically important that we get more people interested in working on the kidney and treating patients with kidney disease as a lifelong mission. That is not going to be easy to do, but I think we have only scratched the surface in thinking about innovative ways to address the challenges involved with building a stronger workforce in nephrology.

Joseph Bonventre, MD, PhD, FASN, is with the Renal Division, Department of Medicine, Brigham and Women's Hospital, Harvard Medical School, Harvard Institutes of Medicine, in Boston.

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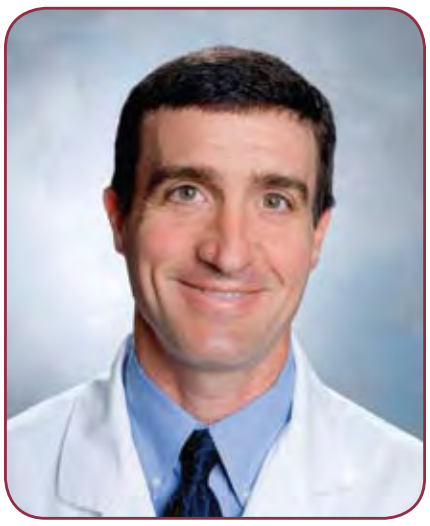
ASN Kidney News *interviewed Gary C. Curhan, MD, ScD, FASN, incoming editor-in-chief of the* Clinical Journal of the American Society of Nephrology (CJASN) *about his aspirations for the journal. Curhan, associate professor of medicine at Brigham and Women's Hospital, Harvard Medical School, takes the helm at* CJASN *in January 2011.*



Gary C. Curhan

What interested you about the *CJASN* editor-in-chief position?

I have served as an associate editor of *CJASN* since its inception. Working with Bill Bennett has been inspirational, and I welcome the opportunity to continue and to expand his work. In addition, there has been a huge increase in the volume of clinical research performed, including clinical research in nephrology, and that is exciting for all those interested in medical advances.

I look forward to the opportunity to build on the work done to date and to continue to improve the quality of the journal.

What do you think *CJASN* has accomplished since its launch?

Far more than anyone expected, in a short time *CJASN* has become a premier nephrology journal. Many clinical investigators consider *CJASN* their primary source of information. Dr. Bennett assembled a group of people with diverse interests and expertise, infused us with excitement and vision for this new journal, and was open to all types of clinical research. Many of the reviews and other invited material that people contributed helped generate interest in the journal. Finally, *CJASN* focused on efficient processes and rapid turnaround, which is always important to authors.

What do you foresee for the next six years of *CJASN*?

We will focus on improving the quality of all the material we publish, particularly original studies. We will devote a fair amount of attention to the presentation of the material we publish. Readers should be able to easily interpret figures and tables; authors should explain how an individual study adds to the current literature; and the writing should be clear. Where appropriate, we will ask authors to provide a brief statement describing the study's impact on clinical practice. In addition, we will take advantage of new technologies to add more interactive features to the online journal, improving educational opportunities by adding links to other published work, and expanding the ways we deliver content to readers.

Editing a journal presents a lot of opportunities to make an impact on a field of study. What opportunities do you consider most important?

The work we publish must be relevant to clinicians and clinical investigators.

I think we will continue to see an increase in the number of submissions. We must focus on printing only the highest quality work and helping all authors understand that we cannot publish everything we receive.

Part of my job as editor will be to define *CJASN*, making it clear to readers and submitting authors why *CJASN* is different from other sources of information.

What are the biggest challenges facing nephrologists today?

Nephrologists are faced with a huge onslaught of information. It can be overwhelming to determine what is credible and what should change practice. Rapidly changing guidelines are generated by different organizations and by changing health care laws, and assessing the value of these is a challenge. Nephrologists want guidelines based on strong evidence whenever possible. Changes in reimbursement put pressure on clinicians to increase their patient load even more.

How nephrologists should interact with primary care physicians needs to be clarified. Both types of physicians are very busy, and I believe it is imperative for optimum patient care that we develop better ways to work together.

How will *CJASN* maintain balance between different areas of nephrology?

CJASN is dependent on the articles submitted, most of which are not invited. We will publish the highest quality submissions we receive in individual topic areas.

Central to maintaining topic balance will be assembling an outstanding group of associate editors with diverse backgrounds and expertise. Bringing their different perspectives to bear on the growing number of submissions will help maintain balance and contribute to the journal's openness to the newest and most exciting work in all subject areas.

What advice do you have for authors who are considering submitting papers to *CJASN*?

The decisions an investigator makes start well before deciding on a journal and center on study design: Is the hypothesis important? How will the study contribute to the existing literature? Will the study generate data of sufficient quality? The next step is to perform a high-quality study, give appropriate attention to detail when analyzing the data, and avoid overinterpreting the data. Authors should write clearly and make sure the data in figures and tables are clear to the reader.

Can you comment on the process of peer review?

Outside perspectives help authors identify how to improve their writing and presentation. That feedback is invaluable since even good work may not get published if the results are not presented with clarity. In my own group, numerous individuals read and critique manuscripts before we ever submit them to journals. Peer review helps authors to modify unclear presentation, encourages authors to consider different approaches to data analysis, and helps tone down overenthusiastic interpretation of results. Peer review almost always substantially improves a paper.

At *CJASN*, all submitted manuscripts are read by the editor-in-chief and then assigned to an associate editor. The associate editor reads the manuscript and decides if it should be sent out for review. Currently, about 50 percent of manuscripts are not sent for review. This proportion may need to increase slightly as the number of manuscripts being submitted to *CJASN* continues to increase. We do not send out all manuscripts because *CJASN* can only publish fewer than 20 percent of the manuscripts submitted; thus, we need to decide at this initial stage whether the article should even be sent for review. This approach is helpful to authors as they do not have to wait weeks or months before sending their manuscript to another journal. Also, we value the time and effort our reviewers devote to the review process. We depend on high quality reviews to guide our decisions. Therefore, we do not want to overburden our reviewers with manuscripts that would not be published regardless of their comments.

How do you think technology will change the world of medical publishing?

Technology provides hugely exciting opportunities. When you think how recently researchers still had to go through the library stacks to read journal articles, it's amazing that now most of us can pull up almost instantly every article we want to read. Journals will apply future technologies to present data in novel ways to make data more interactive and useful to the reader and will allow posting of supplemental material that will expand a reader's understanding of exciting new studies.

How will you judge your success as an editor?

While a variety of metrics are available to assess journal performance, the most important measure of success will be if the quality of science and the way we present the material improves over time. If the number of readers increases, that also demonstrates the value of a publication. I expect the electronic features we will offer will expand the opportunities readers have to access and learn from published studies. Finally, I hope we can make the process from submission through peer review and to final publication as smooth as possible.

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NIDDK Kidney Research: Current State of Funding and Its Impact on Science

Second in a three-part series looking at NIDDK funding

By Daniel Kochis

The year 2007 was a challenging one for researchers. The National Institutes of Health (NIH) funded only 24 percent of proposals (down from 32 percent in 1999) (1), and additional funding for research seemed miles away. Clinical practice, private industry, and foreign countries all threatened to poach valuable talent from the ranks of researchers at U.S. research institutions. After a funding boom earlier in the decade, willingness to devote new dollars for NIH had dried up in Congress. The economy, increased spending for other sectors, and a lack of political urgency drove the trend.

One major concern with these funding constraints is that the pitfalls of an arid funding landscape fall disproportionately on young researchers, who are just entering the pool of NIH grant applicants.

Tight funding at NIH contributed to a host of challenges at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Fewer and fewer proposals were granted funding, review boards began to tend toward more conservative proposals, and second and third applications for the same research proposal became commonplace. According to ASN Councilor Sharon Moe, MD, FASN, who also serves on the ASN research task force, "In the past few years, NIH has had to do the best they can within the bounds of their budget. Unfortunately, a lack of new investment in research today can have an amplified impact on medicine in the future."

One major concern with these funding constraints is that the pitfalls of an arid funding landscape fall disproportionately on young researchers, who are just entering the pool of NIH grant applicants. In 1990, the average age for a researcher's first prestigious R01 grant was 39; in 2007 the age was 43 (1). The inherent risk is that young researchers become frustrated and disillusioned with the application process, encounter difficulty securing continued funding for their research, and decide to pursue alternate career paths.

A 2008 report by some of the country's leading scientists and research institutions sums up the quandary for early career researchers: "They can't get the NIH R01 funding they need to establish a lab and launch an independent career because NIH reviewers say they don't have the data to support their grant applications. Yet the preliminary data and proof that experiments will succeed is hard to come by without that very funding." (1)

As a result, many early career researchers apply first for a career development grant (K grant), which supports burgeoning research careers and acts as a stepping stone for researchers to apply for coveted R01 grants. Morgan Grams, MD, a fellow at Johns Hopkins University is one such researcher. She describes the process of becoming an independent researcher: "One way to do it is to apply for a K23 which is a career development award, and then in the final years of your career development award you apply for an R01."

Competition from foreign countries for talent is also becoming a more serious threat as countries such as China dedicate greater resources toward medical research. In 2009, the United States committed 2.7 percent of gross domestic product (GDP) to medical research; China committed 1.5 percent of its GDP (2). This investment is making for some high profile coups as several established scientists have elected to return to their country of origin, and more than a few young investigators have returned home after attending medical school in the United States.

The United States, however, remains the king of research opportunity and a destination for medical students across the world. According to Dorry Segev, MD, director of clinical research for transplant surgery at Johns Hopkins University and associate professor of surgery and epidemiology at Johns Hopkins University, training programs, availability of data, and the country's reservoir of scientific knowledge and talent are all contributing factors.

"The more we continue to support these types of activities through NIH, through ASN, through other organizations, we will be able to stay at the top of that game," Segev said. "We certainly are at risk of losing our status at the top if we give up some of these endeavors."

So what about the present day? In 2009, Congress passed the American Recovery and Reinvestment Act (ARRA), which included $445 million for NIDDK alone. Over 97 percent of these funds were allocated to extramural research initiatives, with the remainder funding intramural research programs and administrative costs (Figure 1).

Figure 1.

Examples of ARRA-funded kidney research at NIH

Chronic kidney disease (CKD): An assessment of the potential role of endogenous hormones, ouabin and marinobufagenin, in the progression of CKD to cardiovascular disease in African Americans with hypertensive kidney disease

Polycystic kidney disease (PKD): A study to characterize small membrane-bound exosome vesicles in the urine of people with the more common form of PKD, with a goal of developing an assay to permit early diagnosis of PKD

Acute kidney injury (AKI): A study to characterize the role of the pericyte—the support cell for small blood vessels—in development of kidney fibrosis and vascular regeneration following injury of the kidney

Genetics: The first genomewide association study of the kidney disease IgA nephropathy

Source: National Institutes of Health, http://report.nih.gov/recovery/investmentreports/ViewARRAInvRpt.aspx?csid=198

The funding granted a much needed boost to the priority research at NIDDK. However, the one-time nature of ARRA funding means that most of the dollars were put toward projects that only require one or two years funding rather than risk dollars on more ambitious long-term projects that may lack the dollars to come to fruition down the line. ARRA has been a critical stopgap for NIDDK, but it is only a temporary solution, and one that arguably has reinforced the conservative approach toward applications that has become the new reality at NIH.

With the remainder of recovery act funds being distributed in 2010, NIDDK leadership continues to look toward increasing funding for the future. The need for an investment in medical research is evident to account for a growing and aging population and to counteract the institutional roadblocks that threaten the next generation of researchers. Indeed, the outlook may be brightening. Current Senate proposals call for an 11.9 percent increase in the budget of NIH for 2011, but with the current fiscal mood of the country, that increase remains uncertain. One thing is for certain: the status quo is unsustainable in the long term. Without serious changes, the country may be paying the price for decades to come.

References

1. A Broken Pipeline: Flat Funding of the NIH Puts a Generation of Science at Risk. Co-authored by Brown University, Duke University, Harvard University, the Ohio State University, Partners Healthcare, the University of California Los Angeles, and Vanderbilt University, March 11, 2008.

2. LaFraniere. "Fighting Trend, China Is Luring Scientists Home." *The New York Times*. January 6, 2010, NY Edition: A1.

Next month's final installment of this series will assess the future funding outlook for NIDDK and where the institute hopes to be in the future.

Neera Dahl, MD, PhD, and Rex Mahnensmith, MD, examine a CT scan from a PKD patient.

The genetics behind kidney disease are intricate and multi-faceted. Only a few medical institutions in the country have the commitment to understanding and treating inherited kidney diseases and the resources to house the prestigious George M. O'Brien Kidney Research Center and a Polycystic Kidney Disease (PKD) Research Center, all supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). We are one of those centers.

Research Excellence, Clinical Leadership and a Commitment to Our Patients

Our researchers have discovered over fifteen genes for human diseases affecting the kidney and blood pressure. These discoveries cover the gamut from rare disorders of blood pressure regulation through sodium and potassium handling such as Liddle's syndrome, pseudohypoaldosteronism type II and Bartter's and Gittelman's syndromes to such common inherited kidney diseases as polycystic kidney disease (PKD). While our researchers are now seeking to translate these findings to treatments for PKD and other disorders, our nephrologists are using these discoveries to help our patients lead healthy and fulfilling lives.

Being at the forefront of clinical research and treatments means that our physicians and surgeons are furthering the current understanding of kidney disease. Most importantly, it means they are positioned to provide the best care possible to our patients.

Yale-New Haven Hospital is the primary teaching hospital of Yale School of Medicine. Kidney disorders services at Yale-New Haven were ranked 33rd by *U.S.News & World Report* in 2010.

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ASN has built a special theater in the scientific exposition hall to spotlight industry's latest advances in nephrology practices, products, services, and technologies during 60 minute presentations (no continuing medical education credit). Seating is first come, first served and limited to 100 participants.

All presentations include breakfast (morning presentations) or lunch (afternoon presentations.)

Spotlight Schedule

Thursday, November 18, 2010

10:00 a.m. – 11:00 a.m.
The Role of Sensipar® (cinacalcet) in the Management of Secondary Hyperparathyroidism (HPT): A Practical Approach in a Bundled Environment
Presented by AMGEN

12:30 p.m. – 1:30 p.m.
Understanding Hyponatremia: Treating Beyond the Primary Diagnosis
Presented by Otsuka
Otsuka America Pharmaceutical, Inc.

Friday, November 19, 2010

10:00 a.m. – 11:00 a.m.
ACOs and Integrated Care Management: Opportunities for Nephrologists in the Future Healthcare Model
Presented by DaVita

12:30 p.m. – 1:30 p.m.
Advances in Myeloma Kidney Therapy
Presented by GAMBRO

Saturday, November 20, 2010

10:00 a.m. – 11:00 a.m.
Early Management of Hyperphosphatemia and the Impact of Binder Choice
Presented by genzyme

12:30 p.m. – 1:30 p.m.
Managing Hyperuricemia in Your Patients with Gout
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Indication and Important Limitations

- SAMSCA is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)
- Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with SAMSCA. It has not been established that raising serum sodium with SAMSCA provides a symptomatic benefit to patients

IMPORTANT SAFETY INFORMATION

SAMSCA should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely. Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable.

Contraindications: Urgent need to raise serum sodium acutely, inability of the patient to sense or appropriately respond to thirst, hypovolemic hyponatremia, concomitant use of strong CYP 3A inhibitors, anuric patients.

- Subjects with SIADH or very low baseline serum sodium concentrations may be at greater risk for too-rapid correction of serum sodium. In patients receiving SAMSCA who develop too rapid a rise in serum sodium or develop neurologic sequelae, discontinue or interrupt treatment with SAMSCA and consider administration of hypotonic fluid. Fluid restriction should generally be avoided during the first 24 hours
- Dehydration and hypovolemia can occur, especially in potentially volume-depleted patients receiving diuretics or those who are fluid restricted. In patients who develop medically significant signs or symptoms of hypovolemia, discontinuation is recommended
- Gastrointestinal bleeding in patients with cirrhosis: Use in cirrhotic patients only when the need to treat outweighs this risk
- Avoid use with: CYP 3A inhibitors and CYP 3A inducers. Reduced dose of SAMSCA may be needed if used with P-gp inhibitors
- Co-administration with hypertonic saline is not recommended
- Monitor serum potassium in patients with levels >5 mEq/L and in those receiving drugs known to increase serum potassium

Commonly observed adverse reactions: (SAMSCA vs placebo) thirst (16% vs 5%), dry mouth (13% vs 4%), asthenia (9% vs 4%), constipation (7% vs 2%), pollakiuria or polyuria (11% vs 3%) and hyperglycemia (6% vs 1%).

Please see Brief Summary of FULL PRESCRIBING INFORMATION, including **Boxed WARNING**, on following page.

For more information please visit www.samsca.com

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WARNING: INITIATE AND RE-INITIATE IN A HOSPITAL AND MONITOR SERUM SODIUM

SAMSCA should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely.

Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable.

INDICATIONS AND USAGE: SAMSCA is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).

Important Limitations

Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with SAMSCA.

It has not been established that raising serum sodium with SAMSCA provides a symptomatic benefit to patients.

CONTRAINDICATIONS: SAMSCA is contraindicated in the following conditions:

Urgent need to raise serum sodium acutely: SAMSCA has not been studied in a setting of urgent need to raise serum sodium acutely.

Inability of the patient to sense or appropriately respond to thirst: Patients who are unable to auto-regulate fluid balance are at substantially increased risk of incurring an overly rapid correction of serum sodium, hypernatremia and hypovolemia.

Hypovolemic hyponatremia: Risks associated with worsening hypovolemia, including complications such as hypotension and renal failure, outweigh possible benefits.

Concomitant use of strong CYP 3A inhibitors: Ketoconazole 200 mg administered with tolvaptan increased tolvaptan exposure by 5-fold. Larger doses would be expected to produce larger increases in tolvaptan exposure. There is not adequate experience to define the dose adjustment that would be needed to allow safe use of tolvaptan with strong CYP 3A inhibitors such as clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, and telithromycin.

Anuric patients: In patients unable to make urine, no clinical benefit can be expected.

WARNINGS AND PRECAUTIONS:

Too Rapid Correction of Serum Sodium Can Cause Serious Neurologic Sequelae (see BOXED WARNING): Osmotic demyelination syndrome is a risk associated with too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours). Osmotic demyelination results in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma or death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable. In controlled clinical trials in which tolvaptan was administered in titrated doses starting at 15 mg once daily, 7% of tolvaptan-treated subjects with a serum sodium <130 mEq/L had an increase in serum sodium greater than 8 mEq/L at approximately 8 hours and 2% had an increase greater than 12 mEq/L at 24 hours. Approximately 1% of placebo-treated subjects with a serum sodium <130 mEq/L had a rise greater than 8 mEq/L at 8 hours and no patient had a rise greater than 12 mEq/L/24 hours. None of the patients in these studies had evidence of osmotic demyelination syndrome or related neurological sequelae, but such complications have been reported following too-rapid correction of serum sodium. Patients treated with SAMSCA should be monitored to assess serum sodium concentrations and neurologic status, especially during initiation and after titration. Subjects with SIADH or very low baseline serum sodium concentrations may be at greater risk for too-rapid correction of serum sodium. In patients receiving SAMSCA who develop too rapid a rise in serum sodium, discontinue or interrupt treatment with SAMSCA and consider administration of hypotonic fluid. Fluid restriction during the first 24 hours of therapy with SAMSCA may increase the likelihood of overly-rapid correction of serum sodium, and should generally be avoided.

Gastrointestinal Bleeding in Patients with Cirrhosis: In patients with cirrhosis treated with tolvaptan in hyponatremia trials, gastrointestinal bleeding was reported in 6 out of 63 (10%) tolvaptan-treated patients and 1 out of 57 (2%) placebo-treated patients. SAMSCA should be used in cirrhotic patients only when the need to treat outweighs this risk.

Dehydration and Hypovolemia: SAMSCA therapy induces copious aquaresis, which is normally partially offset by fluid intake. Dehydration and hypovolemia can occur, especially in potentially volume-depleted patients receiving diuretics or those who are fluid restricted. In multiple-dose, placebo-controlled trials in which 607 hyponatremic patients were treated with tolvaptan, the incidence of dehydration was 3.3% for tolvaptan and 1.5% for placebo-treated patients. In patients receiving SAMSCA who develop medically significant signs or symptoms of hypovolemia, interrupt or discontinue SAMSCA therapy and provide supportive care with careful management of vital signs, fluid balance and electrolytes. Fluid restriction during therapy with SAMSCA may increase the risk of dehydration and hypovolemia. Patients receiving SAMSCA should continue ingestion of fluid in response to thirst.

Co-administration with Hypertonic Saline: There is no experience with concomitant use of SAMSCA and hypertonic saline. Concomitant use with hypertonic saline is not recommended.

Drug Interactions:

Other Drugs Affecting Exposure to Tolvaptan:

CYP 3A Inhibitors: Tolvaptan is a substrate of CYP 3A. CYP 3A inhibitors can lead to a marked increase in tolvaptan concentrations *[see Dosage and Administration (2.4), Drug Interactions (7.1)]*. Do not use SAMSCA with strong inhibitors of CYP 3A *[see Contraindications (4.4)]* and avoid concomitant use with moderate CYP 3A inhibitors.

CYP 3A Inducers: Avoid co-administration of CYP 3A inducers (e.g., rifampin, rifabutin, rifapentin, barbiturates, phenytoin, carbamazepine, St. John's Wort) with SAMSCA, as this can lead to a reduction in the plasma concentration of tolvaptan and decreased effectiveness of SAMSCA treatment. If co-administered with CYP 3A inducers, the dose of SAMSCA may need to be increased *[see Dosage and Administration (2.4), Drug Interactions (7.1)]*.

P-gp Inhibitors: The dose of SAMSCA may have to be reduced when SAMSCA is co-administered with P-gp inhibitors, e.g., cyclosporine *[see Dosage and Administration (2.4), Drug Interactions (7.1)]*.

Hyperkalemia or Drugs that Increase Serum Potassium: Treatment with tolvaptan is associated with an acute reduction of the extracellular fluid volume which could result in increased serum potassium. Serum potassium levels should be monitored after initiation of tolvaptan treatment in patients with a serum potassium >5 mEq/L as well as those who are receiving drugs known to increase serum potassium levels.

ADVERSE REACTIONS:

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reactions rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse event information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates. In multiple-dose, placebo-controlled trials, 607 hyponatremic patients (serum sodium <135 mEq/L) were treated with SAMSCA. The mean age of these patients was 62 years; 70% of patients were male and 82% were Caucasian. One hundred eighty nine (189) tolvaptan-treated patients had a serum sodium <130 mEq/L, and 52 patients had a serum sodium <125 mEq/L. Hyponatremia was attributed to cirrhosis in 17% of patients, heart failure in 68% and SIADH/other in 16%. Of these patients, 223 were treated with the recommended dose titration (15 mg titrated to 60 mg as needed to raise serum sodium).

Overall, over 4,000 patients have been treated with oral doses of tolvaptan in open-label or placebo-controlled clinical trials. Approximately 650 of these patients had hyponatremia; approximately 219 of these hyponatremic patients were treated with tolvaptan for 6 months or more.

The most common adverse reactions (incidence ≥5% more than placebo) seen in two 30-day, double-blind, placebo-controlled hyponatremia trials in which tolvaptan was administered in titrated doses (15 mg to 60 mg once daily) were thirst, dry mouth, asthenia, constipation, pollakiuria or polyuria and hyperglycemia. In these trials, 10% (23/223) of tolvaptan-treated patients discontinued treatment because of an adverse event, compared to 12% (26/220) of placebo-treated patients; no adverse reaction resulting in discontinuation of trial medication occurred at an incidence of >1% in tolvaptan-treated patients.

Table 1 lists the adverse reactions reported in tolvaptan-treated patients with hyponatremia (serum sodium <135 mEq/L) and at a rate at least 2% greater than placebo-treated patients in two 30-day, double-blind, placebo-controlled trials. In these studies, 223 patients were exposed to tolvaptan (starting dose 15 mg, titrated to 30 and 60 mg as needed to raise serum sodium). Adverse events resulting in death in these trials were 6% in tolvaptan-treated-patients and 6% in placebo-treated patients.

Table 1. Adverse Reactions (>2% more than placebo) in Tolvaptan-Treated Patients in Double-Blind, Placebo-Controlled Hyponatremia Trials

System Organ Class MedDRA Preferred Term	Tolvaptan 15 mg/day-60 mg/day (N = 223) n (%)	Placebo (N = 220) n (%)
Gastrointestinal Disorders		
Dry mouth	28 (13)	9 (4)
Constipation	16 (7)	4 (2)
General Disorders and Administration Site Conditions		
Thirst [a]	35 (16)	11 (5)
Asthenia	19 (9)	9 (4)
Pyrexia	9 (4)	2 (1)
Metabolism and Nutrition Disorders		
Hyperglycemia [b]	14 (6)	2 (1)
Anorexia [c]	8 (4)	2 (1)
Renal and Urinary Disorders		
Pollakiuria or polyuria [d]	25 (11)	7 (3)

The following terms are subsumed under the referenced ADR in Table 1:

[a] polydipsia; [b] diabetes mellitus; [c] decreased appetite; [d] urine output increased, micturition urgency, nocturia

In a subgroup of patients with hyponatremia (N = 475, serum sodium <135 mEq/L) enrolled in a double-blind, placebo-controlled trial (mean duration of treatment was 9 months) of patients with worsening heart failure, the following adverse reactions occurred in tolvaptan-treated patients at a rate at least 2% greater than placebo: mortality (42% tolvaptan, 38% placebo), nausea (21% tolvaptan, 16% placebo), thirst (12% tolvaptan, 2% placebo), dry mouth (7% tolvaptan, 2% placebo) and polyuria or pollakiuria (4% tolvaptan, 1% placebo).

SAMSCA® (tolvaptan)

The following adverse reactions occurred in <2% of hyponatremic patients treated with SAMSCA and at a rate greater than placebo in double-blind placebo-controlled trials (N = 607 tolvaptan; N = 518 placebo) or in <2% of patients in an uncontrolled trial of patients with hyponatremia (N = 111) and are not mentioned elsewhere in the label: *Blood and Lymphatic System Disorders: Disseminated intravascular coagulation; Cardiac Disorders: Intracardiac thrombus, ventricular fibrillation; Investigations: Prothrombin time prolonged; Gastrointestinal Disorders: Ischemic colitis; Metabolism and Nutrition Disorders: Diabetic ketoacidosis; Musculoskeletal and Connective Tissue Disorders: Rhabdomyolysis; Nervous System: Cerebrovascular accident; Renal and Urinary Disorders: Urethral hemorrhage; Reproductive System and Breast Disorders (female): Vaginal hemorrhage; Respiratory, Thoracic, and Mediastinal Disorders: Pulmonary embolism, respiratory failure; Vascular disorder: Deep vein thrombosis.*

DRUG INTERACTIONS:

Effects of Drugs on Tolvaptan:

Ketoconazole and Other Strong CYP 3A Inhibitors: SAMSCA is metabolized primarily by CYP 3A. Ketoconazole is a strong inhibitor of CYP 3A and also an inhibitor of P-gp. Co-administration of SAMSCA and ketoconazole 200 mg daily results in a 5-fold increase in exposure to tolvaptan. Co-administration of SAMSCA with 400 mg ketoconazole daily or with other strong CYP 3A inhibitors (e.g., clarithromycin, itraconazole, telithromycin, saquinavir, nelfinavir, ritonavir and nefazodone) at the highest labeled dose would be expected to cause an even greater increase in tolvaptan exposure. Thus, SAMSCA and strong CYP 3A inhibitors should not be co-administered *[see Dosage and Administration (2.4) and Contraindications (4.4)]*.

Moderate CYP 3A Inhibitors: The impact of moderate CYP 3A inhibitors (e.g., erythromycin, fluconazole, aprepitant, diltiazem and verapamil) on the exposure to co-administered tolvaptan has not been assessed. A substantial increase in the exposure to tolvaptan would be expected when SAMSCA is co-administered with moderate CYP 3A inhibitors. Co-administration of SAMSCA with moderate CYP3A inhibitors should therefore generally be avoided *[see Dosage and Administration (2.4) and Warnings and Precautions (5.5)]*.

Grapefruit Juice: Co-administration of grapefruit juice and SAMSCA results in a 1.8-fold increase in exposure to tolvaptan *[see Dose and Administration (2.4) and Warnings and Precautions (5.5)]*.

P-gp Inhibitors: Reduction in the dose of SAMSCA may be required in patients concomitantly treated with P-gp inhibitors, such as e.g., cyclosporine, based on clinical response *[see Dose and Administration (2.4) and Warnings and Precautions (5.5)]*.

Rifampin and Other CYP 3A Inducers: Rifampin is an inducer of CYP 3A and P-gp. Co-administration of rifampin and SAMSCA reduces exposure to tolvaptan by 85%. Therefore, the expected clinical effects of SAMSCA in the presence of rifampin and other inducers (e.g., rifabutin, rifapentin, barbiturates, phenytoin, carbamazepine and St. John's Wort) may not be observed at the usual dose levels of SAMSCA. The dose of SAMSCA may have to be increased *[Dosage and Administration (2.4) and Warnings and Precautions (5.5)]*.

Lovastatin, Digoxin, Furosemide, and Hydrochlorothiazide: Co-administration of lovastatin, digoxin, furosemide, and hydrochlorothiazide with SAMSCA has no clinically relevant impact on the exposure to tolvaptan.

Effects of Tolvaptan on Other Drugs:

Digoxin: Digoxin is a P-gp substrate and SAMSCA is a P-gp inhibitor. Co-administration of SAMSCA and digoxin results in a 1.3-fold increase in the exposure to digoxin.

Warfarin, Amiodarone, Furosemide, and Hydrochlorothiazide: Co-administration of tolvaptan does not appear to alter the pharmacokinetics of warfarin, furosemide, hydrochlorothiazide, or amiodarone (or its active metabolite, desethylamiodarone) to a clinically significant degree.

Lovastatin: SAMSCA is a weak inhibitor of CYP 3A. Co-administration of lovastatin and SAMSCA increases the exposure to lovastatin and its active metabolite lovastatin-β hydroxyacid by factors of 1.4 and 1.3, respectively. This is not a clinically relevant change.

Pharmacodynamic Interactions: Tolvaptan produces a greater 24 hour urine volume/excretion rate than does furosemide or hydrochlorothiazide. Concomitant administration of tolvaptan with furosemide or hydrochlorothiazide results in a 24 hour urine volume/excretion rate that is similar to the rate after tolvaptan administration alone.

Although specific interaction studies were not performed, in clinical studies tolvaptan was used concomitantly with beta-blockers, angiotensin receptor blockers, angiotensin converting enzyme inhibitors and potassium sparing diuretics. Adverse reactions of hyperkalemia were approximately 1-2% higher when tolvaptan was administered with angiotensin receptor blockers, angiotensin converting enzyme inhibitors and potassium sparing diuretics compared to administration of these medications with placebo. Serum potassium levels should be monitored during concomitant drug therapy.

USE IN SPECIFIC POPULATIONS:

Pregnancy: Pregnancy Category C. There are no adequate and well controlled studies of SAMSCA use in pregnant women. In animal studies, cleft palate, brachymelia, microphthalmia, skeletal malformations, decreased fetal weight, delayed fetal ossification, and embryo-fetal death occurred. SAMSCA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In embryo-fetal development studies, pregnant rats and rabbits received oral tolvaptan during organogenesis. Rats received 2 to 162 times the maximum recommended human dose (MRHD) of tolvaptan (on a body surface area basis). Reduced fetal weights and delayed fetal ossification occurred at 162 times the MRHD. Signs of maternal toxicity (reduction in body weight gain and food consumption) occurred at 16 and 162 times the MRHD. When pregnant rabbits received oral tolvaptan at 32 to 324 times the MRHD (on a body surface area basis), there were reductions in maternal body weight gain and food consumption at all doses, and increased abortions at the mid and high doses (about 97 and 324 times the MRHD). At 324 times the MRHD, there were increased rates of embryo-fetal death, fetal microphthalmia, open eyelids, cleft palate, brachymelia and skeletal malformations *[see Nonclinical Toxicology (13.3)]*.

Labor and Delivery: The effect of SAMSCA on labor and delivery in humans is unknown.

Nursing Mothers: It is not known whether SAMSCA is excreted into human milk. Tolvaptan is excreted into the milk of lactating rats. Because many drugs are excreted into human milk and because of the potential for serious adverse reactions in nursing infants from SAMSCA, a decision should be made to discontinue nursing or SAMSCA, taking into consideration the importance of SAMSCA to the mother.

Pediatric Use: Safety and effectiveness of SAMSCA in pediatric patients have not been established.

Geriatric Use: Of the total number of hyponatremic subjects treated with SAMSCA in clinical studies, 42% were 65 and over, while 19% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Increasing age has no effect on tolvaptan plasma concentrations.

Use in Patients with Hepatic Impairment: Moderate and severe hepatic impairment do not affect exposure to tolvaptan to a clinically relevant extent. No dose adjustment of tolvaptan is necessary.

Use in Patients with Renal Impairment: Exposure and response to tolvaptan are similar in patients with a creatinine clearance 10-79 mL/min and in patients without renal impairment. No dose adjustment is necessary. Exposure and response to tolvaptan in patients with a creatinine clearance <10 mL/min or in patients on chronic dialysis have not been studied. No benefit can be expected in patients who are anuric *[see Contraindications (4.5)]*.

Use in Patients with Congestive Heart Failure: The exposure to tolvaptan in patients with congestive heart failure is not clinically relevantly increased. No dose adjustment is necessary.

OVERDOSAGE: Single oral doses up to 480 mg and multiple doses up to 300 mg once daily for 5 days have been well tolerated in studies in healthy subjects. There is no specific antidote for tolvaptan intoxication. The signs and symptoms of an acute overdose can be anticipated to be those of excessive pharmacologic effect: a rise in serum sodium concentration, polyuria, thirst, and dehydration/hypovolemia.

The oral LD_{50} of tolvaptan in rats and dogs is >2000 mg/kg. No mortality was observed in rats or dogs following single oral doses of 2000 mg/kg (maximum feasible dose). A single oral dose of 2000 mg/kg was lethal in mice, and symptoms of toxicity in affected mice included decreased locomotor activity, staggering gait, tremor and hypothermia.

If overdose occurs, estimation of the severity of poisoning is an important first step. A thorough history and details of overdose should be obtained, and a physical examination should be performed. The possibility of multiple drug involvement should be considered.

Treatment should involve symptomatic and supportive care, with respiratory, ECG and blood pressure monitoring and water/electrolyte supplements as needed. A profuse and prolonged aquaresis should be anticipated, which, if not matched by oral fluid ingestion, should be replaced with intravenous hypotonic fluids, while closely monitoring electrolytes and fluid balance.

ECG monitoring should begin immediately and continue until ECG parameters are within normal ranges. Dialysis may not be effective in removing tolvaptan because of its high binding affinity for human plasma protein (>99%). Close medical supervision and monitoring should continue until the patient recovers.

PATIENT COUNSELING INFORMATION: As a part of patient counseling, healthcare providers must review the SAMSCA Medication Guide with every patient *[see FDA-Approved Medication Guide (17.3)]*.

Concomitant Medication: Advise patients to inform their physician if they are taking or plan to take any prescription or over-the-counter drugs since there is a potential for interactions.

Strong and Moderate CYP 3A inhibitors and Pg-p inhibitors: Advise patients to inform their physician if they use strong (e.g., ketoconazole, itraconazole, clarithromycin, telithromycin, nelfinavir, saquinavir, indinavir, ritonavir) or moderate CYP 3A inhibitors (e.g., aprepitant, erythromycin, diltiazem, verapamil, fluconazol) or P-gp inhibitors (e.g., cyclosporine) *[see Dosage and Administration (2.4), Contraindications (4.4), Warnings and Precautions (5.5) and Drug Interactions (7.1)]*.

Nursing: Advise patients not to breastfeed an infant if they are taking SAMSCA *[see Use In Specific Populations (8.3)]*.

For more information about SAMSCA, call 1-877-726-7220 or go to www.samsca.com.

Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan

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Otsuka
Otsuka America Pharmaceutical, Inc. 0708L-0023B Rev. 05/2009

Brenner Endowed Lectureship to Focus on Diabetic Nephropathy

Rama Natarajan

Diabetic nephropathy will be the focus of the Barry M. Brenner Endowed Lectureship, to be delivered by Rama Natarajan, PhD, FASN, on Thursday, November 18. The title of her talk, "TGF-β and microRNAs in Diabetic Nephropathy," reflects her major research focus on the study of the cellular and molecular mechanisms responsible for the accelerated renal and cardiovascular complications of diabetes.

Dr. Natarajan is a professor in the department of diabetes at the Beckman Research Institute in Los Angeles. For many years, she has been examining how growth factors (in particular, transforming growth factor [TGF]), lipids, cytokines, and short non-coding RNAs augment inflammatory and other pathological genes under diabetic conditions in target cells and in animal models of diabetic complications. She has demonstrated new roles for microRNAs in regulating pro-fibrotic genes in kidney cells related to the pathogenesis of diabetic nephropathy. She has made several contributions to studies examining the role of epigenetics in diabetic vascular inflammation and complications, and in the metabolic memory phenomenon seen in certain diabetic patients. She has also demonstrated new roles for renal microRNAs in diabetic microvascular disease.

Much of this work is funded by grants from the National Heart, Lung, and Blood Institute; the National Institute of Diabetes and Digestive and Kidney Diseases; and the Juvenile Diabetes Research Foundation. She serves on the peer review committees of the Juvenile Diabetes Research Foundation and the National Institutes of Health.

Dr. Natarajan is also active in teaching, mentoring, and training graduate students and fellows. She serves on the editorial boards of *Diabetes, Kidney International, American Journal of Physiology (Renal), and Journal of Lipid Research.*

ASN gratefully acknowledges Monarch Pharmaceuticals for support of the Barry M. Brenner Endowed Lectureship.

Plenary

Insights into Cystic Fibrosis in a Porcine Model to be Discussed

Michael J. Welsh

State-of-the-Art Lecture

A state-of-the-art lecture, "New Insights, Surprises, and Lessons about the Pathogenesis for Cystic Fibrosis Pigs," will be presented by Michael J. Welsh, MD, on Thursday, November 18.

Dr. Welsh is the Roy J. Carver Biomedical Chair in Internal Medicine; professor of medicine, molecular physiology, and biophysics; investigator at the Howard Hughes Medical Institute; director of the Pappajohn Biomedical Institute; and director of the Cystic Fibrosis Research Center at the University of Iowa in Iowa City.

A pulmonary disease expert, Dr. Welsh's research focuses on three main areas: understanding the biology and pathogenesis of cystic fibrosis and developing new treatments; investigating the physiology and cell biology of airway epithelia, including the cilia that cover their surface; and investigating the biology of acid-sensing ion channels in the central and peripheral nervous systems with an emphasis on their role in fear and neurological diseases. His investigations into the biology of sodium channels have explored their involvement in neuronal functions, including panic, seizures, and sensation.

The evolution of disease in cystic fibrosis-affected organs remains poorly understood. Mice targeted with cystic fibrosis gene alterations fail to develop the disease typically found in humans. To generate a new model, Dr. Welsh's research team chose pigs because of the similarity of their anatomy, biochemistry, and physiology to those of humans. They introduced cystic fibrosis mutations, making their pigs the first gene-targeted mammals other than mice to model a human disease. Dr. Welsh will describe how this porcine model offers an exciting opportunity to test key hypotheses about pathogenesis, to study the common cystic fibrosis mutation, and to develop new therapeutic strategies.

Dr. Welsh received his MD from the University of Iowa in 1974. He completed his internship and residency in internal medicine at the University of Iowa, and then trained in pulmonary medicine and research at the University of California at San Francisco and the University of Texas in Houston.

He has served as president of the American Society for Clinical Investigation and president of the Association of American Physicians. He has received many awards, including the Cecile Lehman Mayer Research Award of the American College of Chest Physicians, the Doris F. Tulcin Cystic Fibrosis Research Award, the Paul di Sant'Agnese Distinguished Scientific Achievement Award, the J. Burns Amberson Award of the American Thoracic Society, the Regents Award for Faculty Excellence, the Francis Blake Award of the Association of American Physicians, and the Second Annual Distinguished Mentoring Award from the Roy J. and Lucille A. Carver College of Medicine. He has been inducted into the Institute of Medicine, the American Academy of Arts and Sciences, and the National Academy of Sciences.

Roland Blantz to Receive Peters Award

Roland C. Blantz

The American Society of Nephrology will present its John P. Peters Award to Roland C. Blantz, MD, FASN, at Thursday's plenary session. Established in 1983, the Peters Award honors individuals who have made substantial research contributions to the discipline of nephrology with achievements in one or more areas of academic medicine, including clinical care, education, and leadership.

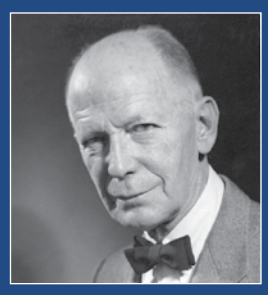
Dr. Blantz is professor of medicine and head of the division of nephrology-hypertension at the University of California, San Diego (UCSD). Previously, he was chief of the nephrology section at the Veterans Affairs Medical Center in San Diego.

A leader in the field, he has served as president of the ASN, chair of the American Kidney Societies, chair of ASN's Chronic Kidney Disease Advisory Group, and chair of the External Advisory Committee of the National Institutes of Health HEMO trial. He has served as chair of the UCSD School of Medicine faculty. He recently won the William Middleton Award for Excellence in Research from the Veterans Administration Research Service.

Dr. Blantz's research has produced many peer-reviewed publications on the role of angiotensin in the regulation of blood pressure and kidney hemodynamics. He has made longstanding contributions to the understanding of the intrarenal tubuloglomerular feedback system and its capacity to temporally adapt to circumstances such as volume status, sodium chloride intake, variations in proximal tubular reabsorption, and loss of nephron mass. His research team has also examined kidney abnormalities in models such as acute kidney injury, glomerular immune injury, chronic kidney disease, and the early diabetic kidney. They have proposed novel mechanisms leading to glomerular hyperfiltration and paradoxical responses to sodium intake in the diabetic kidney. Recent studies have examined the role of variations in metabolism and oxygen consumption in the normal kidney compared with a chronic kidney disease model.

Dr. Blantz received his degree from the Johns Hopkins University School of Medicine in Baltimore and completed his research fellowship in the renal division of the University of Texas Health Science Center in Dallas.

John P. Peters



John P. Peters, MD, was one of the fathers of nephrology and former chief of the Metabolic Division in the Department of Medicine at Yale University. He transformed clinical chemistry from a discipline of qualitative impressions to one in which precise quantitative measurements of body fluids comprise a vital part of the patient examination and provide great explanatory value.

He advanced the view that disease is a quantitative abnormality of normal physiological processes and that, by understanding disease, one could gain a deeper understanding of normal physiology. His enduring scientific contributions paralleled his intense commitment to the care of the sick, as well as his fervent mission to ensure that the physician be an advocate for the patient.

Mineral Bone Disorder in Chronic Kidney Disease to be Focus of Coburn Endowed Lectureship

Keith A. Hruska

Keith A. Hruska, MD, will present the Jack W. Coburn Endowed Lectureship on Thursday, November 18. His talk is entitled "CKD-MBD: The Bone-Gut-Kidney Connection."

Dr. Hruska is professor of pediatrics, medicine, and cell biology as well as director of the division of pediatric nephrology at Washington University in St. Louis.

His laboratory has been a leader in the study of mechanisms of chronic kidney disease (CKD), focusing in particular on the bone, mineral, and cardiovascular complications that have been recently dubbed the CKD-mineral bone disorder (MBD). His team has discovered that CKD directly diminishes bone formation as well as osteoblast number and function, leading to an adynamic bone disorder (ABD) despite normal levels of calcium, phosphorus, parathyroid hormone, and vitamin D. Decreased bone formation and ABD contribute to the development of secondary hyperparathyroidism that causes an osteodystrophy. Renal osteodystrophy is associated with excess bone resorption, which contributes to hyperphosphatemia, which in turn is a direct stimulus to vascular calcification.

Dr. Hruska's team has researched the effects of members of the bone morphogenetic protein (BMP) family on MBD processes. BMP-7 is a critical renal morphogen that can reverse ABD, and holds the promise of eliminating renal osteodystrophy from the list of complications of chronic kidney disease. BMP-7 is expressed in the adult kidney, and its expression is reduced by renal injuries. It exhibits therapeutic potential against renal fibrogenesis and diabetic nephropathy. Although BMP-7 and BMP-2 both support endochondral osteogenesis, their actions differ, and BMP-2 is causative of vascular calcification, while BMP-7 is therapeutic, capable of reversing established calcification.

Dr. Hruska has authored and co-authored more than 300 peer-reviewed publications. He serves as secretary/treasurer of the American Society of Bone and Mineral Research and on the editorial board of the *Journal of Biological Chemistry*.

He received his MD at Creighton University. He completed his postdoctoral training in the renal division of Washington University, which he then joined as an instructor in medicine. He soon became assistant professor and continued rising in duties and responsibilities. He has been director of the division of pediatric nephrology since 2001.

ASN gratefully acknowledges Amgen for support of the Jack W. Coburn Endowed Lectureship.

Plenary Session

Lecture Covers Contributions of Dog Genes to Human Understanding

Elaine A. Ostrander

State-of-the-Art Lecture

"Mapping Genes for Complex Traits Using the Canine System" is the title of a state-of-the-art lecture by Elaine A. Ostrander, PhD, on Friday, November 19.

Dr. Ostrander is chief of the Cancer Genetics Branch at the National Human Genome Research Institute of the National Institutes of Health (NIH) in Bethesda, Md. She also heads the Section of Comparative Genetics.

Her lab at NIH works in both human and canine genetics and focuses on the genetics of complex disease traits including diseases such as cancer and morphologic features such as body size, leg length, and skull shape.

Cancer is the number one killer of dogs. Studying the major cancers in dogs provides a valuable approach for developing a better understanding of cancer in humans because the clinical presentation, histology, and biology of many canine cancers closely parallel those of human malignancies.

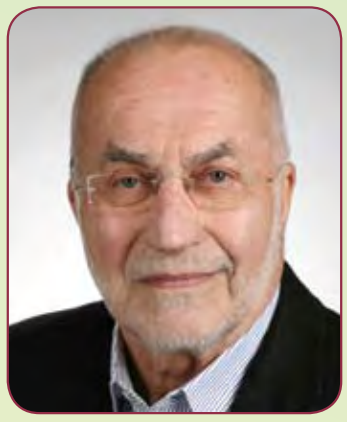
Dog pedigrees are large, multigenerational, and the result of directed matings, all of which favor the expression of recessive disorders, such as cancers. Using information from these pedigrees, Dr. Ostrander's laboratory is constructing high-density maps of the canine genome to identify genes that increase susceptibility to genetic forms of lymphoma, osteosarcoma, and kidney cancer. Her group also has undertaken a large single-nucleotide polymorphism study to determine the inter-relatedness of dog breeds. This study demonstrated that differences among breeds account for about 30 percent of genetic variation within dogs. Her research team has begun cloning genes identified in linkage studies by identifying ancestral chromosomes that contribute the same genetic mutation to a multitude of dog breeds.

Researchers in Dr. Ostrander's laboratory have also performed studies on prostate and breast cancer susceptibility genes in humans. And they have been studying the frequency and distribution of mutations in known cancer susceptibility genes in the general population, rather than in the more-studied high-risk families. For example, they recently completed two screening studies looking for BRCA1 and BRCA2 mutations in women with breast cancer from the general population.

Dr. Ostrander received her doctorate from the Oregon Health Sciences University and did her postdoctoral training at Harvard. She then went to the University of California, Berkeley, and the Lawrence Berkeley National Laboratory, where she began the canine genome project. She worked at the Fred Hutchinson Cancer Research Center and University of Washington in Seattle for 12 years, rising to head of the genetics program.

She is the winner of many awards, including the American Cancer Society Junior Faculty Award, Burroughs Wellcome Innovation Award, American Kennel Club Canine Health Foundation President's Award, and Canine Health Foundation Asa Mays Award for Excellence in Canine Health Research. She has published more than 230 papers and articles.

Wilhelm Kriz to Receive Homer W. Smith Award



Wilhelm Kriz

An honor that recognizes outstanding contributions to understanding how kidneys function in normal and diseased states, the Homer W. Smith Award will be presented to Wilhelm Kriz, DrMed, on Friday, November 19.

Dr. Kriz is professor emeritus of anatomy on the Medical Faculty Mannheim of the University of Heidelberg in Mannheim, Germany. He is acting chairman of the newly founded department of anatomy there. He served as full professor and chairman of the department of anatomy and cell biology at the University of Heidelberg for more than 30 years. Prior to that, he was associate professor in the department of anatomy at the University of Munster.

Born in what is now the Czech Republic, he received his medical degree from the University of Giessen, where he also completed a research fellowship in the department of anatomy.

Among his many medical and societal activities, he was dean of the medical faculty at Heidelberg, a member of the board of examiners responsible for the general examination in medicine in Germany for more than 20 years, and a member of the governing board of the University of Heidelberg for more than a decade.

Dr. Kriz made major contributions to our knowledge of renal function, with his main research interests including the structural organization of the mammalian kidney; structure-function correlations in the renal glomerulus, the juxtaglomerular apparatus, the distal tubule, and the thin limbs of Henle's loop; and the pathology of progressive renal disease.

He has received many awards over the years, including the Jakob Henle Medal from the University of Gottingen in 1990, the Bernd Tersteegen Award from the German Dialysis Society in 1998, and the Franz Volhard Medal from the Gesellschaft fur Nephrologie in 2007. In addition to ASN, he is a member of the Anatomische Gesellschaft, Nephrologische Gesellschaft, the International Society of Nephrology, and the Renal Pathology Society.

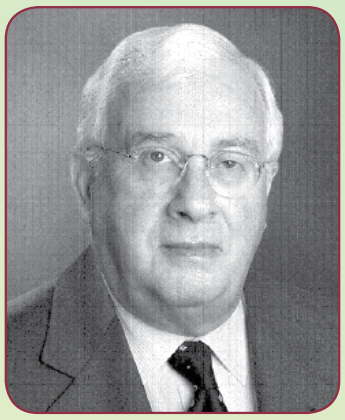
Homer W. Smith

Homer W. Smith was chairman of physiology at the University of Virginia before moving in 1928 to New York University (NYU). As director of the Physiology Laboratories at NYU, he developed and refined the concepts of glomerular filtration and tubular absorption and secretion of solutes.

The clarity of Dr. Smith's logic and the skill with which he explained his ideas transformed them into vivid and powerful concepts that are the cornerstones of our present understanding of normal and abnormal renal function. He attracted the best and brightest to the field, to NYU, and to the Mount Desert Island Biological Laboratory, where he spent many summers studying renal physiology in fish.

The Homer W. Smith award recognizes individuals who contribute to our basic understanding of how the kidneys function in health and disease.

Narins Award to be Presented to Barry Brenner



Barry M. Brenner

Barry M. Brenner, MD, will receive the Robert G. Narins Award on Friday, November 19.

Dr. Brenner is director emeritus of the renal division of Brigham and Women's Hospital and Samuel A. Levine Professor of Medicine at Harvard Medical School in Boston.

The award honors those who have made substantial contributions to education and teaching.

Dr. Brenner earned his MD degree from the University of Pittsburgh School of Medicine in 1962 and completed his internal medicine residency at the Bronx Municipal Hospital Center, Albert Einstein College of Medicine, in 1966. He continued his career in research positions at the National Heart Institute and the University of California, San Francisco, before arriving at Harvard in 1976. He has held various positions at the Brigham and Women's Hospital, including director of the laboratory of kidney and electrolyte physiology. During the period from 1979 to 2001, when he was director, Brigham's renal division was named America's leading nephrology program by *U.S. News and World Report*, a ranking that continues to the present day.

His basic and clinical research has focused on mechanisms of glomerular function in health and disease, for which he is generally considered the world's leading authority.

A former president of ASN, Dr. Brenner has served as an officer in many societies, including as councilor and vice president of the American Society for Clinical Investigation, founding member and president of the American Society of Hypertension, councilor of the International Society of Nephrology, councilor of the American Association of Physicians, and chair of the section on medical sciences of the American Association for the Advancement of Science.

He has held 25 editorial board appointments, published more than 650 scientific articles, edited 48 books, and participated in more than 300 visiting lectures and/or professorships.

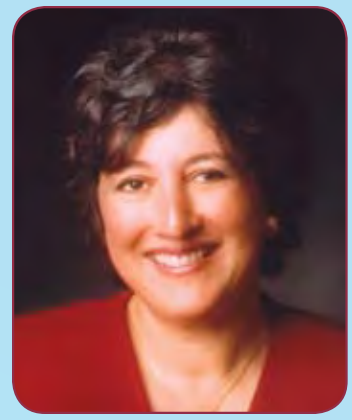
He has received numerous awards and accolades, including Fellow, Royal College of Physicians in London; the Jean Hamburger Award and Amgen Prize of the International Society of Nephrology; the Richard Bright Award of the American Society of Hypertension; the Donald W. Selden and David M. Hume Awards of the National Kidney Foundation; and the Novartis International Award of the American Heart Association. He is the only person to have received both the ASN's Homer W. Smith Award for basic science and John P. Peters Award for clinical science. He has also received honorary degrees from Harvard University, Long Island University, Université de Paris, and Universidad Complutense de Madrid.

Robert G. Narins

Robert G. Narins, MD, was the first recipient of the award bearing his name. He taught and mentored countless students, serving on the faculties of the University of Pennsylvania, UCLA, Harvard University, Temple University, and Henry Ford Hospital.

Well recognized for his contributions in the fields of fluid-electrolyte and acid-base physiology, Dr. Narins has also led numerous education efforts at the national and international levels. Among these, he has chaired the American Board of Internal Medicine's Nephrology Board and worked on the American College of Physicians' Annual Program Committee. From 1994 to 2006, he developed and guided ASN's educational programs, including working to expand educational programs during Renal Week. In addition, he was instrumental in the development of ASN's newest journal, the *Clinical Journal of the American Society of Nephrology*; in establishing the Fellow of the American Society of Nephrology program; and in negotiating ASN's partnership agreements with Hypertension, Dialysis, & Clinical Nephrology (HDCN) and UpToDate. Dr. Narins is also credited with working with organizations in Europe and Asia to help promote education and teaching in nephrology.

Blagg Endowed Lecturer to Discuss Model for Efficient Health Care Delivery



Patricia A. Gabow

In a talk entitled, "Denver Health: A Model for Health Care and Health Care Reform," Patricia A. Gabow, MD, will present the 9th Christopher R. Blagg Endowed Lectureship in Renal Disease and Public Policy on Friday, November 19.

Dr. Gabow is chief executive officer of Denver Health, one of the nation's most efficient and highly regarded integrated health care systems. Denver Health bills itself as Colorado's primary "safety net" institution, providing billions of dollars worth of care for the uninsured. It provides care to 25 percent of Denver residents, or about 150,000 individuals.

During the early 1990s, Dr. Gabow led the effort to convert Denver Health from a part of the city government to an independent governmental authority. She then helped transform the organization into a successful and profitable system that has become a model for the nation. Denver Health addresses the health needs of the entire population with services ranging from trauma care to the Rocky Mountain Poison and Drug Center.

Dr. Gabow will describe how Denver Health integrates acute hospital and emergency care with public and community health to deliver preventive, primary, and acute care services. This integration promotes continuity of care for each patient and ensures that health care is delivered in an efficient, cost-effective setting.

Dr. Gabow joined the staff in 1973 as chief of the renal division. During her tenure in that role and as director of medical services, she became internationally known for her scientific work in polycystic kidney disease. Her current research relates to health services for the underserved. Author of more than 150 publications, Dr. Gabow is professor of medicine at the University of Colorado Denver School of Medicine.

She received her MD degree from the University of Pennsylvania School of Medicine, trained in internal medicine at the University of Pennsylvania Hospital and Harbor General Hospital in Torrance, and in nephrology at San Francisco General Hospital and the University of Pennsylvania School of Medicine.

She has received numerous awards, including the American Medical Association Nathan Davis Award for Outstanding Public Servant, the National Healthcare Leadership Award, the Lifetime Achievement Award from the *Denver Business Journal*, and the Bonfils-Stanton Lifetime Achievement Award from the Bonfils-Stanton Foundation. She was elected to the Colorado Women's Hall of Fame. *Modern Healthcare* magazine named her one of the 100 Most Powerful People in Healthcare and one of the top 25 Women in Healthcare.

She is active in numerous organizations, including the National Association of Public Hospitals, the Commonwealth Commission for a High Performing Health System, and Health Care CEOs for Health Reform.

In December 2009, she was appointed to the Medicaid and CHIP Payment and Access Commission.

ASN gratefully acknowledges the Northwest Kidney Centers and its contributors for support of the Christopher R. Blagg Endowed Lectureship in Renal Disease and Public Policy.

Plenary Session

Lecture Will Explore Strategies to Apply New Data to Improving Practice and Policy

Harlan M. Krumholz

State-of-the-Art Lecture

One of the most important topics in medicine is how to apply the explosion in information to clinical practice and health-care policy. Harlan M. Krumholz, MD, MSc, will explore this subject in a state-of-the-art lecture on Saturday, November 20, "From Data to Knowledge to Wisdom: Improving Practice and Policy in the 21st Century."

Dr. Krumholz's research is focused on determining optimal clinical and population-based strategies for improving the prevention, treatment, and outcome of cardiovascular disease. His research has contributed to elevating the quality of practice, eliminating disparities, defining new treatment standards, improving professional standards, and guiding health care policy.

Dr. Krumholz is the Harold H. Hines Jr. Professor of Medicine and Epidemiology and Public Health at Yale University School of Medicine. He is also director of the Robert Wood Johnson Clinical Scholars Program and director of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation (CORE). He received his MD from Harvard Medical School and a master's degree in health policy and management at the Harvard School of Public Health. He trained in internal medicine at the University of California, San Francisco, and in cardiology at Beth Israel Hospital in Boston.

Dr. Krumholz is an elected member of the Association of American Physicians, American Society for Clinical Investigation, and Institute of Medicine, and was recently designated as a Distinguished Scientist of the American Heart Association. He has published more than 500 articles and is the author of the book, *The Expert Guide to Beating Heart Disease*.

Dr. Krumholz's research has a particular focus on improving care for underserved populations. Using methods of clinical epidemiology and health services research, he has sought to illuminate the risks, benefits, and costs of specific clinical approaches in order to improve the quality of health, monitor changes over time, and guide decisions about the allocation of scarce resources.

He is currently leading Centers for Medicare and Medicaid Services initiatives to develop national measures for public reporting of hospital performance. He chaired the steering committee for an international campaign by the American College of Cardiology to implement key evidence-based strategies aimed at improving hospital outcomes through decreasing treatment time.

He also serves as principal investigator on two multi-center projects sponsored by the National Heart, Lung, and Blood Institute: the VIRGO study, an investigation of issues in the care and outcomes of young women with acute myocardial infarction; and a study examining the effects of telemonitoring on the outcomes of patients with heart failure.

Scribner Award to Honor Work of Hans-Henrik Parving

Hans-Henrik Parving

The Belding H. Scribner Award will go to Hans-Henrik Parving, MD, DMSc, at the plenary session on Saturday, November 20.

Established in 1995, the Scribner Award is presented to individuals who have made outstanding contributions to the care of patients with renal disorders or have substantially changed the clinical practice of nephrology.

Dr. Parving is professor and chief physician in the department of endocrinology at the National Hospital and University of Copenhagen in Denmark. He was chief physician at the Steno Diabetes Center from 1983 to 2006 and is professor of diabetic vascular complications at the University of Aarhus.

Dr. Parving has published more than 410 peer-reviewed papers as well as 80 reviews and textbook chapters. For 35 years, his research has focused on studies on diabetic micro- and macroangiopathy. He undertook large observational studies to track the natural history of diabetic micro- and macroangiopathy, and demonstrated the existence of impaired autoregulation of blood flow in many organs and tissues. His research documented the life-saving importance of early intensive antihypertensive treatment in diabetic nephropathy and the significance of microalbuminuria as a risk marker for development of diabetic kidney disease.

He led several prospective studies that evaluated the genetic and nongenetic risk factors in the initiation and progression of diabetic nephropathy. The researchers' randomized prospective studies evaluated the prevention and treatment of diabetic nephropathy in type 1 patients using angiotensin-converting enzyme (ACE) and non-ACE inhibitors and demonstrated that intensified multifactorial intervention delays the progression of vascular complications in high-risk patients with Type 2 diabetes mellitus and microalbuminuria. Recently, his team documented the renoprotective effects of dual blockade of the renin-angiotensin system and of ultrahigh doses of angiotensin II receptor antagonists, aldosterone blockade, and direct renin inhibition in diabetic nephropathy.

Dr. Parving has served as chair or a member of several national and international boards of scientific societies and councils. He is active in multinational treatment investigations concerning prevention and treatment of renal and cardiovascular disease, including molecular genetics of diabetic nephropathy.

He has received several national and international awards, including the Castelli Pedroli Prize of the European Association for the Study of Diabetes, the Novartis Award in Diabetes, the COZAAR Investigator Award for Renal Dysfunction, the American National Kidney Foundation's International Distinguished Medal, the H.C. Hagedorn Prize, the Viswanathan Gold Medal Award, the European Union's Europe et Medicine Award, and the Outstanding Foreign Investigator Award of the Japanese Society of Diabetic Complications.

Belding H. Scribner

Belding H. Scribner, MD, developed the arteriovenous shunt, which made possible long-term hemodialysis for chronic renal failure.

Dr. Scribner served as head of the University of Washington's Division of Nephrology in the Department of Medicine from 1958 to 1982. He and his co-workers at the Seattle university made numerous contributions to helping patients with end stage renal disease, including establishing the world's first out-of-hospital dialysis unit, developing a home hemodialysis program, improving techniques and equipment for hemodialysis and peritoneal dialysis, and studying the adequacy and complications of chronic renal disease treated by dialysis. Dr. Scribner's work made a significant contribution to transforming nephrology into a major subspecialty of internal medicine.

Promising Genetics Researcher to Receive Young Investigator Award

Nicholas Katsanis

The Young Investigator Award will be presented to Nicholas Katsanis, PhD, who has performed groundbreaking research on Bardet-Biedl syndrome, a rare genetic disorder with symptoms that include renal failure, obesity, and blindness.

Dr. Katsanis is the Brumley Distinguished Professor of Pediatrics, professor of cell biology, and director of the Center for Human Disease Modeling at Duke University in Durham, N.C.

His laboratory is attempting to identify the causative genes of Bardet-Biedl syndrome. To elucidate why the syndrome results in severe symptoms in some patients and only mild symptoms in others, his lab is developing animal models to understand how an individual's genome can influence the clinical presentation of this and other genetic diseases. His group is credited with early work showing that monogenic disorders are much more complicated than was previously believed. Bardet-Biedl syndrome is now a model for oligogenic disease, a category between classical monogenic and complex traits.

In addition, his laboratory is pursuing questions centered on the signaling roles of vertebrate cilia, the role of signaling pathway defects in the causality of ciliary disorders, and the dissection of second-site modification phenomena as a consequence of genetic load in a functional system.

Dr. Katsanis earned his doctorate at the University of London in 1997 and completed his postdoctoral work at Baylor College of Medicine in Houston, where he first worked on the genetics of Down syndrome and then initiated his studies on the genetic and molecular basis of Bardet-Biedl syndrome. He worked for seven years at the Institute of Genetic Medicine at Johns Hopkins University in Baltimore, with appointments in the departments of ophthalmology, molecular biology, and genetics. He joined the faculty of Duke in 2009.

Schrier Lectureship to Focus on Biologic Memory in Acute Renal Failure

Richard A. Zager

Richard A. Zager, MD, will present the Robert W. Schrier Endowed Lectureship on Saturday, November 20, on the subject, "Biologic Memory in Acute Renal Failure."

Dr. Zager is professor of medicine at the University of Washington and director of nephrology at the Fred Hutchison Cancer Research Center in Seattle.

For the past 30 years, Dr. Zager has studied the pathogenesis of acute renal failure, work that has resulted in more than 150 first author or senior author publications. His talk will describe his most recent findings on the role of chromatin remodeling in the Toll-like receptor (TLR) hyper-responsive and cytoresistant states.

His main research focus has been the multifactorial basis of acute renal failure, and how one episode of renal injury alters subsequent injury responses. On the one hand, mild renal injury, such as that induced by gentamicin, can increase susceptibility to imposed acute kidney injury. On the other hand, an episode of severe renal injury can usher in a renal cytoprotective state, commonly know as ischemic preconditioning. Dr. Zager published the first evidence that one episode of tissue ischemia can usher in protection against a second 26 years ago, and since then this phenomenon has been documented in virtually every organ.

More recently, Dr. Zager has described a second major phenomenon of post-renal-injury-induced hyper-inflammatory responsiveness to TLR ligands. This state has broad relevance for renal injury, extra-renal injury, and possibly renal disease progression. Dr. Zager has been exploring the hypothesis that there might be a common thread that leads to both of these phenomena—the cytoresistant state and TLR-hyper-inflammatory state. These two states might reflect a "re-programming" of the kidney, such that one episode leads to "biologic memory," which then alters subsequent injury responses, hence the title of his lecture. Dr. Zager postulates that this biologic memory is expressed at—and possibly mediated by—chromatin changes at relevant cytoresistance and pro-inflammatory genes. His talk will explore this role of chromatin remodeling.

Dr. Zager graduated from Northwestern Medical School and did his postgraduate medical training at the University of California, Los Angeles, Medical Center, the University of Washington, Boston University, and Harvard Medical School.

ASN gratefully acknowledges Otsuka America Pharmaceutical, Novartis, Astellas Pharma US, and several individuals for support of the Robert W. Schrier Endowed Lectureship.

aHUS—the destructive effects of uncontrolled complement

Come to booth 1531 and discover new advances in our understanding of aHUS

Atypical hemolytic uremic syndrome (aHUS) is a rare, chronic, and life-threatening disease in which blood clots in small blood vessels (thrombotic microangiopathy, or TMA) throughout the body lead to stroke, heart attack, kidney failure, and death.[1-3] Approximately 60% of patients with aHUS require dialysis, undergo a kidney transplant, or die within one year of diagnosis.[2]

The majority of aHUS patients who receive a kidney transplant continue to suffer from severe complications of the disease, and more than 90% of these patients experience failure of the donor kidney.[3] Chronic uncontrolled activation of the complement system drives aHUS, putting patients at constant risk of blood clots in vital organs.[2,4]

To learn more about the role of complement in aHUS, please visit booth 1531 and our corporate Web site at www.alxn.com.

References: 1. Hosler GA, Cusumano AM, Hutchins GM. Thrombotic thrombocytopenic purpura and hemolytic uremic syndrome are distinct pathologic entities: a review of 56 autopsy cases. *Arch Pathol Lab Med.* 2003;127(7):834-839. **2.** Loirat C, Noris M, Fremeaux-Bacchi V. Complement and the atypical hemolytic uremic syndrome in children. *Pediatr Nephrol.* 2008;23(11):1957-1972. **3.** Bresin E, Daina E, Noris M, et al. Outcome of renal transplantation in patients with non-Shiga toxin-associated hemolytic uremic syndrome: prognostic significance of genetic background. *Clin J Am Soc Nephrol.* 2006;1(1):88-99. **4.** Ståhl AL, Vaziri-Sani F, Heinen S, et al. Factor H dysfunction in patients with atypical hemolytic uremic syndrome contributes to complement deposition on platelets and their activation. *Blood.* 2008;111:5307-5315.

ALEXION

innovators in complement inhibition

Plenary Session

Interleukin-1 Discoverer to Speak on its Application in Auto-Inflammatory Diseases

Charles A. Dinarello

State-of-the-Art Lecture

Considered a founder of cytokine research, Charles A. Dinarello, MD, will present a state-of-the-art lecture entitled, "Blocking IL-1β in Auto-Inflammatory Diseases," on Sunday, November 21.

Dr. Dinarello led the teams that isolated the cytokine interleukin-1 (IL-1) in 1977 and cloned it in 1984. He has since been producing groundbreaking work on anti-cytokine therapies that block the immune system's inflammatory reaction in opening this new field of study in immunology.

This work, and the subsequent discovery of other interleukins, has resulted in therapies for a host of disorders, including Crohn's disease, diabetes, allergies, rheumatoid arthritis, and graft versus host disease in transplant patients and offers hope for treatment of many more.

Currently professor of medicine and immunology at the University of Colorado School of Medicine in Aurora, over the past 18 months, Dr. Dinarello has won three of the world's most prestigious awards in medicine: the Paul Erlich and Ludwig Darmstaedter Prize in Germany, the Royal Swedish Academy of Sciences Crafoord Prize, and the Albany Medical Center Prize in Medicine and Biomedical Research (the largest prize in medicine in the United States).

Prior to joining the University of Colorado in 1996, Dr. Dinarello was professor of medicine at Tufts University School of Medicine and a staff physician at the New England Medical Center Hospital in Boston. In the 1970s, he was a researcher at the National Institutes of Health (NIH) in Bethesda, Md. He received his medical degree from Yale University and clinical training at Massachusetts General Hospital.

Dr. Dinarello serves on the editorial boards of several scientific journals and has published more than 600 original research articles and 250 reviews and book chapters on cytokines, particularly on interleukin-1, tumor necrosis factor, and their relatives. He has trained more than 40 investigators, many of whom are now recognized experts in their fields. The Institute for Scientific Information listed Dr. Dinarello as the world's fourth most-cited scientist during the 20-year period from 1983 to 2002.

He was elected to the United States National Academy of Sciences and is presently serving on the editorial board of the *Proceedings of the National Academy of Sciences*. He has served on the AIDS Program Advisory Council of the NIH, the Scientific Board of Advisors of the National Institute of Allergy and Infectious Diseases, and the Board of Scientific Advisors of the Alliance for Lupus Research. He has served as vice president of the American Society of Clinical Investigation and president of the International Cytokine Society. He has received the Squibb Award, Ernst Jung Prize in Medicine, Gold Medal of the Heilmeyer Society for Internal Medicine, International Chirone Prize from the Italian National Academy of Medicine, Carol Nachman Prize in Rheumatology, Sheikh Hamdan bin Rashdid al Maktoum Award of the United Arab Emirates, and Beering Award. This year, he also received the Bonfils-Stanton Prize and the Novartis Prize in Immunology.

Renal Week Offerings Expand

The American Society of Nephrology continues to focus on meeting the diverse range of interests and pursuits of the more than 12,000 Renal Week participants. New in 2010, ASN offers three in-depth nephrology courses, a new abstract category, and five new clinical nephrology courses.

In-Depth Nephrology Courses

Assessing and Managing Acid-Base Disorders: Focus on Metabolic Acidosis

Metabolic acidosis is a frequently encountered challenge in kidney practice. To address the substantial advances in our understanding of these disorders, Chairpersons Nicolaos E. Madias, MD, FASN, and Horacio J. Adrogue, MD, present an in-depth course that focuses on the pathophysiology, diagnosis, adverse effects, and management of acute and chronic forms of metabolic acidosis.

Despite advances, there remain controversies and gaps in knowledge about how best to treat metabolic acidosis. This course provides an essential and up-to-date review of every aspect of metabolic acidosis to help support and promote optimum patient care.

Polycystic Kidney Disease: Translating Mechanisms into Therapy

Polycystic kidney disease (PKD) is the most common, potentially fatal, hereditary disease in humans. Autosomal dominant PKD causes ESRD in 50 percent of affected patients, can cause liver cysts, and affects the GI tract and vascular system. The genes responsible for PKD have been identified and sequenced, the sequences of encoded proteins deduced, and protein functions are being elucidated.

Investigators have made significant progress identifying intracellular pathways altered as part of the pathophysiologic mechanisms responsible for the cystic phenotype. These pathways will help target specific therapy for PKD, and results of clinical trials are beginning to appear in the literature. Under the direction of Chair Benjamin D. Cowley, MD, this course provides a comprehensive review of PKD mutations, pathophysiologic mechanisms, renal and extrarenal manifestations, clinical trials, and emerging therapies in PKD.

Professional Development Seminar

This popular course, organized by Women in Nephrology and chaired by Rochelle Cunningham, MD, and Anne Pesenson, MD, expands to one-and-a-half days at the 2010 meeting and now supports four parallel tracks:

- Early career nephrologists and PhD scientists—successful strategies to manage their professional lives, obtain grants, and find the right mentor
- Training program directors—building programs, mentoring trainees, and financing fellowships
- Mid-career nephrologists—leadership skills, financial management, and balancing administrative and professional responsibilities
- Private practice and industry professionals—finding the right practice, contract negotiations, and starting your own company

New abstract category

In 2010, ASN presents bioengineering as an abstract category. The society recognizes the key role bioengineering plays in improving human health and looks forward to sharing knowledge about applying advanced technology to living systems and the complex problems of medical care. Bioengineering in nephrology includes studies of hemodynamics, local drug delivery, nanotechnology, sensors, bioinformatics, imaging (functional, cellular, molecular), and novel dialytic technologies. Using Novel Technologies to Improve CKD/ESRD Care oral presentations will be held on Saturday, November 20.

Fellows lounge

For the first time in 2010, ASN offers nephrology fellows the opportunity to network with their peers and take a break from attending meeting sessions. The society has set aside Room 705 of the Colorado Convention Center for nephrology fellows, and encourages these participants to enjoy the opportunity to meet other fellows from around the world, enjoy a respite from their busy meeting schedules, and discuss the satisfactions and challenges of the fellowship training experience as well as their experiences at ASN Renal Week. ASN will also provide information in this area about how fellows can get the most from ASN membership and their annual meeting experience.

More opportunities to advance professional knowledge

This year ASN offers five more Clinical Nephrology Courses (CNCs) and for the first time offers Clinical Nephrology Courses on Sunday.

ASN invites you to stop by the ASN Service Center in the exposition hall, open Thursday, Friday, and Saturday from 9:30 a.m. to 2:30 p.m.

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On the website you'll find detailed information about the benefits home therapies can offer practices, facilities and their patients. Homebybaxter.com offers quick, easy online access to the tools and resources needed to start, grow and support a robust home program. You can download patient education materials, view online webinars on how to improve outcomes for PD patients and even model the impact the CMS payment bundle will have on your facility. To see everything the new website has to offer, **visit homebybaxter.com today.**

Home Therapies

 AL10360 09/10

Policy Update

Understanding the Appropriations Process
A primer for doctors

By Daniel Kochis

You could spend a lifetime trying to understand the Congressional appropriations process. Some do: Senators, House members, and their staff make navigation of a multifaceted appropriations process their hallmark. The influence at stake and numerous bodies involved make the appropriations process inherently complex. As the 2011 Congressional appropriations continues to play out this winter following the November election, you may wonder, how does this whole process work?

"All bills for raising revenue shall originate in the House of Representatives; but the Senate may propose or concur with amendments as on other Bills."

— United States Constitution Article I, Section VII

Article I of the U.S. Constitution creates the legislative branch and with it the power to raise revenue—a power given to the House of Representatives exclusively. However, the Constitution does not address which body (House or Senate) can appropriate this revenue. While the Senate throughout its history has championed a strict interpretation of this article (an interpretation which would allow the Senate to act first on appropriating money) the House has traditionally declined to act on appropriations bills that originate in the Senate, sending the bills back with a note admonishing it for attempting to usurp the legislative authority of the House. However, despite this Constitutional wrangling, both chambers in effect assist equally in crafting appropriations.

While Congress ultimately passes the budget, the process actually begins well in advance with the Executive branch. The President is required by law to submit a budget to Congress no later than the first Monday in February for the upcoming fiscal year. Work on this budget proposal starts months before, with federal agencies submitting their individual budget requests to the Office of Management and Budget (OMB, the White House office that oversees creation of a budget) for consideration and inclusion in a larger budget proposal.

Upon receipt of the President's budget proposal, a budget committee in both the House and Senate begins work on their individual separate budget proposals. A budget proposal sets the overall spending cap for the upcoming fiscal year while also setting the general framework for allocation of these funds across various federal agencies. Each chamber votes on their respective budget resolutions typically in the spring. Any discrepancies between the two proposals are negotiated on in a conference committee consisting of both House members and Senators. This committee is charged with crafting one resolution out of the two different resolutions. As a budget resolution does not create any new programs, it also does not authorize any new expenditures. As such, it does not require a Presidential signature (Figure 2).

Government spending can be broadly defined as either mandatory or discretionary spending. Mandatory spending is any spending that is required under existing law, an example of which would be entitlement benefits such as Social Security. Discretionary spending is spending that varies year by year. While discretionary spending constitutes a lesser percentage of government spending than mandatory spending, levels are subject to yearly appropriations (Figure 1).

Allocation of federal funding continues in the late spring with the House and Senate Appropriations Committees. These committees allocate discretionary spending across 12 groups, each aligned with a specific subcommittee. The Committee on Appropriations only allocates discretionary spending, which includes investments in NIH and other government-funded medical research.

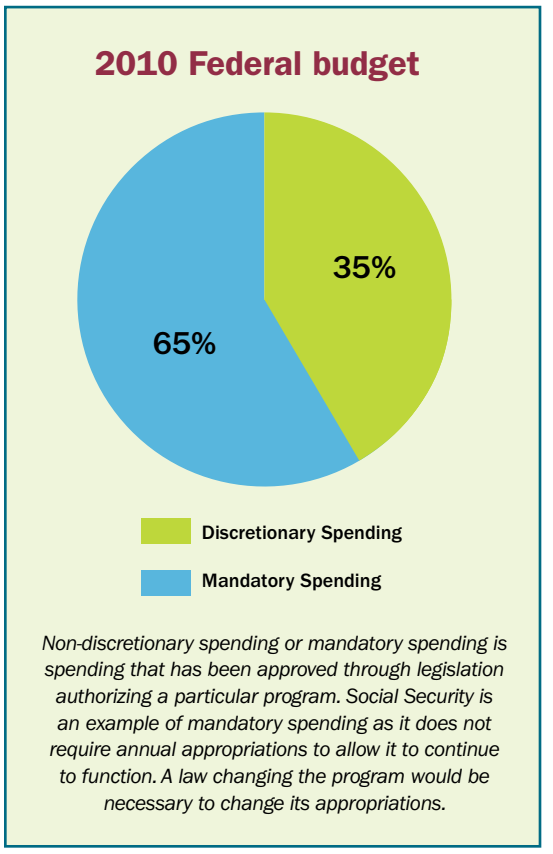
A seat as an appropriator allows an individual Congressional member significant influence over a specific sector of the budget. Upon completion of appropriations bills, each committee submits their respective bills to the full chamber for passage. The same reconciliation process takes place between the House and the Senate in a conference committee to craft one appropriations bill that must again be passed by both chambers before being sent to the President for a signature or a veto.

What seems like a well oiled machine, in recent years the appropriations process has often broken down as appropriations bills stall. This forces Congress to pass what is called a "continuing resolution" to stave off a government shutdown for lack of funding. A continuing resolution simply extends the funding levels of the current year for a determined amount of time.

On September 30, 2010, Congress passed a continuing resolution extending current government funding through December 3, 2010, after the midterm elections. When Congress reconvenes in November after the midterm elections, legislators will likely continue working on 2011 appropriations, weighing important decisions around funding for the numerous federal agencies and programs that rely on discretionary spending to operate. While it remains unclear when work on the 2011 appropriations bills will be completed, the anticipation is for the process to be wrapped up sometime in December before Congress adjourns for the holidays.

To learn how you can advocate during the appropriations process and for a timeline of the appropriations process, visit ASN Public Policy (http://www.asn-online.org/policy_and_public_affairs/medical-research.aspx).

Figure 1.



Non-discretionary spending or mandatory spending is spending that has been approved through legislation authorizing a particular program. Social Security is an example of mandatory spending as it does not require annual appropriations to allow it to continue to function. A law changing the program would be necessary to change its appropriations.

Figure 2.

Common Terms

Appropriations Bill- Bill providing the legal authority to spend United States Treasury funds.

Authorization Bill- Bill that provides the legal authority for a program to exist, often including recommending spending to carry out the program.

Concurrent Resolution- Resolution that does not create law but rather sets forth a joint action or opinion of the House and Senate.

Budget Resolution- Resolution that creates a budget plan, setting spending and revenue targets that appropriations bills should adhere to.

Continuing Resolution- Resolution continuing funding for federal programs at the current level for a set amount of time. Used if the fiscal year ends without a new appropriations bill in place.

Source: CSPAN. 2010. 14 Oct 2010 < http://www.c-span.org/guide/congress/glossary/alphalist.htm>.

As Health Reform Moves Forward, ASN President and Policy Board Chair Advocate for Nephrology

By Rachel Shaffer

Implementation of health reform legislation is underway in Washington, DC. Making sure that the nephrology community is represented as the Department of Health and Human Services (HHS) moves forward in this process, ASN President Sharon Anderson, MD, FASN, and ASN Public Policy Board Chair Thomas Hostetter, MD, FASN, recently collaborated in a series of conference calls with Rep. Steve Kagen (D-WI) to discuss the role of subspecialists in health reform and new care delivery models, such as Accountable Care Organizations (ACOs) and the patient-centered medical home (PCMH).

Their initial conversations came in anticipation of an HHS national summit on health care quality and value in Washington, DC, this fall. A physician himself, Rep. Kagen worked directly with HHS Secretary Kathleen Sebelius to ensure that perspectives from specialist physicians—including nephrologists—are included on the agenda and in discussions during the summit.

"You can't achieve the goals we have in this country without combining specialty care with primary care. Specialty societies, including ASN, understand that specialists provide better outcomes, higher quality, and lower overall costs. That's the voice that is being delivered at the table," Rep. Kagen said following the health care summit. "I'm happy to highlight the important role of medical specialists in the ongoing success of health reform efforts."

Anderson and Hostetter also joined presidents of 10 other medical specialty societies including the American Academy of Neurology, the American College of Gastroenterology, the American Society of Rheumatology, and the American Association of Clinical Endocrinologists, in a joint discussion with Rep. Kagen on this issue. ASN is collaborating with Rep. Kagen to prepare a presentation for Secretary Sebelius and Centers for Medicare and Medicaid Services (CMS) Administrator Donald Berwick, MD, on specialists and health reform, focusing on the burden of kidney disease in the United States and how nephrologists improve quality of care, reduce decay of kidney function, and lower costs for patients with chronic kidney disease and end stage renal disease.

"Not only do nephrologists serve as de facto primary care providers for many of their patients, timely referral to a nephrologist is related to improved survival and better overall outcomes. It's important that nephrology patients and providers be considered in health reform rule making and implementation, and we're proud to be collaborating with Rep. Kagen to make sure that happens," Anderson said. "The wider medical community also has opportunities to learn from nephrology's experience; in the Medicare ESRD program we will rapidly gain experience with both bundled payments and the first-ever pay-for-performance system. As HHS develops pilot programs to improve the coordination, quality, and cost-effectiveness of patient care in other areas, nephrologists will have a unique perspective and should be included in these discussions," Hostetter said.

Anderson, Hostetter, and ASN are continuing collaboration with Rep. Kagen and his staff—as well as other leaders in Congress and federal agencies—to ensure the voices of nephrologists and their patients are heard as HHS moves ahead with health reform implementation and the rule making process.

Industry Spotlight

Second Quarter Financials

The two largest competitors in the dialysis industry, Fresenius Medical (in this case, comparing information for its North America segment) and DaVita, showed remarkably similar numbers in revenue per dialysis treatment for the second quarter of 2010. DaVita fell just below Fresenius, with a treatment revenue of $335 compared with Fresenius' $356 per treatment, and both companies showed overall growth in revenues from the same quarter in 2009.

Whereas DaVita's 2010 second-quarter revenues grew by approximately 4.3 percent over the 2009 second quarter, Fresenius North America saw revenues grow at a rate of 8 percent. Fresenius attributed this growth to reimbursement increases and increased use of pharmaceuticals. Its dialysis product revenue increased by 5 percent (to $210 million) because of higher sales of hemodialysis disposables and dialysis machines, the company reported.

DaVita announced it would revise its outlook by narrowing its operating income guidance for 2010 to a range of $970 million to $1.02 billion. The company also revised its cash flow guidance for 2010 onward. "Our operating cash flow is now projected to be in the range of $725 million to $825 million," the second-quarter report noted. "Our previous operating cash flow guidance for 2010 was in the range of $675 million to $725 million."

Fresenius' CEO Ben Lipps said of North American operations: "We look forward to the opportunities posed by the upcoming 'bundled' reimbursement system in the U.S.—opportunities we feel we are uniquely poised to seize, given our vertical integration." The company confirmed its earlier outlook for 2010, for all operations worldwide, acknowledging that revenue was expected to grow to more than $12 billion in 2010.

When last comparing public dialysis companies in Industry Spotlight, we included publicly traded Dialysis Corporation of America (DCA) in the comparison. By June, U.S. Renal Care (USRC), a private company based in Plano, Texas, had acquired DCA in a transaction valued at approximately $112 million. According to an SEC filing in April, USRC operated 47 dialysis clinics in Texas and Arkansas. With the acquisition, USRC will provide dialysis services to a base of roughly 5500 patients in 84 outpatient dialysis facilities across nine states. In addition, USRC now runs more than 12 home dialysis programs and 24 dialysis programs within acute and specialty hospital facilities.

Table 1

2010 Dialysis Financials To Date	Net Rev 2Q 2010	Net Rev 2Q 2009	Number of Patients 2Q 2010	Number of Patients 2Q 2009*	Revenue per Treatment 2Q 2010	Revenue per Treatment 2Q 2009
DaVita	$1.587 million	$1.519 million	122,000	118,000	$335	$340
Fresenius Medical (North America)	$1.817 million	$1.682 million	135,088	128,655	$356	$344

*End of year 2009

Diabetes Drug Roadblocks

Two drug giants have had to regroup after their diabetes drugs have come under scrutiny. On Sept. 22, Janet Woodcock, MD, of the FDA issued a memorandum restricting access to Avandia (rosiglitazone), a GlaxoSmith-Kline drug that has been used for years to control type 2 diabetes, noting that the true heart attack risk of the drug was unclear. This comes after several years of data collection and reports of heart problems in patients taking the drug.

The new system for Avandia will require both doctors and patients to meet criteria for using the drug. Doctors or health care workers will have to provide complete risk information to each patient and document that the information was understood by the patient.

Doctors will have to note either that their patients are currently taking rosiglitazone if they want to continue or that patients haven't been able to get their blood sugar under control with other medications and have decided not to take pioglitazone (Actos, a diabetes drug made by Takeda Pharmaceuticals) for medical reasons.

An investigation into GlaxoSmith-Kline's records showed that the "company had been trying to hide its evidence that the drug might be less safe than the competitor Actos," *Scientific American* reported on Sept. 24. Based on these findings and other evidence, an FDA advisory panel recommended in July that Avandia be limited, and Woodcock's memo issued details about the restricted access.

Patients, pharmacists, and physicians all need to be enrolled in this new safety program, known as the restricted access program, wrote Woodcock, who is director for the FDA Center for Drug Evaluation and Research.

In a clinical trial development, Roche Holding in Switzerland has suspended trials for its new diabetes drug, Taspoglutide. Subjects were reporting adverse effects such as hypersensitivity (skin rash) and gastrointestinal disturbances such as nausea and vomiting. Others had heart and breathing problems, but every subject recovered, according to news reports.

This setback opens up an opportunity for Eli Lilly and marketing partner Amylin Pharmaceuticals and their competitor drug, Byetta, according to *Bloomberg Businessweek.*

Letters

ASN Kidney News **accepts letters to the editor in response to published articles. Please submit all correspondence to kidneynews@asn-online.org**

Index to Advertisers

DENVER

You've arrived! Now let Denver delight you with its urban culture, rich history, and wonders of the vast outdoors. Located at the base of the Rocky Mountains, the Mile High City (so named because it is exactly one mile above sea level) offers something to please everyone.

Sunshine report

Denver enjoys about 300 days of sunshine a year, so wear sunglasses and sunscreen when you are out. There is 25 percent less protection from the sun at this high altitude. Winters tend to be mild, with November seeing little precipitation. The average high is 54 degrees, and the average low is 23 degrees. It's best to layer clothing—Denver is significantly cooler in the mornings and evenings.

Getting around with ease

With its gridlike design and pedestrian-friendly downtown, Denver is easy to navigate. Catch the free shuttle up and down 16th Street Mall, the heart of the city, to reach many main sites. Buses and light rail also are available, and most main attractions provide public transportation routes on their websites. Of course, you can always grab a taxi or rent a car, but you might opt for more scenic transportation via horse-drawn carriage or rented bicycle—there are a plethora of bike paths throughout the city.

Mile High City must-see sites

In a city that prides itself on its local culture, but also has a worldly feel, there is plenty to entertain you in and around Denver.

To learn fascinating facts of Colorado's past, visit the **Colorado History Museum**. Engage your senses at the "Ancient Voices" exhibit and immerse yourself in the story of Colorado's native Indian tribes. Or stand in awe of WWII 10th Mountain Division soldiers who learned to fight on skis and snowshoes, climb mountains, and survive in icy temperatures. Don't miss "Colorado TimeScape," a three-dimensional, topographical model of Colorado that uses lasers, light, sound, and video to recount Colorado's past 10,000 years.

For art afficionadoes, the **Denver Art Museum (DAM)**'s 60,000-plus works of art can't be beat. Enter through the castle-like North Building, which gleams with over a million exterior glass tiles. Or, start in the Frederic C. Hamilton Building—completed in 2006 by prominent architect Daniel Libeskind—which evokes the Rocky Mountain peaks with its angular steel and glass design. The DAM is recognized for its incredible Native American art collection with pieces from over 100 tribes across the United States. Be sure to see the Pre-Columbian art and textiles, Asian collection, and modern European and American paintings. For additional inspiration, view the western American art and the architecture, design, and graphics galleries. If you have kids in tow, check out the Just for Fun Family Center and the portable art activities.

The **Colorado State Capitol** is another site to add to the itinerary. Designed to resemble Washington DC's Capitol, the Colorado Capitol boasts beautiful stained glass windows, presidential portraits, and Colorado white granite, rose onyx, and Yule marble. Make sure to reserve a free, guided historical tour to marvel at the building's best architectural and artworks and to learn about early Colorado history, the Capitol's construction, and the lawmaking process. Add a trip up the 180-foot, gold-plated dome to your tour and climb the 99 steps to the top for great views of the city skyline and Rocky Mountains.

To see one of the only two places where coins are made in the United States, visit Denver's **United States Mint**. Established in 1863, the Mint also stores gold and silver bullion. Keep your money in your pocket and book a free, guided tour to catch an intimate view of change coming off the production lines and to learn about the history of the Mint and coin manufacturing. The Mint also accepts same-day, walk-in tours every hour on the hour, depending on space availability.

Need a breath of fresh air? Head to the **Denver Botanic Gardens** and meander through 23 acres of outdoor and indoor botanical wonders. Traditional European horticulture merges with diverse plants and design, allowing close to 15,000 species of plants and over 20,000 fungi to thrive. See native and adapted plants flourish in Western gardens—models of drought-tolerance—as well as tropical and aquatic plants, and a host of other botanical ecosystems.

The **Denver Zoo** is a great place to see everything from a Siberian tiger and Komodo dragon to rare plants and insects. Don't miss Mshindi, the world's only rhinoceros who can paint, in the Pachyderm House. Curve through rock ledges and landscaped areas in Predator Ridge to see African lions, African wild dogs, and hyenas. If you need to rest your feet, hop aboard the narrated Pioneer Train tour or ride the Endangered Species Carousel. Check the zoo's website for animal feeding and show times.

To immerse yourself in hands-on education, check out the **Denver Museum of Nature and Science**. Follow a mine shaft into a Mexican silver mine, watch dinosaurs do battle, or observe microscopic cells from your own body. Don't miss the giant, three-dimensional wild animals or a chance to get up close to a real mummy. Enjoy a show on the Phipps IMAX Theater or Gates Planetarium, or stop by the Discovery Zone, an educational play area for kids six months and up.

For pure fun, catch a Broncos football game at **INVESCO Field** or a Nuggets basketball or Avalanche hockey game at the **Pepsi Center**. Tour **Coors Field**, home of baseball's Colorado Rockies, or any of Denver's stadiums, year-round. Need a bigger adrenaline rush? Go skydiving inside at **SkyVenture**, climb one of the Rockies tallest and steepest indoor climbing walls at **Rock'n & Jam'n**, or speed around in a go-kart or bumper boat at **Boondocks Fun Center**.

If you're looking for more culture, treat yourself to a show at the D**enver Center for the Performing Arts**. From Broadway performances and ballet to opera and symphony, the performing arts center has something for all ages.

Travel Tips for Denver and Beyond

Staying safe on or off the beaten path

- Always view a trail map before your outdoor adventure and take note of trail length and ability level.
- It's a good idea to consult with the visitor center or park ranger before embarking on your journey, as natural occurrences like bad weather can result in closed trails or dangerous conditions.

Easy altitude adjustment

- Keep your potassium levels up by eating foods like broccoli, bananas, avocados, dried fruit, and potatoes.
- Drink about two times more water than you would at home.
- Consider decreasing your alcohol intake and exercise routine, as their effects are more intense at high altitudes.

Urban Strolls

Just wandering around the city is a fun, relaxing way to take in the sights and learn about the area. Whether you meet up with a historic walking tour or enjoy the exciting nightlife, these top Denver spots are great for dining, shopping, and entertainment.

The **Lower Downtown Historic District**, affectionately known by locals as **LoDo**, is a hip and historic mix, with many galleries and boutiques, and plenty of bars and nightlife. Ponder cutting-edge art at the *Museum of Contemporary Art* or take the renowned *Denver Microbrew Tour* to discover why Denver is called the "Napa Valley of Beer." When you need respite, sit by the fire with a book and a coffee at the *Tattered Cover Bookstore*, one of the top independent booksellers in the country.

Within walking distance of the convention center is **Larimer Square**, Denver's oldest and most historic block. Window-shop in the trendy stores, stop for a drink at an outdoor patio, or catch a show at *Comedy Works*, one of the best comedy clubs in the nation.

Rest your feet and take the free shuttle up and down **16th Street Mall**. This pedestrian-only esplanade is a good starting point for seeing Denver's top attractions. Or meander along the 16 blocks of shops and restaurants, while stopping to watch a street performer.

To enjoy an upscale atmosphere imbued with shopping, art galleries, and sophisticated restaurants, visit **Cherry Creek North**, a mix of old Victorian charm and modern luxuries. Take a walk on the 22-mile *Cherry Creek Path* and then indulge yourself at the salon or spa.

To continue shopping and fine dining, check out historic **Old South Gaylord Street** and trendier Old South Pearl Street, southeast and southwest of Washington Park, respectively.

For art lovers, be sure to visit **ArtDistrict on Santa Fe**, the hub of Denver's art scene. In over 40 galleries and shops, see everything from watercolors and contemporary sculpture to photography and textiles. Don't miss *Collectors' Night*, a multi-gallery art opening, held every third Friday of the month.

Natural retreats

Given Denver's extensive park system, you can always escape from the city beat to a nearby park or nature path. With 4000 acres of urban parkland and an additional 14,000 acres of nearby mountain parks, Denver boasts the largest city park system in the country. Find a quiet spot to hike, bike, or jog, or hit the snow to ski, snowshoe, or sled.

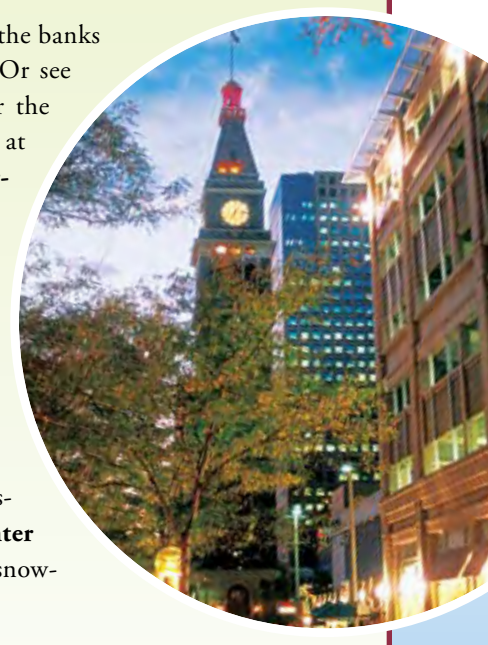
Washington Park, or **Wash Park** to locals, is a popular spot with wide open spaces and over 50 flower gardens. Take the kids to the playgrounds, swim in the indoor pool, or jog on the almost three-mile, crushed granite path. Scenic for inline skating and cycling, you also can rent a boat on the lake or play a game of horseshoes, lawn bowling, croquet, or tennis.

To see the spot where gold was first discovered in 1858, head over to **Confluence Park**, where Cherry Creek and South Platte River meet. Sit on the sandy banks and watch kayakers tackle the rapids, rollerblade on the paved trail, or just take in the panoramic views of downtown Denver. If you're in the mood to test your mountain biking or climbing wall skills, walk up to the *REI Flagship Store* that overlooks the park.

To satisfy your recreational and cultural desires, stroll through **City Park**, Denver's version of New York City's Central Park. The *Denver Zoo, Museum of Nature and Science*, and the *Martin Luther King Memorial* are located here. Paddle on the lakes, golf at the public course, play tennis, or just sit by a fountain and gaze at the Denver skyline and Front Range.

For plant lovers, wander through **Commons Park**'s reconstructed "sand prairie," where many native plants thrive on the banks of South Platte River. Or see gardens patterned after the Gardens of Versailles at **Centennial Flower Gardens**. For more wilderness, visit the natural and undeveloped area at **Bear Creek Park**'s south end.

Hoping for snow? Check out nearby mountain parks like **Echo Lake** for cross-country skiing or **Winter Park** for skiing and snowboarding.



For customized, self-guided tours, build your own "Trek" to learn the stories of Denver's historic landscapes and landmarks. Bike, walk, or drive to the "Story Sites" on your Trek and read about them from pre-printed materials, or listen by phone or downloaded audio file .

Daytrippin' From Denver

Just 15 minutes west of Denver, natural red sandstone formations stand 300 to 500 feet high to create the open-air amphitheatre at **Red Rocks Park**. Hike, bike, or horseback ride on trail loops around the park to get the best views of the 250 million-year-old red rocks. Then stay for an outdoor concert or movie.

Pikes Peak

To see **Pikes Peak**, the most visited mountain in North America, drive 60 miles south of Denver to the Colorado Springs area. Part of the Rocky Mountains, Pikes Peak stands an impressive 14,110 feet above sea level with the red rocks *Garden of the Gods* at its base. Hike on Barr Trail, the longest trail to the top of Pikes Peak, hop on the Pikes Peak Cog Railway, or drive the 19-mile Pikes Peak Highway. There are plenty of attractions around the mountain as well, like *Cave of the Winds* cave tour or the famous *Broadmoor Resort*.

Rocky Mountain National Park

Seventy-one miles northwest of Denver is **Rocky Mountain National Park**, where you can embark on just about any outdoor adventure on over 350 miles of trails. Notice the different climates and ecosystems of plant and wildlife as you climb higher up the mountains. Cross the Continental Divide at over two miles above sea level as you drive Trail Ridge Road, the highest continuous highway in the world. And when you need a break from your mountain pursuits, climb down to the resort town *Estes Park* for some shopping and dining.

Georgetown and Central City & Black Hawk

To see some of Colorado's oldest towns, Victorian architecture, and mining culture, spend some time west of Denver. Quaint and historic **Georgetown** is nestled in a mountain valley, 42 miles west of Denver. Enjoy afternoon tea, tour the *Hamill House and Museum*, or stroll down 6th Street for antiquing and fine dining. Pan for gold or tour a mine in **Central City and Black Hawk**, located 34 miles west of Denver. In the evening, try your luck at one of the 30-plus casinos or visit the *Central City Opera House*.

Dining in Denver

For dining that's classy or casual, hip or traditional, head to one of Denver's top neighborhoods, most within three miles or less of the Colorado Convention Center. Whether it's local or exotic fare, Denver's restaurants are sure to cook up meals, service, and atmosphere worth their award-winning status.

DOWNTOWN

Downtown Denver is home to some of the city's best dining, shopping, and arts and culture. Most eateries are a quick walk from the convention center, or a free ride from the 16th Street Mall, itself populated with many restaurants.

Panzano (Italian, $$$)

909 17th Street
303-296-3525
www.panzano-denver.com
Panzano's contemporary Northern Italian cuisine focuses on local and organic ingredients. Start with homemade bread and dipping sauces, but leave room for fresh fish, pasta, and homemade sausage. Open daily for dinner, Monday through Friday for breakfast and lunch, and weekends for brunch.

Restaurant Kevin Taylor (French, American; $$$$$)

1106 14th Street
303-820-2600
www.ktrg.net/rkt
The cosmopolitan and elegant feel of Restaurant Kevin Taylor is matched by its exceptional service. The French menu also fuses fare inspired from the American Southwest and Asian Rim. Open Monday through Saturday for dinner.

Sushi Sasa (Japanese, $$$)

2401 15th Street
303-433-7272
www.sushisasadenver.com
For traditional Japanese cuisine, dine at Sushi Sasa's upscale, Zen-like restaurant. Order sushi from entertaining chefs at the back bar, or find a table and nosh on creatively cooked Japanese dishes. Open daily for dinner and Monday through Saturday for lunch.

LODO

If you're looking for a vibrant, fun atmosphere, check out the Lower Downtown Historic District of Denver, affectionately known to locals as LoDo. In LoDo, you'll find some of the hippest restaurants in town.

Bistro Vendôme (French; $$, $$$)

1420 Larimer Street
303-825-3232
www.bistrovendome.com
Bistro Vendôme is an authentic French bistro that focuses on local and seasonal ingredients. Opt for a romantic dinner inside, or sit outside on the hidden patio. Open daily for dinner and weekends for brunch.

Rioja (European, $$$)

1431 Larimer Street
303-820-2282
www.riojadenver.com
Enjoy Rioja's chic and energetic atmosphere with a Mediterranean-inspired meal paired with a fine Spanish wine. Try one of the unique pastas, fish, or the signature "Rioja picnic," a mix of artisan appetizers. Open daily for dinner, Wednesday through Friday for lunch, and weekends for brunch.

Wynkoop Brewing Company (American Brewpub, $$)

1634 18th Street
303-297-2700
www.wynkoop.com
Play pool or darts at Wynkoop, Colorado's first brewpub, while enjoying hand-crafted beer and hearty comfort food. Not sure which beer to choose? The Railyard Ale, an India pale ale, and the Sagebrush Stout are sure to please. Brewery tours on Saturday. Open daily for lunch and dinner.

HIGHLAND

The up and coming area of Highland is an alcove of cozy restaurants. Its ethnic diversity and historic charm is a draw for many, along with its martini bars and novelty stores.

Duo (New American, $$$)

2413 West 32nd Avenue
303-477-4141
www.duodenver.com
You'll feel relaxed in Duo's remodeled nineteenth-century mercantile building. Partnering with some of the best Colorado farms, Duo whips up a seasonally changing menu of creative comfort food, including exciting soups. Open daily for dinner and weekends for brunch.

Lola (Mexican; $$, $$$)

1575 Boulder Street
720-570-8686
www.loladenver.com
Mexico's coastal regions inspire the menu at Lola, where you'll find dishes like ceviches, grilled fishes and meats, and seafood stews. Lola's sleek and festive interior was rated one of the top five places in America to drink tequila. Open daily for dinner and weekends for brunch.

Z Cuisine & À Côté (French, $$$)

2239 & 2245 West 30th Avenue
303-477-1111
www.zcuisineonline.com
Z Cuisine is an authentic French Parisian bistro and À Côté is a French wine bar. The tiny restaurant and bar exude charismatic charm and serve up genuine French fare. Z Cuisine is open Wednesday through Saturday for dinner. À Côté is open Tuesday through Saturday for light fare and drinks.

CAPITOL HILL

For a diverse and eclectic atmosphere, reflected in its eateries, stroll through Capitol Hill. You'll find everything from old mansions converted to elegant tea rooms to the home of Denver's punk community.

Bones (Asian Fusion, $$)

701 Grant Street
303-860-2929
www.bonesdenver.com
Bones is a fun and upbeat noodle bar, specializing in creative dishes made with noodles like ramen, soba, or udon. Many of the noodles are imported from Japan. Open daily for dinner and Monday through Friday for lunch.

Mizuna (Continental, French, New American; $$$$)

225 East 7th Avenue
303-832-4778
www.mizunadenver.com
With fine dining and excellent service, Mizuna serves up an impressive menu of Continental, French, and New American fare. Don't miss the lobster macaroni-and-cheese appetizer. Open Tuesday through Saturday for dinner.

Potager American, New American; $$$)

1109 Ogden Street
303-832-5788
www.potagerrestaurant.com
For a friendly and comfortable dining experience, visit Potager's garden-driven restaurant. Seasonal, local, and mostly organic ingredients make up the

American menu. Begin or end in the small lounge with a drink from the eclectic wine list. Open Tuesday through Saturday for dinner.

CITY PARK UPTOWN

Home to the premier park in the city, the City Park neighborhood boasts many hip and lively restaurants, from taco bars to fine dining. Be sure to journey down Restaurant Row on 17th Avenue, from Broadway to City Park.

Encore (American; $$, $$$)

2550 East Colfax Avenue
303-355-1112
www.encoreoncolfax.com
Encore, housed in the old Lowenstein Theater complex, offers a unique and diverse array of American light fare and entrées. Most come for the delectable wood-fired meats, fish, and flat bread pizza. Open Monday through Saturday for lunch and dinner and Sunday for brunch.

Mezcal (Mexican; $, $$)

3230 East Colfax Avenue
303-322-5219
www.mezcalcolorado.com
Mezcal, ever bright and lively, is an authentic Mexican taqueria and cantina. The home-style Mexican food, most of which is smokier and sweeter than traditional Mexican fare, is best paired with a fresh lime margarita, tequila, or mezcal. Open daily for lunch and dinner and weekends for brunch.

Strings (Fusion, $$$)

1700 Humboldt Street
303-831-7310
www.stringsrestaurant.com
For a casual but sophisticated atmosphere, dine on hip and artful food at Strings. The menu combines New American fare with options like fresh seafood and noodle dishes. Open daily for dinner, Monday through Friday for lunch, and weekends for brunch.

WASHINGTON PARK

Centered around Washington Park, the Wash Park neighborhood, as it is known to locals, is celebrated for its trendy coffee shops, bars, and record stores.

Lucile's Creole Café (Cajun, Creole, Southern; $, $$)

275 South Logan Street
303-282-6258
www.luciles.com
Craving some good Southern cooking? Settle in at Lucile's to enjoy a large, gourmet yet simple Cajun, Creole, or traditional Southern meal. Zydeco, jazz, or Cajun music is always playing. Open daily for breakfast, brunch, and lunch.

Table 6 (American, New American; $$$)

609 Corona Street
303-831-8800
www.table6denver.com
For a classic American bistro with a warm and charming atmosphere, dine at Table 6. The American and New American menu is always creative, and the entrée accompaniments are as exciting and tasty as the entrées themselves. Open daily for dinner and Sunday for brunch.

Thai Basil (Thai, Asian; $, $$)

540 East Alameda Avenue
303-715-1188
www.thaibasil.us
One of the "best cheap eats" in town, Thai Basil is a warm and friendly place to nosh on Thai Asian fusion food. The appetizers and soups could be a meal, but leave room for a flavorful meat, fish, or vegetarian entrée. Open daily for dinner and Monday through Saturday for lunch.

CHERRY CREEK

Denver's leading dining and shopping area is located in Cherry Creek. Stroll past quaint architecture and tree-lined streets to an outdoor cafe, local bakery, or coffee shop, or reserve a table at one of the upscale restaurants.

Cherry Cricket (American, Mexican; $)

2641 East 2nd Avenue
303-322-7666
www.cherrycricket.com
Although Cherry Creek is known for its more sophisticated restaurants, you can't pass up this classic neighborhood bar, rated one of the "best cheap eats" in Denver. Cherry Cricket is known for serving up made-to-order burgers in a friendly and unpretentious fashion. Enjoy a beer while you play pool or darts. Open daily for lunch and dinner.

Elway's (New American, Steakhouse; $$$$)

2500 East 1st Avenue, Unit 101
303-399-5353
www.elways.com
If USDA hand-cut prime steaks are what you crave, head to contemporary and elegant Elway's, where the hospitality is top notch. Also impressive are the fin fish, crustaceans, and decadent desserts. Live music plays often at the bar and patio. Open daily for lunch and dinner and weekends for brunch.

Fruition (New American, $$$$)

1313 East 6th Avenue
303-831-1962
www.fruitionrestaurant.com
Although the menu at Fruition may be small, the flavors are big and bold. The seasonally changing menu offers sophisticated comfort food in an intimate and charming atmosphere. Open daily for dinner.

PEARL STREET/ OLD SOUTH PEARL

With cuisine ranging from Hungarian to sushi, you'll find some of the city's most popular fine dining in Old South Pearl. The neighborhood also is known for its coffee shops, wine bars, and neighborhood pubs.

Black Pearl (Seafood, New American; $$$)

1529 South Pearl Street
303-777-0500
www.blackpearldenver.com
The menu at Black Pearl emphasizes fresh oysters and seasonal ingredients acquired from local producers and farmers. The inviting and hip space is great for enjoying everything seafood. Open daily for dinner and Monday through Saturday for lunch.

India's Pearl (Indian, Afghan, Tibetan; $$)

1475 South Pearl Street
303-777-1533
www.indiaspearl.com
For classic Indian food and Asian and Indian fusion, cozy up in the chic and modern ambiance of India's Pearl. Known for their Biryani dishes and Naan, India's Pearl serves up a huge selection of appetizing ethnic dishes. Enjoy the martini lounge upstairs with live entertainment several nights a week. Open daily for lunch and dinner.

Sushi Den (Japanese, $$$$)

1487 South Pearl Street
303-777-0826
www.sushiden.net
Voted one of the best sushi restaurants in the country, Sushi Den offers the latest catches from Japan. The healthy and innovative menu boasts exotic fare, sushi, and entrées including teriyaki, tempura, and steamed fish or vegetables. Open daily for dinner and Monday through Friday for lunch.

Additional Denver Restaurant Information and Reviews:
www.denver-restaurants.com
www.denver.diningguide.com
www.westword.com/restaurants

Price guide: Average cost of dinner for one person, including appetizer, entrée, dessert, coffee, tax and tip. (Alcohol and other beverages not included.)

$ - Inexpensive, under $20
$$ - Moderate, under $35
$$$ - Expensive, under $50
$$$$ - Very expensive, under $75
$$$$$ - Extremely expensive, over $75

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