

ASN Presidential Address 2013: Innovation and Individualization—The Path Forward for Nephrology

Bruce A. Molitoris

Department of Medicine, Indiana University School of Medicine, Indianapolis, Indiana; and Roudersbush Veterans Affairs, Indianapolis, Indiana

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Welcome to the 47th Annual Meeting of the American Society of Nephrology (ASN)—Kidney Week 2013. Thank you for helping to lead the fight against kidney disease in the United States and across the globe. As ASN President, I would like to thank you for the opportunity to lead this outstanding organization over the past year. I did it with the help of a remarkable and interactive ASN Council and the wonderful ASN staff. Special mention goes to the ASN Program Committee (chaired by Anupam Agarwal, MD, FASN) and the Postgraduate Education Committee (chaired by Mark E. Rosenberg, MD, FASN). There are no sufficient accolades to describe what they were able to accomplish and what you will benefit from over the next 4 days. The ASN staff directly responsible for Kidney Week deserves special recognition for their steadfast support. Finally, I would like to acknowledge ASN Executive Director Tod Ibrahim, whose leadership, sense of responsibility, and dedication are reflected throughout the entire organization.

ASN is an outstanding, creative, and growing organization with great leadership. I am pleased to report that ASN has never been in better shape than it is today. However, nephrology faces many challenges now and in the future.

Why am I concerned? And what must we do to reinvigorate one of the most potentially exciting and important areas of medicine? In the United States and many other countries, interest among medical students and residents in nephrology

careers is at an all-time low and has been declining over the past 10 years.^{1–3} This finding is evidenced by a marked multiyear decline in the number of United States medical students entering the nephrology match (most recently, less than 32% of available positions). The United States is fortunate, because talented graduates from international medical schools have filled the available fellowship positions (Figure 1). However, when this year's match results are announced next month, I anticipate that there will not be enough total applicants to fill the available positions, primarily because of a decrease in the numbers of international graduates participating. What does it say about a discipline unable to attract future generations into the field from our own medical schools?

THE NEXT GENERATION OF NEPHROLOGISTS

In 2010, the ASN established a task force to survey medical students, residents, and fellows. What was emphasized in the responses was the lack of innovation leading to advancements in diagnostics and therapeutics in nephrology. Indeed, developments in diagnostics and therapeutic agents have been stagnant for a number of years.^{4,5} One has to look no further than the number of clinical trials, National Institutes of Health (NIH) R01 submissions, or productive physician-scientists entering nephrology to document this trend.^{5,6} In addition, many clinical trends are combining to create a

perfect storm that could minimize the hospital and outpatient roles of nephrologists. Hospitalists on the wards and critical care physicians and anesthesiologists in the intensive care unit now consult on electrolyte and/or acid–base issues or AKI. In many cases, their training is not as rigorous as a nephrologist's training in these areas, and their interest in nephrology is certainly not as high. This declining hospital exposure has also reduced our interactions with and mentoring of medical students and residents.

The lack of interest in following early stage CKD patients as outpatients has further isolated the nephrology community. We have also resisted new challenging and exciting opportunities. A telling example is the reluctance of most interventional nephrologists to take a major role, or even participate at all, in renal artery ablation therapy for refractory hypertension, essentially turning the field over to interventional cardiologists and radiologists, which is a lost opportunity.

Over the past year, under the direction of Work Force Committee Chairman Mark G. Parker, MD, the ASN launched several programs to increase interest in

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Correspondence: Dr. Bruce A. Molitoris, Nephrology Division, Department of Medicine, Indiana University School of Medicine, R-2, Room 266, 950 West Walnut Street, Indianapolis, IN 46202. Email: bmolitor@iu.edu

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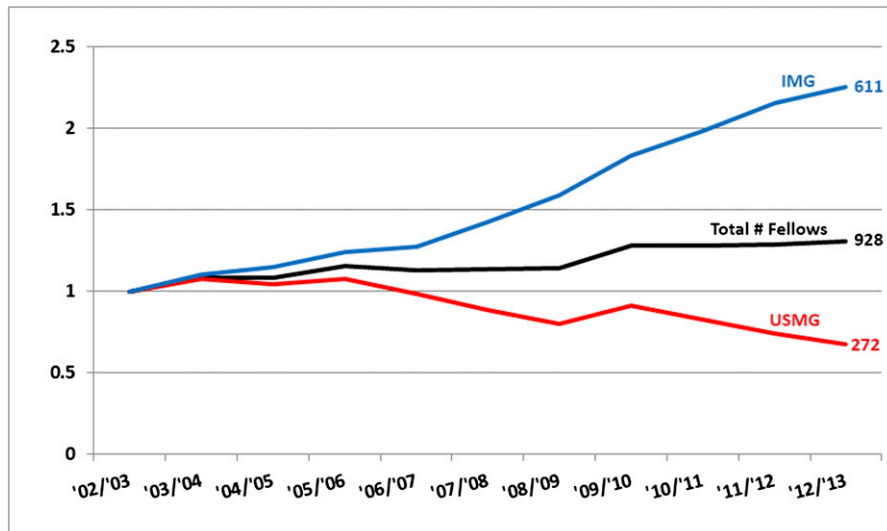


Figure 1. A graph normalized to 2002 shows fold changes in total numbers and composition of nephrology fellows over the last 10 years. A strong trend for the increase in the number of international medical graduates (IMGs) and decrease in the number of United States medical graduates (USMGs) from the 2002–2003 appointment year to the 2012–2013 appointment year is observed. Values at the end of the graph lines represent actual postmatch numbers for appointment year 2012–2013. In the 2013–2014 match (released December 4, 2013; after the ASN Kidney Week) 64 of 145 (44%) nephrology programs did not fill all their available slots, and only 306 of 403 positions filled (75.9%); 29% of fellows matching were USMGs.

nephrology careers. These programs include Kidney Tutored Research and Education for Kidney Scholars (TREKS) and Kidney Mentoring and Assessment Program for Students (MAPS). This week, Kidney MAPS held a kidney disease screening event in conjunction with the ASN Kidney Week 2013. On November 4, the ASN cosponsored the American Kidney Fund's Kidney Action Day in downtown Atlanta, which helped raise awareness about kidney disease and prevention. This year, the ASN also increased the number of residents and medical students that the society funds to attend Kidney Week to 49 medical students and 111 residents.

Kidney TREKS, Kidney MAPS, and the ASN Program for Medical Students and Residents are but small steps to reversing the next generation's opinion of nephrology. I would go so far as to say that the field is perceived by medical students and residents as stagnant and unattractive. This loss of interest in nephrology and clinical care opportunities is not limited to the United States but is seen across the world.⁷ We—the worldwide leaders of nephrology—must understand the foundation of these concerns and use our

understanding and passion for nephrology to build a bright future for this field.

Why Has Nephrology Reached This Point?

For more than 40 years, nephrology has focused on ESRD and RRTs, a vitally important focus given the vulnerability of this population and our responsibility to improve life for patients with kidney failure. Together, we have produced remarkable lifesaving therapies and made huge strides in dialysis and transplant care and delivery. However, this narrow focus has limited care, education, research funding, innovation, and translation in the rest of our discipline. The analogy that I propose is that of an iceberg (Figure 2). Above the water, the iceberg is visible and easily quantified; below the water, the iceberg's mass is unseen, difficult to quantify, and dangerous. Importantly, you cannot decrease the size of the visible component until you reduce the accumulation rate of submerged ice. It has been said that if you let patterns go on too long, they will become your prisons. Have the longstanding patterns in nephrology created a prison?

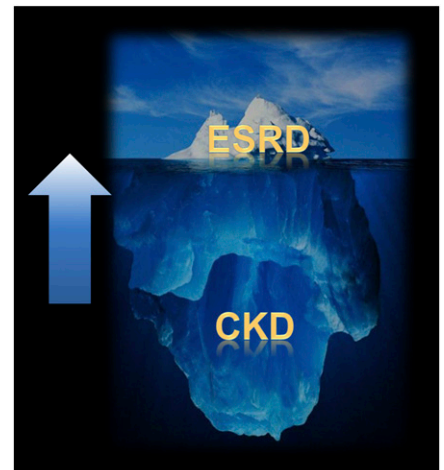


Figure 2. The hidden facts about kidney disease. An iceberg showing the floating aspect and the all too often unrecognized supporting submerged ice. Modification of 3oneseven.com design, Echingenstr 80805, Munich, Germany.

Surmounting challenges that are largely hidden from view requires vigilance, an understanding of the scope of the problem, and a targeted strategy that can be rapidly altered as events unfold. Compromise in one or all of these areas can lead to disaster, which indeed occurred with the RMS

Titanic when the ship failed to avoid the iceberg that doomed the passenger liner on April 15, 1912. Such considerations inform the four pillars that I regard as necessary for the renewed vitality of our discipline that I will subsequently articulate. Before I discuss these pillars further, let me now emphasize the need to reinvigorate nephrology and how it is especially relevant to and beneficial for the CKD population.

How Can We Reinvigorate Nephrology?

As nephrology leaders, we must intensify our efforts to strengthen the discipline that we love. We must move from ordinary to extraordinary care. To make this move, we must see the entire iceberg or the entire spectrum of the problem. We must develop technology to focus on the individual patient, treating people based on their own characteristics and not the characteristics of a population of patients. We must innovate and individualize care to those patients in need at a much earlier time in the disease process. Recent genetic and molecular advances in the ANCA vasculitis and *APOL1* fields make this truth all too apparent. We must build a convincing case that prevention and minimizing progression are cost-effective in addition to saving lives and alleviating human suffering.

The CKD Population Offers the Opportunity to Reinvigorate Nephrology

All too often, we have relegated CKD care to physicians who are less-appropriately trained to provide the care that is deserved and required. The American Board of Internal Medicine certification tests in general internal medicine, geriatrics, and endocrinology indicate that the physicians in these disciplines have not had the training necessary to provide optimal care to CKD patients. However, in the United States, these physicians are caring for a large percentage of CKD patients, and they are also the majority of physicians providing patients for and participating in AKI-CKD clinical studies.

Just last month, the American College of Physicians (ACP), which represents

general internists, determined that it was unnecessary to screen for CKD in asymptomatic adults who lacked risk factors. As the experts in kidney disease, we know that CKD is largely asymptomatic in its early stages and that early detection and early intervention can slow progression of the disease and reduce the likelihood of kidney failure. The ASN, the National Kidney Foundation, and other members of the kidney community responded quickly to the irresponsible recommendations of the ACP.

A fundamental question is why do we limit care by nephrologists to late stage CKD, a point in time when therapeutic success is likely minimal and perhaps not possible? We are told that it is a workforce shortage. However, in many cities in the United States, newly trained nephrologists are becoming hospitalists, because few or no nephrology positions exist. At present, what was to be a shortage of nephrologists is rapidly becoming a surplus as the scope of work becomes narrower and narrower because of an emphasis on the most cost-effective aspects of our profession. I ask every one of you here today: if you knew that you had kidney disease, would you be satisfied not seeing a nephrologist?

We must concentrate on our mission and our commitment to our patients, and we must develop viable health care delivery systems necessary to meet the needs of our patients. The focus on mission and patients will help shift care from ordinary to extraordinary. To make this leap, I believe that there are four pillars to success.

THE FOUR PILLARS FOR NEPHROLOGY

Enhance Public Awareness of Kidney Disease

Currently, the combined cost of ESRD and CKD in the United States totals \$77 billion annually, with up to \$49 billion for CKD stages 2–4 alone.⁸ The lifetime risk for United States citizens developing stage 3b CKD (GFR < 45 ml/min per 1.73 m², which is capable of progressing to ESRD) is estimated at 33%.⁹ The

overall incidence of ESRD is 3.3% and greater than 8% in African Americans. However, we have failed to convey the importance of kidney disease to the public. We can and must improve the message. What we need to realize and make the public aware of is that everyone is at risk of developing kidney disease.

To their benefit and credit, organizations representing patients with Alzheimer's disease, cancer, diabetes, heart disease, and HIV/AIDS have been astonishingly successful in raising awareness and support from the public, press, policymakers, and industry. Nephrology lags in both public awareness and the resulting research funding. Did these highly successful public awareness campaigns limit their message to the at-risk populations? No. Their messages were developed for and understood by all. We have to make the message personal.

Clearly, certain individuals have an increased risk for kidney disease and require increased surveillance. However, AKI knows no boundaries or limitations. AKI has multiple causes, can happen to anyone, and can progress to CKD and ESRD. Recent data indicate that AKI occurs in 21% of hospitalized adults and 33% of hospitalized children, and an unacceptable percentage of these cases progress to CKD and ESRD.¹⁰ Our message must start with a grassroots campaign and reverberate with the public at large to be successful. There must be a sense of urgency in promoting public awareness, because all subsequent advances require and build off awareness.

Emphasize Innovation

Transformation requires innovation, and nephrology lags other medical disciplines in this regard. Nephrologists are iterative by nature, and our discipline has long relied on evolutionary or iterative advances. Innovation is not iterative—it is revolutionary. Paradigm shifts happen when new technology allows novel insights or individuals to think outside of the box. Paradigms are initially fiercely rejected, then resisted, and finally, only accepted when incontrovertible evidence is available.

By definition, innovation cannot be reviewed by peers. The NIH must continue

to support innovation and minimize exerting control over pioneering investigators. We must challenge our present kidney paradigms, invigorate investigators to adapt and develop new approaches and technologies, and recruit new scientists and engineers into the field if we are to achieve maximum success. For therapeutics to be successful, we must reach patients in the early stages of kidney disease and not wait until they have lost more than two thirds of their whole kidney function (including renal reserve). All of us must take responsibility to develop diagnostic techniques to identify patients early to make the ever-present clinical trial end points (the three Ds: doubling of serum creatinine, dialysis, and death) obsolete.

As the leaders of nephrology, we must seriously question if it is possible to make meaningful therapeutic advances at a late point in a chronic disease. Certainly, nothing works for congestive heart failure or chronic obstructive pulmonary disease if one waits too long. During the high-impact clinical trials session at this meeting, we will hear about the bardoxalone experience. This information will be very important data for us to digest.

Think of the diagnostic techniques available to the cardiologist or the breast cancer advances based on tissue diagnostics. We must challenge and fund the field to develop and enable nephropathologists to use molecular diagnostics to advance and individualize patient care beyond the structural features of a biopsy. We must challenge the US Food and Drug Administration (FDA) and similar agencies across the globe to include renal disease diagnostics in their innovation pathway. Individualization of care requires diagnostics that detect and quantify early deterioration, likelihood of progression, and response to therapy, which is especially important in patients with diabetes. We must also be able to differentiate those individuals with a natural age-related decline in GFR as normal if we are to be able to concentrate our limited capacity where needed.

Innovation invigorates, and discoveries are absolutely essential if we are to attract the best and brightest MDs, PhDs, PharmDs, APRNs, and other health care

professionals to nephrology. This effort will be expensive and require a substantial increase in research budgets. We must make the case that, even in times of limited funding, nephrology deserves support based on clinical need and expenditures. In the United States, the NIH invests less on kidney research per affected patient than the agency spends for research on Alzheimer's disease, cancer, diabetes, heart disease, or HIV/AIDS per patient affected. The NIH allocates \$567 to research for every patient with cancer compared with \$28 per kidney patient for kidney research—the lowest for any major disease.

The NIH's National Institute of Diabetes and Digestive and Kidney Diseases has worked hard with a limited appropriation to develop and fund innovative initiatives, but an underfunded initiative is like an underpowered clinical trial—the results are often not beneficial or enlightening. Therefore, we must increase funding for kidney care, research, and education if we are to transform the lives of millions of people with kidney disease. The ASN is calling on Congress and the Obama Administration to appropriate \$150 million/year for 10 years in new funding for kidney research above the current funding level. This \$1.5 billion total, over 10 years, equals 2% of the estimated federal spending each year for treating kidney disease. This percent is still below that for other diseases, but it is a start.

Create New Partnerships

Generating funding for innovation requires broad-based, inclusive, and organized partnerships to inform the public and other stakeholders about the serious consequences of kidney disease. Yesterday, for the first time, the ASN brought together all of the United States kidney organizations, representing health professionals and patients, to set mutual goals for the coming year. This cooperation must continue and grow beyond our borders if we are to accomplish our shared mission of improving kidney health and ultimately, curing kidney disease. By working together and speaking with a united voice, we can benefit our

patients and advance patient care for all. Every kidney disease represented by each respective organization needs and deserves new diagnostics and therapeutics to enhance prevention and early detection and minimize progression.

Similarly, we must increase our scientific diversity if we are to be successful. Science is changing rapidly and now requires extensive interactions and scientific diversity and integration to be successful. This year, the ASN held its first PhD summit to better understand and enhance opportunities for existing basic scientists and develop measures to attract more into the field. We must also increase our public-private partnership interactions to be efficient and successful. Academics, patients, and the government must partner with industry to enhance possibilities for success. Limiting these interactions will only slow progress.

Last year, the ASN, under the leadership of Ronald J. Falk, MD, FASN, developed and launched the Kidney Health Initiative (KHI). The KHI is an innovative partnership between the ASN and the FDA to “advance scientific understanding of the kidney health and patient safety implications of new and existing medical products and to foster development of therapies for diseases that affect the kidney by creating a collaborative environment in which FDA and the greater nephrology community can interact to optimize evaluation of drugs, devices, biologics, and food products.” I am proud to say that, in 2013, its inaugural year, the KHI is off to a fantastic start, with more than 50 members and several important projects underway. Additionally, the ASN has also expanded the Kidney Week Innovators Place to include therapeutics this year. I encourage you to see what is coming down the pipeline and communicate your thoughts to improve care.

Measure Success

Our approaches must change lives, and the data must measure their impact, including our patients' feeling of wellbeing. We must concentrate on our mission and change the focus from cost-effective for nephrology to cost-effective for

society. We must standardize data collection and analysis, including costs, and share data across organizations. As nephrologists, we will be expected to do more and do better with less. This new paradigm is reality.

The Centers for Medicare and Medicaid Services ESRD program mandates data collection. These data have led to changes in care that benefit patients, but we have only begun to scratch the surface of all of the benefits that could be achieved for very little additional cost. A far greater task will be determining the parameters and then obtaining the data necessary to keep score in the CKD population. Governments are already headed in this direction, and we must assist them in determining the metrics that insure progress and efficiency in care. Medicine must not be processed through the collective lenses of administrative values and judgments but based on the betterment of patient care.

Forty years ago, I chose nephrology, because the field was exciting and full of opportunity in cell and molecular biology. I wanted to make a difference. I am now confident that, if we commit ourselves to kidney health and curing kidney disease, the future of nephrology will become even more exciting as we develop

and translate exciting groundbreaking discoveries into patient care through innovation and individualization.

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DISCLOSURES

None.

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