


Building on innovations to inform kidney disease policy and practice



Kidney disease significantly alters the quality of life of millions of people worldwide who live with the illness, as well as the family and friends who may provide care for them. It exacerbates a host of other chronic conditions, contributes to shortened lifespan, and also poses a huge cost burden on the healthcare system. Despite some recent promising trends, the disease remains highly prevalent in the U.S. and around the world, though it is not always recognized as the scourge it is.

The power of collaboration

Over the last several decades, researchers affiliated with the University of Michigan (U-M) have developed expertise across a range of disciplines with the aim of improving the health and quality of life of those living with kidney disease, while improving their access to care, the safety and effectiveness of clinical practice, and reducing costs associated with this illness. Their work has contributed to evidence-based practice and policy changes in the U.S. and globally that have likely helped save countless lives and hundreds of millions of tax-payer dollars. Their efforts are poised to continue to contribute toward stemming the challenges of this persistent public health issue in the future.

The U-M Institute for Healthcare Policy & Innovation (IHPI)'s expertise in kidney disease health services research and policy encompasses the work of dozens of faculty and staff across several partner units and organizations that are dedicated to these fields. Major collaborators, whose work is described in this brief, include the University of Michigan Kidney Epidemiology and Cost Center (U-M KECC), formed in 1993, and Arbor Research Collaborative for Health, founded in 1997.

Fewer Deaths

Deaths among dialysis and kidney transplant patients have dropped by 28 percent and 40 percent, respectively, since 1996.

ESRD Increasing

Prevalence of end-stage kidney disease—the last stage of chronic kidney disease when the kidneys can no longer remove waste and excess water from the body, and dialysis or kidney transplantation is necessary for survival—continued to rise. The size of the dialysis population increased 4 percent in 2013, reaching 466,607, and is now 63.2 percent larger than in 2000.

Larger Waiting List

The active waiting list for kidney transplants was 2.7 times larger than the supply of donor kidneys, with 17,600 kidney transplants performed in 2013.

High Proportion of Costs

Although ESRD patients make up less than 1 percent of all Medicare recipients, they account for 7 percent of all Medicare costs (more than \$30 billion per year).

Home Dialysis

When patients have the ability to clear excess fluid and waste from the kidneys by using a dialysis machine in the privacy of their own home—use is 52 percent higher than a decade ago.

Kidney Disease Trends

2015 USRDS
Annual Data
Report Findings



Kidney disease: A widespread, yet often silent burden

Chronic kidney disease (CKD), which is the gradual loss of kidney function over time, can go undetected for years or even decades, since people may not experience symptoms until they reach the point where their kidneys have nearly ceased working. Although about 14 percent of people in the U.S. are living with CKD, only a small fraction—about 1 in 10 of them—is aware of it.

As CKD progresses into its most severe phase, known as end stage renal disease (ESRD), or permanent kidney failure, the kidneys can no longer support the body's needs, and a transplant or dialysis treatment (using a machine that filters wastes from the blood) is required to replace the work the kidneys would normally perform.

Millions worldwide live with the irreversible end-stage form of the illness, ESRD—some waiting for an organ transplant, and often dependent upon dialysis, a life-sustaining yet also life-consuming treatment in terms of its effect on quality of life for patients and their families. How can the quality of dialysis care be improved for these individuals? And what about reducing the resource use and expenses that the treatment of all stages of kidney disease—estimated at more than \$100 billion for the U.S., taking Medicare, Veterans Administration (VA), and private healthcare costs into account—poses to our healthcare system?

Monitoring the burden and impact of kidney disease

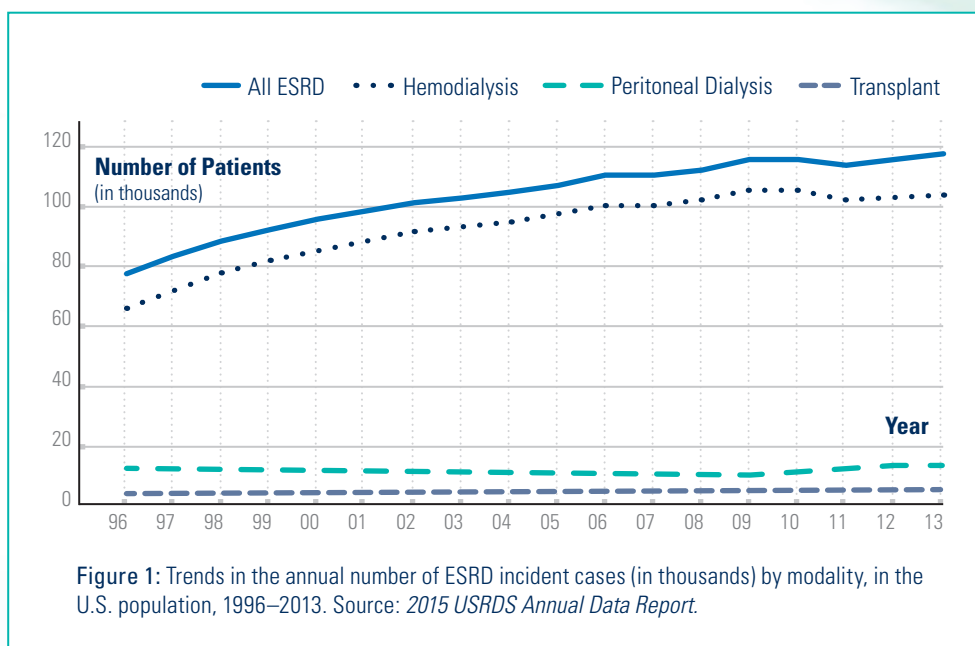
U-M KECC developed and, in partnership with Arbor Research, currently coordinates the largest national registry in the world for monitoring kidney disease in general, and end-stage disease in

particular: the United States Renal Data System (USRDS), launched in 1988. U-M served as the coordinating center for the USRDS from its inception until 1999, and was re-awarded the coordinating center contract in 2014. The USRDS has especially thorough data on the ESRD population because these individuals are required to register for benefits through Medicare, which has provided coverage to all people with permanent kidney failure, regardless of age, since 1972.

U-M KECC investigators, in collaboration with the University of California, San Francisco, and Arbor Research, have also established the first-of-its-kind CKD surveillance system for the United States (funded by the Centers for Disease Control & Prevention), which systematically tracks and reports information on risk factors and disease burden, disease awareness, quality and processes of care, CKD-associated health consequences, and health system capacity available to deal with CKD.

Rajiv Saran, M.D., M.R.C.P., M.S., an expert in renal epidemiology and an associate director of U-M KECC, and U-M colleagues have also recently laid the foundation for a novel kidney disease data/information system for the Veterans Administration, called VA Renal Information System (VA-REINS). U.S. veterans bear a much higher burden of chronic kidney disease than the rest of the country's population. The VA will use this system to monitor the disease in all stages among the millions of veterans it cares for, with the goals of improving early identification and access to care, optimizing disease management at all stages of CKD, reducing care-related costs, and monitoring prevention efforts and health outcomes.

Additionally, with the burden of kidney disease much greater in other parts of the world, U-M KECC is assisting other countries such as China and India in developing surveillance systems to monitor risk factors and early-stage CKD in their populations.



Recent trends in treatment and outcomes

The most recent USRDS data indicate that more than 600,000 people across the U.S. are being treated for ESRD, roughly two-thirds by dialysis. While transplantation is clearly the preferred therapy when indicated, the widespread shortage of transplantable organs makes it available to far fewer than the number who could benefit from it; the active waiting list for kidney transplants is 2.7 times larger than the annual supply of donor kidneys, and many waitlisted patients die or become too ill to benefit from a transplant.

There are some encouraging trends: after a sustained rise in new ESRD cases for nearly three decades, this rate

appears to be levelling off in recent years, according to the 2015 USRDS Annual Data Report (see Figure 1). While mortality rates from kidney disease remain high (approaching 10 percent per year among patients with advanced CKD, and nearly 20 percent among patients on dialysis, with a five-year survival rate of only 40 percent), these rates have also been declining, dropping by 28 percent and 40 percent among dialysis and kidney transplant patients, respectively, since 1996.

Together, these statistics mean that more people will be living with end-stage kidney disease—the number of people on dialysis increased 4 percent in 2013, and is 63.2 percent larger than in 2000.

Promoting patient-centered care and safety for a unique population

While dialysis offers a life-sustaining intervention, its effect on quality of life for individuals and their families can be dramatic. Most dialysis patients require three in-center, half-day hemodialysis treatment sessions per week, and may also need the second half of those days to recover from each session, representing a major loss of freedom and autonomy.

A patient-centered project spearheaded by Francesca Tentori, M.D., M.S., senior research scientist at Arbor Research, seeks to identify the factors most important to patients who are transitioning to dialysis, and to develop a decision aid tool to help them identify the treatment options that would best fit their preferences.

Patient safety also remains a major concern. In-center hemodialysis typically involves the removal of a high volume of fluid in a relatively short time frame, which can dramatically affect blood pressure and cardiovascular stability that can lead to potential organ damage and severe complications—even death—especially if dialysis sessions become unstable following rapid fluid removal.

With the aim of reducing the instability of dialysis sessions and improving patient satisfaction and quality of life, Saran, also a U-M professor of internal medicine and epidemiology, and co-principal investigator Tiffany Veinot, Ph.D., U-M associate professor of information and public health, will be developing educational interventions that will involve patients and providers in creating a culture of safety by focusing on dialysis facility-wide policy changes related to improving health literacy, behavior modification, and ensuring stability of the dialysis procedure.

Using a global perspective to improve dialysis care in the U.S. and worldwide

Since 1996, the Dialysis Outcomes and Practice Patterns Study (DOPPS) has collected observational data on patient outcomes and practice patterns among dialysis facilities around the world, with the goal of identifying optimal treatment practices that extend survival and improve health-related quality of life of patients with kidney failure. The DOPPS family of studies, led at Arbor Research

Measurable differences in dialysis facility practices influence patient longevity, morbidity, and health-related quality of life.

by Principal Investigator Bruce Robinson, M.D., M.S., FACP, with contributions from multiple Arbor Research and U-M collaborators, has now expanded to more than 20 countries, and has tracked over 70,000 patients worldwide.

The motivations driving the DOPPS, borne out through the study's findings over two decades, is that measurable differences in dialysis facility practices influence patient longevity, morbidity, and health-related quality of life,

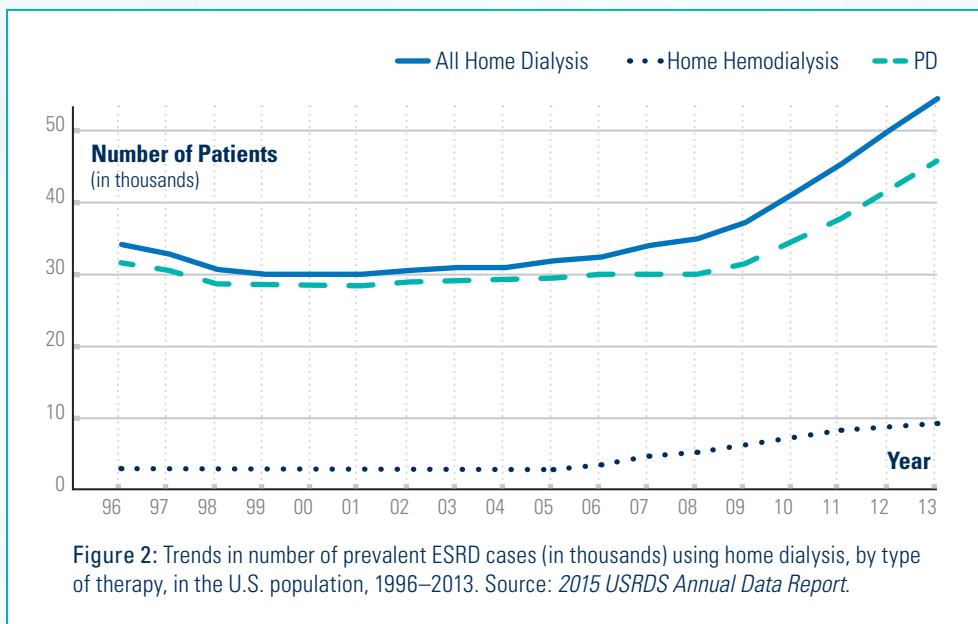
and that disseminating findings on best practices among healthcare providers, researchers, and policymakers can have a meaningful impact on policy and patient outcomes.

By shedding light on the effects of dialysis practices on a wide range of patient outcomes, the DOPPS has uncovered many other discretionary practices among facilities that are likely modifiable for the betterment of patient care, and has also helped identify and promote optimal practices in areas where no clear clinical guidelines exist. These have included findings relevant to trends in dialysis treatment session length, timing of dialysis initiation, and catheter use, evidence that has served as the basis for a number of policy changes around the world.

Improving survival and patient-centered outcomes through the “lifeline”

Hemodialysis requires access to a patient's bloodstream, and there are a number of ways to connect a patient's blood supply to the dialysis machine that filters the blood during the procedure. The most effective means of engineering this vascular access, often referred to as the “lifeline” for patients on dialysis, is usually through an “AV fistula,” which involves forming a new access point by surgically connecting a patient's artery and vein together. Compared to other types of access, AV fistulas are more durable and usually less expensive to maintain. They also tend to have the fewest problems with infection, blood flow, and other important outcomes, including lower risks of death and hospitalization.

In the U.S., however, convenience and reimbursement rates had for decades skewed preferences toward other types of access, such as catheters and artificial grafts. A national study of patients starting hemodialysis published in the *Journal of the American Medical Association* in 1996 by Richard Hirth, Ph.D., M.A., an associate director of U-M KECC and a professor of health management and policy at the U-M School of Public Health, and colleagues was essential in documenting large variations in the relative use of fistulas and grafts, and a trend away from fistulas. By comparing data between the U.S., Japan, and several European countries in



of more expensive drugs as well as inappropriately high doses) and discouraged home dialysis. Congress and the CMS sought to reform dialysis payment by developing a bundled, prospective payment system (PPS) to incorporate the dialysis treatment and all related medications and laboratory tests.

U-M healthcare economist Richard Hirth and colleagues at U-M KECC designed the new PPS with a fundamentally altered incentive structure, in which Medicare offers dialysis centers a flat rate for patients whether the therapy is done at home or in a facility. Since its implementation by Medicare in 2011, the PPS has improved quality of care, efficiency, and patient choice, and contributed to significant cost savings.

the late 1990s and early 2000s, DOPPS researchers found that fistula use was tied to far better outcomes among patients, and that differences in survival among dialysis patients between countries were largely attributable to differences in fistula use among providers in these different parts of the world.

Together, these findings, generated by researchers at Arbor Research and U-M KECC working on the DOPPS study, spurred the Centers for Medicare and Medicaid Services (CMS) in 2003 to launch a major continuous quality improvement initiative (the “Fistula First Breakthrough Initiative”) to promote the use of fistulas for vascular access in the U.S. Since then, fistula use has risen substantially among U.S. patients, and dialysis survival rates have meaningfully improved in large part because of this development, with mortality among this population falling by 23 percent over the last decade.

Impact on access to care and costs

In 2013, total Medicare expenditures for all stages of kidney disease was \$81 billion, more than \$30 billion of which was spent on those with end stage renal disease, according to USRDS estimates. ESRD patients make up less than one percent of all Medicare recipients, but account for seven percent of all Medicare costs.

ESRD is one of only a few diagnoses that qualifies individuals of any age for Medicare, which is typically reserved for people age 65 and older, and as a result the treatments for most ESRD patients are paid through Medicare. These high costs are often due to the underlying disease complications and multiple co-morbidities that plague those with kidney disease, which can lead to high rates of hospital admission and readmissions.

For years, Medicare paid for injectable dialysis medications on a fee-for-service basis, which encouraged overuse (in the form

Initially, the system was designed to save Medicare around \$200 million per year in payments from the change in practice patterns, and the reduced payment rate that Medicare is able to pay facilities because of that change. When PPS changes are fully phased in, annual savings will amount to an estimated \$500–600 million per year, or about five to six percent of total dialysis costs.

Just as importantly, in monitoring key quality measures throughout the dialysis industry, such as mortality and hospitalization rates, evidence points to continued improved outcomes for dialysis patients since the implementation of the PPS.

Meanwhile, home dialysis, which uses far fewer potentially harmful injectable medications, has risen substantially in the last five years (and is 52 percent higher than a decade ago), particularly among patients just starting out with dialysis therapy (see Figure 2). The flexibility that this treatment modality offers makes it a welcome alternative option for eligible patients, and represents a positive development for patient access and choice.

To protect against any unintended consequences or a decline in the quality of care under the PPS, CMS developed the ESRD Quality Incentive Program (QIP), the agency’s first national value-based purchasing program, linking a portion of payment directly to dialysis facilities’ performance on quality of care measures (also known as “pay-for-performance”). Arbor Research has supported CMS since the program’s implementation in 2010, providing CMS with objective data analyses to inform policy decisions that achieve the goals of continuing to improve the quality and efficiency of dialysis care.

In addition, as the CMS contractor for ESRD quality measure support, U-M KECC is responsible for developing, revising, and maintaining various measures related to clinical quality of care, care coordination, population and community health, safety, person-

and caregiver-centered experience and outcomes, and efficiency and cost reduction, many of which are available for patients and families to evaluate themselves in comparing dialysis facilities. Review of these measures helps ensure that dialysis care quality keeps pace with new clinical evidence or changes in guidelines, for example, and that quality responds to policy changes such as those implemented with the new PPS.

Dialysis as a leader in healthcare system-wide policy implementation

The complex health needs of people with kidney disease often require them to visit multiple providers and follow multiple care plans, which can be challenging if care is not coordinated. Hirth and U-M KECC colleagues are also involved in a demonstration project funded by the Center for Medicare & Medicaid Innovation (CMMI) to look at whether the concept of accountable care, which has generally centered on primary care practices and physicians, could be applied to specialty care settings—in this case, dialysis facilities—to improve coordination of these patients' care.

In accountable care generally, groups of healthcare providers bear responsibility for the costs and outcomes of their Medicare

patients, with the goal of ensuring that patients get the right care at the right time, while preventing medical errors and unnecessary duplication of services. If they achieve savings while meeting quality targets, they get to share in those savings, but if targets are not reached, they share in the risk of the higher spending.

If this first-of-its-type project is successful, CMS could extend the model to other chronic conditions, which could have enormous advantages for Medicare beneficiaries and the efficiency of their systems of care, and big potential cost savings.

Conclusion

IHPI-affiliated researchers have made important headway in staunching the impact of kidney disease by monitoring trends in prevention and treatment, addressing quality of life, access to treatment, and patient choice, and helping design pioneering new models to optimize resource use and care coordination. For the significant challenges that remain in prevention and disease management, ongoing collaborations at U-M and among its research partners will continue to develop the evidence and novel approaches to policy and practice that can benefit all who are touched by this disease.

Dive deeper and watch researcher interviews at ihpi.umich.edu/our-work/ihpi-briefs



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