

A Call for Early Diagnosis & Treatment of Chronic Kidney Disease

Insights & Policy Solutions from the American Kidney Fund's
2023 Patient Access Initiative Summit





Overview

Kidneys play a vital role in the human body – cleaning blood, controlling blood pressure, helping produce red blood cells and keeping bones healthy. But chronic kidney disease is growing at an alarming rate. As many as 37 million Americans currently have kidney disease, and millions more are at risk.¹

Kidney disease is most often caused by diabetes or high blood pressure, but not all kidney disease is the same. Some cases are caused by genetic predisposition, hereditary factors and congenital issues. Earlier stages of chronic kidney disease affect all groups at about the same rate, but people of color disproportionately develop the most severe stage, kidney failure.

Whatever the cause of their kidney disease, many people do not experience physical symptoms until the damage to their kidneys is significant. Patients may then face late-stage diagnosis and treatment, which is life-altering, physically challenging and costly. When symptoms do emerge early on, they are sometimes attributed to conditions other than kidney disease.

People with kidney failure – also known as end-stage renal disease (ESRD) – require either dialysis or a kidney transplant to live. Because donor organs are in short supply, most wind up relying on dialysis. About 40% experience an unplanned and abrupt “crash” into dialysis. The result can be longer hospital stays, decreased quality of life and poorer medical outcomes.²

The costs, meanwhile, are staggering. The average annual Medicare expenditure for kidney failure is over \$95,000 for each beneficiary on hemodialysis. For transplant patients, Medicare expenditures average \$39,000 per year.³

Early intervention can significantly slow the progression of the disease, helping people delay or avoid kidney failure and improving patient outcomes. It also reduces costs to both the patient and the overall health care system. To explore the path to more proactive diagnosis and treatment for the millions of Americans with kidney disease, the American Kidney Fund hosted a Patient Access Initiative Summit in Washington, DC in April 2023. The event convened a broad group of stakeholders, including people living with chronic kidney disease, caregivers, advocates, health care providers, industry leaders and medical experts.

This report summarizes the group’s discussion and highlights key remarks from the summit’s speakers.

Screening & Testing

Nine out of every 10 people with chronic kidney disease are unaware they have it.⁴ And nearly half of patients with stage 3b or 4 chronic kidney disease have not been referred to a nephrologist.⁵ Many die from cardiovascular complications before even getting a diagnosis.

To reverse these devastating trends, policymakers and health care providers must prioritize early diagnosis and treatment. That is why testing is so important.

CHALLENGES

The primary challenge with testing is a lack of clear and actionable instruction for health care providers. The U.S. Preventive Services Task Force has not issued guidance on screening for kidney disease but has recently released a research plan to evaluate the efficacy of doing so.

Genetic testing could help to identify hereditary factors early on, but many providers struggle with the complexity of the ever-evolving genetic testing market. Some also have concerns about patients' out-of-pocket costs for genetic testing.

“The coding is highly complex to keep up with these tests,” says Gillian Hooker, PhD, of Concert Genetics. “It’s really maddening for many people—providers, payers and certainly for patients.”

Genetic counselors, who could assist providers and people with chronic kidney disease in navigating the testing market, are often poorly reimbursed and concentrated in academic centers. This presents a barrier to access for patients who live in rural areas or receive treatment at community nephrology practices.

Privacy concerns may make some patients reluctant to undergo genetic testing. Patients' genetic privacy is protected by The Genetic Information and Nondiscrimination Act of 2008, which prohibits most employers or health insurers from using genetic information to discriminate against people.⁶ But certain forms of insurance — life, long-term care and disability — are not covered by the law. Information derived from genetic testing could still impact patients' eligibility, coverage or premiums for these insurance products.

SOLUTIONS



CLEAR GUIDANCE ON SCREENING

Guidelines from the U.S. Preventive Services Task Force should include screening for chronic kidney disease, offering patients better access to affordable, non-invasive screening early in the course of their disease. The promise posed by new and emerging treatment options – as well as research demonstrating the cost-effectiveness of more robust screening⁷ – could compel the task force to move forward on developing recommendations for kidney disease screening.



STRATEGIC USE OF MEDICARE PREVENTIVE VISITS

The “Welcome to Medicare” preventive physical exam should include chronic kidney disease screening, and policies should incentivize at-risk patients to do annual kidney health screenings.



INCENTIVES & FAIR COMPENSATION FOR GENETIC COUNSELORS

To ensure that genetic counselors remain available to patients, Congress should act to ensure that Medicare directly reimburses genetic counselors. The Access to Genetic Counselor Services Act (H.R. 3876 and S. 2323), if passed, would accomplish this goal.

“Genetic counselors tend to be subsidized from research dollars,” says Dr. Hooker. **“So, you don’t find them everywhere – mostly at academic centers and community health systems.”** Efforts to increase the number of counselors should focus on access across underserved communities.



Patient Education & Navigation

Patient education is critical. Many high-risk people aren't aware of their risk factors and simply don't know how or when to ask for screening and treatment for kidney disease.

But patient education can be complex, given the geographical, cultural and economic factors that impact different communities across the country. The heterogeneity of kidney disease also plays a role; patients need personalized information that reflects their genetic predisposition to the disease.

CHALLENGES

People living with chronic kidney disease often don't know if genetic testing is covered by their health plan or if they need genetic testing at all. And they may lack the facts they need to make informed decisions about their health plan coverage from the start.

“Many clients are choosing their health plans based on the perceived costs...not understanding the nuances of the deductibles, cost sharing and the benefits,” says Nicole T. Rochester, MD, of Your GPS Doc, LLC.

The confusion can be compounded when health plans introduce barriers, such as utilization management and high cost-sharing and deductibles. Other variables, such as changes in personal finances or employment, create gaps that further complicate care for patients.

Access barriers and health literacy challenges can pose an outsized burden on populations that already bear the brunt of health disparities. Consider that, compared with white Americans:

- **Black Americans** are 4.2 times more likely to develop kidney failure
- **Native Americans** are 1.9 times more likely
- **Asian Americans** are 1.5 times more likely
- And, compared to non-Hispanic Americans, **Americans of Hispanic ethnicity** are 2.3 times more likely.⁸

These communities often lack access to clinical trials, patient education and treatment options. For example, Black Americans with kidney failure are less likely than their non-Hispanic white counterparts to receive a kidney transplant or home dialysis.⁹

SOLUTIONS



GREATER AWARENESS

Addressing the web of challenges that patients face requires an all-hands-on-deck approach. And it starts with awareness.

“The disparities are significant,” says Nicole T. Rochester, MD. **“But I am encouraged by the increased recognition and awareness of provider bias, access barriers and social drivers of health.”**

Additional physician education programs are needed to increase awareness of provider bias, access barriers and social determinants of health.



HEALTH CARE SYSTEM IMPROVEMENTS

Better alignment and stronger incentives to address barriers are also important. Health advocates should be integrated into health care systems to help patients navigate insurance coverage, and policymakers should continue to provide funding for such resources. Health insurance companies should create reimbursement structures that allow providers to dedicate more time to office visits, especially for patients with complex health care needs.



COMMUNITY CONNECTIONS & CULTURAL COMPETENCY

Partnerships with community organizations also play a role. Community organizations can help facilitate outreach so that people living with chronic kidney disease have access to culturally competent educational materials that address how to choose insurance, self-advocate and deal with insurance barriers.

“We need to build systems that meet the patient where they are,” says Gillian Hooker, PhD.



The Food and Drug Administration Approval Process

Bureaucratic shortcomings can sometimes worsen the challenges that chronic kidney disease patients face. The U.S. Food and Drug Administration, for example, has been slow to approve some treatments for chronic kidney disease. Advocates see a number of ways that the FDA could improve its process and increase timely access to optimal treatment.

CHALLENGES

While the FDA is well known for its efficiency in approving groundbreaking medications for cancer, heart conditions and other health issues, the same cannot be said for kidney disease treatments. More medications for chronic kidney disease have been rejected than approved in recent years, and processes often seem inconsistent.¹⁰

“It’s very clear that renal has a much higher bar than other products in getting them over the line and approved,” explains Jennifer Robinson of Spherix Global Insights.

“The FDA is reluctant to approve [kidney disease] therapies and is completely out of alignment with other initiatives to accelerate therapies,” says Jay Wish, MD, of the Indiana University School of Medicine. **“The lack of innovation will continue to place a strain on the nation’s health care.”**

One clear problem is the lack of nephrology expertise at the FDA, creating a dearth of real-world understanding about barriers that impact people with chronic kidney disease. The FDA’s Cardiovascular and Renal Drugs Advisory Committee has 11 voting members, but only four are nephrologists. The majority are cardiologists.

SOLUTIONS



MORE NEPHROLOGY EXPERTISE

To better serve the needs of millions of kidney disease patients, the FDA should ensure there is a balance of nephrology and cardiovascular expertise on the Cardiovascular and Renal Drugs Advisory Committee. Alternatively, the agency could consider creating a separate advisory committee dedicated specifically to nephrology. The agency could also benefit from having a kidney disease patient advocate as a permanent member of the Cardiovascular and Renal Drugs Advisory Committee.

Changes like these will ensure that, when the FDA reviews an application for a kidney disease medication, the required expertise is available.



OPPORTUNITIES FOR CLINICIAN & PATIENT INPUT

Clinicians and patients across the board need more avenues to provide input. Clinicians need more ways to engage with the FDA, and people living with chronic kidney disease need more opportunities to share their experiences and insights. Kidney organizations should also provide educational opportunities and ways for people living with chronic kidney disease and advocates to share their stories.

“Advocates should get educated and get involved in FDA regulatory policy,” says Sara Froelich of Akebia Therapeutics.



A blue-tinted background image showing a medical prescription form with fields for 'Patient Information', 'Patient name', and 'Patient address'. A large 'RX' symbol is visible. A stethoscope is also present in the upper left corner.

Coverage Issues

The Center for Medicare and Medicaid Innovation (CMMI), established by the Affordable Care Act in 2010, looks for ways to reduce costs while preserving high-quality care for Medicare and Medicaid patients. Some CMMI payment models have focused on issues and incentives related to payments for kidney disease care.

Another key challenge with payment incentives and insurance design is the lack of financial incentives for commercial insurance to prioritize early treatment of kidney disease. Because Medicare covers most people who are on dialysis regardless of age, the current commercial insurance system does not encourage upstream care and early interventions.

“If we catch people early enough, we can delay or stop the treatment of kidney disease,” says former Secretary of Health and Human Services Alex Azar. “We need primary care and regular kidney disease screening.”

CHALLENGES

One CMMI model, introduced in 2015, worked to reduce unnecessary health care services and improve dialysis care. It also invested in home dialysis infrastructure.

A second model, launched in 2022, focuses more on patients holistically, before they reach end-stage renal disease. It creates financial incentives to provide the right care at the right time. But these models are growing more complex, putting patients and providers at a disadvantage as they try to navigate, for example, the program’s benchmarking techniques.

Meanwhile, coverage issues with private payers persist. Because most patients automatically qualify for Medicare when they are on dialysis, there are few incentives for private insurers to encourage testing or cover innovative treatments for earlier-stage kidney disease.

Additional coverage challenges stem from the FDA approval process. For example, some chronic kidney disease drugs are first denied before they are approved by FDA. Even after approval, the initial denial can dampen patient and provider uptake and confidence in the medications.

“Health plans can use initial denials to justify delaying or limiting reimbursement,” says Jennifer Robinson of Spherix Global Insights.

Prior authorization in particular puts an administrative burden on physicians and causes excessive delays for people living with chronic kidney disease. “It’s the prior approval,” says Robert E. Blaser of the Renal Physicians Association. “If you’re a doctor, you have to spend two hours on the phone with the insurance company.”

High cost sharing can also significantly limit patient access, as can step therapy, a process that forces people living with chronic kidney disease to try insurer-preferred medications before accessing their actual prescribed medication. Sodium-glucose cotransporter-2, or SGLT2 inhibitors, are a prime example of an effective class of drugs for chronic kidney disease that many patients cannot access in a timely manner.

SOLUTIONS



MODELS THAT ADDRESS GAPS IN KIDNEY CARE

Any new models from CMMI should address persistent gaps in kidney disease care. That includes encouraging participation in programs that incentivize early-stage detection and care — and supporting new payment models among private payers.

“We need to promote the health of the kidney and understand cost savings and where they occur,” says Christopher Passero, MD, of the University of Pittsburgh Medical Center.

CMMI may embark upon new specialty care models later this year, which could offer stakeholders opportunities to weigh in on innovative approaches to kidney care.



NOVEL & VALUE-BASED PAYMENT APPROACHES

Innovative approaches, such as value-based payment models, are becoming more prominent. These models pay health care providers based upon the quality of care they provide. Value-based payment models among private insurers need better support so that insurers can prioritize preventive care and improved health outcomes. Incentives should align to encourage better coverage for early-stage treatment. Policymakers may do well to explore payment models that pay for value and result in better health outcomes.



UTILIZATION MANAGEMENT REFORM

Policymakers should also prioritize reforms to health plan utilization management. Tactics such as prior authorization and step therapy can delay or obstruct patients’ ability to receive timely treatment. People living with chronic kidney disease should not have to go through multiple and time-consuming hurdles to get the treatments they need. To protect both their quality and quantity of life, chronic kidney disease patients need timely access to the medications their health care providers prescribe.





Conclusion

With more new treatments available than ever before, health care providers have better ways to identify kidney disease and — most importantly — provide earlier treatment and work toward better outcomes.

To continue elevating awareness, encouraging prevention and early-stage detection and treatment, and ensuring patients' access to treatment, advocates and policymakers must focus on:

- **Making screening and testing more widely available** through clear guidelines
- **Educating both health care providers and patients** about kidney disease and treatment options
- **Pursuing improvements** in the FDA review and approval process
- **Advocating for comprehensive coverage** and value-based payment models for commercial insurers
- **Identifying opportunities for advocates and policymakers** to weigh in on policies that impact chronic kidney disease care

With resolute policymaking and continued advocacy, the American Kidney Fund and fellow stakeholders can shape a brighter future for people living with chronic kidney disease.

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About the American Kidney Fund Patient Access Initiative Summit

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