

Addressing the Unknown Causes of Kidney Disease



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EXECUTIVE SUMMARY

A variety of health and environmental conditions can lead to kidney disease and, in some cases, kidney failure. Identifying the root cause of patients' kidney disease, both early in the disease and as a life-preserving necessity, is important for making crucial treatment decisions. However, this process can be difficult. Studies suggest the cause of kidney failure is unknown for between 5 and 20 percent of patients.^{1,2,3}

A growing body of research suggests that a subset of these unknown designations may actually be attributable to genetic conditions. One recent study performed at Columbia University Vagelos College of Physicians and Surgeons found that one in ten cases of chronic kidney disease in adults was due to a genetic cause.⁴ Other recent studies have shown that 20 percent of cases of kidney disease of unknown etiology can be attributed to Mendelian etiologies.⁵ These findings suggest that a sizable portion of the undiagnosed causes of kidney disease could be identified through genetic screening and testing.

A timely diagnosis can reduce stress and provide an opportunity for patients to seek more information from providers and involve their broader support system. It can also assist patients and their providers in seeking earlier interventions to mitigate or slow the progression of their disease and to develop appropriate treatment plans tailored to the specific needs of the patient. In addition, a diagnosis allows providers to inform patients of any genetic based susceptibility for family members. To better treat patients and increase the proportion of cases that are accurately diagnosed, increasing access to genetic screening, biopsies, imaging, and other diagnostics as part of an accurate diagnosis is essential. Moreover, genetic testing provides an opportunity to identify patients who may be appropriate candidates for participating in a clinical trial. Providers will need to determine the appropriate options on a case-by-case basis with their patients based on cost, patient hesitancy, and other factors, particularly since chronic kidney disease (CKD) is often multi-factorial, which can significantly affect the disease phenotype.

As a champion of people living with kidney disease, the American Kidney Fund (AKF) has long been engaged with stakeholders across the healthcare sector. AKF has used that engagement to identify both the barriers that this patient population faces in seeking a diagnosis and the challenges that not having a clear diagnosis cause in patients' lives.

AKF held the Unknown Causes of Kidney Disease Summit in December 2020, which convened a diverse consortium of leading authorities in renal care, people living with kidney disease, and caregivers. Attending professionals included researchers, nephrologists, nurses, patient advocacy organizations, and government officials. The Summit's primary goal was to reach alignment on the policies and practices that facilitate identification of the cause for a patient diagnosed with kidney disease. Many people are unaware that they have kidney disease, even if it is advanced. Therefore, a secondary goal was to identify opportunities to raise awareness about CKD among patients and providers and develop actionable next steps for education and advocacy.

Summit participants highlighted three areas that are particularly problematic in obtaining a timely diagnosis and effective treatment: 1) a lack of standardized genetic testing guidelines in CKD diagnosis; 2) inadequate patient access to the full range of diagnostics and specifically to genetic testing and screening; and 3) insufficient education of providers and patients on the range of diagnostic tools (kidney biopsy, imaging tests, etc.) and methods. In particular, participants called for further diagnostic training for primary care providers (PCPs) to facilitate more timely referrals and greater use of testing by specialists to uncover the cause of kidney disease when unknown. In addition to incorporation of the genetic tests in diagnostic assessments in cases where the causes of kidney disease are unknown, empowering patients to communicate effectively with their providers can help ensure that patients receive the information and diagnosis they need to make informed decisions about their care.

As a leader in education, research, financial assistance and advocacy for individuals living with kidney disease, AKF is well-positioned to spearhead the necessary efforts to effect systemic change and increase the likelihood that more patients will learn the true origin of their kidney disease. However, support, collaboration, and commitment from the broader kidney community will be necessary to drive the level of change needed to transform the landscape in a comprehensive, coordinated way.

After refining the key takeaways from the Summit, AKF developed the Roadmap to present a path forward for improving the diagnosis of the causes of kidney disease and kidney failure. The Roadmap identifies four focus

areas, describes the associated challenges, and provides strategies for addressing those challenges.

While some strategies can be implemented relatively quickly, many can only be achieved through substantial

research, a significant investment of resources, and consistent collaboration among stakeholders. By following this Roadmap, AKF and the broader kidney community can together promote systemic change in the diagnosis and treatment of kidney disease.

ROADMAP FOR ADDRESSING THE UNKNOWN CAUSES OF KIDNEY DISEASE

FOCUS AREA	THE CHALLENGE	THE ROAD AHEAD
IMPROVING ACCESS TO GENETIC TESTING FOR PEOPLE WITH KIDNEY DISEASE TO INCREASE THE NUMBER OF CLEAR DIAGNOSES	Genetic testing for kidney disease is not widely covered in public and private healthcare.	More widespread and equitable coverage of genetic testing and counseling will provide answers to patients seeking to understand the cause of their kidney disease.
DEVELOPING NATIONAL STANDARDS RELATED TO GENETIC TESTING THROUGH A CONSENSUS-DRIVEN PROCESS LEVERAGING BEST PRACTICES	There is a lack of standards, best practices, and uniform data collection for genetic testing in kidney disease. Additionally, available information is not well disseminated among stakeholders.	Establishing cohesive guidelines for genetic screening and testing within kidney disease care will help ensure that high quality care is consistently provided to all patients, regardless of where they live or seek treatment.
EXPANDING PROVIDER EDUCATION AND REALIGNING FINANCIAL INCENTIVES TO PRIORITIZE DEFINITIVE DIAGNOSIS OF THE CAUSE OF KIDNEY DISEASE	Limited provider knowledge on the availability and benefit of genetic testing can restrict patients' ability to receive a diagnosis for their kidney disease. Additionally, providers are not consistently incentivized to prioritize diagnosing the unknown causes of kidney disease.	Creating and disseminating educational materials for providers, such as further diagnostic training for PCPs and nephrologists, can raise awareness of the role genetic testing plays in arriving at an accurate diagnosis. Educational materials can provide guidance on patient-provider communication best practices. Further, realigning provider incentives, such as incorporating greater use of testing by specialists , to diagnose unknown causes of kidney disease can drive systemic change in kidney care and improve treatment upon diagnosis.
EDUCATING PATIENTS ABOUT KIDNEY DISEASE AND TESTING IN AN EFFECTIVE, CULTURALLY COMPETENT MANNER	Often, patients and caregivers are left confused and frustrated when confronting a complex healthcare system and medical condition. For minority patients, who disproportionately develop kidney disease, targeted outreach is necessary to educate them on the options available for reaching an accurate diagnosis and to reduce disparities. In fact, many patients remain fearful that genetic testing results may impact life, disability or long term care insurance, because they may then be identified as a person who has a pre-existing condition. Additional concerns may exist regarding genetic data being maintained as personal health information (PHI) or collected in other databases. All of these factors can impede the overall acceptance of genetic testing by patients and their families.	Developing accessible resources and support systems for all patients, especially those from communities of color, will arm them and their caregivers with the right information to seek and fully understand a kidney disease diagnosis as well as improve patient-provider communication.

OPTIMAL TREATMENT OF KIDNEY DISEASE IS DETERMINED BY ITS ROOT CAUSE

According to the United States Renal Data System (USRDS) 2021 Annual Report, 15 percent of US adults are living with CKD.⁶ However, symptoms often do not present until kidney disease has advanced. Tests for kidney function (i.e., albumin-creatinine-ratio (ACR) testing and calculation of estimated glomerular filtration rate (eGFR)) are not routinely ordered for patients, even for those who may be high-risk, such as diabetic patients.⁷ As a result, many individuals in the earlier stages of kidney disease (i.e., stages 1-3) may be unaware of their condition. What is perhaps more disturbing, is that nearly 38 percent of stage 4 patients, who are experiencing a severe decline in kidney function, may not know they have CKD.⁸ Genetic testing and screening at the appropriate stage for patients who do not have a clear diagnosis is one option for improving patient awareness. In particular, PCPs need to understand the importance of early referral to a nephrologist so that they can determine whether a genetic test should occur before or during a kidney biopsy. Further, providers should be better trained on the range of tools available, including renal biopsy or imaging (ultrasound, CT, MRI), to reach a clear diagnosis and patients should be educated on those choices.

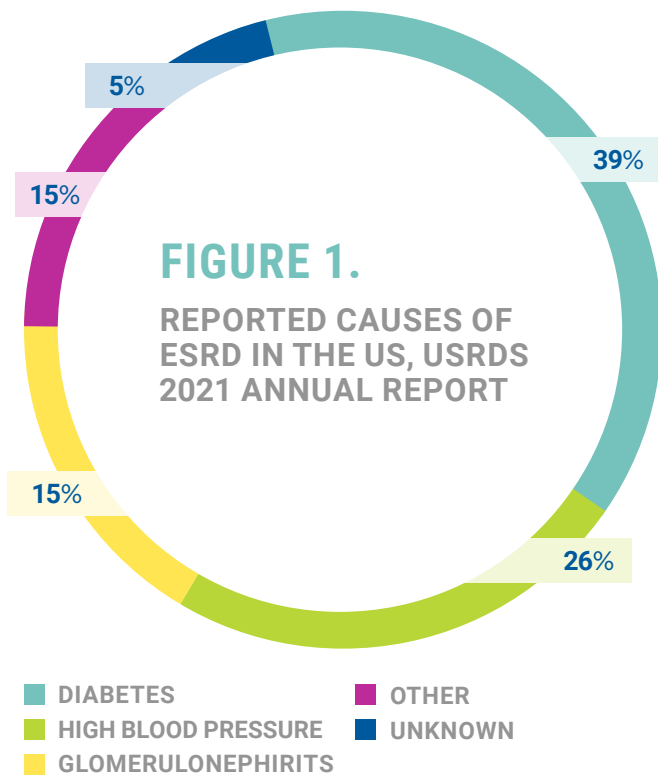
“From the patient side of things, it’s frustrating not knowing why you’re having all these problems and then, all of sudden, you end up in the ER and they’re telling you that you have no kidney function. It’s so much to deal with all at once. When you don’t have a reason why, it’s even harder.”

**Theresa,
Transplant patient**



While genetic testing, biopsies, imaging tests, and other diagnostics for a possible rare disease should optimally occur earlier on in the disease stage to inform treatment and interventions, performing these tests in later stages of the disease can still provide helpful information. In some instances in the later stages of kidney disease, nephrologists may take a biopsy and the results will prove to be inconclusive. In this instance, genetic testing can inform the patient’s care. Additionally, newer studies have shown that genetic testing may be beneficial as a first mode of diagnostic for patients under the age of 50 who are at risk of developing end stage renal disease (ESRD).⁹

Aside from more commonly linked conditions, such as diabetes and high blood pressure, kidney disease can also be caused by a variety of other conditions, including glomerulonephritis, rare diseases, autoimmune disorders (e.g., lupus nephritis), cancer, or genetic abnormalities (e.g., polycystic kidney disease, Fabry disease). Even for those with more commonly associated causes, Summit participants felt the primary causes were sometimes misdiagnosed. For example, participants cited their belief that some patients who present to an emergency department with both advanced kidney disease and high blood pressure have hypertension falsely attributed as the primary cause. An accurate diagnosis of the cause of kidney disease is important since it can influence the presentation and progression of symptoms and is compounded by family history, lifestyle, and comorbidities. Of the patients followed



in the USRDS study from 2000 to 2018, by the end of 2018, a significant percentage had reached advanced stages of the disease with nearly 71 percent undergoing dialysis and nearly 30 percent receiving a kidney transplant.¹⁰

As stated above, studies diverge on the percentage of patients' kidney failure that is of unknown cause. A 2021 fact sheet from The Centers for Disease Control and Prevention (CDC) referenced data from the USRDS report showing the cause for ESRD as unknown for five percent of patients (Figure 1).^{11,12} A much higher percentage (14 percent) of individuals receiving financial support from AKF self-reported they did not know the primary cause of their kidney failure.¹³ In part, the higher percentage may be attributed to the method of data collection. The data was

either self-reported by the patient or entered manually by a member of their care team, rather than pulled from electronic health records. But it also reflects the need for greater provider-patient communication, particularly for higher risk individuals. Obtaining a diagnosis of the root cause of kidney disease or kidney failure can help providers, researchers, and life science companies identify—and ultimately treat—a wider array of conditions that lead to kidney disease. This knowledge may also improve population health by identifying a subset of patients at high risk for developing kidney disease based on medical or family history or environmental factors that can allow for earlier prevention or treatment efforts, and ultimately reduce the high cost of CKD and ESRD borne by the healthcare system.

FIGURE 2.

LIKELIHOOD OF BLACK, HISPANIC, AND NATIVE AMERICANS DEVELOPING KIDNEY FAILURE COMPARED TO WHITE AMERICANS¹⁷

4X

Black Americans

1.3X

Hispanics

1.2X

American Indian /
Alaska Natives



KIDNEY FAILURE DISPROPORTIONATELY AFFECTS PEOPLE OF COLOR

While the overall prevalence of CKD in the US has remained relatively constant for the last five to six years, the disparate incidence of kidney disease in minority populations continues to increase.¹⁴ Both in and outside of the US, underserved populations have a higher burden of kidney disease and a small subset may be more genetically predisposed due to *APOL1* or other factors.¹⁵ Black, Hispanic, and Native Americans are all more likely to develop kidney failure in their lifetime than individuals not in these groups.

The stark disparities of the health-related outcomes of kidney disease (Figure 2) are in part due to the lack of access to quality healthcare, implicit and explicit biases when interacting with medical professionals, environmental contaminants, inconsistent access to transportation and paid sick leave, housing stability, and other stressors that these individuals may encounter on a daily basis.¹⁶ These factors exacerbate poor kidney health and are not necessarily treated through a doctor's visit. Difficulties accessing care, especially the tests and referrals to genetic counselors and nephrologists, may be intensified for these populations.

To help mitigate the effects of kidney disease and avoid kidney failure, early detection of the disease is critical. Early intervention is not frequent enough, and as a result, many are not diagnosed or do not seek care until renal replacement therapy (dialysis or transplant) is necessary to survive. Even at this point, many patients are still unaware of why their kidneys failed. If diagnoses can be reached earlier on or at all, then targeted treatment and preventive strategies can help patients achieve better health outcomes and ultimately allow them to live fuller, higher quality lives.

TARGETED GENETIC TESTING MAY PROVIDE ANSWERS FOR A SUBSET OF PATIENTS

Researchers are exploring the unknown causes of kidney disease and the associated burden of delayed treatment. A study on the global disease burden of CKD found that kidney disease of unknown causes resulted in a higher number of years of life lost by age group to illness,¹⁸ likely influenced by the lack of early intervention in this population. Investigating unknown causes of CKD through genetics research is revealing the complexity and importance of genome sequencing. A 2019 study, the “Diagnostic Utility of Exome Sequencing for Kidney Disease” led by Dr. Ali Gharavi focused on a cohort of individuals with CKD of various causes who went through exome sequencing, or genetic screening of the coding portion of genes. As a result of that sequencing, a diagnostic variant was found in 9.3 percent of patients.¹⁹



PROVIDER SPOTLIGHT

DR. ALI GHARAVI

Dr. Gharavi is the chief of the division of nephrology at New York-Presbyterian/Columbia University Medical Center. He leads research specializing in the genetic causes of kidney disorders, believing that timely referrals, better data and genetic testing can help patients and clinicians get to the exact causes of kidney failure.

“Diagnosing the precise cause of kidney disease early on can reduce progression to renal failure and damage to other organs, help people prepare for the next step, [kidney transplant] and mitigate kidney transplant complications. Additionally, genetics can help identify family members who may be at risk and screen living related relatives that may want to donate kidneys.”



PATIENT SPOTLIGHT

SHAYLA

Shayla, a former Division I athlete and seemingly healthy young adult was referred to a nephrologist after severely swollen feet led her doctor to conduct bloodwork. After additional testing, the nephrologist told Shayla that she would need a kidney transplant or dialysis to survive. Shayla was incredibly fortunate to receive a transplant from her twin sister, Ivy, 10 years ago. Now married and the mother of two young boys, Shayla is participating in research led by Dr. Martin Pollak, investigating genetic markers of kidney disease. She hopes to discover whether her kidney failure has genetic origins so that her sons can live healthier lives.

For 34 percent of the cases reviewed in this study cohort, the genetic findings reclassified the disease or provided a cause for undiagnosed nephropathy.²⁰

Discovering the root cause of an individual’s kidney disease can provide clinical insight for the provider and have life-saving implications for the individual. The genetic cause of kidney disease can dictate the type of treatment a patient receives (e.g., steroid avoidance, referral to a new clinical trial), raise awareness for family members who may be at risk, and inform healthy individuals’ decisions to donate kidneys.

Genetic testing for patients when the cause is unknown can not only help at the individual level, but also provides significant insight into the disease burden and treatment options at the population health level. For example, the discoveries made by Dr. Martin Pollak and his colleagues revealed that the two genetic variants in the *APOL1* gene, found mostly in individuals of West African descent, can individually protect against African sleeping sickness but can also increase risk for focal segmental glomerulosclerosis (FSGS) and non-diabetic

kidney disease in those who have inherited two risk variants.²¹ Genetic predisposition in groups such as Black Americans, that have a variation in the *APOL1*, explains a significant fraction of non-diabetic kidney disease disparity in this group.²²

Research has identified more than 600 genetic diseases that can directly or indirectly affect the healthy functioning of the kidneys.²³ Although classified as rare among the general population, at least ten percent of adults and almost all children who receive renal replacement therapy have an inherited kidney disease, such as Fabry disease.²⁴ Genetic

testing can be quite complex including considerations within a suspected rare disease with variations based on the sex of the patient.

Beyond explaining the origins of kidney disease, knowing a patient's kidney disease proclivity can benefit their family members and relatives. Additional insight into genetic predispositions and disease raises awareness, encourages lifestyle choices that promote kidney health, and presents an educational opportunity to refer patients and family members to additional resources, including clinical trials.

AKF'S ROADMAP FOR ADVANCING KIDNEY CARE SOLUTIONS

At its Unknown Causes of Kidney Disease Summit in December 2020, AKF gathered a diverse set of stakeholders to identify, discuss, and prioritize specific solutions that will facilitate identification of the cause for a patient diagnosed with kidney disease (see Appendix A for a list of Summit participants). These experts reviewed and

discussed gaps in existing data and research, identified barriers to progress, and developed potential next steps. The strategies described in greater detail below present a Roadmap for the kidney care community to address the barriers currently preventing many patients and providers from identifying the root causes of kidney disease:

1. **Improving Access to Genetic Testing for Patients with Kidney Disease to Increase the Number of Clear Diagnoses**
2. **Developing National Standards Related to Genetic Testing Through a Consensus-Driven Process Leveraging Best Practices**
3. **Expanding Provider Education & Realigning Financial Incentives to Prioritize Definitive Diagnosis of the Cause of Kidney Disease**
4. **Educating Patients About Kidney Disease & Testing in an Effective, Culturally Competent Manner**

While some reforms can be implemented relatively quickly, many will require substantial research, significant investment of resources, and consistent collaboration between stakeholders to achieve. By following this Roadmap, AKF and the broader kidney health-community

can together promote meaningful, systemic change to ensure that patients with kidney disease get the diagnosis they need and the care they deserve.

1. IMPROVING ACCESS TO GENETIC TESTING FOR PATIENTS WITH KIDNEY DISEASE TO INCREASE THE NUMBER OF CLEAR DIAGNOSES

Stakeholders should identify opportunities at the state and federal level to promote policies that increase access to genetic testing and genetic counseling services while also protecting patients' privacy.

THE CHALLENGE

While genetic testing is often covered in the commercial insurance market, payers may struggle to keep pace with rapidly advancing genetic testing technology. In addition, there are unique patient access hurdles in federal healthcare programs, which may have a disproportionate impact on people of color. As a result, patients seeking to identify the cause of their kidney disease or failure may not be able to access the genetic tests that could provide needed answers.

Research shows that genetic testing can be a crucial tool for genetic diagnosis of a patient's kidney disease, developing a targeted treatment plan, and ensuring that the appropriate steps are taken to prevent kidney failure (Figure 3).²⁵ Further, genetic testing can inform family members of their potential risk, can help in the selection of living related donors, and can be integrated with family and reproductive counseling. Support from a genetic counselor is essential to help patients and providers interpret test results and understand the implications for a patient and their family members.

However, access to the genetic tests that could assist with a clear diagnosis for the cause of kidney disease—and to the counselors who can provide necessary expertise and guidance—is not widely available to all those who may need it. Although coverage of genetic tests varies by payer, typically a test will be covered by private insurance if recommended by their provider. However, Summit participants noted that coverage of genetic tests among private insurers is not always consistent even if recommended by the patient's provider. For example, insurers may not cover the test and/or charge high out-of-pocket costs (copays, coinsurance, or even the full cost of a service) for the genetic counseling necessary to interpret results and inform treatment plans. In addition, providers can experience administrative barriers working with insurance companies such as the completion of complex prior authorization forms.

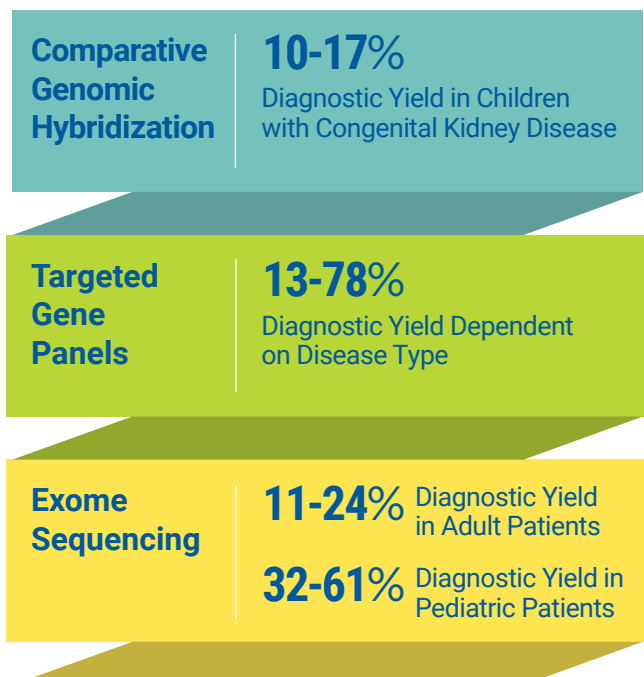
FIGURE 3.

BENEFITS OF GENETIC TESTING

Genetic testing can provide a range of benefits, including:

- 1 Obtaining a precise diagnosis
- 2 Improving decision-making about available therapies
- 3 Screening at-risk family members
- 4 Facilitating selection of living related donors
- 5 Informing family/reproductive counseling

DIAGNOSIS SUCCESS RATES OF GENETIC TESTS²⁶



Coverage challenges are even more pronounced for patients receiving their health insurance coverage through federal programs. Medicare and Medicaid, which insure approximately 140 million Americans combined,²⁷ do not have statutory requirements to cover genetic testing and in Medicaid coverage is often dependent on a patient's geographic location.

Medicare does not cover genetic screening services, under which genetic testing and counseling fall, unless expressly authorized by law. The Centers for Medicare & Medicaid Services (CMS) implements the statute through regulation, sub-regulatory guidance, and coverage determinations. The coverage of screening and testing of a specific service is dependent on whether CMS deems it “reasonable and necessary for the diagnosis or treatment of an illness or injury.”²⁸ If strong evidence shows that a test has clinical effectiveness, then CMS can determine whether it will cover a service at the local or national level.

- CMS can make local coverage determinations (LCDs), which make a test and service available in a specific geographic area, or CMS can make national coverage determinations (NCDs), which make a test or service available to all beneficiaries.²⁹ For example, prior to 2010, genetic testing and screening for breast cancer was covered at the local level, but not available to all beneficiaries. In the past few years, CMS has approved NCDs for genetic testing of other types of cancer³⁰ but has not approved coverage for kidney-related genetic testing.
- Given Medicare’s statutory obligation to cover patients with ESRD, coverage of genetic testing would not only improve treatment plan efficacy but could potentially reduce program spending. One percent of Medicare beneficiaries have kidney failure, but they account for seven percent of total Medicare costs.³¹ Beyond the traditional over-65 population, patients under 65 can become eligible for Medicare after they reach kidney failure, an additional reason for policymakers to reassess coverage for genetic screening services in the Medicare program.

Under **Medicaid**, genetic testing is an optional benefit and coverage and access vary substantially by state. Typically, Medicaid covers genetic screening and testing for infants.³² In Well-Child visits, which are part of Medicaid’s Early, Periodic, Screening, Treatment, and Diagnostic (EPSDT) services, a blood test is administered to newborns to screen for genetic abnormalities with a specialist referral if necessary.^{33,34} For other types of genetic testing and screening, coverage and access vary by state, and state Medicaid programs issue their own genetic coverage guidelines. However, due to budget constraints, states do not consistently release guidelines.

The limitations of coverage in public programs, and Medicaid in particular, falls disproportionately on people of color.³⁵ In 2019, only 53.7 percent of Black adults and 48.8 percent of Hispanic adults between the ages of 18-64 had private health insurance coverage, compared to 77.5 percent of Asian adults and 74.5 percent of white adults. Approximately 34 percent of Black adults and 23 percent of Hispanic adults rely on public coverage.³⁶



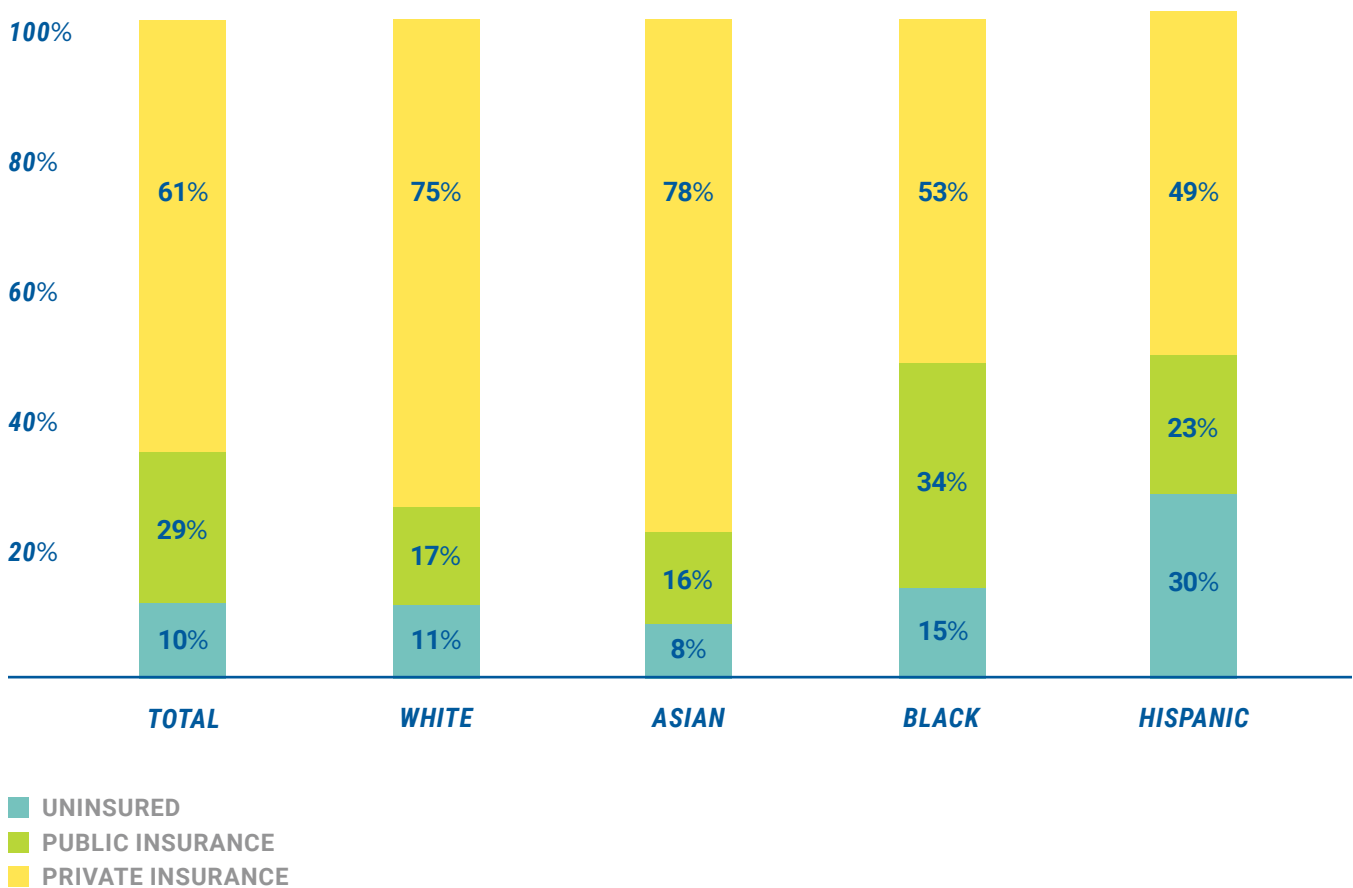
SUCCESSES IN GENETIC SCREENING: LESSONS LEARNED FROM BREAST CANCER

The health and economic benefits of developing genetic testing and screening standards are well documented. In 2010, the Affordable Care Act (ACA) required that insurers cover an assessment of family history that could make a patient predisposed to breast cancer. If family history indicates a high-risk case, then insurance must cover the full cost of genetic counseling and genetic testing. The Health Resources and Services Administration’s (HRSA) Women’s Preventive Services Initiative supports and gathers information contributed by providers, researchers, and health-focused organizations to consistently update preventive guidelines related to genetic testing and screening for breast cancer, among other conditions.³⁷ Breast cancer screenings every two years have led to several positive outcomes: a 26 percent reduction in breast cancer deaths per 1,000 women screened, increase in 5-year survival rates, and reductions in costs through early-stage interventions and treatment.³⁸

Black and Hispanic people also are more likely to be uninsured than white or Asian people, exacerbating access issues and contributing to disparities in health outcomes for these populations.^{39,40} Ensuring that people have equitable access to adequate and affordable health

insurance is critical to mitigating the health disparities that exist in the current healthcare system. In addition, the scope of coverage must meet the needs of the patient community and should not be dependent on the source of coverage, whether private or public.

FIGURE 4.
DISTRIBUTION OF INSURANCE COVERAGE BY RACE,
2019 CDC NATIONAL HEALTH INTERVIEW SURVEY⁴¹



THE ROAD AHEAD

Advocate for widespread and equitable coverage of genetic testing and counseling.

Summit participants agreed that the rapidly evolving fields of genetic testing and counseling have made it challenging for federal and state policymakers and private payers to keep pace. AKF is committed to collaborating with policymakers and other stakeholders to advance broader reforms but recognizes the importance of building consensus around the gaps and limitations of current laws and regulations, an important goal of the Summit. Key themes to promote patient access to genetic testing and counseling include:

1. **Evaluating the State Genetic Testing and Counseling Coverage Landscape to Identify Current Policies that Limit Access:** Before pursuing policy changes, stakeholders should establish a comprehensive understanding of the current policies in the states, DC, and the territories that inhibit access to genetic tests and counseling. In particular, understanding the variance in policies across states is critical (e.g., state Medicaid program regulations, lack of licensing for genetic counselors, differences in the tests currently covered, etc.). Initially stakeholders should conduct a landscape analysis to identify policy and procedural hurdles, barriers to utilization, and gaps in patient or caregiver awareness.

One such example of a barrier is hesitancy by some individuals to seek services due to fear of discrimination by their health or life insurer or employer. Although the Genetic Information Nondiscrimination Act of 2008 (GINA) protects against genetic discrimination in health insurance and employment broadly, there are exceptions that could leave patients vulnerable.⁴² While GINA does address health insurance and employment, patients may be concerned that this data can be used to adversely impact access to disability and life insurance policies, or could be accessed through other databases. Using such resources as the National Institutes of Health's Genome Statute and Legislation Database,⁴³ state laws and individual

insurance policies, or lack thereof, can be evaluated to understand the coverage of genetic tests, licensure of genetic counselors, protections against discrimination, and safeguards of patients' privacy. This database does not include state regulations so it would require supplementation by other resources to ensure a comprehensive review of laws and regulations.

2. **Convening Stakeholders to Define and Pursue Advocacy Priorities for Increasing Coverage of Genetic Testing and Counseling:** Following the analysis, states should be prioritized for legislative advocacy and a mechanism developed to share state best practices for increasing genetic testing access where appropriate among stakeholders. In addition to assessing gaps and best practices at the state level, it will be crucial to identify opportunities for the federal government to implement changes to reduce disparities between states. Using a framework similar to the ACA's mandate requiring genetic screening and counselors for women at high risk for breast cancer, the research described above can serve as a guideline for presenting a collective voice to state legislatures, CMS, and other policymakers in support of coverage for genetic services.
3. **Providing Support to Underinsured and Uninsured Patients:** While reforming genetic testing and coverage policies is an important goal, patients who need immediate genetic testing and counseling services cannot wait for policy changes to take effect. AKF suggests that stakeholders consider strategies for connecting patients with existing resources to assist with out-of-pocket costs, such as opportunities to receive free genetic testing for certain diseases. Ensuring that patients have adequate and affordable healthcare coverage through charitable premium assistance and access to public programs would also help with patient access.

THREE ASPECTS OF GENETIC CARE ARE KEY IN HELPING PATIENTS SEEK & UNDERSTAND THEIR DIAGNOSIS

SOME DISEASES, INCLUDING KIDNEY DISEASE, ARE CAUSED BY GENETIC ABNORMALITIES, WHICH CAN BE DETECTED THROUGH THE APPROPRIATE TEST

1

Genetic Evaluation

- To determine if a patient needs a genetic test, a provider must conduct a screening, or an evaluation, of the patient's family history, medical history, signs and symptoms, and lifestyle.
- Based on the results of the screening, the provider can recommend a genetic test to help determine the cause of the patient's symptoms.

2

Genetic Testing

- Once a genetic test is recommended and taken by a patient, the provider can reach a diagnosis, rule out certain conditions, and decide on the best course of treatment and next steps for the patient.
- In the event that the patient doesn't want to know the results, de-identified data can be used to contribute to the scientific body of kidney disease research.

3

Genetic Counseling

- To assist the patient with interpreting the results of a genetic test, genetic counselors are an integral step in this process.
- Genetic counselors can connect patients to appropriate resources, and discuss implications for family members.

GENETIC TESTING OPTIONS AND POTENTIAL BENEFITS AND LIMITATIONS

TEST OPTION	DESCRIPTION	BENEFITS	LIMITATIONS
SINGLE SITE	Testing one gene for a specific mutation	Simplified process to evaluate for presence/absence of a known mutation in a family. May have comparatively lower cost and/or faster turnaround time.	Does not identify other renal genetic conditions that could be present.
TARGETED PANEL	Testing a set of related genes on a single panel (e.g., glomerulopathies)	More information than single site, fewer genes tested than larger panels means fewer variants of unknown significance (VUS) results.	Many renal conditions have crossover between disease categories and a targeted panel may not include a broad enough spectrum of conditions. Unknown etiology of CKD has a high yield from genetic testing across different categories, so a targeted panel may not have enough disease coverage. If negative, provider may need to consider ordering another panel, delaying overall turn around time (TAT) and increasing costs.
BROAD PANEL	Comprehensive panel of renal-specific genes across disease categories	Provides more information than a targeted panel, ⁴⁵ less likelihood of missing a genetic diagnosis due to clinical misclassification. NGS technology typically does not confer much, if any, additional cost for larger panels compared to smaller panels, so may be more cost effective.	More VUS information (if reported) than smaller panels, but may still not have all relevant genes included.
WHOLE EXOME SEQUENCING (WES)	Broad sequencing of 20,000 protein-coding genes ⁴⁴	Broad analysis of all coding regions, including non-renal genes.	Increased cost and TAT compared to smaller panels, more VUS data, and heavier reliance on laboratory curation and reporting.
WHOLE GENOME SEQUENCING (WGS)	Complete sequencing of entire human genome	Creates catalogue of an individual's genome and may find additional information.	Largest cost and longest TAT. Most data not relevant for renal diseases, and coverage of disease genes overall is lower.

2. DEVELOPING NATIONAL STANDARDS RELATED TO GENETIC TESTING THROUGH A CONSENSUS-DRIVEN PROCESS LEVERAGING BEST PRACTICES

Stakeholders must collaboratively develop and disseminate genetic testing standards among patients to inform patient participation in treatment decisions.

THE CHALLENGE

Stakeholder consensus on best practices to inform clinical decision making on the use of genetic testing for patients with kidney disease is limited. Despite advances in genetic testing and an increase in access to genetic counselors and available technologies, up-to-date information regarding best practices is not well disseminated among providers, counselors, and patients. As a result, the quality of testing for patients with kidney disease or kidney failure seeking the root cause of their condition is highly variable. While genetic testing is beneficial for patients in increasing overall knowledge of their diagnosis, the information provided by this testing may or may not ultimately impact the patient's treatment plan.

Even in cases where genetic testing and counseling are covered by insurance, the circumstances under which such services should be prescribed may still be unclear to providers and patients. Experts from the Summit noted there are no uniform standards, guideline recommendations, or consensus statements guiding eligibility determinations for genetic tests and/or access to genetic counseling. Moreover, there are no clinical pathways that could aid providers in those determinations. The fields of genetics, genetic testing, and gene identification methodologies for specific diseases are all advancing rapidly,⁴⁶ creating a landscape that is challenging for providers and patients to easily navigate.

"I wish the doctor did more tests to determine the right diagnosis, and I wish I was connected with a specialist earlier on."

**Paul,
Fabry disease patient**



According to the NIH's National Human Genome Research Institute (NHGRI), fewer than 200 CPT codes—the codes used to distinguish which medical services were performed so a provider can receive payment—exist for over 70,000 types of genetic tests.⁴⁷ The minimal number of codes can make it difficult to bill for or to even determine which genetic tests were provided. Genetic counselors participating in the Summit reinforced this finding—genetic tests are swiftly evolving, leaving providers, patients, and payers without the tools to incorporate them into the healthcare system infrastructure. Throughout the Summit, participants agreed on the common barriers to the use of genetic tests by providers, payers and patients:

- **Complexity of the Genetic Landscape:** Genomic information and the development of genetic tests is a constantly evolving landscape. The sheer complexity and types of genetic tests available leave patients, providers, and payers confused about their application and utility.
- **Inconsistent Data Sharing:** A low prevalence of interoperability among EHRs can leave providers without adequate knowledge of a patient's medical history. A common data set associated with CKD screening and counseling that ensures consistent data capture across health records, systems, and networks may facilitate information sharing for kidney care patients that need care in multiple settings across several providers.
- **Lack of Reimbursement for Genetic Tests:** Even when patients are aware of or recommended for genetic screening, insurance may not cover it, especially in public programs, leaving patients vulnerable to out-of-pocket costs or foregoing a test altogether. The only other external avenue for the patient would be participating in a clinical trial.

Clear guidelines on which patient populations would benefit most from genetic testing are sorely needed. In addition to the racial and ethnic disparities discussed earlier in this report, it has been demonstrated that genetic testing among some pediatric populations is particularly beneficial. Testing of rare kidney diseases in pediatric populations is correlated with a high rate of successful diagnoses, leading to advances in genetic research for adults as well as children.⁴⁸ Without clear guidelines, Summit participants noted that referral to genetic testing can seem arbitrary and subject to the knowledge of individual providers.

Data sharing between providers and health systems adds a further layer of complexity in determining which patients are best served through expanded genetic testing as pertinent patient information can be obstructed by software, privacy issues, and general health information technology shortcomings. These issues must also be considered to ensure providers are making the best treatment decisions for and with their patients.

“Genetic testing is a new tool and its adoption will be facilitated by clear guidelines so clinicians can order the right test. There are a lot of tests out there and interpretation of testing results can be complicated. Providers need to feel comfortable with interpreting test results to take appropriate actions.”

Dr. Ali Gharavi



THE ROAD AHEAD

Elevate the need for, and adoption of, genetic testing through the creation of national standards and guidelines.

As demonstrated by the robust collaboration among the breast cancer advocacy community that resulted in eligible patients receiving earlier diagnoses, a set

of national standards can benefit not only patients and providers, but also others who may be directly or indirectly affected. Evidence-based guidelines will aid both insurers in standardizing genetic tests and counseling reimbursement policies and family members in assisting in testing and treatment decisions.

Stakeholders should advocate for national genetic testing and counseling standards for kidney disease—particularly in cases where the cause of kidney disease and kidney failure is unknown—and pursue change by:

1. **Collaborating in the Development of Genetic Testing Standards:** In the short-term, stakeholders should align on standards for determining which tests are most appropriate for patients based on medical, family history, or other relevant factors (e.g., identify when a broad panel screening is necessary and when to test for individual genetic variants). Best practice guidelines should be formulated for nephrologists based on the results of a genetic test (e.g., shared decision—meeting with the patient regarding treatment and/or next steps, need for follow up care, or referral to a different provider). To ensure these standards are comprehensive and accurate, this process should be iterative and include review and feedback. The group should also determine the most appropriate channels for disseminating this information to ensure it reaches the intended audiences. AKF believes interested stakeholders should collaborate with existing guideline and standards developers, both within nephrology (such as KDIGO) and outside nephrology (such as NIH). AKF is not seeking through this document to set independent guidelines.
2. **Developing Targeted Guidelines for the Most At-Risk Patient Populations:** In addition to achieving consensus on broader guidelines, stakeholders should identify standards and best practices for the most at-risk patient groups. Follow-up convenings focused on identifying subpopulations who may be at greatest risk of developing kidney disease (e.g., family history of CKD/ESRD) can lead to the development of a more targeted set of guidelines

3. EXPANDING PROVIDER EDUCATION & REALIGNING FINANCIAL INCENTIVES TO PRIORITIZE DEFINITIVE DIAGNOSIS OF THE CAUSE OF KIDNEY DISEASE

AKF, providers, and other stakeholders should develop resources and educational opportunities for providers to facilitate the delivery of informed, culturally competent care and to improve patient outcomes.

THE CHALLENGE

Providers' ability to improve patient care is hampered by limited coordination among the care team, insufficient education on the genetic causes of kidney disease, and provider-patient communication challenges. Moreover, current payment and quality programs offer little incentive for providers to diagnose the root cause of a patient's kidney disease. This could partially be addressed by expanding the CPT codes needed to cover the appropriate genetic testing of CKD patients.

AKF will seek to work with providers and other stakeholders to develop an educational campaign for providers on screening, diagnosing, and treatment best practices. This will facilitate greater coordination among providers, improve the process and timeliness for securing an accurate diagnosis of the patient's disease, and enhance provider-patient communication. The earlier the testing in the patient's life, the better. Many dietary, lifestyle and pharmaceutical interventions can be started prior to onset of overt symptoms and minimize the overall costs of managing kidney disease over the lifespan of the patient.

Participants in the Summit noted that many patients initially seek treatment through their PCP and breakdowns in communication and knowledge begin there leading to late referrals and poorer health outcomes for patients.⁴⁹ In particular, PCPs may not be adequately trained to interpret lab results that are indicative of kidney disease and may not understand when a referral to a nephrologist is warranted. Education campaigns tailored to helping PCPs recognize the early indicators of possible CKD in lab results would help mitigate delayed referrals. An example of an improved process flow is illustrated in Figure 5.

Compounding this issue is the lack of understanding among both PCPs and patients of CKD and the close association of more commonly understood comorbid conditions such as diabetes and hypertension.⁵⁰ A survey of PCPs' perceived barriers treating and discussing kidney disease with patients revealed six key problem areas:⁵¹

- **Perceived Lack of Understanding by Patients:** Providers believe that CKD is not well understood among patients, making treating the common symptoms (e.g., high blood pressure) a priority rather than discussing the ramifications of CKD.
- **Association with Comorbid Conditions:** Because of the strong relationship between diabetes and hypertension with CKD, PCPs do not always regard CKD as a distinct disease requiring separate treatment.
- **Gaps in Knowledge and/or Skills:** Generally, PCPs' knowledge of and/or associated skills in addressing kidney disease is limited and therefore inadequate when recognizing and diagnosing the disease. Gaps in knowledge also degrade effective communication with patients.
- **Fears of Overwhelming Patients:** Given the stress that can come with a CKD diagnosis, providers are hesitant to discuss kidney disease with patients and prefer to focus on more immediate tangible issues.
- **Time and Reimbursement Constraints for Patient Education:** The length of routine visits often puts CKD as a lower priority, excluding it from discussion. Taking additional time to educate patients may not be reimbursed in the current system disincentivizing providers.
- **Education Resource Availability:** Providers were unaware of both patient education resources and other available resources such as genetic counseling.

Of course, PCPs are not entirely responsible for the outcome of a patient's kidney care journey. Other providers, such as endocrinologists, cardiologists, emergency physicians, urologists, and nurses, interact with patients who may be presenting symptoms of kidney disease or are experiencing kidney failure—all of whom can contribute to a timelier referral to kidney care specialists and patient education. However, it is important to educate PCPs on the best type of nephrologist for referral. For example, early in the course of disease progression a nephrologist whose primary practice is dialysis may not be the best choice. For nephrologists, education should focus on when, why, and how patients should be tested.

However, nephrologists participating in the Summit noted that a passive approach is common among kidney care specialists diagnosing patients with late-stage kidney

disease. Because treatment at that juncture is focused on initiating dialysis or transplant, nephrologists often do not attempt to diagnose the root cause of the kidney failure, leaving patients and their families with an incomplete understanding of their disease. In addition, the transition of care among multiple providers and settings of care can leave patients confused and disoriented. For example, nephrologist communication between transplant centers, a critical step in the kidney care process, varies widely and is highly dependent on educational training (e.g., communication workshops) and information sharing policies.⁵² Fractured communication across the care continuum is problematic and additional provider incentives should be considered to prompt providers to diagnose the root cause of kidney disease or failure.



PROVIDER SPOTLIGHT

DR. JULIE WRIGHT NUNES

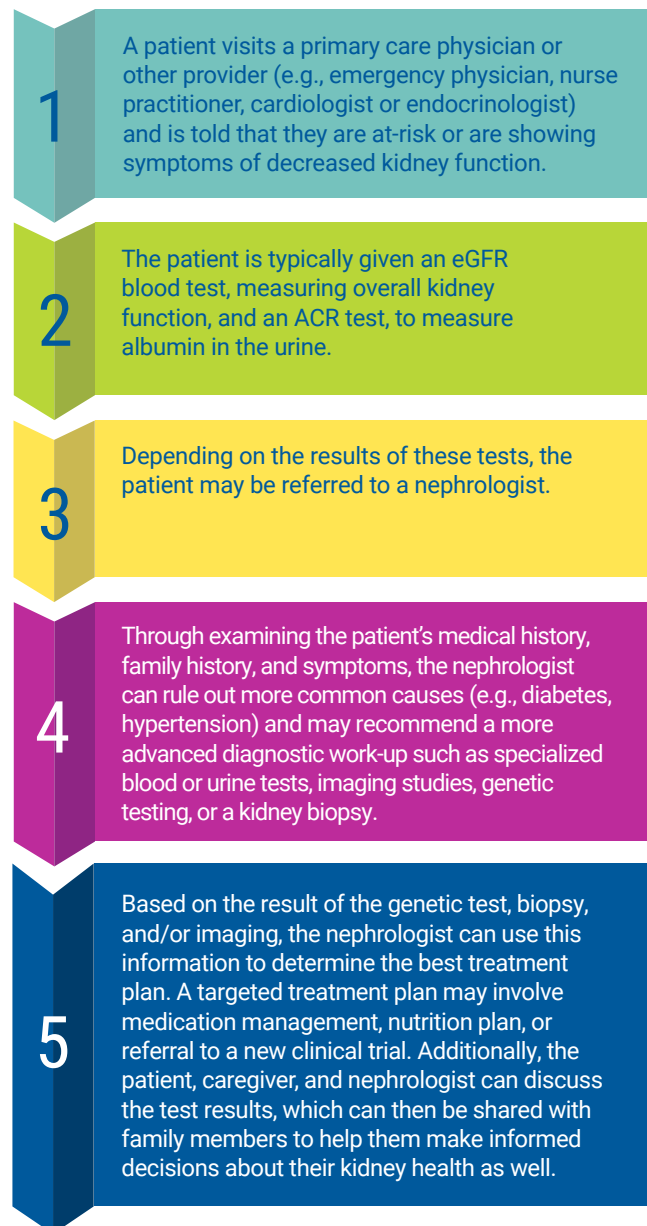
Dr. Wright-Nunes holds a faculty position in the University of Michigan's Internal Medicine's Division of Nephrology. Her work centers on prevention of chronic kidney disease and the development of methods and tools help facilitate and optimize patient-provider disease related communication.

“The disconnect... is bigger than unknown causes [of kidney disease]. There's a bigger disconnect between CKD and providers in general... Unknown causes of kidney disease add a layer of complexity. It doesn't answer the questions patients have about their condition or answer the question providers have – how to care for their patients in the best possible way.”



FIGURE 5.

IDEALLY, GENETIC TESTING AND SCREENING CAN BECOME A STANDARD PART OF KIDNEY CARE, GIVING PATIENTS AND CAREGIVERS ALL THE TOOLS NECESSARY TO LEARN ABOUT THE ROOT CAUSE OF KIDNEY DISEASE



THE ROAD AHEAD

Increase providers' awareness of the range of potential root causes of kidney failure, improve their ability to communicate clearly with patients and expand incentives to diagnose the root causes of kidney disease and kidney failure.

Understanding provider challenges in diagnosing the cause of kidney disease or kidney failure, increased training for PCPs on the indicators of CKD and facilitating greater communication throughout the care continuum are key components for improving CKD diagnosis and treatment. Providers, patient advocates and other stakeholders should jointly develop targeted educational materials and training opportunities to meet these challenges as well as identify opportunities to realign incentives so providers are encouraged to focus on kidney care:

1. **Identify Providers' Current Challenges and Needs:**

As a first step, convene targeted focus groups including PCPs and specialists to understand barriers in identifying and accurately diagnosing kidney disease and the tools and resources needed to overcome those barriers. Insights from these conversations can inform a broader provider survey that assesses the educational and comfort level providers have with genetic testing, the range of causes of kidney failure, the perceived systemic barriers for administering tests, the issues communicating the nature and significance of kidney disease and the recognized challenges communicating with patients.

2.

Develop and Disseminate Educational Materials: Based on the needs identified in the focus groups and survey, develop trainings and educational materials to address these barriers. As broader care teams become more prevalent in the delivery of care these materials will need to address the proper role for all in achieving increased patient understanding of and better care outcomes for CKD patients. In addition, stakeholders including provider and community organizations, should identify the best methods for material dissemination and provider training uptake (e.g., webinars, continuing education, workshops, lectures, etc.).

3.

Propose Novel Solutions to Reimbursement Structures:

In addition to identifying needs for increased education, a survey of providers will likely reinforce Summit participants' conclusion that current reimbursement structures do not provide the necessary incentives for providers to focus on addressing the unknown causes of kidney disease. While changing complex incentive structures will be difficult, stakeholders should first evaluate the current reimbursement environment to identify policies that either incentivize providers to, or discourage them from, administering genetic tests and providing comprehensive kidney care and education more broadly. Once these policies are identified, stakeholders can advocate for modification of the policies that are detrimental and support expansion of policies that provide appropriate incentives in government programs. For example, a working group could develop position papers that recommend such changes as evaluating the Medicare Physician Fee Schedule for CKD-related reimbursement, including kidney care criteria in Wellness Visits, or engaging the US Preventive Services Task Force to assess genetic screenings for certain populations.

"It's all part of a continuum...providers need to have the right verbiage about a diagnosis for each patient...and be able to communicate it at the right time..."

Dr. Julie Wright Nunes



4. EDUCATING PATIENTS ABOUT KIDNEY DISEASE & TESTING IN AN EFFECTIVE, CULTURALLY COMPETENT MANNER

AKF seeks to partner with providers, payers, and other stakeholders to increase health literacy and deliver culturally competent care to populations disproportionately affected by kidney disease.

THE CHALLENGE

Understanding the root cause for onset of a debilitating disease is vitally important to the overall treatment plan. Without this information, patients and their families may not be equipped to become active participants in managing their condition or developing the best treatment plan. Targeted outreach is necessary to educate minority populations regarding the options available for reaching an accurate diagnosis and to reduce disparities.

Patients diagnosed with kidney disease are naturally concerned about understanding both the cause and any available treatment options. This anxiety is likely heightened for populations with a lower health literacy and/or little experience navigating the US healthcare system. It can also be compounded by historical mistreatments of these minority populations and socioeconomic disparities in underserved communities. It is critically important to provide appropriate educational resources and care to address these circumstances.

Patients with suspected kidney disease often need to see several providers and undergo multiple tests to receive even a preliminary assessment of their condition. This experience can be daunting for any patient but is particularly challenging for populations who may utilize care less frequently but are disproportionately diagnosed with kidney disease. Studies show wide disparities in how patients are able to navigate the healthcare system, and their source of care, leading to inequitable outcomes for certain patient populations.⁵³ For example, approximately 15 percent of white Americans do not have a regular source of care compared to 19 percent for Black Americans and almost 30 percent for Hispanics.⁵⁴

Additionally, language barriers exist for those who do not speak English as a first language, and difficulties with comprehension may prevent the patient from following up,

adhering to care, and asking questions.⁵⁵ One survey found that minority patients express lower quality interactions with their providers, due to the patients feeling the clinician did not treat them with respect.^{56,57} Providers sometimes assume that minority patients or patients with lower levels of education will not understand or be interested in information about their health.



PATIENTS MAY NOT ASK KEY QUESTIONS ABOUT THEIR KIDNEY HEALTH & TREATMENT, INCLUDING:

- Should I have my kidney function tested?
- Do I need to see a nephrologist?
- Do I need a kidney biopsy or imaging test?
- Do I need a genetic test?
- Is genetic testing and counseling covered by my insurance?
- If not, are there programs that could help cover the costs?
- What are the potential implications of my genetic test results for my relatives?
- How will my data be used and protected and who will have access to my genetic information?

Withholding information, and a lack of interactive communication and trust between the patient and provider is especially detrimental for minority and other underserved patients. This in turn can inhibit patients and families from learning about genetic testing, congenital disorders, and the root cause of kidney disease or kidney failure. A Department of Veterans Affairs study on



CULTURALLY COMPETENT KIDNEY CARE: WHY IT MATTERS FOR KIDNEY DISEASE DIAGNOSIS

Increasing the diversity of the kidney specialist workforce is needed to improve culturally competent care for patients and should be considered as a longer-term goal. Currently only 17.1% of the specialist workforce identifies as Asian, 5.8% as Hispanic, and 5.0% as Black or African American, which is not reflective of the diverse populations they serve.⁵⁸ The evidence showing that kidney failure disproportionately affects minority populations is clear, as well as the poor experience that minorities too often encounter when interacting with the healthcare system. Especially for a disease as complex as CKD, it is crucial that providers, patients and caregivers work in partnership to develop a trusting relationship and that all parties understand the options available for reaching an accurate diagnosis and the implications of their diagnosis.

Although Hispanics have a higher prevalence of ESRD than white Americans, they donate and receive disproportionately fewer kidney transplants. While only three (as of 2017) culturally targeted kidney transplant interventions have been documented, they were effective in raising awareness and public knowledge within the Hispanic population.⁵⁹ The three targeted interventions were: (1) mass media campaign, (2) exposure to a bilingual website, and (3) exposure to a culturally competent kidney transplant program. The lack or abundance of targeted and informative materials can impact patients' perceptions of healthcare.

If the aforementioned Hispanic patient population received information about diagnosing the cause of their kidney failure in a similar manner, then increased awareness may result in inquiring about genetic testing, receiving a diagnosis, and then informing family members who may be at risk depending on the results of the genetic test. Ascertaining a diagnosis would not only improve treatment for the patient but could potentially improve the health of the family members as well.

Culturally competent care involves creating an inclusive environment, both through language, understanding of and sensitivity to cultural norms for disparate patient populations, and fostering diversity and inclusion on the provider side as well.⁶⁰ Given the racial differences documented in kidney failure, tailoring materials and communications to disparate groups can support the development of rapport between providers and patients, and then empower patients and families to ask questions about their kidney health, especially regarding genetic testing if they are experiencing kidney disease or failure for an unknown reason.

provider-patient communications highlights four barriers to effective communications:⁶¹

- **Passive Listening:** Patients expected their provider would deliver all necessary information and did not feel empowered to engage in a conversation about their health. PCPs when diagnosing diabetes or hypertension should also educate the patient about possible impacts to kidney function and the best options for mitigating these impacts.
- **Limited Kidney Disease Knowledge:** Patients did not fully understand associated treatment options and complications that can accompany kidney disease.
- **Medically Complex Language:** The terminology used by

providers left patients confused, which discouraged patients from asking questions.

- **Unsatisfactory Patient-Provider Relationship:** Patients expressed a lack of rapport with their provider, noting that treatment felt insensitive at times.

External factors, like environmental stressors and communication barriers, can have a negative impact on health outcomes. Patient education is more than just having all the right information, it is about conveying crucial health-related information in a culturally competent and inclusive way.⁶² With kidney disease, where provider guidance and intervention are essential, so are the ways in which patients are told information about their health.

THE ROAD AHEAD

Develop accessible patient resources that aid in the entirety of their kidney care journey, including in the initial diagnosis of the root cause of kidney disease or kidney failure.

Each step along the kidney care journey can be overwhelming and complicated, particularly for patients who know that their kidneys are failing or have failed, but do not know why. AKF is committed to partnering with the patient community and other stakeholders to ensure that patients have access to the appropriate resources they need to face their kidney disease confidently. This is particularly important for the most vulnerable patients who may be more hesitant to ask questions or engage their providers in understanding their options or the origin of their disease. Addressing information asymmetry between patients and providers will take time, but initial steps stakeholders should take include:

- 1. Develop Accessible Resources for Patients:** Patient advocates, community organizations, and other stakeholders should develop comprehensive, culturally competent, and accessible educational resources targeted to patients with kidney disease with an unknown cause. The development of these resources should be done in conjunction with providers and other members of the health care team who need these materials given the time constraints associated with a standard office visit. As a first step, information gaps should be identified working closely with the patient community. Following the creation of educational materials to address these gaps, partnerships with community organizations can ensure that tailored resources are distributed to communities and subpopulations and that trust is established among a wider range of communities. Ongoing conversations with the patient community can help ensure the distribution strategy evolves to meet the needs of specific patient populations.

- 2. Involve Providers and Organizations Across the Kidney Care Continuum:** In addition to developing materials that patients can access themselves, stakeholders should also work with patient advocates and other partners to develop materials that providers can share with patients. Through timely engagement with providers, patients can be made aware of kidney issues early on and seek a diagnosis. Providers already treating patients with kidney disease or failure can educate patients regarding obtaining genetic testing and educating family members who may be at risk for kidney disease or kidney failure. Patients and family members can also be provided materials upon hospital admission. This strategy should include engagement with all members of the care team to ensure all patients have access to the resources they need to better understand their potential condition and next steps.

A CALL TO ACTION: HELPING PATIENTS RECEIVE A DIAGNOSIS & MANAGE THEIR KIDNEY CARE EXPERIENCE

Overcoming barriers to identifying the root cause of kidney disease for currently unknown reasons, will not be accomplished quickly. However, thoughtful, dedicated collaboration among the kidney care community can result in steady progress toward expanding access to genetic testing, reducing systemic inequalities, engaging

providers, and empowering patients. The solutions that AKF outlines in this Roadmap, based on expert input from the Summit, and supported by educational resources and best practices for patient-provider communication, can help reduce the number of patients unaware of the origins of their kidney disease:

Increase Access & Coverage for Genetic Testing	Expanding coverage of genetic tests and counseling in public programs can help ensure that financial barriers and other access challenges do not prevent kidney patients who need genetic tests from receiving them.
Establish National Standards for Genetic Testing	National guidelines can ensure that providers, payers, and other stakeholders have a consistent understanding of best practices for prescribing and administering genetic tests in cases where causes are unknown.
Educate Providers & Financial Incentives	Educational materials will give providers the information they need to pursue a diagnosis for the root causes of kidney disease or failure and to have clear conversations with patients about genetic testing.
Develop Accessible Resources for Patients & Caregivers	Comprehensive and inclusive resources will help patients with their kidney care journey and empower them to seek the answers they deserve when confronted with kidney disease or failure with an unknown cause.

Increasing the proportion of patients who receive an accurate diagnosis for their kidney disease through genetic testing or other means may not only improve the care for those patients but also prevent or slow the progression of the kidney disease of similarly situated

individuals. Through ongoing partnership and continued research and advocacy, AKF and its partners can pursue reforms that will make a meaningful difference in patients' lives.

ABOUT THE AMERICAN KIDNEY FUND

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. With programs that address early detection,

disease management, financial assistance, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator for 19 consecutive years and the Platinum Seal of Transparency from GuideStar.

APPENDIX A: UNKNOWN CAUSES OF KIDNEY DISEASE SUMMIT PARTICIPANTS

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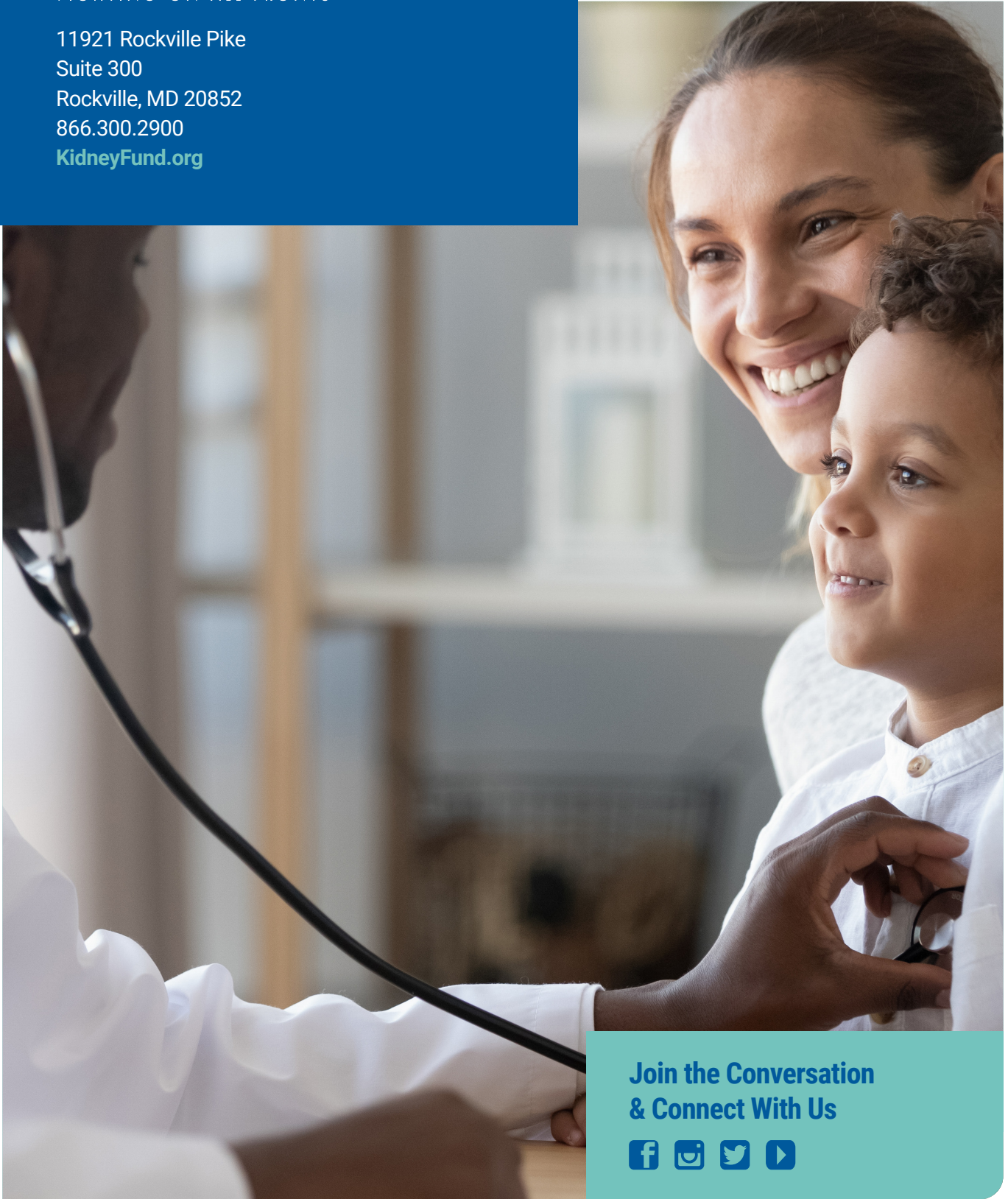
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