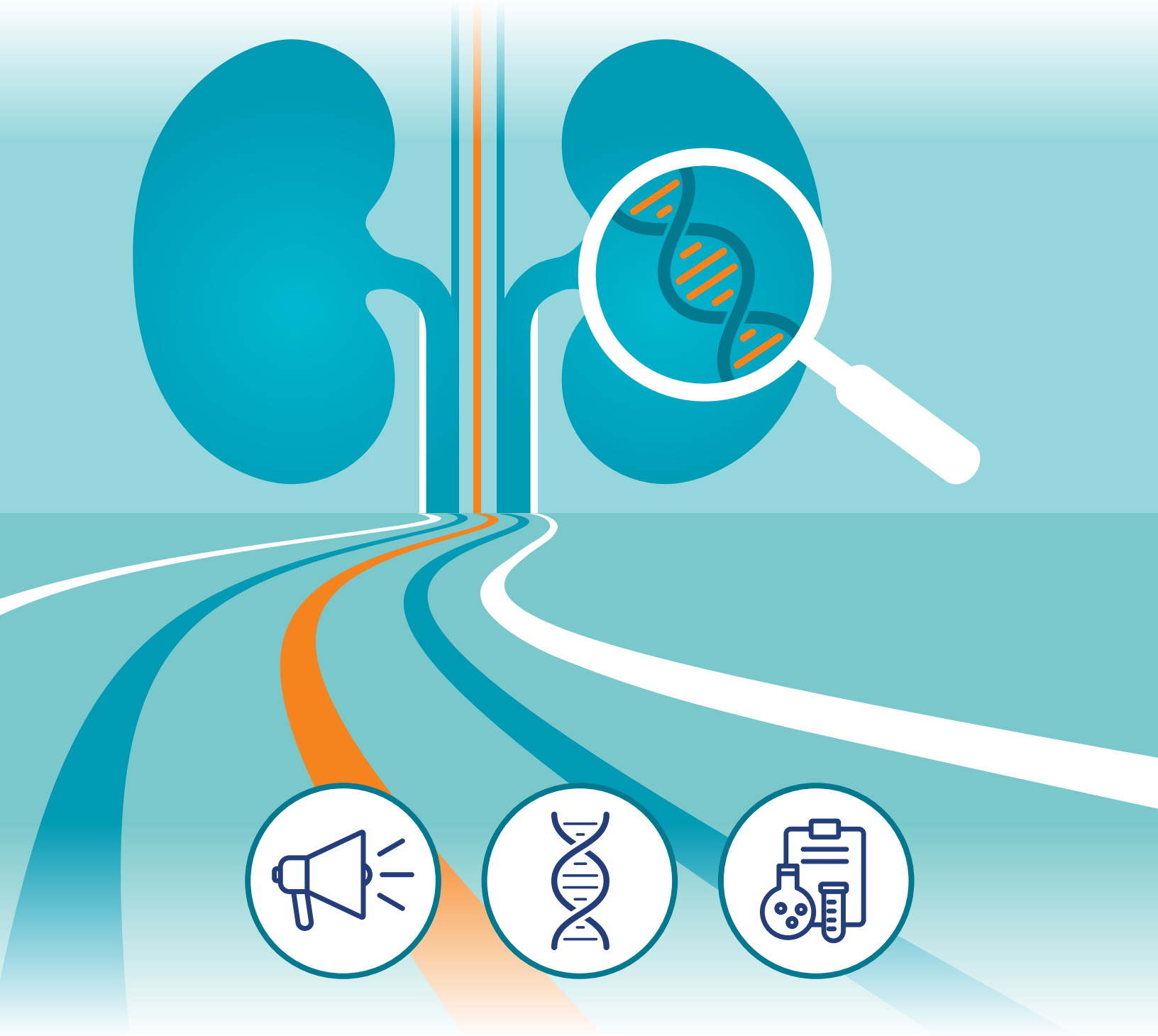
ROADMAP

FOR ADVANCING AWARENESS, GENETIC TESTING, AND CLINICAL STUDIES OF **APOL1 KIDNEY DISEASE**



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KHI KIDNEY HEALTH INITIATIVE

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EXECUTIVE SUMMARY

APOL1 kidney disease (APOL1 KD) is a driving force behind health disparities in chronic kidney disease (CKD) characterized by worse health outcomes for those of African ancestry. Despite this, there is little acknowledgement of APOL1 KD in kidney care, and only a few clinical studies currently seek to develop targeted treatments for this disease.

Recognizing these gaps, the Kidney Health Initiative (KHI) initiated this effort to examine the APOL1 KD landscape and develop a roadmap to support the kidney health community in a coordinated effort to address APOL1 KD.

The three goals of this roadmap are to: increase APOL1 KD awareness, increase access to and awareness of genetic testing and associated counseling, and empower patients with APOL1 KD to make informed decisions about participating in clinical studies. These three goals also underpin the critical need to address the racial disparities in CKD that disproportionately burden people of African ancestry. By working toward and achieving these goals, we hope to make progress in closing the racial disparities gap in CKD.[1,2]

This roadmap serves as a resource for healthcare providers, patients and their families, payers, patient advocacy groups, professional societies, policy makers, pharmaceutical companies, leaders within communities of those at risk, and more, who all have important roles in implementing the action items in this roadmap to drive change.

While KHI has taken the lead in developing this roadmap, we acknowledge that there are other efforts currently underway to address APOL1 KD and health disparities in CKD. For example, patient advocacy organizations, also represented in the KHI workgroups, frequently host education and genetic testing events to raise awareness of APOL1 KD in populations of African ancestry. There are also ongoing clinical studies for therapeutic agents and associated education and awareness efforts led by companies such as AstraZeneca, Lilly, and Vertex, among others.[3]

Our goal is to serve as a convener of the various audiences identified to implement the action items in the roadmap, while complementing other existing efforts to bring awareness to APOL1 KD and drive progress in the treatment and management of APOL1 KD.

We call on the kidney disease community to join KHI and others in a collective effort to advance the action items included in this roadmap. Together, we can increase awareness of APOL1 KD in people of African ancestry, increase *APOL1* genetic testing, empower those at risk to make informed decisions about participating in clinical studies, and ultimately, make APOL1 KD therapies available to improve health outcomes.

ABOUT THIS ROADMAP

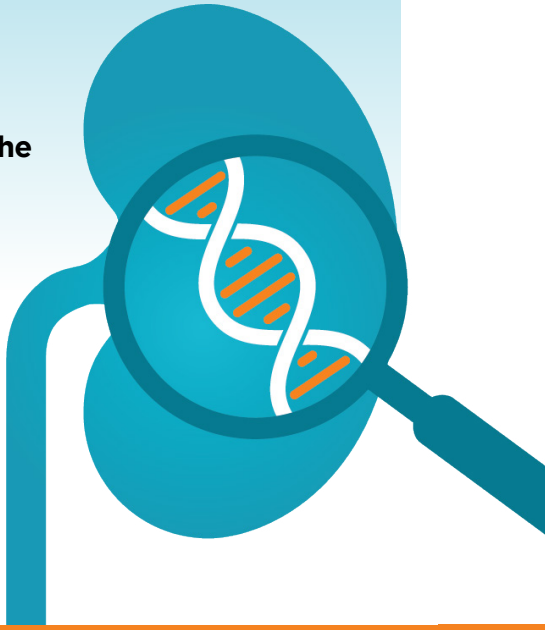
The **Kidney Health Initiative (KHI)** is a public-private partnership between the Food and Drug Administration (FDA), the American Society of Nephrology (ASN), and more than 80 member organizations committed to catalyzing innovation and the development of safe and effective patient-centered therapies for people with kidney diseases.

In 2022, the **KHI APOL1 KD steering committee** started the development of this roadmap to support the kidney health community in the journey to address APOL1 KD. The KHI APOL1 KD steering committee is composed of experts in the fields of nephrology, clinical studies, patient advocacy, health equity, genetic counseling, and clinical product development (Appendix A).

Expert volunteers supported the development of this roadmap by participating in four distinct workgroups:

- Disease Landscape
- Education and Awareness
- Genetic Testing and Genetic Counseling
- Clinical Studies

To gather expert information from across the field, the steering committee identified **advisors**, including APOL1 KD experts, patients, advocates, and others, who were **interviewed about their perspectives on the challenges, best practices, and potential solutions** to address APOL1 KD.



What is APOL1 KD?

APOL1 KD is a genetic condition that affects people who carry high-risk *APOL1* gene variants, and most people with those variants are of African ancestry. African Americans represent 13% of the U.S. population, yet account for approximately 32% of patients receiving dialysis treatment.[4] Of those receiving dialysis treatment, a substantial number of individuals have *APOL1* variants. Furthermore, about 50% of African Americans with non-diabetic chronic kidney disease (CKD) have the high-risk *APOL1* variants.[5,6] Therefore, *APOL1* high-risk variants may account for much of the increased burden of CKD in people of African ancestry, further described in Disease Course, Diagnosis, and Treatments.[7]

APOL1 Nomenclature

This roadmap uses the term APOL1 KD; however, there are currently no guidelines for standard nomenclature. **APOL1 KD may also be referred to as APOL1-associated nephropathy, APOL1-associated kidney disease, and APOL1-mediated kidney disease in other literature**. Each of these terms can have nuanced differences in their meaning and interpretation. It will be important for progress in the field of APOL1 KD to support more guidelines around terminology and naming conventions.

Goals and Action Items

This **roadmap establishes three goals and corresponding action items** that can improve health outcomes and kidney health equity for people of African ancestry. The three goals are as follows:

Goal 1: Increase Awareness of APOL1 KD

Action items:

- Focused Educational Efforts to Increase Awareness
- Engagement to Build Trust and Empower
- Provider Training

Goal 2: Increase Access to and Awareness of Genetic Testing of APOL1 KD and Associated Counseling

Action items:

- Provider Training
- Systemic Efforts to Support Access to Testing
- Efforts to Enhance Testing Awareness

Goal 3: Empower Patients to Make Informed Decisions Regarding Clinical Study Participation

Action items:

- Community Outreach and Engagement
- Provider Training

Conceptual Framework: Advancing Systems Thinking and Health Equity

This roadmap leverages the Socio-Ecological Model (Appendix B) which is based on the idea that a person's health outcomes are not isolated, but rather connected to larger systems (e.g., family, caregiver, health care, community etc.) Ecological models of human interaction have been used to study complex community problems that affect health disparities.[8,9]

The roadmap incorporates this model by considering entities that can take action to address challenges based on an entity's level of influence on persons affected by or at risk for APOL1 KD. Leveraging the Socio-Ecological Model ensures that this roadmap centers health equity and patient-centeredness as key concepts. Solutions and actions are presented with consideration as to how to reach patients and at-risk individuals in associated spheres of influence. These may include engagement and culturally informed discussions with healthcare providers.

The actions in this roadmap were also developed with consideration to how to have an impact on the broader systems that influence health outcomes, such as advocacy at the healthcare system or policy levels. Addressing social factors on a population level, through government and community intervention and action, will be needed to advance health equity in CKD and APOL1 KD.

Who Should Read This Roadmap

This roadmap is a resource for healthcare providers, patients and their families, communities of those at risk, payers, patient advocacy groups, professional societies, policy makers, pharmaceutical and biomedical companies, leaders within communities of those at risk, and other audiences. While the audiences identified in this roadmap are not exhaustive, they can serve as key entities in connecting the right people and implementing or promoting the action items identified in this roadmap.

In addition, we have further grouped these audiences into primary and secondary groups (Figure 1) to highlight those whose roles can directly and significantly contribute to the goals of this roadmap.

This roadmap is a resource for healthcare providers, patients and their families, communities of those at risk, payers, patient advocacy groups, professional societies, policy makers, pharmaceutical and biomedical companies, leaders within communities of those at risk, and other audiences.

Figure 1. Primary and secondary audiences of the roadmap.

Primary Audiences

Patients	Community	Healthcare Providers and Professional Associations	Healthcare Systems and Organizations	Policy/Payers
• People of African ancestry • People with family history of kidney disease • Patients with CKD and other kidney diseases	• Patient advocates • Advocacy organizations • Trusted community leaders and advisors	• Nephrologists • Geneticists • Genetic counselors • Primary care physicians • Nurse practitioners • Professional societies	• Healthcare systems • Healthcare facilities and other medical institutions • Federally qualified health centers	• Centers for Medicare & Medicaid Services (CMS) and other public insurers • Private Insurers • Federal policy makers

Secondary Audiences

Patients	Community	Healthcare Providers and Professional Associations	Healthcare Systems and Organizations	Policy/Payers
• Communities and networks of people at risk	• Faith leaders • Community organizations	• Pharmacists • Lab directors • Dialysis specialists • Transplant specialists • Academic and other training institutions • Social workers • Caregivers • Endocrin-ologists • Cardiologists	• Biomedical companies • Pharmaceutical companies • Genotyping assay/test manufacturers • Clinical research organizations (CROs) • Laboratory diagnostics companies	• State, and local policy makers (e.g., state health departments)

Landscape Assessment

To inform the development of this roadmap, KHI interviewed advisors chosen for their expertise in kidney health, health equity, clinical studies, and APOL1 KD treatment and research, as well as their involvement and experience working on APOL1 KD or other rare or genetic diseases. KHI also interviewed patients, community-based researchers, and patient organization representatives and advocates to understand patients' perspectives on CKD and APOL1 KD. Interviews were conducted to gather information about the challenges, barriers, successes, and promising practices to achieve the three goals of this roadmap.

Interviews

An expert moderator conducted virtual interviews with 10 advisors, 4 patient organization representatives, and 2 patients, who had diverse and relevant backgrounds, ranging from community engagement work, patient care, genetic counseling, research, and directing clinical studies. Interviewees were identified and selected by the KHI steering committee and workgroup members (Appendix C).

Starting in February 2023, initial outreach to selected advisors was carried out by ASN leadership, and subsequent outreach was done by ASN/KHI staff. Interviews were conducted from April through June of 2023.

A semi-structured interview guide was developed with questions that covered each goal area of the roadmap. The initial guide was used as a blueprint for interview guides tailored to each advisor. A separate interview guide was developed by KHI staff to interview patient organization representatives.

Advisors provided extensive information on APOL1 KD, challenges related to disease awareness, testing, and clinical studies, as well as potential solutions to address the challenges. Their expertise is provided throughout the roadmap without citations.

Resources

During the development of this roadmap, relevant resources to support the implementation of the action items have been collected and are available in Appendix D.

OVERVIEW OF APOL1 KD

Disease Information

The *APOL1* gene encodes the apolipoprotein L1 (APOL1) protein. The association between CKD and the *APOL1* gene was identified in 2010.[10] Variants in *APOL1*, G1 and G2, are genetic mutations. When individuals carry two copies of *APOL1* variants, there is a greater risk for developing CKD and an increased risk and rate of CKD progression. CKD that develops with the influence of *APOL1* high-risk variants is called APOL1-mediated kidney disease, hereafter referred to as APOL1 KD.[11]

Further, recent APOL1 KD literature suggest the *APOL1* variants may affect the overall function of the kidneys;[12] however, the way the variants affect the kidneys is not yet fully known.[13,14,15,16,17,18] In patients with autoimmune diseases that affect the kidneys, such as lupus, or hypoxic kidney injury associated with sickle cell disease or other conditions, *APOL1* variants are associated with worse kidney prognosis.[19,20,21] Additionally, patients with collapsing focal segmental-glomerulosclerosis (FSGS) who have the high-risk variants develop FSGS at an earlier age.[22]

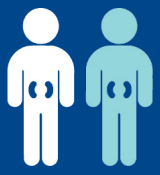
Not all individuals with the *APOL1* high-risk variants develop APOL1 KD. Inflammation seems to worsen progression, and there is likely a "second hit" that triggers development of kidney disease. These include environmental or lifestyle factors, or viral infections like HIV and COVID-19.[23]

About 50% of African Americans carry at least one APOL1 variant, and 13% carry the high-risk variants. The highest frequencies are found in West African populations and their descendants.[4,5] To identify carriers of the *APOL1* variants, or people who may be at risk for CKD, it is therefore important to consider a broad association with African ancestry rather than self-reported race or ethnicity, as African ancestry can occur in those who do not identify as Black or African American, including those who identify as Hispanic, and those of Caribbean descent.[24,25]

Immediate family members of individuals who test positive for any of the *APOL1* variants have a greater risk of kidney health issues. This may also affect family members' eligibility to serve as kidney donors due to concerns about the the effects of carrying one or more of the *APOL1* variants on the potential success of the transplant.[26]

13%
of all African Americans have the high-risk *APOL1* genotype.

50%
of African Americans with non-diabetic chronic kidney disease (CKD) have the high-risk *APOL1* genotype.



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Disease Course, Diagnosis, and Treatments

Disease Course

- *APOL1* high-risk variants are associated with earlier onset of CKD compared to people who do not carry the high-risk variants
- **Most patients with APOL1 KD experience disease onset before age 50, earlier than is typically seen with CKD due to other causes**
- Individuals with the high-risk *APOL1* variants also experience an increased rate of disease progression which leads to initiation of dialysis almost a decade earlier than patients without the high-risk variants[28]
- Some of the earliest clinical signs that precede symptoms include leakage of protein into the urine (proteinuria) or a decline in glomerular filtration rate greater than what is age-appropriate
- Symptoms that indicate general worsening kidney function, particularly in the more advanced stage of CKD, include swelling in the lower extremities, fatigue, infrequent urination, loss of appetite, shortness of breath, and fluid retention[19]

Diagnosis

- Most people with APOL1 KD do not know that they have kidney disease because APOL1 KD is asymptomatic until it reaches advanced stages
- Furthermore, many people with APOL1 KD do not know they have a genetic form of kidney disease because genetic testing is not currently routine in nephrology practice.
- Like CKD, APOL1 KD may go undiagnosed or be overshadowed by other medical conditions such as hypertension and high cholesterol[28]
- While CKD may be diagnosed by a urine test and biopsy, a genetic test is required to diagnose APOL1 KD
- Since *APOL1* genetic testing is not routinely done, an APOL1 KD diagnosis may be delayed for many patients with CKD
- It is likely that by the time APOL1 KD is diagnosed, a patient's kidney function has already been adversely affected[29]

Treatments

- **There are currently no approved targeted therapies for APOL1 KD**
- Instead, agents such as renin-angiotensin-aldosterone system (RAAS) inhibitors are used to mitigate kidney dysfunction and related conditions by decreasing proteinuria, controlling hypertension, and controlling other risk factors for kidney disease progression.
- This further emphasizes the need to support clinical studies to advance treatments.

GOALS

This roadmap establishes three goals:

Goal 1: Increase Awareness of APOL1 KD

Goal 2: Increase Access to and Awareness of Genetic Testing of APOL1 KD and Associated Counseling

Goal 3: Empower Patients to Make Informed Decisions Regarding Clinical Study Participation

In this section, current challenges in each goal area have been identified, and solutions and strategies to address those challenges are proposed. Corresponding action items are also outlined.

Goal 1. Increase Awareness of APOL1 KD

Increasing awareness of APOL1 KD is foundational to advance change and meet the overall goals of this roadmap. Increasing awareness is a cross-cutting goal that intrinsically includes genetic testing and clinical study awareness. This section covers approaches to address many of the challenges associated with APOL1 KD and increase awareness among people of African ancestry, healthcare providers, and the broader healthcare community.

Potential solutions and strategies that can increase awareness of APOL1 KD include:

- Education to address health literacy among at-risk individuals and their communities.
- Engagement to address mistrust in the healthcare system.
- Training to address provider awareness of APOL1 KD.

Education to Increase Health Literacy

Education for at-risk individuals may increase health literacy which may in turn promote self-advocacy when seeking care. It can also empower at-risk individuals to engage with others within their communities to raise awareness of APOL1 KD, advocate for policy change, and participate in research.

Challenge: Health Literacy

Persons who may be at-risk for APOL1 KD may be unaware of the science and risks associated with having the *APOL1* gene variants compared with other risk factors for CKD, such as diabetes and hypertension. While research has shown that people of African ancestry have expressed interest in learning more about APOL1 KD,[30] awareness is still low, especially since there have been few concerted educational initiatives in this area.[31,32,33,34]

Low health literacy may contribute to a general lack of understanding of diseases, including CKD and its disease course. Misconceptions or misinformation about CKD may contribute to the stigma around the disease. As a result, patients may avoid seeking care or information. Furthermore, people may be largely unaware of testing and diagnosis processes and clinical study procedures, leading to difficulties navigating care and research participation options.

Solution: Education

Develop Educational Resources

Education efforts should aim to increase overall health literacy and awareness of APOL1 KD among patients with APOL1 KD and people at risk for APOL1 KD, as well as their communities, providers, and policy makers. Educational materials on APOL1 KD should include resources on APOL1 KD clinical studies, and tools on managing and understanding APOL1 KD and its risk factors. When developing resources for patients and at-risk persons, important considerations include gathering patient and community input to ensure that materials are tailored, patient-centered, and culturally inclusive and are written in plain language to meet the health literacy needs of the community. Similar resources and tools should be developed for policy makers and payers to increase awareness of APOL1 KD.

Disseminate Resources

As with other public health and healthcare initiatives, education should extend beyond the development of resources. Entities should commit to disseminating new and existing resources and frequently engaging with individuals and their communities to further support education and awareness.

Engagement to Address Mistrust

Addressing mistrust among people of African ancestry may lead to beneficial health outcomes if it supports increased interactions between people with African ancestry and healthcare systems. Increased engagement can empower those at risk for APOL1 KD to participate in APOL1 KD programs and activities.

Challenge: Mistrust

People of African ancestry are more likely to express mistrust of the healthcare and medical research communities and receive suboptimal care due to systemic racism, discrimination in healthcare service delivery, and mistreatment in research.

Mistrust stems from historical events including the Tuskegee syphilis study, an unethical study of syphilis in African American males conducted by the United States Public Health Service, and is reinforced by pervasive, systemic health system issues and discriminatory events that continue to this day.[35] Broken trust creates a barrier to achieving health equity,[36] and mistrust in the healthcare system is a primary barrier to participation in medical research.[37] Additionally, when community engagement is sporadic and lacks transparency, mistrust grows between communities and the organizations that serve them.[38] These reasons suggest a need for the healthcare system and its providers to build trust by providing more culturally competent care.[39]

Solution: Engagement

Engage with Patients

Patient engagement can be an effective means to address mistrust of the healthcare system. Healthcare systems and providers should strive to establish and maintain relationships with patients to improve communication and build trust. Further, patients and their communities should be empowered to participate in educational and awareness efforts, as they can inform the development of meaningful messaging that resonates within their communities.

Engage with Communities

Engaging with community leaders and organizations to promote APOL1 KD awareness, genetic testing options, and clinical study participation among at-risk populations can be an effective strategy. Community-based participatory research (CBPR) may help address these health disparities, but CBPR must also address mistrust in order to be accepted in the community.[40] A clear understanding of existing systems and how to leverage these systems can form the basis of a sustainable CBPR approach that increases engagement and builds trust between communities and organizations.

Leverage Existing Infrastructure

Another approach is using existing infrastructures to support sustainable engagement with communities. Church-based health promotion (CBHP) interventions reaching broad populations have shown success in reducing health disparities.[41] Faith leaders can be effective trusted messengers for health information among communities of African ancestry. For example, pastors in Black churches were instrumental in disseminating public health information and promoting vaccine uptake and COVID-19 testing during the COVID-19 pandemic.[42,43,44] Research has suggested that public health organizations should maintain relationships with faith communities built on trust. This can be achieved by partnering with pastors when conducting programs to address well-being in communities of African ancestry.[45] Researchers have also leveraged spaces such as barber shops to increase education on health issues such as prostate cancer screening.[46]

Engaging with community leaders and organizations to promote APOL1 KD awareness, genetic testing options, and clinical study participation among at-risk populations can be an effective strategy.

Tailor Messaging
Messaging should be tailored to issues that matter to people, such as the impact knowing one's *APOL1* status can have on an individual or their family, and safeguards that are now routine elements of clinical studies. Community liaisons can help bridge access to their communities by extending the reach of information and creating awareness of efforts that have been developed and vetted by the communities, for the communities.

Establish Patient Advisory Boards
Patient advisory boards can also be an effective approach to foster meaningful engagement with patients, as they can help provide insight to patient priorities, advise on best approaches, and help address barriers such as misinformation. Entities in the *APOL1* research and medical device communities should consider developing patient advisory boards to elevate the patient voice in clinical studies and the treatment development process, as well as to reestablish trust and instill confidence within patients, their families, and their communities.

Training to Address Provider Awareness of APOL1 KD

With increased training, providers may be more actively engaged in communicating and disseminating information on APOL1 KD to their patients and within their networks.

Challenge: Provider Awareness of APOL1 KD

APOL1 KD is currently under-diagnosed due to several factors. Healthcare providers may lack sufficient education about CKD screening and diagnosis, and existing guidelines and research may not reach the right audiences. There may also be insufficient understanding of APOL1 KD, the risks associated with the *APOL1* variants, and the *APOL1* genetic test. Providers may also lack awareness of "second hit" conditions, such as viral infections, inflammatory conditions, and a variety of other conditions that increase the risk for developing either CKD or APOL1 KD. Primary care providers in particular may experience screening fatigue and may be less likely to screen for rare diseases. Therefore, screening for another condition or recommending a patient for genetic testing may be an added burden to primary care practitioners.

To receive optimal care, CKD and APOL1 KD patients may be referred to a nephrologist who will assist in obtaining a definitive diagnosis and maintaining good kidney health; however, inadequate access, fragmented healthcare systems, or insufficient coordination between different provider types can have an impact on the continuity of care. For example, primary care providers may be unaware of the need to refer high-risk patients to nephrologists in the early stages of CKD, which may present as proteinuria with or without a mildly decreased glomerular filtration rate (the rate at which materials filter through the kidneys).

Even providers who are aware of APOL1 KD may not be transparent with patients about the *APOL1* gene variants and their associated risks. This can be due to several factors, such as the lack of treatment options, costs of genetic testing to patients, lack of training in discussing genetic test results, and a lack of awareness of APOL1 KD clinical studies that might benefit patients. Such conversations may also be hindered by a lack of cultural competency in the healthcare system, provider discomfort in initiating these conversations, and provider implicit bias against patients of African ancestry, which results in physicians failing to ask these patients about their interest in participating in studies or new treatment programs.[47]

APOL1 KD research faces the additional challenge of APOL1 KD not having an International Classification of Diseases, 10th Revision (ICD-10) code. **Having an ICD-10 code would support tracking and reporting of APOL1 KD for purposes such as quality assurance and quality improvement (QA/QI) efforts, diagnosis, reimbursement for healthcare services, and data collection efforts.**

Solution: Training

Develop APOL1 KD Training for Providers

Training should address provider knowledge of CKD, APOL1 KD, *APOL1* genetic testing, and APOL1 KD clinical studies. Training healthcare providers on three specific areas can support culturally competent and better care to patients of African ancestry. These areas include:

- APOL1 KD generally (diagnosis, disease journey, and management).
- Culturally relevant communication styles.
- How to reduce racism and bias in healthcare settings.

Develop CME for Providers

Continuing medical education (CME) for healthcare providers on APOL1 KD can be effective in supplementing provider training. Other avenues for training include convenings such as conferences, seminars, and communities of practice. Additionally, healthcare systems should employ, train, and encourage the use of patient navigators who can guide patients through complex processes and information.

Incorporate Genetic Disease Information into Medical Training

There is also an opportunity to incorporate more information on genetic diseases into current medical training. Academic and other training institutions should consider ways to include or update nephrology training to address APOL1 KD, including the disease landscape, *APOL1* genetic testing, and improved provider-patient communication.

Provide Culturally Competent Communication Training for Providers

Culturally competent communication training for providers that promotes shared decision making between the provider and patients should be developed and providers should be trained on the importance of transparent discussions with patients about APOL1 KD risk factors and clinical study options for those who are positive for the *APOL1* variants. To promote inclusion of people of African ancestry in clinical studies and to increase the use of new treatments and therapies that may benefit these patients, healthcare providers need to be made aware of possible personal biases. Studies have shown such biases can lead providers to recommend fewer patients of African ancestry for clinical studies,[48] and that providers unfairly associate patients of African ancestry with being less cooperative, less compliant, and less responsible.[49] Empathy also plays an important role in building the patient-provider relationship. A good patient-provider relationship helps build trust, improves patient adherence to treatment plans, and increases the likelihood that a healthcare provider will ask a patient to participate in research studies.[50]

Develop and Disseminate Information and Best Practices on APOL1 KD

Further, institutions that issue clinical guidelines have an important role in developing and disseminating information and best practices on APOL1 KD. Practicing providers can benefit from consistent information from credible sources, which may help them improve their practice.

Goal 2. Increase Availability and Awareness of Genetic Testing for APOL1 KD and Associated Counseling

Genetic testing helps to accurately diagnose many rare and genetic kidney diseases that may go undiagnosed or incompletely diagnosed, including APOL1 KD. Although genetic testing is a relatively new tool in nephrology, it contributes to empowering patients to understand the true cause of their CKD, and despite the current absence of a specific treatment for APOL1 KD, it assists clinicians in providing patients with the best course of treatment for genetic kidney diseases.

Genetic testing for *APOL1* in people of African ancestry with CKD is uncommon, even though individuals of African ancestry have expressed a desire to be informed of their *APOL1* genetic status.[51,52]

More widespread *APOL1* genetic testing, accompanied by genetic counseling, could support individuals in making decisions to manage APOL1 KD risk, such as engaging in health-promoting behaviors upon a positive genetic test result. Family members of those with CKD or APOL1 KD may find learning their genetic test result beneficial to understand their risk for developing APOL1 KD. For those undergoing CKD treatment and who are newly diagnosed with APOL1 KD after a positive genetic test result, knowing one's *APOL1* status could encourage greater adherence to care that modifies kidney disease risk factors in the absence of specific APOL1 KD treatment. Finally, greater testing could help identify persons who may be able to participate in APOL1 KD clinical trials and may support innovation in developing treatment options.[53,54]

Potential solutions and strategies to address challenges in genetic testing of APOL1 KD and associated counseling include:

- Training to improve healthcare provider practices.
- Advocacy to increase APOL1 testing access.
- Engagement and training to address concerns related to genetic testing.

Training to Improve Healthcare Provider Practices

Healthcare provider practices that support increased APOL1 genetic testing could improve the health and well-being of patients, the broader community, and those at risk for APOL1 KD. Practices such as referring patients to kidney specialists, ordering tests, following up on results, and using culturally competent communication to talk about testing, can all contribute to improved patient outcomes.

Challenge: Provider Awareness of APOL1 KD

APOL1 genetic testing is not consistently used and often varies by provider and site. While many healthcare professionals may be unaware of APOL1 KD, those who are aware of the condition or of the potential health risks posed by *APOL1* risk variants do not regularly discuss *APOL1* testing options with patients. This can be due to several factors:

- Providers may be reluctant to discuss testing, as there is no therapeutic intervention to offer upon a positive result.
- Providers are neither trained to manage communication and logistics for *APOL1* genetic testing, nor to interpret results.
- Providers may be unaware of the role of genetic counselors, owing largely to poor incorporation of genetic counseling into healthcare practice.
- Not all *APOL1* genetic tests are done in Clinical Lab Improvement Amendments (CLIA)-certified laboratories, yet testing in CLIA-certified laboratories is necessary to ensure results are clinically actionable.
- Genetic testing is not commonplace in nephrology practice.

Solution: Training

Embed Genetic Testing into Routine Care Practices

Training about *APOL1* genetic testing should emphasize the importance of embedding testing into routine care practices. Training should promote awareness and emphasize the importance of *APOL1* genetic testing, emphasize the role of genetic counselors, and improve testing logistics. Training for genetic counselors on *APOL1* can also support meaningful interpretation and communication of results to address patient concerns, which are addressed further in this roadmap.

Promote Adequate Genetic Counseling and Follow-Up

APOL1 genetic testing, especially if widespread and routine, should be anchored with adequate genetic counseling and follow-up, which should include transparent information about risk, disease course, available testing options, and clinical study participation, and address patient concerns. In addition, working in close collaboration with genetic counselors, or referring patients to genetic counselors for further follow-up can minimize patient concerns and false interpretations.

APOL1 genetic testing could also be beneficial for potential kidney donors and kidney transplant recipients by stratifying for potential risk for future kidney failure in eligible live kidney donors with African ancestry.[55,56] Because of this, providers should make an effort to report results promptly and effectively to those who are considering becoming kidney donors. In a cohort of transplant surgeons, transplant nephrologists, and general nephrologists, 93% would be comfortable offering *APOL1* testing if professional guidelines were available, and 69% believed that kidney donors of African ancestry should be informed of their risk status.[57]

Develop and Disseminate Best Practices

Institutions that issue clinical guidelines also have an important role in developing and disseminating information and best practices that include:

- Communication regarding APOL1 genetic testing.
- Managing testing processes and logistics.
- Referrals to genetic counselors.
- Communication about possible participation in clinical studies.

Advocacy to Increase APOL1 Testing Access

Coordinated efforts are still required to ensure testing availability and access.

Challenge: *APOL1* Testing Availability and Access

While several companies and academic institutions offer *APOL1* tests, including a few that provide no-cost testing, the cost can be a burden, especially for individuals with low incomes.[58] Coverage for tests would make them more affordable and reduce financial burden; however, some insurance companies and government coverage providers may not cover them. Additionally, tests that are not carried out in CLIA-certified laboratories may not be used to guide clinical decision making, and not all *APOL1* tests are analyzed in CLIA-certified laboratories.

Solution: Advocacy

Advocate for APOL1 *Testing*

Advocacy may increase access to *APOL1* testing. Efforts should be actionable, encourage buy-in, promote incentives for testing, justify payer coverage of *APOL1* testing and genetic counseling services, reduce discrimination around test results and genetic status, and encourage use of CLIA-certified facilities for *APOL1* testing.

Reach Policy Makers

Advocacy efforts should be coordinated for greater impact and aim to reach officials from various levels of policy making (e.g., federal, state and local), and those in positions that can influence decision making, such as healthcare leadership, and trusted community advisors. Healthcare systems for example, have an important role in establishing practices that address patient data concerns and that facilitate ordering tests and referrals to counseling and adequate follow-up and care. Test developers and laboratories can also support actions to encourage testing in CLIA-certified laboratories.

Close Gaps in GINA

Policy makers can address gaps in the Genetic Information Nondiscrimination Act of 2008 (GINA) as outlined in the section below, to ensure genetic testing results do not affect access to insurance.

Engagement and Training to Address Concerns Related to Genetic Testing

By engaging communities to take part in genetic testing, more people would be able to know their *APOL1* status, and may be able to take action that may improve their health outcomes. For example, in a study of persons without kidney disease, but with knowledge of their *APOL1* risk status, individuals had improved health behaviors resulting in reduced blood pressure, increased kidney disease screening, and positive self-reported behavioral changes.[51]

Challenge: Individuals' Concerns

Persons considering testing may be concerned about possible discrimination based on test results. While individuals are protected by GINA from discrimination in circumstances such as hiring and obtaining health insurance, there are gaps in GINA that do not protect people from discrimination related to genetic information in all circumstances.

Further, those familiar with historical research injustices may not be open to testing due to not distinguishing between testing in a treatment setting vs. testing in a research setting. Even with testing in a treatment setting, individuals may be skeptical about where their genetic results will end up, who will access their data, and how the data will be handled, especially given valid concerns about data privacy violations, including by law enforcement.[59] In addition to the effects of historical injustices, contemporary, personal experiences with systemic racism in the healthcare system may further intensify patient mistrust of providers. For example, due to the historically perceived genetic inferiority of people of African descent among some people in the healthcare and research environments, people may view present day suggestions for genetic testing as a method to further perpetuate these perceptions.

Some healthcare providers may lack the cultural competency skills to bridge these concerns when communicating with patients about testing. Poor cultural competency further reinforces bias, systemic racism, and mistrust in the healthcare system. Additionally, a lack of racial concordance between patients and providers may contribute to misunderstandings between patients and providers.

Other psychological impacts may contribute to whether individuals decide to get tested for the *APOL1* risk variants. For example, individuals may consider the stress, depression or other effects on their mental health that could come from a positive *APOL1* test result, which may especially be the case when providers do not provide adequate follow-up or referral to genetic counseling services to discuss test results, leaving patients without a clear path forward.

Solution: Address Concerns and Mistrust

Convey Concept of Precision Genetic Medicine

Individuals' concerns can be addressed through education, engagement and healthcare provider training. These solutions are further described under Goal 1. For those considering testing, education about the myths of discrimination related to genetic testing can help alleviate concerns. Genetic counselors are particularly well-positioned to address such concerns. For example, since self-identified African ancestry is currently the best indicator of potentially carrying *APOL1* variants, genetic counselors can help convey the idea that genetic testing for *APOL1* is part of precision genetic medicine rather than perpetuating race-based medical practice.

Communicate Effectively

Those involved in community-level education efforts as discussed under Goal 1, can promote genetic testing for people of African ancestry while addressing misconceptions and misinformation about testing and the implications of positive test results. Additionally, those engaged in communication and healthcare provider education should develop and disseminate culturally competent training to healthcare providers to address patient concerns.

Protect Data

While data remains a challenge in the greater healthcare community, strong efforts should be made to enforce data protection policies, promote transparency about data usage to individuals, and communicate

how and why data will be used. For example, frequently asked questions related to test data can be developed and disseminated to both providers and individuals considering testing.

Provide Information on GINA

Processes should also be put in place to limit any adverse effects of testing on individuals. Promoting awareness of the protective measures that are outlined in GINA would help ensure that individuals are aware of their rights to be protected from discrimination based on their genetic testing results. For example, education on GINA may help patients understand that genetic testing in patients already diagnosed with CKD does not increase the possibility of being denied life or health insurance. Additionally, guidance should also convey the implications in obtaining life or health insurance upon a positive *APOL1* test result in individuals who do not have CKD or who are in the military (in cases where GINA does not apply).[60]

Diversify the Healthcare Workforce

Finally, boosting efforts to build a diverse healthcare workforce can help promote provider-patient concordance, which can build trust and support. Collaboration with academic and other training institutions can help support a diverse workforce and ensure that more providers of African ancestry or who can credibly speak to the experiences of those of African ancestry, are adequately represented in the workforce.

Goal 3. Empower Patients to Make Informed Decisions Regarding Clinical Study Participation

Clinical studies are central to advancing the treatment of APOL1 KD. However, people of African ancestry are underrepresented in all areas of clinical studies. Robust participation in APOL1 KD clinical studies can be achieved when individuals feel empowered and motivated to participate.

Potential solutions and strategies to address challenges in clinical study participation include:

- Community outreach and engagement to promote clinical study participation.
- Training for healthcare providers to promote clinical studies to patients.

Community Outreach and Engagement to Promote Clinical Study Participation

Meaningful outreach and engagement with communities at risk can help provide people with the information necessary to make informed decisions about participating in clinical trials.

Challenge: Disparities and Mistrust in Clinical Study Participation

Studies on clinical study participation have found that people of African ancestry are underrepresented. Despite making up about 13% of the U.S. population, only 6% of all clinical study participants in 2021 identified as Black/African American.[61] Furthermore, people of African ancestry are underrepresented in nephrology clinical studies despite a high burden of kidney diseases among this population. A study on participation in nephrology clinical studies found that Black/African American individuals made up only 18% of CKD trial participants and 11% of acute kidney injury trial participants, compared to White individuals who represented 57% and 74% of participants, respectively.[62]

Despite concerns about clinical studies, many individuals of African ancestry have expressed interest in participating in and learning more about clinical studies; however, there are lower rates of provider referral of patients of African ancestry to clinical studies than of White and Asian patients. Due to lower community participation in studies, many people of African ancestry are unfamiliar with clinical studies and research practices.

Diverse representation in clinical studies is not simply a matter of biology, but a matter of health equity, fairness, and public trust.[63] A study on African American participation in clinical studies found four key barriers to participation: lack of awareness about studies, economic factors, communication issues, and mistrust.[64]

Equity is particularly important with respect to equal access and representation in clinical studies. Underrepresentation of minority patients in clinical studies compromises the generalizability of study results,[65,66,67] and may lead to miscalculations of disease-free survival rates and to erroneous estimates of treatment efficacy.[68,69,70,71] As a result, this underrepresentation may further exacerbate health disparities.[72]

There are additional concerns associated with participating in clinical studies. For example, participants are often inadequately compensated for their time, and even with adequate compensation, clinical trials that are not tailored to reflect the daily realities participants face may present logistical barriers to participation. In addition, participants may perceive that clinical study investigators profit from their illness, and without a guarantee of a treatment that improves a patient's health outcomes, participating may not seem beneficial. Additionally, potential participants may be concerned about data collection and utilization practices by investigators.

Finally, since genetic testing for *APOL1* is often a requirement for participating in APOL1 KD clinical studies, this may deter those who are concerned about getting tested, as outlined in the Testing section above.

Solution: Community Outreach and Engagement

Build Community Engagement into Clinical Studies

Clinical studies should specifically include community engagement components to build trust with participants and their communities. Those involved in clinical studies should also promote the personal, family, and community benefits of participating in studies, as people eligible to participate in clinical studies may feel a sense of fulfillment in contributing to medical research and making an impact within their community and the broader population.

Create User-Friendly APOL1 KD Clinical Study List

Finally, there should be a concerted effort to disseminate information on existing clinical studies to those within the healthcare community and individuals who may be eligible to participate. For example, a user-friendly listing of clinical studies that also addresses frequently asked questions can be informative to providers and be beneficial in generating interest among those who may be eligible to participate in APOL1 KD studies.

Training for Healthcare Providers to Promote Clinical Studies to Patients

Challenge: Referral of Patients to Clinical Studies

Many providers may be unaware of active APOL1 KD clinical studies, and therefore would not consider whether a patient may be eligible to participate. For providers who are aware of *APOL1* KD clinical studies, they may not perceive a potential benefit for their patients or their practice for referring patients that may be eligible and willing to participate in studies.

Further, information about existing clinical trials may be limited, or challenging to access or navigate. Websites like clinicaltrials.gov list current clinical studies, however, important information may be confusing and difficult to find.

Solution: Provider Training

Inform Providers about APOL1 KD Studies

Learning about existing APOL1 KD clinical studies, understanding how to identify patients eligible for studies, and incorporating best practices for ethically and equitably communicating about clinical studies can help providers more effectively promote studies to their patients.

Promote Clinical Studies in Nephrology Practice

Training providers on APOL1 KD clinical studies requires a culture shift that promotes clinical studies in nephrology practice. Specifically, guidelines that provide guidance or recommendations for discussing clinical trial participation with patients as part of the model for optimal, comprehensive, and culturally competent care should be developed. Approaches to this may include:

- Promoting the benefits of clinical studies in clinical guidelines.
- Facilitating access to information about clinical studies by creating easy-to-access and easy-to-navigate platforms.
- Disseminating research findings through credible sources.

ACTION ITEMS

The action items listed below were developed to **operationalize the proposed solutions and strategies** outlined in each goal area of this roadmap. These action items are central to advancing the goals and creating change.

The actions are grouped into themes corresponding to the proposed solutions and strategies for each goal:

Actions to Advance Goal 1: Actions to Increase Awareness of APOL1 KD

- Focused Educational Efforts to Increase Awareness
- Engagement to Build Trust and Empower
- Provider Training

Actions to Advance Goal 2: Actions to Increase Genetic Testing of APOL1 KD and Associated Counseling

- Provider Training
- Systemic Efforts to Support Access to Testing
- Efforts to Enhance Testing Awareness

Actions to Advance Goal 3: Actions to Empower Patients to Make Informed Decisions Regarding Clinical Study Participation

- Community Outreach and Engagement
- Provider Training

While some of the action items or entities listed may appear broad and the responsible entities unspecified, it is our intention that during the implementation of this roadmap, we will identify "implementers" who will lead or support specific actions within defined timeframes.

Further, while all the action items outlined in this roadmap are important to address the three goals, in Appendix E we have selected 10 action items that may achieve progress on the roadmap goals most rapidly based on ease of implementation. We also understand that the implementers may prioritize them differently based on their priorities, resources, and availabilities.

GOAL 1: Actions to Increase Awareness of APOL1 KD

Focused Educational Efforts to Increase Awareness

Action	Who can take the action?	When can the action be completed?
A1: Develop, disseminate, and leverage existing resources on CKD, APOL1 KD, and risk factors for persons and communities.	Healthcare, public health or related organizations, associations, or societies; Academic research institutions; Health agencies; Patient advocacy organizations; Healthcare providers	Mid-Term (2026-2028)
A2: Develop, disseminate, and leverage existing resources on APOL1 KD clinical studies and genetic testing tailored to patients and their families.	Healthcare, public health or related organizations, associations, or societies; Academic research institutions; Healthcare systems; Healthcare providers; Health agencies; Patient advocacy organizations	Mid-Term (2026-2028)
A3: Host informational sessions (e.g., webinars) to educate, provide clarity, and address concerns.	Healthcare, public health or related organizations, associations, or societies; Community organizations and partners; Health agencies; Patient advocacy organizations	Mid-Term (2026-2028)
A4: Provide information on CKD and APOL1 KD to policy makers.	Healthcare, public health or related organizations, associations, or societies; Health agencies; Patient advocacy organizations	Mid-Term (2026-2028)
A5: Lead, advocate for, or support efforts for the creation of an ICD-10 code for APOL1 KD.	Healthcare, public health or related organizations, associations, or societies; Healthcare systems; Health agencies; Patient advocacy organizations	Mid-Term (2026-2028)
A6: Develop data collection processes to inform best practices, policy making, and educational efforts in APOL1 KD.	Healthcare, public health or related organizations, associations, or societies; Patient advocacy organizations	Long-Term (2028+)
A7: Develop or update kidney clinical guidelines, genetics guidelines, and recommendations on APOL1 KD to the general healthcare provider community.	Clinical guidance issuing entities (e.g., Kidney Disease: Improving Global Outcomes (KDIGO)); Research and academic institutions; Health agencies; Patient advocacy organizations	Long-Term (2028+)

Engagement to Build Trust and Empower

Action	Who can take the action?	When can the action be completed?
A8: Establish patient advisory boards.	Patient advocacy organizations; Healthcare, public health or related organizations, associations, or societies; Healthcare systems	Mid-Term (2026-2028)
A9: Engage patients in the APOL1 KD treatment development process.	Healthcare systems; Biomedical research community	Mid-Term (2026-2028)
A10: Promote APOL1 KD awareness and activism among organizations embedded in communities of African ancestry.	Patient advisory boards; Patient advocacy organizations (e.g., Patient Family Partnership Council (PFPC)); Community organizations; Local and State Departments of Health, Health Ministries, and Social and Civic Organizations	Near-Term (2024-2026)
A11: Establish and implement efforts to facilitate the coordination of care between providers.	Professional associations	Long-Term (2028+)
A12: Employ, train, and encourage the use of patient navigators.	Healthcare systems; Healthcare providers; Policy makers; Health agencies	Mid-Term (2026-2028)
A13: Engage patients, communities, and faith leaders in development of patient-centered resources and leverage existing resources.	Healthcare, public health or related organizations, associations, or societies; Patient advocacy organizations (e.g., Patient Family Partnership Council (PFPC)); Community organizations; Health agencies; Community health workers	Mid-Term (2026-2028)
A14: Connect with and maintain respectful relationships with community liaisons.	Clinical guidance issuing entities (e.g., Kidney Disease: Improving Global Outcomes (KDIGO)); Research and academic institutions; Health agencies; Patient advocacy organizations	Long-Term (2028+)

Provider Training

Action	Who can take the action?	When can the action be completed?
A15: Develop and leverage existing continuing education for healthcare providers, such as nurse practitioners and physician assistants.	Healthcare, public health or related organizations, associations, or societies; Academic institutions; Patient advocacy organizations	Mid-Term (2026-2028)
A16: Establish workforce training efforts or processes that support patient-provider racial concordance to communicate about APOL1 KD.	Healthcare, public health or related organizations, associations, or societies; Healthcare systems; Academic institutions; Patient advocacy organizations; Diversity, Equity, and Inclusion (DEI) experts	Long-Term (2028+)
A17: Create educational materials on provider-patient communication about APOL1 KD.	Healthcare, public health or related organizations, associations, or societies; Pharmaceutical/biomedical industry	Mid-Term (2026-2028)
A18: Train primary care providers on when to suspect APOL1 KD and on the need for prompt referral in such patients.	Healthcare, public health or related organizations, associations, or societies; Healthcare providers	Long-Term (2028+)
A19: Incorporate training about diagnosis and management of rare diseases and genetic-mediated kidney diseases into healthcare education.	Academic and training institutions	Long-Term (2028+)
A20: Develop and implement cultural competence trainings for providers.	Academic and training institutions; Professional associations; Healthcare systems; DEI experts	Mid-Term (2026-2028)

GOAL 2: Actions to Increase Genetic Testing of APOL1 KD and Associated Counseling

Provider Training

Action	Who can take the action?	When can the action be completed?
A21: Develop and implement continuing medical education that promotes awareness of *APOL1* genetic testing, including options and processes for healthcare providers.	Healthcare, public health or related organizations, associations, or societies; Medical education institutions; Laboratory diagnostics companies	Mid-Term (2026-2028)
A22: Develop and implement continuing medical education for healthcare providers to understand the role of genetic counselors and counseling options.	Hospital systems; Healthcare, public health or related organizations, associations, or societies; Medical education institutions; Laboratory diagnostics companies	Mid-Term (2026-2028)
A23: Develop resources and train healthcare providers on streamlined processes for ordering and managing *APOL1* genetic tests.	Healthcare, public health or related organizations, associations, or societies; Medical education institutions; Laboratory diagnostics companies	Mid-Term (2026-2028)
A24: Provide CME to train healthcare providers (e.g., nephrologists, primary care providers, pharmacists) on discussing APOL1 KD testing options, genetic counseling, and mental health concerns with patients.	Patient advocacy organizations; Healthcare, public health or related organizations, associations, or societies; Medical education institutions; Patient advocacy organizations	Mid-Term (2026-2028)
A25: Offer information on *APOL1* testing to potential kidney donors.	Patient advocacy organizations	Near-Term (2024-2026)
A26: Offer healthcare providers (e.g., nephrologists, primary care providers, pharmacists) and allied health professionals training on GINA to inform patients of their rights.	Healthcare, public health or related organizations, associations, or societies; Patient advocacy organizations; Healthcare systems	Mid-Term (2026-2028)

Systemic Efforts to Support Access to Testing

Action	Who can take the action?	When can the action be completed?
A27: Engage with biomedical industry leaders to advocate for CLIA-supported *APOL1* testing development.	Healthcare, public health or related organizations, associations, or societies; Research institutions; Policymakers	Long-Term (2028+)
A28: Promote inclusion of *APOL1* in American College of Medical Genetics and Genomics (ACMG) guidance on genes that should be evaluated in individuals undergoing clinical exome and genome sequencing.	Healthcare, public health or related organizations, associations, or societies; Patient advocacy organizations	Mid-Term (2026-2028)
A29: Support efforts to promote affordability of *APOL1* genetic testing (i.e., insurance coverage).	Healthcare, public health or related organizations, associations, or societies; Patient advocacy organizations; Biomedical and pharmaceutical companies; Biomedical and pharmaceutical companies; Health agencies; Policymakers	Long-Term (2028+)
A30: Support *APOL1* genetic testing awareness in state and local health departments.	Policymakers; Patient advocacy organizations; Health agencies	Long-Term (2028+)

Efforts to Enhance Testing Awareness

Action	Who can take the action?	When can the action be completed?
A31: Establish trusted relationships with communities of African ancestry to promote *APOL1* genetic testing.	Patient advocacy organizations; Community organizations; Local healthcare centers; Trusted advisors; Health agencies	Long-Term (2028+)
A32: Implement sustainable *APOL1* genetic testing programs that are accessible to communities of African ancestry.	Community organizations; Health agencies	Long-Term (2028+)
A33: Offer resources (e.g., GINA factsheets) to address concerns or implications for testing.	Trusted advisors; Community organizations; Health agencies	Near-Term (2024-2026)

GOAL 3: Actions to Empower Patients to Make Informed Decisions Regarding Clinical Study Participation

Community Outreach and Engagement

Action	Who can take the action?	When can the action be completed?
A34: Build community engagement into APOL1 KD clinical studies.	Clinical study investigators; Biomedical research community; Faith leaders	Long-Term (2028+)
A35: Build sustainable relationships with community organizations and trusted advisors to promote clinical studies among people of African ancestry.	Clinical study investigators; Biomedical research community; Faith leaders	Long-Term (2028+)
A36: Hold community events and healthcare screenings among communities of African ancestry to promote APOL1 KD clinical studies.	Clinical study investigators; Biomedical research community; Community organizations; Patient advocacy organizations; Healthcare organizations; Community health workers	Near-Term (2024-2026)
A37: Develop and disseminate resources on current APOL1 KD clinical studies.	Patient advocacy organizations; Community health workers	Near-Term (2024-2026)
A38: Meet with trusted advisors within communities to promote APOL1 KD studies.	Patient advocacy organizations; Clinical study investigators	Near-Term (2024-2026)

Provider Training

Action	Who can take the action?	When can the action be completed?
A39: Develop and disseminate resources on current APOL1 KD clinical studies for primary care providers, nephrologists, clinical geneticists, and other healthcare specialties	Healthcare, public health or related organizations, associations, or societies	Near-Term (2024-2026)
A40: Develop CME courses on APOL1 KD that include information on clinical studies.	Healthcare, public health or related organizations, associations, or societies	Mid-Term (2026-2028)
A41: Develop culturally inclusive communication training for providers to encourage transparent conversations about clinical studies with patients of African ancestry.	Healthcare associations; DEI experts	Mid-Term (2026-2028)
A42: Support training to develop a more diverse pool of research staff.	Clinical study investigators; Biomedical research community; Faith leaders	Long-Term (2028+)
A43: Include clinical study consideration in nephrology guidelines to foster consideration of studies and innovation in the nephrology community.	Healthcare, public health or related societies, associations, or organizations; Biomedical research community; Medical education institutions	Mid-Term (2026-2028)
Action 44: Develop tools to enable data exchanges between electronic health records and APOL1 KD clinical studies	Biomedical research community; Technology companies	Mid-Term (2026-2028)

APPENDIX A

KHI WORKGROUP MEMBERS (STEERING COMMITTEE + WORKING GROUPS)

Table 1. KHI APOL1 Steering Committee, listed alphabetically by last name

Name	Organization
Ogo Egbuna, MD, M.MSc	Vertex Pharmaceuticals
Patrick O. Gee, Sr., PhD, JLC	KHI Patient and Family Partnership Council; APOLLO
Barbara Gillespie, MD, MMS , FASN (KHI Board Liaison)	KHI Board of Directors; Fortrea; University of North Carolina
Nicolas Guzman, MD	KHI Board of Directors; AstraZeneca
Christine Lee, PhD, PharmD	FDA Office of Minority Health and Health Equity
Susanne B. Nicholas, MD, MPH, PhD	ASN Health Care Justice Committee; David Geffen School of Medicine at University of California, Los Angeles
Uptal D. Patel, MD	KHI Board of Directors Chair; HI-Bio; Duke University
Glenda V. Roberts	KHI Board of Directors; APOLLO Community Advisory Committee; Center for Dialysis Innovation; Kidney Research Institute
Aliza M. Thompson, MD, MS	KHI Board of Directors; FDA Center for Drug Evaluation and Research

Table 2. KHI APOL1 Disease Landscape Workgroup, listed alphabetically by last name

Name	Organization
Dhruti Chen, MD	University of North Carolina
Robert Flemming, PhD	Centers for Medicare and Medicaid Services
Raven Hardy, PhD, MA	Food and Drug Administration, Office of Minority Health and Health Equity
Julie Hsieh, PhD	Food and Drug Administration, Office of Minority Health and Health Equity
Courtney Keplinger, MBA	Vertex Pharmaceuticals
Christine Lee, PhD, PharmD	Food and Drug Administration, Office of Minority Health and Health Equity
Jennifer Nwosu	Food and Drug Administration, Office of Minority Health and Health Equity

Table 3. KHI APOL1 Testing Workgroup, listed alphabetically by last name

Name	Organization
Jonathan Berg, MD, PhD	University of North Carolina at Chapel Hill
Ogo Egbuna, MD, MSc	Vertex Pharmaceuticals
Michael Spigler	American Kidney Fund

Table 4. KHI APOL1 Education Workgroup, listed alphabetically by last name

Name	Organization
Ghelatia Araia, MPH	HHS - KidneyX Fellow
Lenore Threadgill Coleman, PharmD	Healing Our Village
Lauren Eva	NephCure
Barbara Gillespie, MD, MMS, FASN	KHI Board of Directors; Fortrea; University of North Carolina
Maurice Madden	NephCure
Susanne B. Nicholas, MD, MPH, PhD	ASN Health Care Justice Committee; David Geffen School of Medicine at University of California, Los Angeles
Ike Ogbaa, MD	Chinook Therapeutics
Glenda V. Roberts	KHI Board of Directors; APOLLO Community Advisory Committee; Center for Dialysis Innovation; Kidney Research Institute

Table 5. KHI APOL1 Clinical Trials Workgroup, listed alphabetically by last name

Name	Organization
Barbara Gillespie, MD, MMS, FASN	KHI Board of Directors;Fortrea; University of North Carolina
Nicolas Guzman, MD	AstraZeneca
Charlotte Jones-Burton, MD, MS	Chinook Therapeutics
Courtney Keplinger, MBA	Vertex Pharmaceuticals

The Steering Committee and workgroups members were also supported by KHI staff.

Table 6. KHI Staff, listed alphabetically by last name

Name	Organization
Seyi Balogun, MPH	KHI Program Manager
Mark David Lim, PhD, PMP	KHI Vice President, Research, Discovery, and Innovation
Cesia Portillo, MPH	KHI Program Coordinator
Grace Squillaci, MBA	KHI Project Consultant

APPENDIX B
SOCIO-ECOLOGICAL MODEL

The Socio-Ecological Model is a framework describing how larger systems can influence an individual's health outcomes.[8,9] This model was used to inform how we addressed the challenges and solutions in the roadmap.

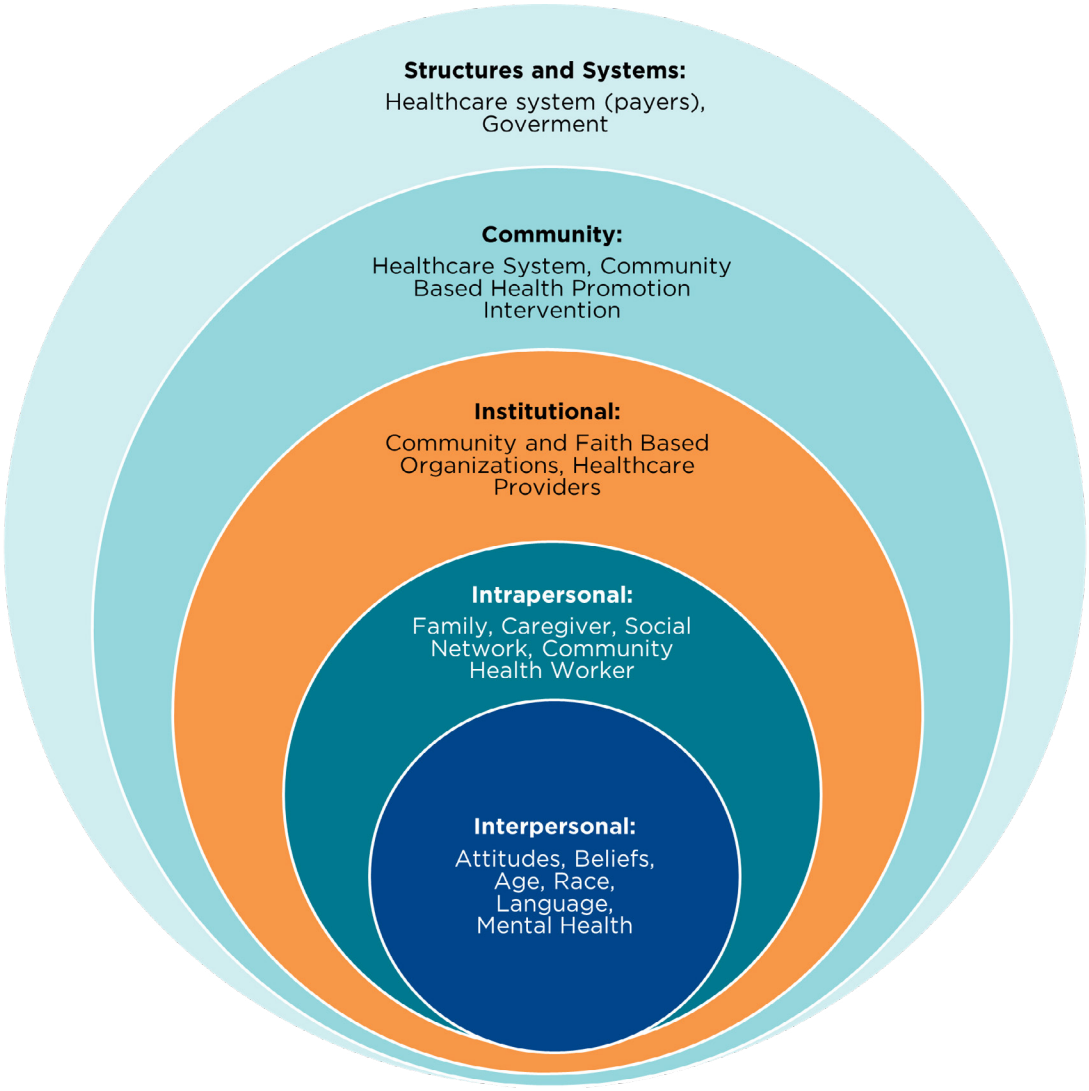

Figure 2. Socio-Ecological Model adapted to APOL1 KD from Centers for Disease Control and Prevention (2017).[73]

APPENDIX C
ADVISORS

Table 7. Advisors who participated in APOL1-KD interviews

Advisor	Specialization/Affiliation
John Sedor, MD	Cleveland Clinic
Gillian Hooker, PhD, ScM, CGC	Concert Genetics
Carol Horowitz, MD, MPH	Icahn School of Medicine at Mount Sinai.
Trudy McKanna, MS	GRAIL
Barry Freedman, MD	Wake Forest University Institute for Regenerative Medicine.
Ali Gharavi, MD	Columbia University Vagelos College of Physicians and Surgeons.
Opeyemi Olabisi, MD, PhD	Duke University School of Medicine.
Nadine Barrett, PhD	Duke University School of Medicine
Lionel Phillips, MBA	Inside Edge Consulting Group
Judy Greener, PhD	Inside Edge Consulting Group
Patient Organizations Represented	
National Kidney Foundation	
NephCure	
American Kidney Fund	
Alport Syndrome Foundation	

APPENDIX D
RESOURCES

These resources are provided as supporting materials related to the roadmap goals. This list is not exhaustive, but is rather intended as a living document. We welcome additions from the broader community.

Name	Source	Type	Brief Description	Relevant Goal Areas
ACO REACH And Advancing Equity Through Value-Based Payment, Part 1	Health Affairs	Webpage	Overview of the application of value-based payment (VBP) models for reducing health inequities	1
Advancing American Kidney Health	Office of the Assistant Secretary for Planning and Evaluation	Government webpage	A strategic plan and vision for advancing American kidney health	1,2,3
Alonzo Mourning Champions Fight Against Kidney Disease Primarily Affecting People of African Ancestry	Black Enterprise	Webpage	Highlights a patient's experience with kidney disease	1
American Kidney Fund: *APOL1*-Mediated Kidney Disease	American Kidney Fund	Webpage	Information about *APOL1*	1
APOL1 Genotype, Varies	Mayo Clinic	Test catalog	Information on genetic testing	1,2
APOL1-Related Chronic Kidney Disease	23andme	Webpage	Description of the influence of genetics on CKD	1,2
APOL1 Genetic Variant Animation - Patients/ Veterans (General)	Leaping Media	YouTube video	Information on *APOL1* variants	1,2
Apolipoprotein L1 (*APOL1*) Renal Risk Variant Genotyping	Quest diagnostics	Webpage	FAQs about *APOL1* renal risk variant genotyping	1,2
Apolipoprotein L1 (*APOL1*) in African Americans SLE | Michelle Petri MD	Johns Hopkins Medicine	YouTube video	Information about the connection between Lupus and *APOL1*	1,2
Barry Freedman's Quest to Redefine Kidney Disease and Revolutionize Kidney Transplantation	Wake Forest	Webpage	A collection of patient journey stories and information on *APOL1*	1
Understanding a Genetic Kidney Disease Known as APOL1-Mediated Kidney Disease (AMKD)	Blackdoctor.org	Webpage	An overview on *APOL1*	1

Name	Source	Type	Brief Description	Relevant Goal Areas
Black Health Matters Talks FSGS With NephCure's Lauren Lee	Black Health Matters	Webpage	Interview with a leadership member at NephCure	1
Black Health Matters: Kidney Disease	Black Health Matters	Webpage	Information on kidney disease	1,2,3
Black Health: Is FSGS Caused by a Genetic Variant?	Black Health Matters	Webpage	Information on the link between FSGS and *APOL1*	1,2
Black Women's Health Imperative: Black & Rare: Understanding APOL1	Black Women's Health Imperative	YouTube video	Discussion on the causes of *APOL1* genetic variants and the medical outcomes that can arise from them.	1,2
ClinicalTrials.gov	ClinicalTrials.gov	Webpage	Listing of clinical trials, where APOL1 KD clinical trials can be found by searching for *APOL1* under condition or disease	3
Could a Community-Based Approach to Genetic Testing Help African Americans Reduce Risks of Chronic Kidney Disease?	Mount Sinai	Press release	Information on an *APOL1* pilot study	1,2,3
Clinical trials: recommendations and resources	Clinical Trials Transformation Initiative	Webpage	Information on engaging patients for different clinical trials	1,3
Coding and Billing of Molecular Pathology and Genetic Testing	BC advantage	Website	Information on CPT codes	1
Clinical trial diversity craters out to lowest level in 10 years, IQVIA finds	Fierce Biotech	Webpage	Statistical data on minority inclusion in clinical trials	3
How the Social Ecological Model Influences Health Outcomes	Karna	Webpage	Example of the application of the Social Ecological Model on health outcomes	1
How To Improve Race, Ethnicity, And Language Data and Disparities Interventions	Health Affairs	Webpage	Article on using race, ethnicity, and language data to identify and intervene on urgent population priorities	1

Name	Source	Resource Type	Brief Description	Goal Areas
Renasight; Kidney Gene Panel	Natera	Research poster	Research study on genetic testing on end-stage renal disease (ESRD)	1,2,3
Understanding APOL1 Kidney Disease Among Black Americans	NephCure Kidney International	Webpage	Information on *APOL1* kidney disease, including *APOL1* FSGS	1
Major Studies of Patients with Lupus Lead to Groundbreaking Discoveries	NYU Langone Health	NYU Langone Health news coverage on Lupus-Associated renal disease	Interview with Dr. Ashira Blazer who investigates the correlation between APOL1 and lupus amongst Ghanian patients	1,2
Only 5.7% of US doctors are Black, and experts warn the shortage harms public health	CNN	News article	The impact of racial disparities among U.S. doctors	1
How are variations in the APOL1 gene linked to risk of kidney disease?	Stat News	Article	Article on *APOL1* and its impact on Black communities	1
Community Education	The Sickle Cell Disease Foundation	Blog posts	Information on community education programs and services	1
The Faces of APOL1-Mediated Kidney Disease: Improving Diagnosis, Treatment, and Management Strategies to Promote Health Equity	PRIME®	Interactive webpage	Interactive survey and video with Dr. Olabisi.	1
APOL1-Mediated Kidney Disease Background	Arkana Laboratories	Webpage	Information about a No Cost to Patient *APOL1* Genotyping Program	1,2
Assessing Meaningful Community Engagement in Health Care Policies and Programs	National Academy of Medicine	Webpage	Resources to measure community engagement	1,2,3
Toward Equitable Innovation in Health and Medicine: A Framework	National Academies of Sciences, Engineering, and Medicine	Consensus study report	A framework for developing and using technologies in health and medicine with ethical and equitable principles	2,3

APPENDIX E
PRIORITIZED ACTION ITEMS

While all action items are important, we have selected 10 that may help achieve progress on the roadmap goals in a more rapid timeframe.

Patient and Community Engagement

GOAL 1: Actions to Increase Awareness of APOL1 KD

Focused Educational Efforts to Increase Awareness:

- Action 1: Develop, disseminate, and leverage existing resources on CKD, APOL1 KD, and risk factors for persons and communities.
- Action 5: Lead, advocate for, or support efforts for the creation of an ICD-10 code for APOL1 KD.

Engagement to Build Trust and Empower

- Action 10: Promote APOL1 KD awareness and activism among organizations embedded in communities of African ancestry.

Provider Training

- Action 19: Incorporate training about diagnosis and management of rare diseases and genetic-mediated kidney diseases into healthcare education.

GOAL 2: Actions to Increase Genetic Testing of APOL1 KD and Associated Counseling

Provider Training

- Action 21: Develop and implement continuing medical education that promotes awareness of *APOL1* genetic testing, including options and processes for healthcare providers.
- Action 26: Offer healthcare providers (e.g., nephrologists, primary care providers, pharmacists) and allied health professionals training on GINA to inform patients of their rights.

Systemic Efforts to Support Access to Testing

- Action 28: Promote inclusion of *APOL1* in American College of Medical Genetics and Genomics (ACMG) guidance on genes that should be evaluated in individuals undergoing clinical exome and genome sequencing.

Efforts to Enhance Testing Awareness

- Action 31: Establish trusted relationships with communities of African ancestry to promote *APOL1* genetic testing.

GOAL 3: Actions to Empower Patients to Make Informed Decisions Regarding Clinical Study Participation

Community Outreach and Engagement

- Action 34: Build community engagement into APOL1 KD clinical studies.

Provider Training

- Action 43: Include clinical study consideration in nephrology guidelines to foster consideration of studies and innovation in the nephrology community.

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