

# Journal Pre-proof



A National Registry for People With All Stages of Kidney Disease: The National Kidney Foundation (NKF) Patient Network

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## **A National Registry for People With All Stages of Kidney Disease: The National Kidney Foundation (NKF) Patient Network**

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**PLAIN LANGUAGE SUMMARY**

The NKF Patient Network (NKFPatientNetwork.org) is a nationwide kidney disease patient registry created to improve the lives of people with kidney disease through research, clinical care, and drug development. The Network has a secure portal for participants to share their experiences and data, and for providers to upload electronic health records upon patient consent. The Network also offers individualized education and support. In this feasibility study, we found low awareness of kidney disease for many participants and a challenge in recruiting vulnerable populations. These are short-term goals of the Network following the national launch in February 2021. Overall, the Network will facilitate real-world data collection to inform the development of patient-centered research, care, and treatments for people with kidney disease.

**ABSTRACT**

**Rationale & Objective:** The National Kidney Foundation (NKF) launched the first national U.S. kidney disease patient registry, the NKF Patient Network, opened to patients throughout the continuum of chronic kidney disease (CKD). The Network provides individualized education, and will facilitate patient-centered research, clinical care, and health policy decisions. Here, we present the overall design and the results of a feasibility study that was conducted July through December 2020.

**Study Design:** Longitudinal observational cohort study of patient-entered data with or without electronic healthcare records (EHR) linkage in collaboration with health systems.

**Setting and Participants:** People with CKD, age  $\geq 18$  years, are invited through their provider, NKF communications, or national outreach campaign. People self-enroll and share their data through a secure portal that offers individualized education and support. The first health system partner is Geisinger.

**Exposure(s):** Any cause and stage of CKD, including dialysis and kidney transplant recipients.

**Outcome(s):** Feasibility of the EHR data transfer, participants characteristics, and their perspectives on usability and content.

**Analytical Approach:** Data were collected and analyzed through the registry portal powered by the Pulse Inframe healthie™ 2.0 platform.

**Results:** During the feasibility study, 80 participants completed their profile and 42 completed a satisfaction survey. Mean age was 57.5 years, 51.3% were women, 83% were White, and 89% were non-Hispanic or Latino. 60% of the participants were not aware of their level of estimated glomerular filtration rate (eGFR) and 91% of their urinary albumin/creatinine ratio (UACR).

**Limitations:** Challenges for the Network are lack of awareness of kidney disease for many with CKD, difficulty in recruiting vulnerable populations or those with low digital readiness, and loss to follow-up, all leading to selection bias.

**Conclusions:** The Network is positioned to become a national and international platform for real-world data that can inform the development of patient-centered research, care, and treatments.

**Keywords:** registry, chronic kidney disease, patient-reported outcomes, electronic health records

## INTRODUCTION

Chronic kidney disease (CKD) is a worldwide public health problem, characterized by increasing prevalence, high cost, and poor outcomes.<sup>1</sup> In the United States (U.S.), CKD affects 37 million adults.<sup>2,3</sup> Poor outcomes from CKD include progression to kidney failure, often requiring kidney replacement therapy with dialysis or kidney transplant, increased risk for acute kidney injury (AKI), cardiovascular disease (CVD), and mortality among other complications.<sup>1-4</sup> CKD and kidney failure with replacement therapy (KFRT) together impose a high financial burden accounting for over \$110 billion yearly in Medicare cost.<sup>5</sup>

Despite the high prevalence and burden of this disease, approximately 90% of patients with CKD in the U.S. are unaware of their condition because of the asymptomatic nature of the disease and underdiagnosis by providers.<sup>6-8</sup> Importantly, there are effective therapeutic strategies to slow CKD progression, but lack of awareness hampers use of these therapies.<sup>9,10</sup> In other fields, real-world evidence (RWE) studies based on real-world data (RWD), such as patient registries, are becoming central to overcoming such obstacles in the care and management of many diseases.<sup>11-15</sup>

In 2021, the National Kidney Foundation (NKF) launched the first national U.S. kidney disease patient registry, the NKF Patient Network (referred to as The Network hereon in). The Network is the first ever national registry of adult patients with all stages of CKD that links patient-entered data on medical history, demographics, lifestyle, and perceptions with clinical and laboratory data from electronic health records (EHRs). The overall goal of the Network is to create an interactive community of patients throughout the continuum of CKD to enable individualized educational resources, and will facilitate research, clinical care and health policy decisions centered on patient perceptions and priorities. Ultimately one of the major goals is to improve patient outcomes and patients' experience with treatment for their disease.

In this paper, we describe the overall design of the Network and the results from the feasibility study that informed the U.S. national launch in February 2021, and our plans going forward.

## METHODS

### Design

The Network is a longitudinal, retrospective and prospective, observational cohort study of patient-entered data that collaborates with health systems to obtain additional EHR data. The Network was designed to include EHR data because laboratory data is necessary to define and stage CKD, and laboratory values and clinical conditions change frequently, making it challenging for patients to continually update them over time.

The short- and long-term goals of the NKF Patient Network are listed in **Box 1**. This study is approved by the Tufts Health Sciences Institutional Review (IRB # STUDY00000053), which serves as the IRB of record for all U.S. sites (see **Item S1**).

### Population

The Network welcomes patients with any stage of kidney disease, including kidney transplant recipients and patients on dialysis, who are 18 years or older, and willing to provide informed consent in English. Overall, the Network expects to recruit 1,500 U.S. patients by summer 2022, and 10,000 to 50,000 U.S. patients by 2026.

### Data architecture and content

**Figure 1** describes the overall architecture of the Network. Data is provided by patients through direct input or through integration with the participant's EHR. As such, the data is owned by the participants and the health system partners and managed by the NKF. Pulse Inframe (Pulse) is the partner responsible for the development and implementation of the registry on their healthie™ 2.0 Amazon Web Services® (AWS®) Global Cloud platform and data management using the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM). All data collected through the NKF Patient Network will be stored on the healthie™ 2.0 platform, a highly secure system that meets existing GDPR, HIPAA and other international established standards for security of health information (see **Item S1** for details).

The data dictionary was developed by NKF with the members of the Data Input and Integration Committee at the time, whose membership includes patients with kidney disease. Parameters for kidney disease were first identified, and separated out into those which were appropriate for patient-entered data, EHR-derived data, or both. Parameters include CKD stages, kidney replacement therapies experience, cause of kidney disease, family history, CKD complications, comorbid conditions, and medications (see **Table S1**). Members of the Patient Advisory Working Group reviewed all of the questions asked to ensure that the language was familiar and clear.

Summary data will be available to the Network participants and partners via analytic portals, real-time dashboards, and/or specialized reports. Researchers will be able to submit proposals for review and approval, with the analyses performed by the Data Coordination Center or Pulse depending on the request (**Figure 2A**).

### **Patient recruitment**

Patient recruitment targets two audiences: general public and closed systems. The general public is reached through a comprehensive outreach that includes other NKF programs, local NKF field offices, participants from clinical trials for kidney disease treatments, referrals from other Network's participants, professional societies and patient advocacy groups, and a direct public relations campaign. The closed systems include among others health systems, academic medical centers, testing laboratories, or rare kidney disease groups. Here, patients will be recruited using the methods available at each organization (e.g., e-blasts, newsletters, provider, or care manager recommendation, MyChart messages).

Potential participants can self-enroll online at NKFPatientNetwork.org where they are required to fill out an eligibility screening questionnaire. Participants are then asked to provide informed consent, in a document unique to the source from which the participant was recruited (**Figure S1**). EHR data sharing occurs only if participants are affiliated with health systems that are partners of the Network.

### **Human-centered design**

The human experience through the Network was critical to its design.<sup>16</sup> The Network's design team in collaboration with Pulse developed four journeys, one for each persona that we understood would interact with the Network, i.e., a person recently diagnosed with early CKD, a person with progressive CKD and comorbid conditions, a person with KFRD receiving dialysis, and a person with CKD who received a kidney transplant.<sup>17</sup> The journeys highlighted the challenges and goals of each persona and provided insights on what in the Network would be most important to them. Next, the team developed user-friendly solutions to deliver content and engage participants while capturing structured data through a guided process (**Figure S2** and **Item S1**). All surveys were designed specifically for 8<sup>th</sup> grade reading level and to help navigation. For example, surveys have a brief description and instructions at the beginning, and a progress bar at the top to track the number of remaining questions.

At baseline, all participants are asked to submit their patient profile (**Table S1**), patient-reported outcome measures [PROM; EuroQol 5 Dimension 5 Level (EQ-5D-5 L) and Kidney Disease Quality of Life (KDQOL-36)] and patient-reported experience measures (PREM; **Table S2**). EHR data is automatically extracted from the sites upon receipt of consent. Both patient-entered data and EHR data are collected at baseline and at least every six months thereafter (**Table S2**). Requests for other surveys will be sent out via e-mail as they become available. To limit potential burden to participants, only a limited number of surveys per year will be allowed.

Enrolled participants will receive a quarterly newsletter and email notifications of local events, latest findings in research, and clinical trial recruitment, if so indicated by them on the informed consent form. Participants can have continual access to educational resources and individualized materials tailored to their disease stage via the NKF tool, Kidney Pathways.<sup>18</sup> Registry participants can also connect with other patients dealing with kidney disease through secure online communities.<sup>19</sup>

### **Governance structure**

The NKF Patient Network is governed by a robust governance structure with representation from patient advocacy, health systems, sponsors, and external experts from multiple disciplines (**Figure 2A-B** and **Item S1**). The NKF oversees the Steering Committee (SC) and together they jointly developed the principles that guide the multistakeholder participation in the committees (**Figure 2B** and **Item S1**). There are six committees which report to the SC: Patient Advisory Working Group, Patient Recruitment and Retention Committee, Data Input and Integration Committee (DIIC), Data Use and Publications Committee (DUPC), Technology Committee, and Finance Committee. A sub-committee of the DUPC will review and approve all surveys. All but the Finance Committee include patients. By design, including patients and other stakeholders enables multiple perspectives on most aspects of the operations of the Network (**Figure 2B**).

### **Stakeholder engagement and benefits to partners**

The Network is positioned to engage with a variety of stakeholders with different levels of interest in the study and abilities to influence it, which require *ad hoc* management models by NKF (**Figure 3** and **Item S1**). There are three main categories of stakeholders that were involved early on in the inception of the study and with whom the NKF developed specific engagement strategies: patients with kidney disease, the health systems, and the sponsor companies (**Box 2**).

### **Feasibility Study**

A feasibility study was conducted from July to December 2020 (see **Item S1**). Patients were recruited from members of the NKF's Kidney Advocacy Committee (KAC) via email and at the Network's first health system partner, Geisinger, via pre-notification letters or emails and followed by phone calls. Geisinger is an integrated health system that serves more than 1.5 million patients in Pennsylvania and New Jersey. Data were collected using the Pulse healthie™ 1.0 Azure® cloud platform, which was the platform available at the time. EHR data was shared between Geisinger and the healthie™ 1.0 platform via a process that was developed and tested during the feasibility study and implemented for the national launch (see **Item S1**). Goals of the feasibility study were to test the EHR data sharing process, collect the characteristics of the participants enrolled and their perspectives on usability and included resources.

## **FEASIBILITY STUDY RESULTS**

### **Participants' self-enrollment and response rates to surveys**

A total of 716 patients received an invitation to participate in the feasibility study (204 from the NKF email list and 512 from Geisinger; **Figure 4** and **Table S3**). Geisinger's study coordinator

followed-up with patients after an initial pre-notification letter or email was sent to gauge interest and offer additional information (via phone or email). **Table S4** summarizes the patient recruitment experience at Geisinger. In total, 101 people signed-up (74 from NKF, 27 from Geisinger) and 98 provided informed consent (72 from NKF, 26 from Geisinger; **Figure 4**). The uptake at Geisinger was lower compared to the NKF's (5% vs 36%) but compatible with the uptake observed for similar projects at Geisinger that were also based on pre-notification letter or email invitations without in clinic recruitment.

### **Baseline characteristics of feasibility study participants**

A total of 80 consented participants completed the patient profile, 74% were from the NKF KAC and 26% were from Geisinger. Of the 80 participants, 60 (75%) completed the EQ-5D-5L instrument, and 59 (74%) completed the KDQOL-36 instrument (**Figure 4**). Among the 80 participants, mean age was 57.5 years, 51.3% were women, 82.5% were White, and 88.8% were non-Hispanic or Latino (**Table 1**). Despite 4% of the Geisinger patients who were invited to join were Black or African American, 100% of the Geisinger participants who signed the informed consent were White and non-Hispanic or Latino. Information on race and ethnicity are not available for the NKF KAC.

A total of 23.8% of the participants self-reported to have CKD stage 5 or ESKD, 6.3% were on dialysis and 57.5% were kidney transplant recipients. Geisinger participants were older and at earlier stages of CKD compared to the NKF cohort. Approximately 30% had family history of kidney disease. The most frequent causes of CKD reported were diabetes and hypertension. Glomerulonephritis, focal segmental glomerulosclerosis, and IgA nephropathy were also common causes of kidney disease (**Table S5**).

Most participants were not aware of parameters related to their kidney disease. For example, only 40% said they were aware of the level of eGFR and 9% of the level of UACR. When asked about CKD Stage, 35% said they were not aware of and 5% did not answer. Results were overall similar between NKF and Geisinger participants, although higher proportion of Geisinger participants reported their UACR compared to the entire cohort (19% vs 5%, either exact or approximate) possibly due to the high UACR testing at the site.

EHR data of the Geisinger patients was successfully transferred to the healthie™ 1.0 platform. In the overall cohort using EHR data, mean eGFR  $\pm$  SD was  $47 \pm 22$  mL/min/1.73m<sup>2</sup>, but it was  $81 \pm 110$  mL/min/1.73m<sup>2</sup> in the 6 participants who reported exact eGFR value (**Table 2**). Interestingly, only 4 and 7 Geisinger participants out of 21 reported diabetes and hypertension as comorbidities despite 91% and 57% having diabetes and hypertension based on EHR data, respectively (**Table 2**).

### **Participant feedback**

Forty-two out of 80 (53%) participants who completed the patient profile submitted the satisfaction survey (**Figure 4** and **Table S6**). A total of 69% of the participants reported that the patient profile was 'easy' to 'extremely easy' to complete; 60% found the educational resources 'useful' to 'extremely useful' whereas 29% did not view the educational resources; 81% were 'likely' to 'extremely likely' to recommend the Network to another patient with kidney disease (**Figure S3** and **Table S7**). In the open field questions, participants liked that the Network is a good way to get information whenever necessary, it gives free access to organized resources, and it welcomes people at all stages of the disease. However, participants also commented that the informed consent was too long, the educational resources were not patient friendly and neither new nor extensive enough, the patient profile and surveys were cumbersome, and too many emails and reminders were received.

## DISCUSSION

In February 2021, the NKF launched the NKF Patient Network, the first U.S. kidney disease patient registry that links the patient voice on patient outcomes and experiences with clinical and laboratory data from EHR. This novel infrastructure complements existing real-world data (RWD) for kidney disease,<sup>20-24</sup> and enables individualized educational resources, research, clinical care, and health policy decisions to be centered on patient perceptions, priorities, and activities (**Box 3**). Participation is open regardless of the type or stage of kidney disease, without requirement for health insurance or enrollment in a health care system.

A central goal of the registry is to promote patient engagement among patients who are not currently engaged. Paradoxically, participation in the Network requires awareness of the disease.<sup>8</sup> Indeed we saw that, in our feasibility study, a third of participants had a family history of kidney disease and more than half received a kidney transplant, indicating already engaged communities. Thus, a key challenge of the Network will be to enroll people with early CKD stages who may be largely unaware of their diagnosis or its significance. To overcome this challenge, NKF has developed a multipronged approach. First, the NKF partnered with the U.S. Department of Health and Human Services (HHS) and the American Society of Nephrology (ASN) on a nationwide public awareness campaign which focuses on the 33 percent of American adults at risk for developing kidney disease.<sup>25</sup> The Network will be offered as a resource to the people at risk who engaged with the campaign and eventually received a CKD diagnosis. Second, the NKF plans to engage directly with all providers who manage the care of kidney patients, including primary care doctors and other specialty doctors like cardiologists and endocrinologists.<sup>26</sup> The NKF will work with the health system partners to identify strategies that can be implemented locally, e.g., presentation of the registry at departmental conferences, distribution of informational materials during patient events and at physician's offices. Each tactic will be monitored over time and will require input from the Patient Recruitment and Retention Committee and a multidisciplinary team at the NKF with expertise in patient education, patient engagement and marketing.

Results from the feasibility study showed that even within the engaged community there are sharp discrepancies of the EHR and patient-entered data. Prior studies in the U.S. and other countries have shown low awareness of CKD with >90% unaware of kidney dysfunction among adults with stage 3 CKD and 60% with stage 4 CKD.<sup>7,27,28</sup> Thus, our finding of poor awareness of eGFR and UACR level is not surprising and reinforces the importance of having EHR-based laboratory values as a central tenet to the design of the Network. As we recruit a less engaged community, we expect we will find greater discrepancies. We encourage researchers to leverage the registry's data to understand patient knowledge about their kidney disease and to identify gaps in education and quality care (**Box 3**). The NKF will also direct communications to participants who seem to be mostly unaware of the disease and its ramifications to provide educational resources and support.

In the design of the Network, we used both patients' perspectives as well as industry standards to develop the portal that we aimed to be a user-friendly experience. Nevertheless, the results of our feasibility study together with ongoing progress in the field helped us improve the Networks' usability. For national implementation, we shortened the online informed consent form and simplified its layout, we lowered the reading level from 12<sup>th</sup> to 8<sup>th</sup> grade, we developed videos explaining the importance of the consent process<sup>29</sup> and the benefits of participating in the Network,<sup>30,31</sup> we published a patient podcast on the topic,<sup>32</sup> and we expanded the educational content in the registry. Coincident to these changes, Pulse migrated to a new AWS® cloud platform (healthie™ 2.0 described above) with enhanced user experience and interface that allowed the implementation of navigation tools, a more intuitive way of filling in the surveys, and

a less burdensome email schedule. Moving forward, the Patient Advisory Working Group will review all platform enhancements and any changes to the patient-facing materials.

Kidney disease manifests stark racial inequities in the U.S.<sup>33,34</sup> Having a diverse group of participants in the registry creates new opportunities to provide individualized education, support, and access to clinical trials to a wider population, which could ultimately propel advancements in precision medicine and health equity. Specifically, the NKF established a Patient Recruitment and Retention Committee to help strategize on methods to ensure representation of diverse populations. The Network is partnering with health systems and community organizations that serve a large population of underrepresented minorities or uninsured individuals and is working with the NKF's local offices and medical advisory board members to promote the Network in their communities. The Network will soon launch in Spanish essential for the engagement with Hispanic communities. Lastly, the NKF is working towards diversity of the governance committees' members.

Challenges to the use of digital technologies to support health are digital readiness, eHealth literacy, and access to technology. There is a digital divide in the CKD population in the use of all forms of technologies, driven by socioeconomic status, age, and racial minority status.<sup>35,36</sup> Recent data shows that non-White individuals have greater interest in the future use of mobile Health technologies than White individuals and are more reliant on the mobile web for internet access.<sup>35</sup> The Network is mobile ready and thus can be utilized by diverse populations with a smartphone or tablet, without the need for in-home internet. For populations who might not be comfortable with technology, the NKF will provide low literacy tutorials to mitigate issues with eHealth literacy and digital readiness. Furthermore, NKF local offices and health systems partners will seek to identify the barriers to technology in their area and develop solutions (e.g., provide computer stations at NKF events; offer online access to the Network during in-clinic visits). These activities are critical to the equitable engagement of the Network by diverse populations and reduce selection bias.

The Network is continuing to expand and develop. First, inclusion of multiple health system partners with access to electronic longitudinal data and integration with other data sources are critical for success. As result of lessons learned from the EHR data sharing during the feasibility phase, the NKF and Geisinger co-developed an onboarding guide to share with potential partners. In Fall 2021 the Network has partnered with Labcorp Drug Development that is assisting with patient recruitment through promotion to their patients, with data transfer anticipated in the future. Linking the Network with individualized Medicare administrative data via the Centers for Medicare & Medicaid Services (CMS) Blue Button 2.0 service is underway:<sup>37</sup> Medicare claim data integration will help promote partnerships with healthcare organizations and health systems to understand healthcare utilization data including cost of care for patients with CKD. Second, NKF has partnered with Alport Syndrome Foundation (ASF) in what we hope is the first of strategic partnerships with rare disease patient organizations. This partnership is extremely synergistic, providing renewed focus on the importance of collecting genetics and comprehensive family histories to understand kidney disease.<sup>38,39</sup> Third, the NKF is expanding internationally, beginning with Canadian sites. Fourth, the NKF is developing ways to self-sustain the Network as it begins to have sufficient data to be used in development of clinical trials. Finally, with the success of the national launch, the Network has turned to the central challenge of patient retention, i.e., keeping the Network participants engaged and activated.

In summary, the NKF has successfully launched the first national U.S. kidney disease patient registry that links patient-entered data with laboratory and clinical information about their disease. The Network is well positioned to become a national and international longitudinal initiative focused on the diversity of the patient population with CKD and based on real-world observations that can inform the development of patient-centered research, care, and treatments.

## **SUPPLEMENTARY MATERIAL**

**ITEM S1.** Patient protections and detailed methods.

**Figure S1.** Schematic of the NKF Patient Network informed consent flow

**Figure S2.** NKF Patient Network patient journey

**Figure S3.** Satisfaction survey responses submitted by the participants of the feasibility study (N=42)

**Table S1.** Summary of the variable categories collected in the data dictionary

**Table S2.** List of surveys collected in the registry during the feasibility study and after the national launch

**Table S3.** Baseline characteristics of NKF and Geisinger patients invited to join the feasibility study

**Table S4.** Summary of the patient recruitment at Geisinger during the feasibility study

**Table S6.** Patient-reported baseline characteristics of the study participants who submitted or did not submit the satisfaction survey during the feasibility study

**Table S7.** Patient-reported kidney disease severity and awareness of the study participants who responded to be 'likely' to 'extremely likely' to recommend the Network to another patient with kidney disease

## **Article Information**

**AUTHORS' CONTRIBUTIONS:** Research idea and study design: LAI, KW; data acquisition: LAI, MB, LB, ARC, CJD, DF, BG, KL, CM, KRM, MVR, LAS, NT, CW, KW; data analysis/interpretation: LAI, SF, ARC, JC, FGS, MRZ; supervision or mentorship: LAI, AB, ARC, KC, DF, PG, KRM, KPM, MVR, AS, NT, KW. Each author contributed important intellectual content during manuscript drafting or revision and agrees to be personally accountable for the individual's own contributions and to ensure that questions pertaining to the accuracy or integrity of any portion of the work, even one in which the author was not directly involved, are appropriately investigated, and resolved, including with documentation in the literature if appropriate.

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## REFERENCES

1. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney International Supplements*. 2013;3:1-150. doi, [https://kdigo.org/wp-content/uploads/2017/02/KDIGO\\_2012\\_CKD\\_GL.pdf](https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf).
2. Levey AS, Coresh J. Chronic kidney disease. *Lancet*. 2012;379(9811):165-180. doi:10.1016/S0140-6736(11)60178-5.
3. Levey AS, Stevens LA, Schmid CH, et al. A new equation to estimate glomerular filtration rate. *Ann Intern Med*. 2009;150(9):604-612. doi:10.7326/0003-4819-150-9-200905050-00006.
4. Sarnak MJ, Amann K, Bangalore S, et al. Chronic Kidney Disease and Coronary Artery Disease: JACC State-of-the-Art Review. *J Am Coll Cardiol*. 2019;74(14):1823-1838. doi:10.1016/j.jacc.2019.08.1017.
5. Saran R, Robinson B, Abbott KC, et al. US Renal Data System 2019 Annual Data Report: epidemiology of kidney disease in the United States. *Am J Kidney Dis*. 2020;75(1)(suppl 1):S1-S64. doi:10.1053/j.ajkd.2019.09.003
6. Centers for Disease Control and Prevention (CDC). Chronic Kidney Disease (CKD) Surveillance System. <https://nccd.cdc.gov/CKD/default.aspx>. Accessed April 27, 2020.
7. Plantinga LC, Tuot DS, Powe NR. Awareness of chronic kidney disease among patients and providers. *Adv Chronic Kidney Dis*. 2010;17(3):225-236. doi:10.1053/j.ackd.2010.03.002.
8. Alfego D, Ennis J, Gillespie B, et al. Chronic Kidney Disease Testing Among At-Risk Adults in the U.S. Remains Low: Real-World Evidence From a National Laboratory Database. *Diabetes Care*. 2021;44(9):2025-2032. doi:10.2337/dc21-0723.
9. Chatzimanouil MKT, Wilkens L, Anders HJ. Quantity and Reporting Quality of Kidney Research. *J Am Soc Nephrol*. 2019;30(1):13-22. doi:10.1681/ASN.2018050515.
10. Thakar CV. Treatment of Diabetic Nephropathy: Changing Landscapes and New Horizons. *Adv Chronic Kidney Dis*. 2021;28(4):279. doi:10.1053/j.ackd.2021.11.001.
11. Kidney Research UK. <https://kidneyresearchuk.org/>. Accessed April 25, 2020.
12. NephCure Kidney International. <https://nephcure.org/>. Accessed April 25, 2020.
13. NEPHCURE Kidney International. Cure Glomerulonephropathy (CureGN). <https://curegn.org/>. Accessed April 25, 2020.
14. PKD Foundation. ADPKD Registry. <https://pkdcure.org/>.
15. RareRenal. National Registry of Rare Kidney Diseases (RaDaR). <https://rarerenal.org/radar-registry/>. Accessed April 25, 2020.
16. Melles M, Albayrak A, Goossens R. Innovating health care: key characteristics of human-centered design. *Int J Qual Health Care*. 2021;33(Supplement\_1):37-44. doi:10.1093/intqhc/mzaa127.

17. National Institute of Diabetes and Digestive and Kidney Diseases. Patient Persona. Accessed April 26, 2020.
18. National Kidney Foundation. Kidney Pathways. <https://www.kidney.org/phi/form?version=health>. Accessed April 25, 2020.
19. National Kidney Foundation. Online communities. <https://www.kidney.org/online-communities>. Accessed July, 2021.
20. Norris KC, Duru OK, Alicic RZ, et al. Rationale and design of a multicenter Chronic Kidney Disease (CKD) and at-risk for CKD electronic health records-based registry: CURE-CKD. *BMC Nephrol.* 2019;20(1):416. doi:10.1186/s12882-019-1558-9.
21. Tuttle KR, Alicic RZ, Duru OK, et al. Clinical Characteristics of and Risk Factors for Chronic Kidney Disease Among Adults and Children: An Analysis of the CURE-CKD Registry. *JAMA Netw Open.* 2019;2(12):e1918169. doi:10.1001/jamanetworkopen.2019.18169.
22. Mendu ML, Ahmed S, Maron JK, et al. Development of an electronic health record-based chronic kidney disease registry to promote population health management. *BMC Nephrol.* 2019;20(1):72. doi:10.1186/s12882-019-1260-y.
23. Norton JM, Ali K, Jurkowitz CT, et al. Development and Validation of a Pragmatic Electronic Phenotype for CKD. *Clin J Am Soc Nephrol.* 2019;14(9):1306-1314. doi:10.2215/CJN.00360119.
24. Shin JI, Chang AR, Grams ME, et al. Albuminuria Testing in Hypertension and Diabetes: An Individual-Participant Data Meta-Analysis in a Global Consortium. *Hypertension.* 2021;78(4):1042-1052. doi:10.1161/HYPERTENSIONAHA.121.17323.
25. National Kidney Foundation. Are you the 33%? [https://www.kidney.org/phi/form?version=awareness&utm\\_source=NKF&utm\\_medium=Web&utm\\_campaign=RiskCampaign](https://www.kidney.org/phi/form?version=awareness&utm_source=NKF&utm_medium=Web&utm_campaign=RiskCampaign). Accessed November, 2021.
26. National Kidney Foundation. CKDintercept <https://www.kidney.org/CKDintercept>. Accessed July, 2021.
27. Stolpe S, Kowall B, Scholz C, Stang A, Blume C. High Unawareness of Chronic Kidney Disease in Germany. *Int J Environ Res Public Health.* 2021;18(22)doi:10.3390/ijerph182211752.
28. Whaley-Connell A, Sowers JR, McCullough PA, et al. Diabetes mellitus and CKD awareness: the Kidney Early Evaluation Program (KEEP) and National Health and Nutrition Examination Survey (NHANES). *Am J Kidney Dis.* 2009;53(4 Suppl 4):S11-21. doi:10.1053/j.ajkd.2009.01.004.
29. National Kidney Foundation. Informed Consent and Data Security. <https://www.youtube.com/watch?v=PSpGoSD76vg>. Accessed September 3, 2021.
30. National Kidney Foundation. How to Become Part of the NKF Patient Network. <https://www.youtube.com/watch?v=zBwii4mcrEw>. Accessed September 3, 2021.
31. National Kidney Foundation. Join the NKF Patient Network. <https://www.youtube.com/watch?v=SUpR0pC0WtY>. Accessed September 3, 2021.
32. National Kidney Foundation. Hot topics in kidney health. Episode 3: New way to get involved in research. <https://open.spotify.com/episode/1mYcPCffr6XL8RES3BXwBE?si=qgXdhJLEQzivlBau nmBJ4Q&nd=1>. Accessed September 3, 2021.
33. Mohottige D, Diamantidis CJ, Norris KC, Boulware LE. Racism and Kidney Health: Turning Equity Into a Reality. *Am J Kidney Dis.* 2021;77(6):951-962. doi:10.1053/j.ajkd.2021.01.010.
34. Delgado C, Baweja M, Burrows NR, et al. Reassessing the Inclusion of Race in Diagnosing Kidney Diseases: An Interim Report From the NKF-ASN Task Force. *Am J Kidney Dis.* 2021;78(1):103-115. doi:10.1053/j.ajkd.2021.03.008.

35. Schrauben SJ, Appel L, Rivera E, et al. Mobile Health (mHealth) Technology: Assessment of Availability, Acceptability, and Use in CKD. *Am J Kidney Dis.* 2021;77(6):941-950 e941. doi:10.1053/j.ajkd.2020.10.013.
36. Diamantidis CJ, Becker S. Health information technology (IT) to improve the care of patients with chronic kidney disease (CKD). *BMC Nephrol.* 2014;15:7. doi:10.1186/1471-2369-15-7.
37. Centers for Medicare and Medicaid Services. Blue Button 2.0. <https://bluebutton.cms.gov/>. Accessed April 25, 2020.
38. Hays T, Groopman EE, Gharavi AG. Genetic testing for kidney disease of unknown etiology. *Kidney Int.* 2020;98(3):590-600. doi:10.1016/j.kint.2020.03.031.
39. Groopman EE, Marasa M, Cameron-Christie S, et al. Diagnostic Utility of Exome Sequencing for Kidney Disease. *N Engl J Med.* 2019;380(2):142-151. doi:10.1056/NEJMoa1806891.

## FIGURE LEGENDS

**Figure 1. Schema of the National Kidney Foundation (NKF) Patient Network.** The registry links patient-entered data on their medical history, outcomes and preferences with clinical and laboratory data obtained from electronic health records (EHRs). Subjects will be enrolled by wide recruitment methods directed to the general market and closed systems. Closed systems include health systems, academic medical centers, testing laboratories, rare kidney disease groups, commercial healthcare plans, contract research organization (CRO), biotech, or federal agencies. Participants will submit a signed electronic consent form followed by creation of unique identifier. Data will be entered or uploaded in the web based NKF Patient Network platform maintained by Pulse on a secured AWS® platform. Summary data will be available to the partners of the NKF Patient Network via collaboration portals and to the rest of scientific community for use in approved research studies or clinical trials.

**Figure 2. NKF Patient Network Governance Structure.** (A) Schematic of the NKF Patient Network governance structure. Grey boxes represent entities with whom NKF has contractual agreements with. \*Affiliated to the Biostatistics, Epidemiology and Research Design Center (BERD), Tufts Clinical and Translational Science Institute (CTSI). Together, the Steering Committee and the six working committees constitute the NKF Patient Network Governance Committees. (B) Categories of stakeholders represented on the NKF Patient Network governance committees. CRO: Contract research organization.

**Figure 3. Stakeholder map by degree of interest and influence.** In bold are the stakeholder's goals and in italics are the NKF's actions in response to the stakeholder's goals.

**Figure 4. NKF Patient Network Feasibility Study.** Participants' self-enrollment and response rates to surveys during the U.S. feasibility study (July-December 2020).

**Box 1.** Goals of the National Kidney Foundation (NKF) Patient Network.

<b>Short-term goals</b>
<ul style="list-style-type: none"> <li>• Promote patient disease awareness by educating patients through resources that are individualized to patients' stage of disease and related health conditions.</li> </ul>
<ul style="list-style-type: none"> <li>• Increase the number of patient advocates volunteering at the NKF or other organizations.</li> </ul>
<b>Long-term goals</b>
<ul style="list-style-type: none"> <li>• Promote patients' interactions with each other as well as with their clinicians and the research community.</li> </ul>
<ul style="list-style-type: none"> <li>• Create a robust database of patient outcomes, perceptions, priorities, and activities that will facilitate research, clinical care, and policy decisions to improve patients' experience and outcomes.</li> </ul>
<ul style="list-style-type: none"> <li>• Promote partnerships with healthcare organizations and health systems to understand healthcare utilization data including cost of care for patients with CKD.</li> </ul>
<ul style="list-style-type: none"> <li>• Provide a large, diverse pool of patients for clinical trial recruitment, and input on patient-centered trial designs and opportunities for post-trial surveillance.</li> </ul>

**Box 2.** Engagement strategies with patients with kidney disease, health systems, and sponsor pharma companies.

<b>Patients with kidney disease</b>
<ul style="list-style-type: none"> <li>• Access to user-friendly dashboard and individualized education resources tailored to their disease stage via the NKF Kidney Pathways.<sup>18</sup></li> </ul>
<ul style="list-style-type: none"> <li>• Ability to connect to other people with similar kidney disease stage and demographic characteristics via online communities,<sup>19</sup> and notifications of local events, latest findings in research, and clinical trial recruitment via a quarterly newsletter.</li> </ul>
<ul style="list-style-type: none"> <li>• Collection of PROMs and PREMs on a regular frequency to explore and help prioritize symptomatology, preferences for and use of healthcare resources, lifestyle/diet modifications, changes in treatment, quality-of-life, and other measures.</li> </ul>
<b>Health systems that contribute to patient recruitment and EHR data integration</b>
<ul style="list-style-type: none"> <li>• Access to a researcher portal with analytic interface for de-identified data analysis, a dashboard showing real-time clinical insights and patient-reported surveys with the ability to compare the aggregate Network data with the individual health system data.</li> </ul>
<ul style="list-style-type: none"> <li>• Ability to survey the Network's participants affiliated with the health system or the rest of the Network's population with custom surveys.</li> </ul>
<ul style="list-style-type: none"> <li>• Membership on the Data Input and Integration Committee or another relevant Committee, based on expertise, all seats to staggered biannual rotation</li> </ul>
<ul style="list-style-type: none"> <li>• Recognition on all marketing materials.</li> </ul>
<b>Health systems that exclusively contribute to patient recruitment</b>
<ul style="list-style-type: none"> <li>• Recognition on all marketing materials.</li> </ul>
<b>Sponsor pharmaceutical companies</b>
<ul style="list-style-type: none"> <li>• Access to a researcher portal with analytic interface for de-identified data analysis and a dashboard showing real-time clinical insights on the aggregate Network's data.</li> </ul>
<ul style="list-style-type: none"> <li>• Ability to survey the Network's participants with custom surveys, approved by the Data</li> </ul>
<ul style="list-style-type: none"> <li>• Subscription reports by data scientists on epidemiological questions about the Network data.</li> </ul>
<ul style="list-style-type: none"> <li>• Membership on the Data Input and Integration Committee and/or the Steering Committee based on sponsorship agreements, all seats to staggered biannual rotation</li> </ul>
<ul style="list-style-type: none"> <li>• Recognition on all marketing materials.</li> </ul>

**PROMs:** Patient-reported outcomes measures; **PREMs:** Patient-reported experience measures.

**Box 3.** Patient-focused projects organized by topic that can be addressed in the future using the Network's data.

<b>Patient education and support</b>
<ul style="list-style-type: none"> <li>• Improve patients' health literacy related to CKD by using state of the art technologies to individualize the content and delivery.</li> </ul>
<b>Patient outcomes, perceptions, priorities, and activities</b>
<ul style="list-style-type: none"> <li>• Improve understanding of epidemiology of CKD particularly as related to patient reported social determinants of health and activities, such as impact of nutritional and lifestyle modifications on CKD progression.</li> <li>• Explore impact of CKD on patients' lives, such as quality of life, socio-economic challenges, work habits, lifestyle and nutritional modifications, and determine their perceptions of and priorities for managing their disease.</li> </ul>
<b>Health policy</b>
<ul style="list-style-type: none"> <li>• Support new kidney care models that align the needs of patients, providers, and healthcare plans.</li> </ul>
<b>Clinical Trial Recruitment and Post-trial Surveillance</b>
<ul style="list-style-type: none"> <li>• Facilitate meaningful dialogue between patients and investigators to enhance patient-centered clinical trial design and expand participation in clinical trials in CKD.</li> <li>• Develop improved understanding of risks and benefits of medication usage, particularly novel medications, by facilitating reporting of adverse (or positive) effects with medication usage.</li> <li>• Increase understanding of impact of treatments by allowing for passive follow-up, subsequent to drug approval.</li> </ul>

**Table 1.** Baseline characteristics of the study participants who signed the informed consent and submitted the patient profile during the feasibility study.

	Entire cohort (Patient- entered data)	NKF (Patient- entered data)	Geisinger (Patient- entered data)
<b>Patient profile submissions, N</b>	<b>80</b>	<b>59</b>	<b>21</b>
<b>Demographics</b>			
Age, years	57.5±13.3	55.6±12.6	65.7±12.1
Women, N (%)	41 (51.3%)	31 (53.0%)	10 (47.6%)
Race, N (%)*			
• Asian American	1 (1.2%)	1 (1.7%)	0
• Black or African American	9 (11.3%)	9 (15.2%)	0
• White	66 (82.5%)	45 (76.3%)	21 (100.0%)
• Native Hawaiian or Other Pacific Islander	0	0	0
• American Indian or Alaska Native	2 (2.5%)	2 (3.4%)	0
• Multiracial	2 (2.5%)	2 (3.4%)	0
• Unknown	0	0	0
• Prefer not to answer	0	0	0
Ethnicity, N (%)			
• Hispanic or Latino	7 (8.8%)	7 (11.9%)	0 (0.0%)
• Not Hispanic or Latino	71 (88.8%)	50 (84.7%)	21 (100.0%)
• Unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)
• Prefer not to answer	2 (2.5%)	2 (3.4%)	0 (0.0%)
<b>Kidney disease</b>			
Currently on dialysis (%)	5 (6.3%)	4 (6.8%)	1 (4.8%)
Kidney transplant recipient (%)	46 (57.5%)	46 (78.0%)	0 (0.0%)
eGFR known, N (%)			
Yes, I am aware	32 (40.0%)	24 (40.7%)	8 (38.0%)
Exact value, N (ml/min per 1.73 m <sup>2</sup> )	27 (88.3±113.3)	21 (90.3±116.8)	6 (81.2±110.3)
OR eGFR Category			
eGFR ≥90	0	0	0
eGFR 89-60	1	1	0
eGFR 59-30	4	2	2
eGFR 29-15	0	0	0
eGFR <15	0	0	0
No, I am not aware	30 (37.5%)	22 (37.2%)	8 (38.0%)
I prefer not to answer	2 (2.5%)	2 (3.4%)	0 (0.0%)
I am not sure	12 (15.0%)	8 (13.6%)	4 (19.0%)
Did not respond	4 (5.0%)	3 (5.0%)	1 (4.8%)
CKD stage, N (%)			
I know my CKD stage, N (%)			
Stage 1	3 (3.8%)	2 (3.4%)	1 (4.8%)
Stage 2	2 (2.5%)	2 (3.4%)	0 (0.0%)
Stage 3	18 (22.5%)	12 (20.3%)	6 (28.6%)
Stage 4	6 (7.5%)	3 (5.1%)	3 (14.3%)

Stage 5 or ESKD	19 (23.8%)	19 (32.2%)	0 (0.0%)
I am not sure	28 (35.0%)	18 (30.5%)	10 (47.6%)
Did not respond	4 (5.0%)	3 (5.0%)	1 (4.8%)
UACR known, N (%)			
Yes, I am aware	7 (8.8%)	3 (5.0%)	4 (19.0%)
Exact value, N (mg/g)	4 (95.7±94.7)	3 (120.6±98.6)	1 (21)
Or Approximate value (mg/g):			
<30	2	0	2
30-300	1	0	1
>300	0	0	0
No, I am not aware	43 (53.8%)	33 (55.9%)	10 (47.6%)
I prefer not to answer	3 (3.8%)	3 (5.1%)	0 (0.0%)
I am not sure	23 (28.8%)	17 (28.8%)	6 (28.6%)
Did not respond	4 (5.0%)	3 (5.0%)	1 (4.8%)
Causes of your kidney disease known, N			
Yes, I am aware	47 (58.8%)	39 (66.1%)	8 (38.0%)
No, I am not aware	13 (16.3%)	6 (10.2%)	7 (33.3%)
I am not sure	9 (11.3%)	6 (10.2%)	3 (14.3%)
I prefer not to answer	7 (8.8%)	5 (8.5%)	2 (9.5%)
Did not respond	4 (5.0%)	3 (5.0%)	1 (4.8%)
Family history of kidney disease (%)	24 (30.0%)	17 (28.8%)	7 (33.3%)
<b>Exam and Comorbid conditions</b>			
Hypertension (%)	11 (13.8%)	7 (11.9%)	4 (19.0%)
Diabetes (%)	17 (21.3%)	10 (16.9%)	7 (33.3%)

Data are presented as mean ± standard deviation, absolute number (N) when data was not available for all participants, or percent for categorical variables. \*, multi-selection allowed for patient-entered data; CKD: chronic kidney disease; ESKD: end-stage kidney disease; eGFR, estimated glomerular filtration rate; UACR, urinary albumin/creatinine ratio.

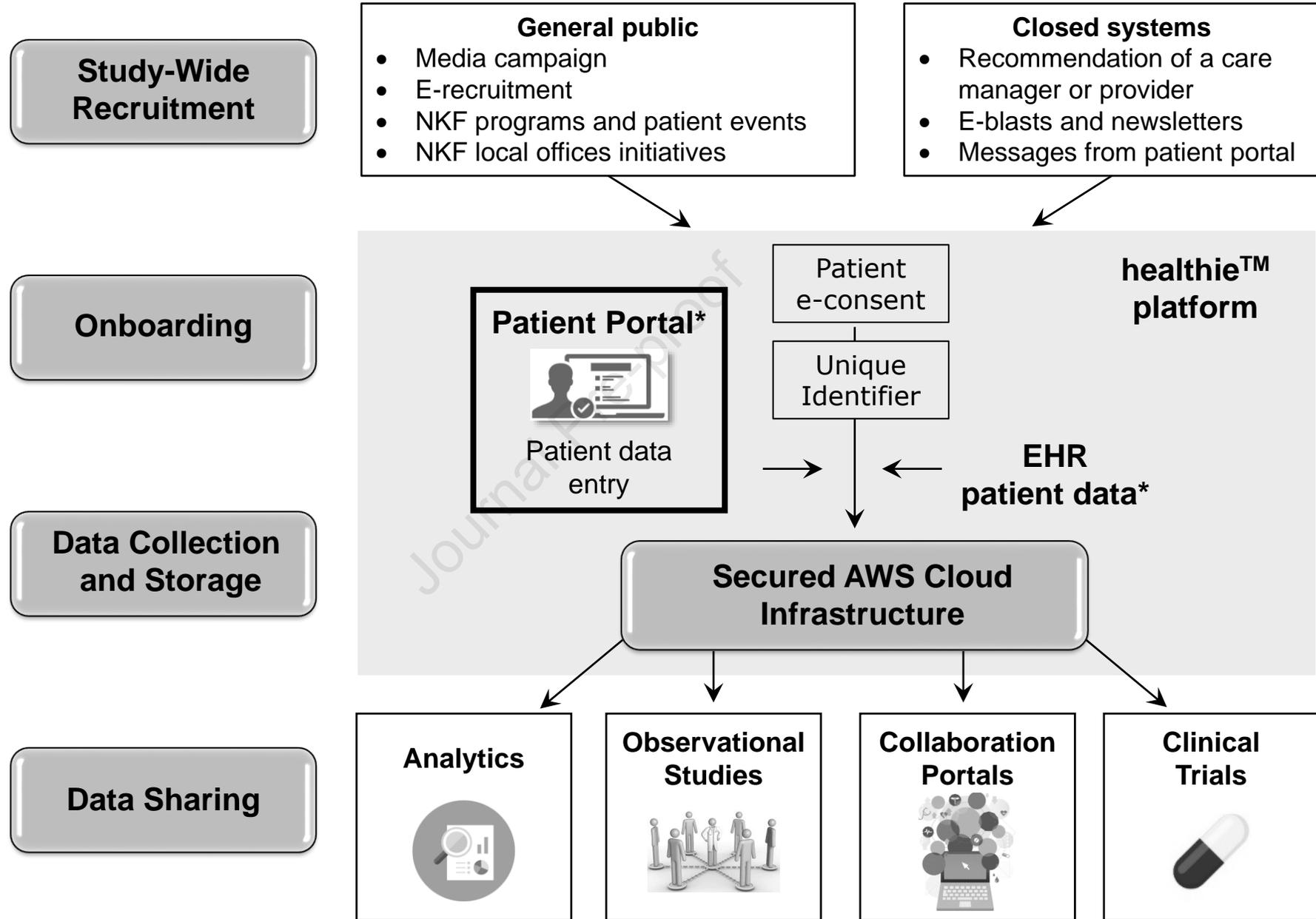
\*See **Table S4** for specific cause(s) of kidney disease

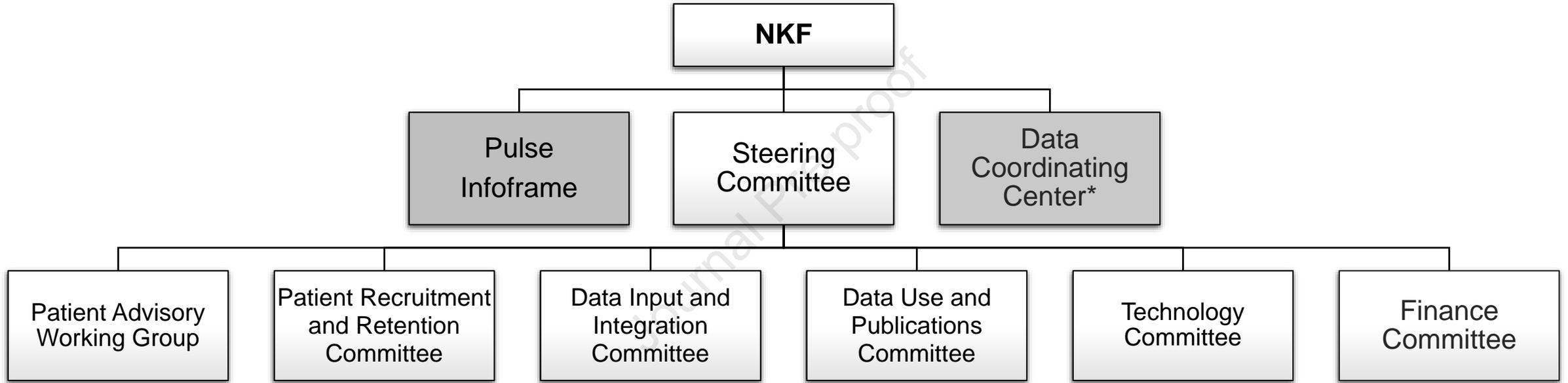
**Table 2.** Comparisons of patient-entered data to EHR data for the Geisinger participants.

	Geisinger	
	Patient-entered data	EHR data
<b>Patient profile submissions, N</b>	<b>21</b>	<b>21</b>
<b>Kidney disease</b>		
Currently on dialysis (%)	1 (4.8%)	1 (4.8%)
Kidney transplant recipient (%)	0%	0%
Family history of kidney disease (%)	7 (33.3%)	1 (4.8%)
eGFR, N (ml/min per 1.73 m <sup>2</sup> )	6 (81.2±110.3)	20 (46.6±21.8)
UACR, N (mg/g)	1 (21)	18 (410.5±850.5)
CKD stage, N (%)		
Stage 1	1 (4.8%)	1 (0%)
Stage 2	0 (0%)	3 (0%)
Stage 3	6 (28.6%)	9 (38.1%)
Stage 4	3 (14.3%)	6 (28.6%)
Stage 5 or ESKD	0 (0.0%)	2 (9.5%)
<b>Exam and Comorbid conditions</b>		
BMI (kg/m <sup>2</sup> )	-	31.8±7.2
SBP (mmHg)	-	128.8±14.9
DBP (mmHg)	-	73.2±10.7
Hypertension, N (%)	4 (19.0%)	19 (90.5%)
Diabetes, N (%)	7 (33.3%)	12 (57.1%)
HbA1c (%)	-	6.7±2.0
<b>Medications</b>		
ACEIs/ARBs (%)	-	17 (81.0%)
SGLT2-i (%)	-	5 (23.8%)

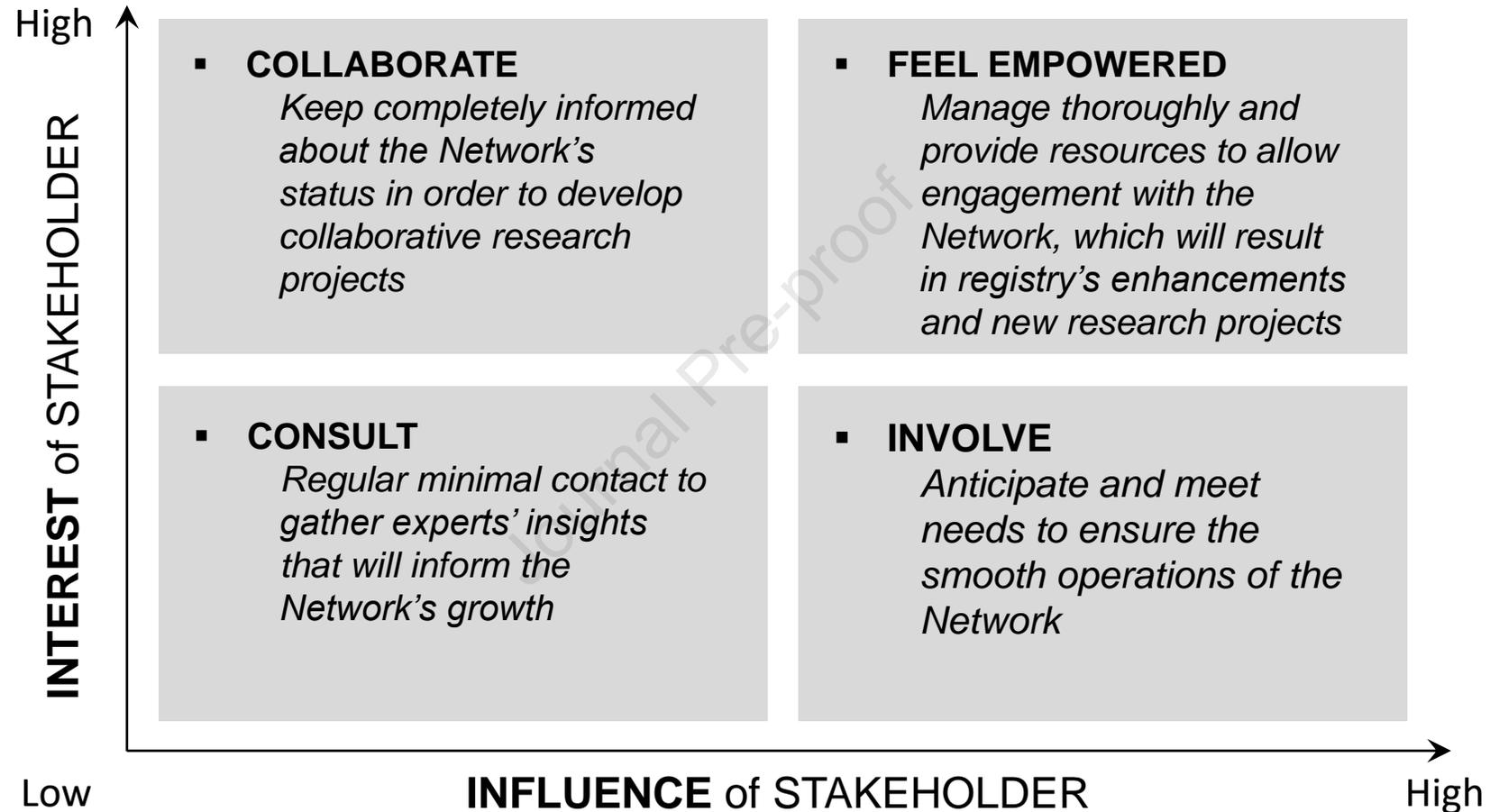
Data are presented as mean ± standard deviation, absolute number (N) when data was not available for all participants, or percent for categorical variables. – indicates data that was not collected. CKD: chronic kidney disease; ESKD: end-stage kidney disease; eGFR: estimated glomerular filtration rate; UACR: urinary albumin/creatinine ratio; BMI: body mass index; HbA1C: hemoglobin A1C; SBP: systolic blood pressure; DBP: diastolic blood pressure; ACEIs/ARBs: angiotensin converting enzyme inhibitors/ angiotensin-receptor blockers; SGLT2-i: sodium/glucose cotransporter-2 inhibitors.

a)





Committee	Stakeholder category						
	Patients	Academics	Community nephrology	Pharma	Health systems	NKF	Other
Steering	✓	✓	✓	✓		✓	CRO
Patient advisory working group	✓					✓	
Patient engagement	✓	✓		✓		✓	CRO
Data input and integration	✓	✓		✓	✓	✓	
Data use and publications	✓	✓			✓	✓	
Finance						✓	
Technology	✓					✓	Tech consultant



**U.S. FEASIBILITY STUDY**

July-December 2020

