How Community Engagement Is Enhancing NIDDK Research

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Introduction
Patient engagement may enhance research efficiency; increase relevance, utility, and importance of study outcomes to patients; facilitate recruitment; and enable translation of results to real-world settings (1). Early community-engaged research efforts suggest benefits in cancer, diabetes, and other diseases may translate to nephrology research, particularly given the racial, ethnic, and socioeconomic disparities that characterize kidney disease. Recent experiences from two National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) consortia reflect potential benefits of community-engaged research to nephrology.

The APOL1 Long-Term Kidney Transplantation Outcomes Consortium
Because APOL1 genetic variants are associated with increased kidney disease risk, concerns persist about the health of recipients of kidneys donated by people of African descent (African Americans, Afro Caribbeans, Latinos of African descent, etc.) and long-term outcomes in living kidney donors of African descent (2). The NIDDK initiated the APOL1 Long-Term Kidney Transplantation Outcomes (APOLLO) Network in 2017 to launch a nationwide cohort study of kidney donors of African descent and their recipients.

APOL1 genetic variants are almost exclusively present in individuals of African descent. Therefore, APOLLO study participants will be disproportionately of African origin. Yet, funded researchers were almost exclusively white. Recognizing the importance of having study leadership from people whose lived experiences align with those of participants, the NIDDK formed a Community Advisory Council (CAC). Including two African American patients with kidney disease or their family members from each site. The Steering Committee includes a patient representative as a full voting member.

The CAC was crucial when the Observational Study Monitoring Board (OSMB) raised concerns about the APOLLO’s return of results policy. The CAC emphatically restated that a “desire to know” policy regarding genetic results was its choice—even if the results might not be actionable. In the official APOLLO response, the CAC invited the OSMB to attend their meetings to witness their deliberations if they doubted the validity of patients’ opinions.

In addition to establishing formal structures for patient and participant engagement, the APOLLO Network has taken steps to ensure that patients and participants are involved as full research partners. For example, the APOLLO Steering Committee meeting room has a central table and additional peripheral seating. At the first meeting, study leaders noticed that researchers sat at the table and patients sat on the periphery. The APOLLO took active steps to give patients a literal seat at the table, asking sites to seat only one researcher at the table and encouraging patients to take the open seats. Although this may seem like a small or even insignificant gesture, enabling patients and caregivers to sit at the table ensured that the APOLLO Network recognized community representatives as peers.

The Kidney Precision Medicine Project Consortium
Advancing treatment for patients with kidney diseases requires a deeper understanding of human kidney tissue, how its cells and interstitial components interact, and the heterogeneous pathways that lead to both AKI and CKD. Because progress would be difficult if not impossible to achieve without analysis of human kidney tissue, the NIDDK explored an initiative to collect and analyze research kidney biopsies. Given the risk posed to potential participants by kidney biopsies and the relatively limited likelihood of direct individual benefit, the NIDDK viewed input from patients and potential study participants as critical in considering study ethics and feasibility. Patient voice was central in the NIDDK Kidney Precision Medicine Meeting (https://www.niddk.nih.gov/news/meetings-workshops/2016/kidneyprecision2016), which explored initiating such a study. Views expressed at that meeting by patients with prior kidney biopsies—who emphasized their interest in such research for the...
benefit of those who might develop AKI or CKD in the future, despite limited individual benefit—encouraged the NIDDK to pursue the initiative.

The Kidney Precision Medicine Project (KPMP; https://kpmp.org) was established in 2017 to build the science to enable clinicians to get the right treatment to the right patient at the right time. From the first Steering Committee meeting, patient participants attended the entire meeting; asked questions in open sessions; participated as peers in all working groups, subgroups and committees; and contributed their insights regarding study protocol, community engagement, ethical questions, and data analyses. An active Community Engagement Working Group (CEWG), composed primarily of patients, wrote the first draft of the Informed Consent document and participated in its review by the Institutional Review Board. This information was critical to the Data Safety Monitoring Board (DSMB) in evaluating study risks and benefits. The CEWG has actively advocated for purchase of study insurance to ensure that participants who may experience adverse events during the study do not bear resulting costs. Patients also serve as spokespersons for the study, providing a trusted source of information to the broader community of patients with kidney disease. KPMP patient participants helped determine how best to return results of biologic profiling in an ethical and culturally sensitive manner to patients and clinicians and developed public education materials to explain the study to fellow patients. In addition to raising awareness regarding the intellectual contributions that patients make to science, patient participation in KPMP has increased investigator appreciation of patients’ physical contributions. One researcher noted that he would never again allow “leftover” kidney biopsy tissue to go to waste.

Benefits of Community-Engaged Research

Community-engaged research encompasses a spectrum of approaches with varying degrees of community involvement. This spectrum ranges from traditional research approaches, where patients are external to all decisions and engage only as participants, to community-based participatory research, “a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings” (3), valuing contributions of researchers and patients as equally valid and worthwhile.

Community-engaged research may benefit basic, clinical, and dissemination/implementation science (1,4). Just as investigators are authorities in their scientific fields, patients and families are experts in the lived experience of illness, including the day to day context, challenges, and priorities that affect disease burden and management. Community research provides an opportunity to incorporate this unique knowledge, helping researchers to understand the condition and the people who they study; increasing the likelihood that research targets outcomes are relevant, useful, and important to the individuals most affected by them; and improving the ability to translate these results to real-world settings (1).

Community research also provides opportunities to better educate patients about research areas, findings, and processes—directly for those engaged in the study and indirectly by acquiring patient guidance regarding how best to share results with the broader community (1,4). Such information exchange may better connect the public to research and increase awareness of its benefits and limitations, which may, in turn, promote participant recruitment and research funding (1,4). In kidney disease, where racial and ethnic disparities persist, meaningfully involving the community in research may help alleviate the understandable distrust that under-represented and minority populations harbor toward medical and research institutions (1).

It is important to acknowledge, however, that community-engaged research has challenges. Community research requires effort, time, and money as well as tact, openness, and humility. Beyond involving the community, fully realizing its benefits also requires training and equipping community members with the knowledge, skills, and resources to optimally collaborate (5). Other challenges include adequately including different perspectives within relevant heterogeneous communities and navigating power and privilege imbalances that may exist between researchers and community members (6). However, we suggest that including patients in research is well worth the investment.

Brief History of Community-Engaged Research

As the nephrology community begins to implement community-engaged research practices, it has the opportunity to learn from fields spanning public health, nursing, sociology, anthropology, social work, psychology, and industrial design among others. The origins of community-engaged research date to Lewin’s “action research” of the 1930s (7). In 2003, the Institute of Medicine (now the National Academy of Medicine) identified community-based participatory research as an area critical to the future of public health (8). In 2010, Congress authorized the Patient-Centered Outcomes Research Institute to advance comparative effectiveness research on outcomes of importance to patients. Nephrology researchers took advantage of this opportunity to engage people living with kidney disease in research (9). The US Food and Drug Administration (FDA) patient-focused drug development effort aims to ensure that patients’ experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation (10). The Kidney Health Initiative—a public-private partnership led by the American Society of Nephrology and the FDA—facilitates inclusion of patient perspectives and preferences in FDA prioritization and workflows (11).

Future of Community-Engaged Research at the NIDDK

Community-engaged research is an area of growing emphasis at the NIDDK. The Division of Kidney, Urologic and Hematologic Diseases has been late to appreciate the need for community research. The Modification of Diet in Renal Disease and the African American Study of Kidney Disease and Hypertension studies did not include community engagement efforts. The Chronic Renal Insufficiency Cohort, initiated almost 20 years ago, will now include participants in research efforts. The Division encourages investigators conducting basic, clinical, or dissemination/implementation research to involve patients, caregivers, and other community representatives.
in research ranging from small investigator-initiated studies to large multisite consortia. Community members may be engaged as members of advisory boards, working groups, steering committees, and/or DSMBs among other venues. Optimal methods for and levels of community engagement will vary across studies depending on available resources, research objectives, and affected communities.

Conclusions

Putting patients first and meaningfully involving them in nephrology research as full partners may increase research relevance and efficiency, with particular benefits for studies addressing underserved or minority populations. The NIDDK acknowledges the patient and community perspective as an important component of scientific expertise. Inclusion of this perspective across the spectrum of nephrology research may benefit patients, investigators, and the nephrology field as a whole.

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Ms. Jefferson is President of Home Dialyzors United, a patient advocacy organization. In addition, she is in the Community Engagement Working Group for the Kidney Precision Medicine Project and a member of the Steering Committee on the APOL1 Long-Term Kidney Transplantation Outcomes Project.

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