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Establishing and Sustaining the Kidney Stone Engagement Core: A Model for Patient Engagement in Benign Urologic Disease

STAKEHOLDER engagement in research informs (1) patient-centered study questions, (2) optimal strategies for study recruitment and retention, and (3) dissemination activities to increase impact. Stakeholder engagement may be supported by community movements with a shared vision or by investigators in a particular disease space.[1] Several urologic malignancies, such as bladder and prostate cancer, have established patient engagement movements arising from advocacy and survivorship groups, for instance.[2,3] However, many common benign urologic diseases, such as nephrolithiasis, urinary tract infections, or hydronephrosis, often lack this infrastructure. Herein we describe a 2-year process to create the Kidney Stone Engagement Core (KSEC) with the goal of developing a patient-prioritized research agenda. We propose that KSEC could be a model for stakeholder engagement for urologists, particularly in those disease processes without a readily mobilized stakeholder base.

THE VALUE OF SUSTAINED STAKEHOLDER ENGAGEMENT IN CLINICAL RESEARCH DESIGN

The term “stakeholders” encompasses a broad group of individuals with shared priorities for any given project. For the purposes of this discussion, we will refer to patients, caregivers, advocates, researchers, and clinicians collectively as stakeholders. Including these stakeholders, particularly patients and caregivers, in the research design process ensures that studies are responsive to the priorities and needs of patients, maximize recruitment and retention, and can effectively disseminate results to communities that would benefit from the emerging knowledge. Examples of this value proposition include amplification of minority voices in research[1-3] and patient selection of outcomes and follow-up protocols for clinical trials.[4] One essential component of the engagement process is returning value to the communities and participants. In this way, engagement is sustained and cyclically reinforced (Figure).

DEVELOPMENT AND LOGISTICAL SUPPORT OF KSEC

Stakeholder Recruitment

KSEC was convened via a stakeholder engagement award from the Patient-Centered Outcomes Research Institute to (1) define a patient-prioritized research agenda for future trials of kidney stone disease and (2) generate actionable recommendations for future trials. As such, KSEC developed in a project-based framework, which provided a shared mission around which the core has coalesced. Since its inception in 2021, KSEC has been composed of 7 researchers and clinicians and 7 patients, caregivers, and advocates. Patient and caregiver KSEC members were referred to the group from clinician or advocate members of KSEC. We intentionally recruited individuals from communities that are typically underrepresented in kidney stone disease research, namely vulnerable populations including individuals with disabilities and their caregivers, children and their caregivers, and individuals with rare genetic diseases. Notably, patients and caregivers were most effectively recruited when asked by a trusted source (eg, their personal urologist) followed by individualized communication from a member of the KSEC team. All KSEC members have knowledge of kidney stone disease gained through specific training, profession, or lived experiences. Patients, caregivers, and advocates underwent partnership-based research training using Fyreworks (https://www.fyreworkstraining.com/) to orient members to research methodology and engagement structure.

Stakeholder Onboarding

From a regulatory standpoint, KSEC is considered an advisory body to the research project. KSEC members are not considered research participants and, indeed, due to the nature of the role in research development, are necessarily separate from participants. KSEC members do not have access to identified data and therefore are not required to complete regulatory research training (ie, Collaborative Institutional Training Initiative). Logistically, patient

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and caregiver members of KSEC are considered independent consultants and remunerated at an hourly rate. KSEC activities included standing virtual meetings, asynchronous work, ad hoc “sprint” meetings for time-sensitive deliverables, and a hybrid capstone conference. We noted a particular benefit of in-person team building following 20 months of virtual-based project development.

COMMUNITY-BUILDING THROUGH A SHARED MISSION

Patients and caregivers represent an omnipresent force around which our research endeavors necessarily revolve. The process of project-based work in KSEC contributed to team building, a sense of shared mission, and ultimately a core team of individuals that will help sustain KSEC moving forward. Trial proposals that originate from the prioritized research agenda will be familiar to and endorsed by KSEC members, who will also be able to provide insights into patient-centered facets of trial design and development.

Stakeholder Engagement in Study Design

Identification of high-impact research questions that will be valued by patients and their caregivers is the key first step toward meaningful scientific inquiry. To this end, a patient-driven engagement core such as KSEC can provide an ideal platform for ideation of a research agenda. This work entails the process of not only distilling and prioritizing research topics (often from mixed methods approaches), but also providing invaluable insights into aspects of research trial design. For instance, KSEC will be able to provide suggestions to optimize trial recruitment, especially for populations of interest and/or those individuals who are not typically represented in research trials.

Stakeholder-Driven Assessment/Contextualization of Findings

Translating trial findings into meaningful conclusions will also be enhanced by collaboration with an engagement core. KSEC members, already instrumental in the conception and design of ongoing research, will be poised to provide their insights into how specific research findings could impact patients and caregivers directly. For instance, stakeholder insight into outcomes most likely to impact patient experiences can translate into decisions for how findings are reported and displayed.

Dissemination to Communities of Interest

Ultimately, such knowledge must be disseminated back to communities of interest not only via the traditional channels of communication (ie, medical journals, conference proceedings), but also via nontraditional channels to reach patients and caregivers directly. Engagement cores can help by identifying trusted methods as well as effective targets (ie, social media groups, newsletters, advocacy organizations) of dissemination. This important step serves 2 key roles: first, returning value to communities directly empowers patients and caregivers with emerging data; second, expanding the discourse surrounding engagement openly invites new and motivated stakeholders to participate in future efforts.

KSEC: LESSONS LEARNED

While KSEC is explicitly focused on kidney stone disease, this infrastructure may be readily reproduced across other urological diseases, especially those processes that are common, episodic, and lack a large,

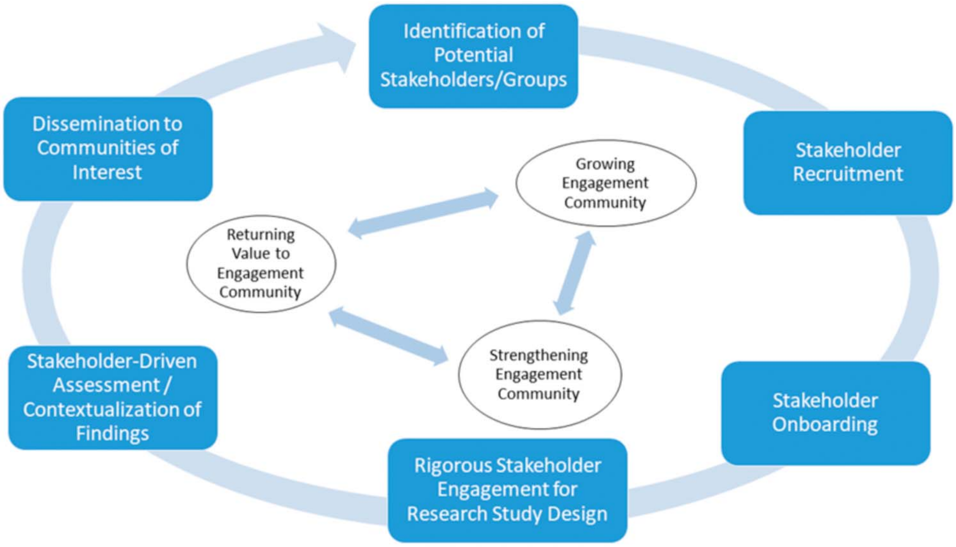

Figure. Cyclic nature of stakeholder engagement in research and enhancement of engagement community.

dedicated advocacy or survivorship network. We found that intentional recruitment of individuals with a broad set of experiences, often with 1-on-1 interactions initially to build trust, was instrumental in ensuring a diverse set of voices within the group. Partnering with the Oxalosis and Hyperoxaluria Foundation provided a dedicated group of patients, caregivers, and advocates who shared insight through the lens of rare kidney stone disease. These voices were complimented by those patients with idiopathic stone disease, reinforcing the value of engagement across a spectrum of disease severity. We leveraged regulatory and remuneration mechanisms that explicitly separated KSEC from research participants, thereby clarifying roles and responsibilities. The project-focused trajectory enhanced opportunities for team building and skill development centered around a central mission. To date, KSEC members have contributed to several publications, presentations, and grant applications. We view this experience as a roadmap for other investigators interested in enhancing stakeholder engagement in urologic disease.

Nayan Shah,[1] Gregory E. Tasian,[2,3]
and Jonathan S. Ellison[1] on behalf of the Kidney
Stone Engagement Core
[1] *Department of Urology, Medical College of Wisconsin*
Milwaukee, Wisconsin

[2] *Department of Surgery, Division of Urology*
The Children's Hospital of Philadelphia
Philadelphia, Pennsylvania

[3] *Department of Biostatistics, Epidemiology, and Informatics*
Perelman School of Medicine at the University of Pennsylvania
Philadelphia, Pennsylvania

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Kidney Stone Engagement Core: Jonathan S. Ellison, Hunter Beck, Bryan Clinstman, Casey Dauw, Kim Hollander, Dirk Lange, Kristi Ouimet, Carswell Ouimet, Kristina Penniston, Charles D. Scales Jr, Katherine Sheridan, Samantha Siodlarz, Ryan Spiardi, Kristin Whitmore, Mike Witt, Greg E. Tasian.

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Corresponding Author: Jonathan S. Ellison, MD, 999 N 92nd St, Milwaukee WI 53217 (jellison@childrenswi.org).

REFERENCES

1. Dy GW, Blasdel G, Downing JM. Centering transgender and nonbinary voices in genital gender-affirming surgery research prioritization. *JAMA Surg.* 2022;157(7):628-629.
2. Smith AB, Chisolm S, Deal A, et al. Patient-centered prioritization of bladder cancer research. *Cancer.* 2018;124(15):3136-3144.
3. Nyame YA, Schraidt JA, Chakoian M, et al. A patient-centered approach to research prioritization in prostate cancer. *J Urol.* 2022;208(2):277-283.
4. Ellison JS, Lorenzo M, Beck H, et al. Comparative effectiveness of paediatric kidney stone surgery (the PKIDS trial): study protocol for a patient-centred pragmatic clinical trial. *BMJ Open.* 2022;12(4):e056789.