

# Cultivating a Research-Ready Dialysis Community

Jennifer E. Flythe,<sup>1,2</sup> Julia H. Narendra,<sup>1</sup> Tandra Hilliard,<sup>3</sup> Karen Frazier,<sup>3</sup> Kourtney Ikeler,<sup>3</sup> Andrew Amolegbe,<sup>3</sup> Denise Mitchell,<sup>3</sup> Adeline Dorough,<sup>1</sup> Shoou-Yih Daniel Lee,<sup>4</sup> Antoinette Ordish,<sup>5</sup> Caroline Wilkie,<sup>6</sup> and Laura M. Dember,<sup>7,8</sup>

for the Building Research Capacity in the Dialysis Community at the Local Level Stakeholder Workshop Participants<sup>a</sup>

<sup>1</sup>Division of Nephrology and Hypertension, Department of Medicine, University of North Carolina School of Medicine, University of North Carolina Kidney Center, Chapel Hill, North Carolina; <sup>2</sup>Cecil G. Sheps Center for Health Services Research, University of North Carolina, Chapel Hill, North Carolina; <sup>3</sup>American Institutes for Research, Chapel Hill, North Carolina; <sup>4</sup>Department of Health Management and Policy, University of Michigan School of Public Health, Ann Arbor, Michigan; <sup>5</sup>Vancouver, Washington; <sup>6</sup>Punta Gorda, Florida; and <sup>7</sup>Renal-Electrolyte and Hypertension Division, Department of Medicine, and <sup>8</sup>Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania Perelman School of Medicine, Philadelphia, Pennsylvania

*J Am Soc Nephrol* 30: 375–380, 2019. doi: <https://doi.org/10.1681/ASN.2018101059>

Individuals with kidney failure receiving dialysis have high morbidity and mortality rates and their condition is associated with poor health-related quality of life.<sup>1</sup> To address these unacceptably poor outcomes, the nephrology community has called for innovation in dialysis therapy and clinical practice. Initiatives such as the Kidney Innovation Accelerator (KidneyX) Re-design Dialysis prize competition,<sup>2</sup> the Kidney Health Initiative's Renal Replacement Roadmap,<sup>3</sup> and the Kidney Disease Improving Global Outcomes' dialysis controversies conference series<sup>4</sup> seek to identify novel therapies with transformative potential. To support these and other endeavors, it is necessary to increase the quantity and quality of research in the dialysis setting. Well executed dialysis research has the potential to yield findings that can meaningfully improve patients' lives in many ways, such as by decreasing mortality rates, addressing symptoms, and improving processes of care. In fact, many individuals engage in research with the explicit hope of improving the lives of others.<sup>5</sup>

Given that individuals receiving dialysis have frequent health care encounters that generate copious granular data within a delivery system backed by strong infrastructure and governance,<sup>6</sup> the dialysis community would appear to be well positioned to implement research efficiently. However, many dialysis trials,

particularly in the United States, have low recruitment and retention rates and challenges with protocol adherence. These factors suggest that research capacity, which involves individual stakeholders and systems facilitating high-quality research through the development of supportive infrastructure and culture,<sup>7</sup> currently falls short in the dialysis setting.

Capacity-building strategies are often aimed at improving skills and knowledge to promote enhanced research readiness and sustainable research practices.<sup>8–10</sup> Engaging diverse stakeholders throughout the research process—from study design to dissemination of study results—is essential to building research capacity. Barriers to such engagement in research include knowledge gaps, mistrust, competing personal and professional priorities, and misaligned clinical and research activities, among others.<sup>5,6</sup>

To identify opportunities to enhance dialysis research capacity, we convened a stakeholder workshop in May of 2018, with representation from seven dialysis provider organizations (Supplemental Material). Participants included patients, care partners, clinic personnel, medical providers, clinician and nonclinician researchers, and representatives from corporate dialysis organizations, community organizations, and government. In this Perspective, we report consensus findings from the workshop.

## CULTIVATING A RESEARCH-READY DIALYSIS ENVIRONMENT

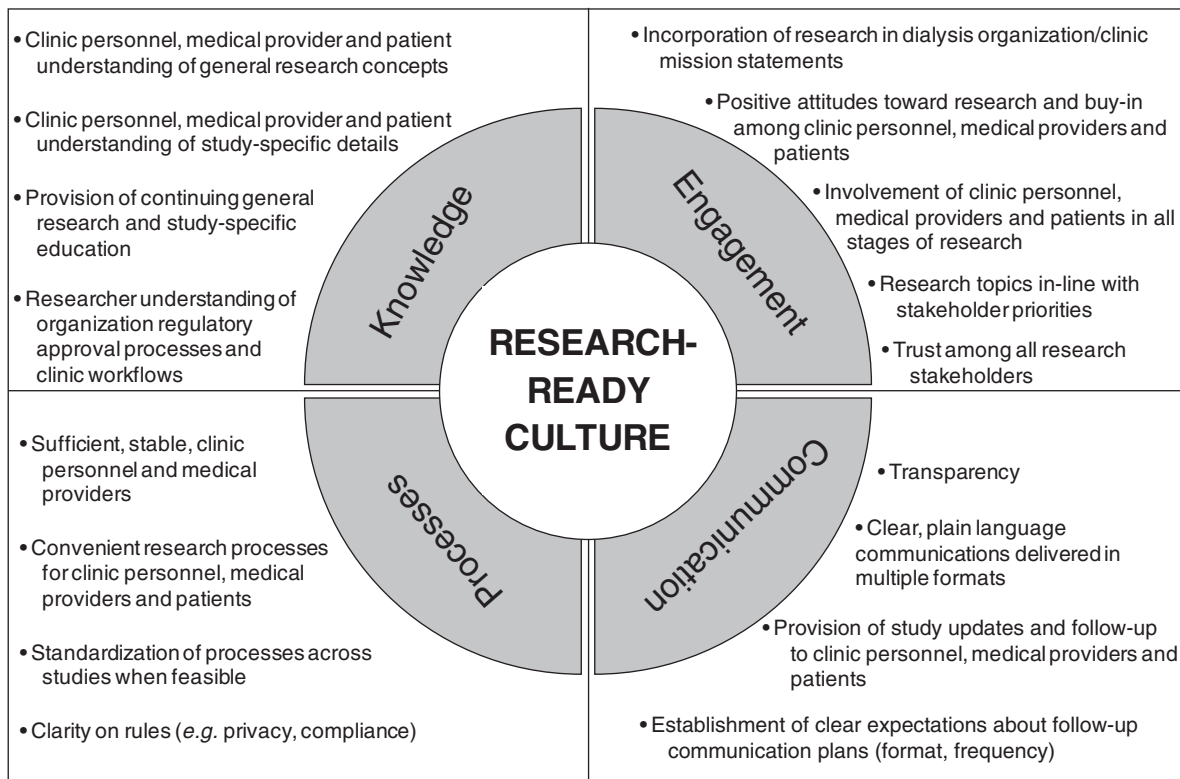
In a research-ready dialysis culture (Figure 1), research and clinical care are synergistic—each informing and improving the other. Research is expected and supported within clinical workflows in a way that prioritizes research without compromising clinical care delivery. At all stages of research, involvement of diverse stakeholders—researchers, clinic personnel, medical providers, and patients—is essential, enhancing research relevance and feasibility and promoting engagement and trust.

In today's dialysis delivery system, however, improving research readiness requires overcoming several key cultural challenges (Table 1). These include communication gaps and mistrust among stakeholders; lack of buy-in and enthusiasm among clinic personnel, medical providers, and patients; stakeholders' perception of a lack of commitment to research by corporate dialysis organizations; insufficient

Published online ahead of print. Publication date available at [www.jasn.org](http://www.jasn.org).

**Correspondence:** Dr. Jennifer E. Flythe, UNC School of Medicine, University of North Carolina Kidney Center, 7024 Burnett-Womack CB #7155, Chapel Hill, NC 27599-7155. Email: [jflythe@med.unc.edu](mailto:jflythe@med.unc.edu)

Copyright © 2019 by the American Society of Nephrology



**Figure 1.** Components of a research-ready dialysis environment. Key components of a research-ready dialysis clinic environment include sufficient knowledge, meaningful stakeholder engagement, transparent and consistent communication, and research processes that minimize the burden of research in the setting of clinical care.

understanding of general research concepts among clinical personnel and patients; and unequal relationships between researchers and other stakeholders.

Deficient communication is likely the most critical and common factor that underlies other cultural challenges to a research-ready dialysis environment. Examples of poor communication include long and unexplained gaps between initial research team communications and study start, inconsistent communication about study progress, complicated and lengthy study explanations, and failure to share study updates or results. Although most stakeholders accept delays as part of the research process, absence of explicit communication about such delays seeds mistrust and disengagement. Communication gaps also contribute to a mismatch between researchers' expectations and the limitations imposed by practical realities of clinical care delivery, often manifesting in protocols that cause workflow disruptions and unanticipated burdens to patients and clinic personnel.

Central to improving communication is educating researchers about the nuances of dialysis clinic environments, perhaps through development of best practices for research in the dialysis setting. Better communication to other stakeholders may be accomplished through establishing clear expectations for follow-up and providing research-related materials in plain language and multiple formats, tailored to their intended audiences (e.g., medical providers or patients). Such efforts may combat perceptions that researchers tend to have one-sided relationships with other stakeholders—taking data and time, but not giving much in return. Providing general education about research is also important. An example of research education for dialysis clinic personnel and patients, codeveloped with diverse stakeholders, is available online at [go.unc.edu/DialysisResearchEducationToolkit](http://go.unc.edu/DialysisResearchEducationToolkit).

Once a sound knowledge foundation is established, researchers can cultivate stakeholder buy-in by articulating the

potential benefits of proposed research, focusing on patient-prioritized research topics, and using strategies such as patient and clinic personnel “champions” to connect clinic stakeholders and researchers. A strong commitment to research from dialysis organizations is essential to these endeavors. Incorporating such a commitment to research into the mission statement for the organization and clinics is one way to explicitly convey support. Allocating professional time for research engagement by clinic personnel is another way that dialysis providers can support research readiness.

## OVERCOMING BARRIERS TO DIALYSIS RESEARCH IMPLEMENTATION

To enhance dialysis research capacity, the community must overcome numerous barriers to research implementation across the research process, from design to dissemination (Table 2).

**Table 1.** Key cultural challenges to a research-ready dialysis environment<sup>a</sup>

No.	Challenge
1.	Communication gaps among all stakeholders
2.	Mistrust among all stakeholders
3.	Lack of buy-in and enthusiasm among clinic personnel, medical providers, and patients
4.	Perceived lack of corporate dialysis commitment to research among other stakeholders
5.	Insufficient understanding of general research concepts among clinic personnel and patients
6.	Unequal relationships between researchers and other stakeholders

<sup>a</sup>As collaboratively identified by workshop attendees.

### Design Phase

Researchers often wait too long to engage dialysis organizations, clinics, and patients in protocol development, frequently delaying until the study is otherwise ready to be launched. One challenge to engaging dialysis organizations early in planning is the requirement at some organizations for Institutional Review Board approval before the organization's review of a proposed study. Other challenges include lack of transparency in organization and clinic research policies, inconsistencies in policies within and across organizations, and lack of consensus guidelines for research in dialysis settings. Such obstacles hinder efficient, feasible research design and lead some clinics to adopt research policies that are more stringent than required by corporate regulations to ensure compliance with regulatory and payer policies. Examples of potential solutions to these challenges include the creation of formal channels for researchers to obtain early practical input from corporate- and clinic-level dialysis stakeholders, including patients, and the development of centralized, dialysis provider-specific repositories for research policies.

### Conduct Phase

Better stakeholder engagement in the design phase could prevent many of the challenges that often arise in the research conduct phase. This is especially pertinent when researchers attempt to implement study protocols that are not aligned with dialysis clinical care and regulations. For example, protocols may not account for clinic workflows and personnel

regulatory requirements, or for patient privacy, transportation needs, and cultural or linguistic differences. High rates of clinic personnel turnover and the resulting need to train new clinic employees add to the difficulty of conducting research, and most protocols (and budgets) do not account for sufficient personnel training and retraining. These challenges are exacerbated by the lack of standardized forms for data collection and informed consent, as well as by difficulties researchers experience in accessing dialysis information technology infrastructure. Moreover, conflicts over clinical data ownership can lead to duplicative data collection.

There are a number of strategies that can help overcome such challenges. By tailoring implementation plans to individual dialysis organization policies, researchers can facilitate incorporation of research tasks into routine care processes. In some cases, clinic-level environmental assessments may help researchers better align study protocols with unique aspects of clinic workflows. The clinic governing body is also a rich but underutilized source of information. In some cases, pilot feasibility studies may inform implementation plans for subsequent larger studies. To address gaps in clinic personnel training, researchers must budget and plan for personnel training and retraining, and funding and regulatory agencies must recognize the need to allocate such funds. Finally, standardizing and simplifying consent and data collection forms, and increasing transparency around data access policies, would minimize clinic personnel and patient

confusion and reduce researcher burden.

### Dissemination Phase

Lack of transparency about dialysis organizations' regulations and uncertainty about best practices for sharing information about research results are obstacles to effective dissemination of research results. Standardized but customizable templates for research updates and results, approved by the dialysis organization, provide one potential solution to this challenge. Results may also be shared through a centralized research newsletter, "lobby days," and presentations at clinic governance meetings. However, formally evaluating the effectiveness of such strategies is needed to inform efforts. Finally, funders could help convey the importance of engagement, communication, and dissemination efforts by requiring applicants to articulate their plans for such efforts in funding applications.

### LOOKING FORWARD: ENHANCING DIALYSIS RESEARCH CAPACITY

Advancing research capacity in the dialysis setting requires an overarching strategic vision that fosters interdisciplinary partnerships to break down cultural and procedural barriers. Implementing potential solutions such as providing ongoing research education and training, promoting a culture of trust and transparency, incorporating stakeholder input throughout the research process,

**Table 2.** Barriers to dialysis research implementation and identified solutions by research phase<sup>a</sup>

Barriers	Solutions
<b>Design phase</b>	
<ol style="list-style-type: none"> <li>1. Lack of early involvement of dialysis organizations, clinics, and patients in protocol development</li> <li>2. Lack of guidance on how to incorporate local stakeholders into research development</li> <li>3. Disconnect among researchers, dialysis organizations, clinics, and patients</li> <li>4. Lack of researcher (especially industry-based researcher) access to medical providers</li> <li>5. Lack of transparency about dialysis organization and clinic research policies</li> <li>6. Variation in research policies within and across dialysis organizations</li> <li>7. Burdensome, multistep approval processes</li> </ol>	<ul style="list-style-type: none"> <li>● Plan ahead so there is time to consider stakeholder perspectives</li> <li>● Develop formal processes for researchers to obtain early (<i>i.e.</i>, before funding and IRB approval) input from stakeholders</li> <li>● Develop a crossdialysis organization research consortium to facilitate better understanding between dialysis providers and researchers</li> <li>● Develop best practices for research design in the dialysis setting with input from all stakeholders</li> <li>● Develop organization-specific, on-line repositories for research policies that are accessible to clinic personnel and researchers</li> <li>● Reduce redundancy in approval processes</li> </ul>
<b>Conduct phase</b>	
<ol style="list-style-type: none"> <li>1. Complex, burdensome protocols that are unaligned with the practicalities of dialysis clinical care and regulations</li> <li>2. Competing demands for clinic personnel time, including regulatory requirements for care delivery</li> <li>3. Protocols that do not account for patient routines, physical limitations (<i>e.g.</i>, vision, dexterity), privacy, transportation, or cultural and/or linguistic barriers</li> <li>4. Hidden protocol costs including personnel burden, transportation, physical space, and clinic supplies</li> <li>5. High personnel turn-over resulting in need for retraining that is not accounted for in timelines or budgets</li> <li>6. Clinic personnel uncertainty about who to contact with protocol questions</li> <li>7. Overly complicated study explanations for clinic personnel and patients</li> <li>8. Insufficient communication during study conduct</li> <li>9. Lack of standardized data collection and informed consent forms and complicated patient and clinic personnel-facing study materials</li> <li>10. Researcher difficulty in accessing dialysis IT infrastructure, leading to duplicative data collection</li> </ol>	<ul style="list-style-type: none"> <li>● Emphasize engagement of all stakeholders in design phase with ongoing engagement through conduct phase</li> <li>● Engage in forward-thinking discussions with CMS, NIH, and ASN about the practical costs and potential savings from stakeholder-informed research</li> <li>● Develop a “day-in-the-life of a dialysis clinic” video for researchers new to the dialysis environment</li> <li>● When feasible, perform environmental assessments to understand clinic-specific workflows and cultures</li> <li>● When feasible, conduct pilot studies to inform design of larger studies</li> <li>● Use the governing body as a key informant/partner</li> <li>● Utilize clinic personnel, medical provider, and patient “champions”</li> <li>● Allot professional time for clinic personnel engagement and identify meaningful incentives for personnel and medical providers</li> <li>● Maintain privacy (<i>e.g.</i>, portable cubicles, tablet with earphones; separate area) for patients participating in research</li> <li>● When feasible and appropriate, use “warm hand-offs” between clinic personnel and research teams where trusted individuals introduce research team members to potential study participants</li> <li>● Include budget in funding applications to account for stakeholder engagement and sufficient personnel training and retraining</li> <li>● Empower clinic personnel to ask questions by making research team contact information prominent</li> <li>● Provide prespecified, regular study updates and use plain language communications delivered in multiple formats</li> <li>● Utilize videos to convey information</li> <li>● Set expectations about communication plans</li> <li>● Develop standardized data collection and informed consent forms that can be tailored to individual studies</li> <li>● Develop clear policies for how researchers can access research participant medical information</li> </ul>
<b>Dissemination phase</b>	
<ol style="list-style-type: none"> <li>1. Lack of transparency about dialysis organizations’ rules and regulations related to dissemination</li> </ol>	<ul style="list-style-type: none"> <li>● Develop organization-approved templates for research updates</li> </ul>

Table 2. Continued

Barriers	Solutions
<p>2. Lack of channels for dissemination; researchers with limited access to contact information and information often out-of-date</p> <p>3. Study results that are inaccessible to diverse stakeholders (e.g., provided as scientific communications only)</p>	<ul style="list-style-type: none"> <li>● Develop relatable messaging for study updates and results</li> <li>● Distribute a research newsletter; use “lobby days”; give thank you notes with study results; provide updates at governance meetings</li> <li>● Utilize patient organizations to disseminate results (e.g., monthly patient newsletters, social media accounts)</li> <li>● Require communication and dissemination plans in funding applications</li> <li>● Evaluate the effectiveness of research dissemination efforts</li> </ul>

IRB, institutional review board; CMS, Centers for Medicare and Medicaid Services; NIH, National Institutes of Health; ASN, American Society of Nephrology; IT, information technology.

<sup>a</sup>As collaboratively identified by workshop attendees.

and enhancing communication to strengthen stakeholder relationships will require obtaining commitment across stakeholder groups, investing the necessary resources, and developing infrastructure to sustain new processes. It will also require innovation in stakeholder engagement and in research design and conduct. For insight, the nephrology community might consider efforts of other disciplines. For example, the oncology community has successfully created “on-study” cultures in which community-based practitioners and their patients routinely engage in research. By increasing research capacity, the dialysis community can more fully realize the potential of exciting initiatives for innovation in dialysis therapy and clinical practice that have the potential to meaningfully improve patients’ lives.

## ACKNOWLEDGMENTS

We dedicate this article to the memory of Celeste Castillo Lee, a tireless advocate for individuals on dialysis and their care partners. Celeste contributed to the development and early execution of this project. Her spirit, along with her vision for meaningful stakeholder engagement, were guiding forces for the investigative team throughout the project. We thank the members of our stakeholder panel for their time and expertise: Cynthia Christiano, Jessica Farrell, Richard Fissel, Barbara Gillespie, Jay Ginsberg, Colleen Jabaut, Jenny Kitsen, Brigitte Schiller, Terry

Sullivan, and Amy Young. We also thank Magdalene Assimon, Katie Huffman, Caroline Poulton, and Matthew Tugman for their assistance with workshop logistics and note-taking. Finally, we thank all of the attendees for their contributions to the workshop discussions.

This project was funded through a Patient-Centered Outcomes Research Institute (PCORI) Eugene Washington PCORI Engagement Award (EA-3253) to J.E.F. The funder had no role in the study design, data collection, analysis, manuscript writing, or the decision to submit the report for publication. J.E.F. is supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health grant K23 DK109401. L.M.D. is supported by NIDDK grants UH3DK102384 and U01DK099919.

## DISCLOSURES

In the last 2 years, J.E.F. has received speaking honoraria from American Renal Associates; the American Society of Nephrology; Dialysis Clinic, Incorporated; the National Kidney Foundation; and multiple universities as well as research funding for studies unrelated to this project from the Renal Research Institute, a subsidiary of Fresenius Kidney Care North America. J.E.F. is on the medical advisory board to NxStage Medical and has received consulting fees from Fresenius Kidney Care North America. A.O. is an employee of Fresenius Kidney Care. Fresenius had no role in the design or implementation of this study or in the decision to publish. L.M.D. receives compensation from the National Kidney Foundation as a Deputy Editor for the American Journal of Kidney Diseases, is a member of a Data Monitoring Committee for Proteon Therapeutics, and has received speaking honoraria from multiple universities. J.H.N., T.H., K.E., K.L., A.A., D.M., A.D., S.-Y.D.L., A.O.,

and C.W. declare that they have no relevant financial interests.

## SUPPLEMENTAL MATERIAL

This article contains the following supplemental material online at <http://jasn.asnjournals.org/lookup/suppl/doi:10.1681/ASN.2018101059/-/DCSupplemental>.

Workshop Description.

Supplemental Table 1. Workshop participants.

Supplemental Table 2. Application of patient-centered outcomes research engagement principles to workshop development and execution.

Supplemental Table 3. Workshop agenda.

Supplemental Table 4. Description of workshop participants.

## REFERENCES

1. U.S. Renal Data System: USRDS 2014 annual data report: Atlas of chronic kidney disease and end-stage renal disease in the United States, Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2014
2. United States Department of Health and Human Services: KidneyX, 2018. Available at: <http://www.kidneyx.org/>. Accessed December 30, 2018
3. Kidney Health Initiative: Roadmap for innovations in renal replacement therapy, 2018. Available at: <https://www.asn-online.org/khi/project.aspx?ID=65>. Accessed December 30, 2018
4. Kidney Diseases Improving Global Outcomes: Controversy conferences, 2018. Available at: <https://kdigo.org/conferences/>. Accessed December 30, 2018
5. Flythe JE, Narendra JH, Dorough A, Oberlander J, Ordish A, Wilkie C, et al.: Perspectives on research participation and facilitation among dialysis patients,

- clinic personnel, and medical providers: A focus group study. *Am J Kidney Dis* 72: 93–103, 2018
6. Dember LM, Archdeacon P, Krishnan M, Lacson E Jr., Ling SM, Roy-Chaudhury P, et al.: Pragmatic trials in maintenance dialysis: Perspectives from the kidney health initiative. *J Am Soc Nephrol* 27: 2955–2963, 2016
  7. Segrott J, McIvor M, Green B: Challenges and strategies in developing nursing research capacity: A review of the literature. *Int J Nurs Stud* 43: 637–651, 2006
  8. McCance TV, Fitzsimons D, Keeney S, Hasson F, McKenna HP: Capacity building in nursing and midwifery research and development: An old priority with a new perspective. *J Adv Nurs* 59: 57–67, 2007
  9. Trostle J: Research capacity building in international health: Definitions, evaluations and strategies for success. *Soc Sci Med* 35: 1321–1324, 1992
  10. Matus J, Walker A, Mickan S: Research capacity building frameworks for allied health professionals - a systematic review. *BMC Health Serv Res* 18: 716, 2018

---

<sup>a</sup>See Supplemental Table 1 for workshop participants.