

## Policies to Support Home Dialysis Patients: Patients Need Help Too

Frank Liu, Vesh Srivatana, and Page Salenger



The Advancing American Kidney Health Initiative heralded a new era in American kidney care. As home dialysis doctors, we were excited about the emphasis on home dialysis. In practical terms, however, nothing has changed for patients themselves. Our patients and their care partners continue to perform medical procedures that are usually the province of professionals, incur unexpected expenses, and manage complicated logistics, the day-to-day details of which are often underestimated and overlooked by policymakers. Unsurprisingly, up to a third of all new home patients suffer technique failure by the end of their first year.<sup>1-4</sup> Despite this, the levers that emerged to increase home dialysis use involve payment changes to dialysis facilities and nephrologists. While we support provider-side initiatives, focusing only on the provider does not directly address the patient experience with home dialysis. The lack of direct support for our patients will become an urgent unmet need as home dialysis grows. Herein, we advocate a paradigm shift that elevates patient experience to an equally important focal point of policy interventions.

The current situation is perfectly encapsulated by one of our patients, who would seem an ideal home dialysis candidate—a young health care worker with a supportive care partner. Training for HHD required a 6-week unpaid leave of absence, and, although she was able to return to work, she became overwhelmed with managing her job, personal life, and everything that accompanies HHD: the treatments themselves, keeping track of supplies, coordinating deliveries of 75+ boxes at a time, managing enormous amounts of trash and disposables, and adhering to the program requirements. Ultimately, between her full-time job and HHD, she is laboring 70 hours per week. In-center respite has not been a viable option because the clinic schedule is incompatible with her work and family schedule. She is “burning out.” How can we help her, and the many other patients in a similar situation?

### Making It Easier to Start Home Dialysis

In the following, we discuss some important patient-facing barriers limiting access to home

dialysis. Our proposed solutions are summarized in [Box 1](#).

### Address Limitations of Device User Friendliness

The complexity of many home devices discourages patients. Patients may look at the device and say, “I can’t learn that,” and default to in-center. Even well-meaning nephrologists or dialysis educators may believe many patients are incapable of operating a complicated device, and subconsciously (or overtly) steer patients away from the modality. Moreover, complexity tends to extend training time, an obstacle to patients with work and/or family responsibilities.

New devices are now available (with more in testing or awaiting regulatory approval) that are designed for layperson use, with modern touchscreen interfaces and on-screen animations that facilitate training and troubleshooting. However, in the capitated reimbursement environment of the US dialysis bundle, these more expensive devices may not be financially feasible for many dialysis providers. To aid the adoption of new technologies, the 2021 End Stage Renal Disease (ESRD) Prospective Payment System expanded TPNIES to include additional payments for innovative home dialysis devices. As reviewed by Reddy et al,<sup>5</sup> TPNIES eligibility, duration, and reimbursement should be expanded in order to more effectively encourage use of new technologies.\*

### Unexpected Costs Magnify Financial Disparities

Many patients or care partners cannot afford to miss weeks of work or pay for childcare during training. Other unexpected costs include potentially expensive electrical or plumbing modifications and ongoing unreimbursed costs for increased use of utilities

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*Policy Forum highlights aspects of nephrology relating to payment and social policy, legislation, regulation, demographics, politics, and ethics, contextualizing these issues as they relate to the lives and practices of members of the kidney community, including providers, payers, and patients.*

\*As currently constructed, TPNIES covers only 65% of the incremental device cost for just 2 years. Based on a straight 5-year depreciation of a new device (20% of cost per year), paying 65% of 20% of cost for 2 years would lead to an add-on payment equivalent to just 26% of the incremental new device cost.

**Box 1.** Proposed Policy Interventions to Improve Access for and Retention of Home Dialysis Patients**Making Home Therapies Easier for the Patient to Use and Access**

- Encourage use of newer, more patient-friendly technologies
  - ◊ Ease restrictions on qualifying criteria for new technologies in TPNIES
  - ◊ Improve cost-sharing of new technologies by expanding the duration and magnitude of TPNIES payments
- Address financial disparities that limit access to home therapies
  - ◊ Expansion of paid family and medical leave policies for up to 12 weeks for training
  - ◊ Programs to address unreimbursed costs of starting and continuing home therapy, such as:
    - Direct, nontaxable cash payments to offset home therapy costs (as is done in Australia<sup>19</sup> and parts of Canada,<sup>20</sup> where uptake of home therapies is much higher)
    - Discounts or reimbursements for utilities costs associated with home dialysis therapies
    - Safe harbor<sup>a</sup> from Stark Anti-Kickback regulations from the Office of the Inspector General<sup>21</sup> for dialysis providers to cover cost of home modifications for equipment
    - A tax-advantaged FSA to offset the hidden costs of home therapies: home modifications for equipment, increased utility costs, increased costs for waste disposal, and childcare or transportation costs during the training period
- Rethink facility-side incentives that bypass patient choice and may discourage patients from home dialysis
  - ◊ Remove or modify QIP and DFC scoring for HHD patients with tunneled catheters

**Optimizing Patient Workload and Quality of Life**

- Dedicated patient survey for home patients, allowing firsthand feedback on issues important specifically to home patients
- Creation of a multidisciplinary technical expert panel to recommend appropriate (and remove unnecessary) quality metrics for home patients, and to evaluate and optimize necessary tasks for patients and care partners
- Permanent waivers allowing audio-only telehealth visits for patients without smartphones or broadband internet access
- Reduce need for time-consuming in-person visits by reimbursing the use of local labs or mobile phlebotomy units for monthly labs, especially for PD patients
- Rapid evaluation and, if appropriate, approval and coverage of oral medications that can reduce the need for superfluous in-person visits (ie, visits just for medication administration)
- Federal tax credits or other benefits for care partners of home patients to reduce financial burden and recognize their contribution
- Provision of some amount of staff-assisted dialysis
  - ◊ Safe harbor from anti-kickback violations for facilities' provision of staff-assist personnel
  - ◊ Reimburse dialysis providers for up to 4 weeks per year of staff-assisted in-home respite treatments for HHD and PD patients
  - ◊ Funding for a staff-assisted PD or HHD feasibility pilot study

Abbreviations: FSA, flexible spending account; HHD, home hemodialysis; PD, peritoneal dialysis; TPNIES, Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies.

<sup>a</sup>The "safe harbor" regulations describe various payment and business practices that, although they potentially implicate the federal anti-kickback statute, are not treated as offenses under the statute.<sup>14</sup>

and waste management resources. These expenses constitute a hidden cost-sharing to which in-center patients are not subject. While PD patients currently are less affected by utility costs than HHD patients, on-demand peritoneal dialysate generation systems are in development that would require similar utilities. Notably, 34% of Australian in-center hemodialysis survey respondents indicated they would try home dialysis if associated costs were reimbursed, compared with only 13% if such costs were not reimbursed.<sup>6</sup> Potential solutions for mitigating home dialysis costs are shown in [Box 1](#).

### **Facility-Side Regulatory Incentives Can Bypass Patient Choice and Discourage Patients From Going Home**

Fear of self-cannulation and needle dislodgement are important reasons why patients decide against HHD.<sup>7-9</sup> Moreover, increased peripheral access-related complications are a downside of more frequent and nocturnal hemodialysis regimens.<sup>10,11</sup> Both the ESRD QIP and DFC Star Rating strongly disincentivize catheter use by threatening

severe financial and reputational penalties. However, the benefit of peripheral access is unclear for HHD patients. While studies suggest HHD patients with peripheral access have lower mortality than HHD patients with catheter access,<sup>12</sup> there are no data on how catheter access in home patients compares with peripheral access in in-center patients, prompting the question: would we rather have patients at home with a catheter or in-center with a fistula? To remove a facility-side disincentive to home dialysis, HHD patients with catheters could either be excluded from the denominator of QIP measures, or, similar to how "self-care" patients are considered "half" a home patient in the ESRD Treatment Choices model, be partially discounted in vascular access quality measures.

### **Making It Easier to Stay on Home Dialysis**

The expansion of telehealth for home dialysis patients introduced in the 2019 CHRONIC Act significantly benefited home patients, minimizing missed days of work and struggles finding childcare and transportation. Remaining problems and mitigation strategies are in [Box 1](#).

### ***We Don't Know What We Don't Know About the Home Patient Experience***

Although efforts are ongoing to create a survey for home patient experience,<sup>13</sup> the only current approved survey excludes home dialysis patients. The lack of a validated, independently administered experience survey is a critical missed opportunity to understand the lives of home dialysis patients and investigate why some patients persist for years while others drop out after just weeks. Ironically, the lack of a survey for home patients may actually penalize facilities with large home populations, as returned In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) surveys represent a smaller proportion of the facility's total census.

### ***Optimizing Patient Workload***

Home dialysis patients have innumerable tasks to complete, and, while each task may seem relatively straightforward, the sum of these contributes to patient burnout. For example, current regulations require a monthly urea reduction ratio (URR) for all patients on hemodialysis, including HHD. This requires the patient to laboriously draw, centrifuge, package, and ship the sample. Without the need for a postdialysis urea nitrogen, blood could be drawn at a local laboratory, by the facility during an in-person visit, or even by a mobile phlebotomy service, thereby reducing patient burden. Is a monthly URR for HHD patients truly necessary, or is the requirement carried over from in-center HD? Assessing adequacy every quarter in stable patients (similar to PD) would promote patient-centeredness while still ensuring patient safety.

Similarly, PD patients are often required to travel to the facility for routine blood draws or intravenous medications. Local or mobile phlebotomy services and appropriate oral medications could suffice but are often not covered by payers. Unnecessary travel impacts patient quality of life, and efforts to promote self-dialysis should also aim to minimize unnecessary tasks when appropriate.

Everything we ask of our home patients should be examined for utility and more patient-friendly alternatives, and discarded or modified if found not useful. To find the proper balance between safety, quality, and patient experience, a technical expert panel focused purely on home therapies should be convened, with representation from patients, care partners, nephrologists, nurses, and biomedical and quality improvement experts.

### ***Making Respite More Accessible and Patient-Friendly***

Full-time jobs require some vacation or respite; few would willingly take a job that provided neither. For HHD, which can require an amount of work equivalent to a full-time job, this has historically meant "backup" in-center HD. However, the travel and scheduling issues of in-center backup may present an additional burden to patients. This has been particularly apparent during the pandemic;

most facilities have required COVID-19 testing or very limited "person under investigation" shifts for patients who do not have a negative COVID-19 swab. For PD patients, it is even more difficult; unless there is existing hemodialysis access, there is no PD "backup" treatment.

Ideally, all home patients would have some option for respite whereby the "backup" treatment would travel to the patient, such as staff-assisted respite dialysis for both HHD and PD patients. Perhaps giving access to staff-assisted respite home dialysis for up to 4 weeks per year could decrease the burnout that all home dialysis patients feel.

In addition to respite for existing patients, we believe hesitant patients who might otherwise choose in-center HD could be persuaded to attempt home dialysis if they knew they would have assistance during the transition home, for example, up to a month of assistance after the initial training on either PD or HHD.

Primary regulatory barriers to staff-assisted home dialysis in the United States include lack of reimbursement and clarity about whether provision of assisting staff may constitute an inducement or other violation of the Anti-Kickback Statute. Potential solutions can be seen in [Box 1](#). Notably, various models of staff-assisted dialysis exist in many countries and generally are not cost-prohibitive.<sup>14-18</sup>

In summary, the government has rightfully decided that home dialysis is underutilized. It is now time that policymakers introduce initiatives that not only offer carrots and sticks to providers but also offer tangible support for the people actually performing these treatments. As with most things that require multistakeholder support and potentially new dollars, none of our suggested steps will be easy or straightforward to accomplish, nor are they necessarily the only steps. However, we believe that beginning the conversation about patient experience is essential to improving home dialysis.

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