



Commentary

Annotated Barriers to Peritoneal and Home Hemodialysis in the U.S.

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Abstract: In the last decade, barriers to the growth and utilization of home dialysis have been described in mainstream and significant Nephrology journals. Since then, the suggested solutions have received little attention or have proven ineffective. This situation is even more significant because, in 2019, President Trump issued an executive order to increase the utilization of home dialysis and transplantation. The reasons for failing to achieve the stated goals of the executive order are numerous and can be attributed to barriers at many levels in the health care system. Some of the barriers are unique to the United States and learning from foreign systems would be beneficial. This correspondence attempts to describe and annotate these barriers. I classify them such that local institutions can identify and prioritize solutions. Home dialysis growth can only occur with all stakeholders committing to that end.

Keywords: peritoneal dialysis; dialysis administration; end-stage kidney disease; Medicare; staffing ratios

1. Introduction

The barriers to home dialysis, and peritoneal dialysis (PD) in particular, are an obvious microcosm of the problems with health care delivery in the United States (U.S.). The broader world-wide problems are somewhat related, but they are not the focus of this correspondence. U.S. readers will easily recognize that this detailed discussion is what they observe in their routine provision of care. This frustrating situation distracts time, energy, and other resources away from what clinicians prefer in delivering care. In the past decade, there have been several relevant reviews of this topic (Table 1) [1–3]. This communication is intended as an expansion and partial update to those reviews, and the reader is strongly advised to revisit them. A consistent theme of the action plans to address the barriers was aligning the incentives of all stakeholders such that patient care is the highest priority.

In the summer of 2019, President Trump introduced an executive order establishing the Advancing American Kidney Health Initiative (AAKHI) to enhance the utilization of home dialysis [4]. Several components of the AAKHI attempt to address some barriers more along the lines of incentives (and punishments) for achieving (or not) established goals in enrolling patients on home dialysis or transplant wait lists. To date, the nephrology community has demonstrated only marginal progress in the status of home dialysis, prompting another reassessment of the barriers and possible resolutions. The goal here is to enhance the recognition and understanding of these common barriers, a prerequisite to overcoming them.



Academic Editor: Jaime Uribarri

Received: 17 January 2025

Revised: 21 April 2025

Accepted: 21 April 2025

Published: 9 May 2025

Citation: Golper, T.A. Annotated Barriers to Peritoneal and Home Hemodialysis in the U.S. *Kidney Dial.* **2025**, *5*, 18. <https://doi.org/10.3390/kidneydial5020018>

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Table 1. Summary of barriers from Reference [1].

Educational Barriers	Possible Action Plans
Patient education	Easily accessible Internet resource center, linked sites, chat arrangements
Physician education	Mandatory training for program certification; ongoing and immersion courses: local, regional, and national
Dialysis staff education	Designated time and resources; certification; centers of excellence
Governmental Barriers	Possible Action Plans
Visit requirements	Local lab services; all frequencies determined by clinical need
Dialysis access payment	Align payment incentives for the best access for that patient; awareness of retroactive payment for home dialysis initiates
Partner support	Cost analysis and feasibility study
Accreditation and certification	Eliminate differences between CMS and The Joint Commission regulations; define precise time frame for certification
Staff home visits	Clinical judgment defines necessity; use phone photographs
Make available “state-of-the-art” equipment	FDA to streamline approval process; encourage efficiency research; industry–government collaboration
Provider Organization Barriers	Possible Action Plans
Availability of solutions and equipment	Eliminate inappropriate restriction policies; clinical judgment prevails
Delivery of supplies	Accommodate unique patient needs; local and regional depots
Pharmacy	Prompt and efficient drug delivery and availability; address and alleviate The Joint Commission restrictions and requirements
Business conflicts to patient care	Patient care takes priority
Laboratory services	Improve data sharing; more raid-specific responses
Quality improvement	Select meaningful data; standardize data collection and reporting
Independence	Recommended; encourages problem solving andcreativity but does not occur in a vacuum
Physical environment	Appreciate home programs’ unique requirements
Staffing	Discourage boilerplate thinking; develop criteria for appropriate staffing ratios; consolidate programs; share staff

2. Governmental Authoritarianism Through Guidelines

As chair of the initial National Kidney Foundation (NKF) Dialysis Outcomes Quality Initiative (DOQI), I was involved in the intricate aspects of guideline development. I raised my concerns about guideline overreach and wrote the following in the 1997 Clinical Practice Guidelines for Peritoneal Dialysis Adequacy Guidelines [5]:

“These guidelines are intended for use by health-care professional trained to understand variations in the practice of medicine and the necessity for such variation. These guidelines are not intended for punitive use by any oversight official who does not understand the reasons or necessity for practice variations including variations in societies different from that of the United States.”

The Centers for Medicaid and Medicare (CMS) used these guidelines to define the adequacy of PD by a Kt/V_{urea} threshold. Failure to meet that threshold resulted in a reduction in the payment to the facility for providing dialysis services. CMS clearly failed to appreciate the practice variation aspect. Some examples, among many, are palliative PD and patient-centered PD [6], where what the patients truly needed in the holistic sense did not necessarily achieve the CMS “adequacy” threshold. Perhaps as a consequence of CMS using guidelines to formulate rigid metrics affecting policy and payment, the International Society of Peritoneal Dialysis (ISPD) changed the terminology by labeling its

advice “practice recommendations”. This became evident when the ISPD announced its Practice Recommendations for patient-centered PD prescriptions [7]. A U.S. commentary on the ISPD Practice Recommendations concluded that there was no high-quality evidence to support the achievement of a specific Kt/V_{urea} target [8].

Since the CMS is the major payer for dialysis services in the U.S., it is quite reasonable that it recognizes value for its expenditure; in fact, this was demanded by Congress. Rather than investigate a thorough approach to defining value, it simply took a threshold from the 1997 DOQI Clinical Practice Guidelines for the Adequacy of Peritoneal Dialysis [5] and drew a line in the sand. The immediate consequence of this hard-stop threshold was the negative impact on the growth of PD in the U.S. This problem remains today even after the Executive Order by President Trump in 2019 that specifically encouraged the expansion of home dialysis.

In the meantime, several PD advocates have tried to convince the CMS to approach this differently utilizing existing CMS methodology [9–11]. Leading a related strategy, Drs. Osama El Shamy and Ankur Shah have approached the dialysis industry, the USRDS, and the Innovation branch of CMS to define “adequacy” in a more scientific, holistic, and comprehensive manner than a Kt/V_{urea} threshold. This may take years to accomplish, will be costly, and may not even be successful. As discussed above, the 1997 PD Adequacy Guidelines were not intended for this use. I have suggested retracting the guidelines such that CMS would have lost the foundation for its threshold. However, the formal guideline process does not allow retraction unless there is an error, which is not applicable in this case. Guidelines can be “sunsetting” if outdated, which also does not apply. There is little likelihood that the National Kidney Foundation would or could change the title from “Clinical Practice Guidelines” to “Practice Recommendations” following the ISPD.

The only immediate recourse is that the CMS changes its approach. One simple solution is that, if the Kt/V_{urea} threshold is not met, there can be an explanation (justification) in the medical record, but full payment can be made. CMS inspectors can review these explanations and determine fraud or abuse. This is advantageous to the CMS but also for the direct care of the patient, since the medical record will contain the explanation/rationale for the management of that patient.

State inspectors certify and review program performance for the CMS. Another mandate in some states is the reporting of the peritoneal equilibration test (PET) result. While this is an occasionally helpful test, it is not necessary to provide high-quality PD [12]. Far more often, observations on the details of the therapy are more informative than a PET. The PET takes more than one-half of a patient’s day as well as nursing time and laboratory expense. The PET should not be mandated.

As mentioned above, as the payer, the CMS is justified to specify what it is paying for. On the other hand, the American taxpayer also should be heard. We have no current forum for the patients’ opinions, but we have research on the topic of patient preferences and patient-reported outcomes. There is a broad international movement to consider medical evidence but also to include the personal and unique aspects of the patient’s situation into the decision making [13]. The SONG initiative described PD patients’ and caregivers’ priorities [14]. Americans ranked infection concern, fatigue, and time flexibility first through third, while other nationalities ranked infection, mortality, and fatigue first through third. What Americans ranked higher is important and consistent with my 45 years of experience with PD. Mandated Kt/V_{urea} and PET are only faintly related, if at all, to the priorities of patients and caregivers.

3. Administrative Authoritarianism

Separate from the regulatory stipulations just mentioned, local administrative mandates may generate barriers to PD. Each dialysis facility is required by the CMS to have a

medical director. While the duties may be legally and administratively dispersed, there is one final responsible physician director. The overriding job of the medical director is to oversee the quality of care provided. The medical director must work in close coordination with the facility administrator and nursing leadership. However, the final decider on medical issues is the physician medical director. This is how it is supposed to work, but, on too many occasions, it does not. The facility administrator, probably representing the dialysis organization, informs the physician medical director that certain things must be implemented. However, the “must” part is sometimes arbitrary, unnecessary, and inappropriate.

Examples of barriers that I classify as administrative are the following:

- A. The choice of antibiotics for exit-site topical prophylactic care, empiric exit-site infection treatment, and empiric peritonitis treatment are medical decisions only. Yet facility administrators weigh in based on expense and availability. Obviously, these are negotiable, but often the medical directors acquiesce to the financial/administrative argument at the expense of medical justification.
- B. Icodextrin has a slight cost differential to standard dextrose PD solutions. Once, a Large Dialysis Organization administrator told a PD-savvy nephrologist friend that, if she knew more about how PD works, she would not need to prescribe icodextrin. There are certain patients that benefit from more than one icodextrin exchange per day [15–18]. Despite being off FDA labeling, this practice is safe and effective and can prolong PD technique survival for many months.
- C. Similarly, the use of a certain type of cyclor may advantage one clinical situation over another, but, for contracts (read that as expenses), only a certain type of cyclor is offered in that clinic. This is relevant for several clinical reasons such as the ability for remote monitoring of the treatment and for addressing drainage issues. Again, medical decisions and opportunities can be and are jeopardized by local administrative decisions.
- D. There are patients who would greatly benefit from the hybridization of hemodialysis with PD [19–22]. This most often occurs while electively transitioning from one to the other, but, in Japan, for example, this is not an infrequently occurring practice. Administrative prohibitions may dominate.
- E. Staffing is a component of the quality of care. Some administrators defer to a standard staffing ratio of patients per nurse (social worker, dietician) regardless of the setting. By setting, I refer to location (e.g., urban, dense urban, suburban, rural, distant rural), access to the Internet, experience of the staff, back-up facilities and their proximity, number of clinicians referring and their experience, the expertise of the medical director, and the off-site support from the dialysis organization. What I term “the Godzilla Effect” is that size does matter for many of these settings. It is well described that outcomes are vastly superior in larger PD programs [23–25]. The advantages of a larger program are described in Figure 1.



Figure 1. Advantages of a larger program (the Godzilla Effect: size matters).

Clearly, I think larger programs will be more easily managed and more successful than smaller ones. Small programs may be necessary in some situations, and I encourage such programs to partner with various entities for support. Such entities could be regional or national and have individualized affiliation arrangements for mutual benefit. That may or may not lead to consolidation, which is something I have suggested for years. Candy Regua, an RN, in Phoenix, was able to successfully consolidate five separate and competing PD programs into three. If distance and proximity issues dominate, after the first three months of PD, telehealth visits can be utilized for two monthly visits each quarter. Thus, even for more remote programs, travel could be reduced to once per quarter for stable patients. This topic will emerge again below in the Frequency-Related Barriers Section. I have not discussed competition between practices and PD programs as a barrier to PD in general, and it may or may not be a barrier to improved care. I personally think the competition is between us providers and the malady, not between providers. Nonetheless, my suggestion here is that larger programs have better outcomes [23–25] and that consolidation can build the program to enjoy the advantages of the Godzilla Effect.

4. Frequency-Related Barriers

In-center hemodialysis patients travel to their facility as often as their treatments occur. There, their lab work is sampled, and they see their providers. Unlike in-center hemodialysis, patients dialyzing at home generally are minimizing the frequency of visits to the home dialysis facility. Medicare is the predominant payer for dialysis services in the U.S., and it essentially mandates the frequency of provider–dialysis patient face-to-face visits. This mandate applies to every patient regardless of the payer source because it is a condition of Medicare certification (coverage) for the facility. Such in-person visits to the PD clinic are valuable, but the frequency of such visits should be determined by medical necessity. While surveillance and prevention are wise strategies that occur during face-to-face visits, they could be addressed remotely in many circumstances. Many of their benefits can be derived by less intense methods. Some patients may live a substantial distance from the dialysis facility, and, consequently, they and their helpers may sacrifice an entire day of employment to make the trip. The travel could be both a financial and a logistical burden. Medical necessity should be the determinant of face-to-face visit frequency. This is the norm in almost every other country. The Bipartisan Budget Act of 2018 legislated the availability of telehealth visits for home dialysis patients under the conditions that the home is the originating site and that three monthly face-to-face (in-person) visits occur prior to the telehealth visits [26]. A face-to-face visit has to occur once every calendar quarter to accompany the two monthly telehealth visits that quarter. There are variations by state, so local policies should be reviewed.

While the telehealth visits are a welcomed change, Medicare still mandates monthly lab results. It is not the intent of this correspondence to detail the ideal hemoglobin, calcium, or phosphorus concentration for best outcomes nor how often they should be measured. I do think the clinical necessity of needing the information should determine the frequency of the measurements. However, Medicare not only demands monthly measurement but punishes the facility in their absence. The frequency of the lab measurements is possibly even more of a burden on patients than the in-person visits, which were minimized by telehealth visits. Some local physician offices, clinics, hospitals, and dialysis facilities may provide a phlebotomy service. However, this is rarely implemented because those entities are busy, often overwhelmed with their own obligations, and are not reimbursed for the expense of the blood drawing, processing, mailing, or reporting. Consequently, home dialysis patients make the trek to the home dialysis facility for blood work and face-to-face visits. Some nephrologists insist on lab results being available prior to the in-person visit.

For the patient, that results in two clinic visits that month, one for labs and one for the nephrologist face-to-face visit. An alternative is drawing the labs at the face-to-face visit and the nephrologist following up a few days later when the results are available. This practice should be reserved for stable patients. This strategy relieves the patient of the two-visit burden but requires the nephrologist to revisit the patient's status when the lab results are available. This becomes a burden for a busy nephrology practice and sets the stage for errors. The solution to these problems is that the frequency of lab measurements should be determined by the medical necessity, which may justify the burdens described. Absolute mandates of frequencies of face-to-face visits and lab measurements may not improve care and certainly are added barriers to the utilization of home dialysis and increase costs.

When PD utilization initially grew in the 1980s, the dialysis solutions and equipment suppliers provided home deliveries twice monthly and emergently on occasion. Depending on population density and other relevant factors, supply deliveries may occur as infrequently as monthly, and no emergency deliveries may transpire at all. Since patient conditions can change abruptly, and some patients may have limited storage capacity, it would be ideal if the frequency of deliveries is determined by necessity. This is a heavy ask of the industry, but local storage sites could be created to accommodate urgent modifications of solution prescriptions. Alternatively, the dialysis facilities could be the depository of extra solutions. This would require regulatory modifications.

The ideal staffing of a PD unit is such that there are technicians, nurses, and physicians always available on call, which means 24 h per day and 7 days per week (24/7). The cyclor manufacturers typically provide technical support 24/7, and the physicians are on call but are likely not technically savvy enough to solve such problems. They do take medical issue call 24/7. In general, only the larger PD programs offer 24/7 nursing calls (Godzilla Effect, size matters). Patients, emergency departments, hospitals, and nephrologists all would prefer the home PD nurse to be available 24/7. Those opposed to it are the administrators responsible for funding it and, sometimes, the nurses themselves. There is a general shortage of PD nurses. An onerous call schedule is another barrier to growth in this specialty. Consequently, the infrequency or lack of nursing calls affects the overall performance of the PD program.

5. Special Space and Service Designations

There is emerging evidence of a benefit to the growth of home dialysis from the utilization of transitional care units. In this special setting, incident dialysis patients are initiated in a space that uses home dialysis equipment and staff and is designed for education about dialysis options and especially options for home dialysis. This is particularly applicable to patients who have not received and benefitted from pre-dialysis or late-stage chronic kidney disease care. This logical strategy may not always be practical. It requires designated equipment, space, and staff. The lack of a transitional care program is a barrier to the growth of PD.

Home dialysis clinics must have their own space and staff that are exclusively designated to home dialysis and not under the jurisdiction of the in-center hemodialysis unit. The overlap to the in-center HD unit is the transitional care unit. The home dialysis unit staff and space require this separation because problems in the in-center unit may tempt the commandeering of the home dialysis staff or space for the solution. This separation may require a unique Medicare provider designation. The home dialysis nurses should be cross-trained in HD and PD, because the effort should be to keep patients at home even if a transition between modalities is indicated. There is no barrier to the training and examining rooms of the home dialysis clinic being suitable for both PD and HD. The fact that the home

dialysis nurses are trained in both modalities provides an enormous educational boon to the patients, dieticians, social workers, and clinicians.

PD patients who require hospitalization should ideally go to a hospital that has designated PD services because of experience with PD patients and techniques. Insurance, patient and clinician preferences, and emergencies all play a role in determining which hospital PD patients are admitted to. Those situations can often be barriers to the patients receiving hospital care in a PD-experienced designation. A PD-experienced emergency room knows how to handle the catheters, solutions, and sampling, as well as having awareness of other unique complications of PD. The same applies to the radiology department, the operating rooms, the intensive care units, and the regular wards. For example, are cyclers available in the ICU and general wards? Are solutions available, especially icodextrin? Addressing the patient's preference is the first step. The Godzilla Effect (size matters) demonstrates the benefit so that this should influence patients if they are the deciders on which hospital to patronize. Insurers will follow suit if the data are presented to them. Then, the issue is contractual between the hospital and the insurer. Since most patients are still under Medicare, the issue then is the role of hospital administration. The hospital dialysis staff must be cross-trained in PD and HD and adept with cyclers and manual exchanges. Intensive care unit staff may be trained on how to use cyclers or to perform manual exchanges. Each of these barriers will be overcome by size. It is starting that requires the investment in space and staff. PD-trained caregivers (e.g., spouses) should be allowed to assist with in-hospital PD in some circumstances.

Special staff designations will benefit the patients and the PD program. The special nurses were discussed above. Technicians can provide a variety of services but under different privileges and credentialing according to state regulations. Examples include performing PETs, sampling potential infected effluents, obtaining vital signs, phlebotomy, loading supplies, inventory, copying, and much more. Pharmacists can recommend specific drug dosing and prepare bags, syringes, or vials for home use. Some pharmacists are involved in anemia management regarding iron and erythropoietic stimulating agents. Radiologists with PD expertise may place or reposition PD catheters but also need to interpret images with an understanding of PD; examples here are fluid loculation, intraperitoneal air, catheter tip location, stool burden, and much more. Surgeons with experience in PD are invaluable. Placement, removal, exit-site location and debridement, repositioning, addressing omental wrapping or other obstructions, hernia evaluation and repair, and other surgical emergencies are just some of the expertise needed. The absence of these specialty designations are barriers to the success of PD programs.

6. Solutions and Opportunities

The first and foremost step to overcoming barriers is to identify and understand them. Throughout this article I mention potential solutions to specific barriers, but a broader approach is important. Sometimes simple misunderstandings are the barrier, and discussion may resolve them. Many are more nuanced or complex. Sometimes both parties are spot-on correct or clearly wrong. Thus, recognition helps the resolution process. Understanding the other side of the barrier is mandatory. To get there, knowing the pertinent finances of the facility will expedite negotiations over resources. Home dialysis programs tend to attract a clientele more likely to be covered by commercial insurance instead of Medicare, and the former pays much more than Medicare does. Thus, the revenue from home dialysis contributes proportionally much more to an institution's success than in-center HD. This provides negotiating leverage. On the other hand, one must recognize the entire needs of the facility. Awareness of financial details influences the efforts to overcome barriers.

Other areas of knowledge may be particularly relevant in addressing barriers. The pertinent regulatory bodies include traditional Medicare; commercial insurers whether employer based, private or Medicare Advantage, the Veterans Administration, Tri-care, state, or other local regulators; The Joint Commission; and hospital credentialing committees for hospital-based activities, to name a few. Understanding the position of these entities is of value because they are not always correct. Pointing out those errors with facts and data sets the stage for negotiations, which can be beneficial to all parties. A classic example is the formal privilege of placing PD catheters by nephrologists and radiologists, where the precedent was placement only by surgeons. Telemedicine can include the electronic transmission of photos of the exit site and edema exams. The same methodology can suffice and replace the telefaxing of documents.

On the horizon and in maturation are technical innovations that provide solutions to some barriers. The remote monitoring capabilities of cyclers are yet to be properly exploited. Several ongoing studies are underway to improve our understanding and utilization of these technologies. One dialysis solution vendor is trying to link its remote monitoring to a popular electronic medical record system. Another example of technical improvement concerns the cyclers themselves. This is less likely to affect prospective PD patients but is highly relevant to prevalent PD patients. Attributes such as portability, noise (alarms and background), setup time and complexity, size (relates to space mentioned above), possibility of being battery powered, and again space for consumables were all rated as important by patients, care partners, and nurses [27].

Staff-assisted PD is in part available in Canada, the United Kingdom, France, and Scandinavia [28–32]. One small U.S. dialysis organization demonstrated its feasibility in practical terms but not financially [33]. Global capitation systems might convert travel funds toward paid home helpers, and if the payment structure remains as it is currently, it may even provide a margin to the program. Oliver and Salenger have articulated the feasibility in the U.S. [34], and they and others representing the ISPD have formulated practice recommendations for staff-assisted PD [35].

Organization of like-minded PD thinkers is important. The North American Chapter of the International Society of PD has formed a public policy committee to begin to address these prevalent and systematic barriers to home dialysis of all types. To that end, Ankur Shah in Providence, Rhode Island, and I are urging interested readers to contact us. An example of what we are trying to address and reconcile is the differences in regulations imposed on hospital-based PD programs while stand-alone PD programs are exempt. In some of these regulations, The Joint Commission is amenable to discussion and modification and may have been misinterpreted from the onset. Thus, awareness of the regulations, identifying the barriers, studying the specifics and rationales, and negotiating with the interested affected parties can often lead to a satisfactory resolution.

I close with this admonition: recognize that the competition is not among the providers in health care; the competition is between the collective providers and the disease we are treating.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: The original contributions presented in this study are included in the article. Further inquiries can be directed to the corresponding author.

Acknowledgments: My involvement in the International Society of Peritoneal Dialysis, The Renal Physicians Association, and Home Dialysis University is the source of my interest in this subject.

Conflicts of Interest: The author declares no conflicts of interest.

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