Peritoneal Dialysis International, Vol. 37, pp. 542–547
www.PDIConnect.com

0896-8608/17 $3.00 + .00

EFFECTS OF A COMPREHENSIVE PREDIALYSIS EDUCATION PROGRAM ON THE HOME DIALYSIS THERAPIES: A RETROSPECTIVE COHORT STUDY

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♦ ***Background:*** **Improvement in the rates of home dialysis has been a desirable but difficult-to-achieve target for United States nephrology. Provision of comprehensive predialysis education (CPE) in institutes with established home dialysis programs has been shown to facilitate a higher home dialysis choice amongst chronic kidney disease (CKD) patients. Unfortunately, limited data have shown the efficacy of such programs in the United States or in institutes with small home dialysis (HoD) programs.**

♦ ***Methods:*** **We report the retrospective findings examining the efficacy of a CPE program in the early period after its establishment, with reference to its impact on the choice and growth of a small HoD program.**

♦ ***Results:*** **Over the initial 22 months since its inception, 108 patients were enrolled in the CPE clinic. Seventy percent of patients receiving CPE chose HoD, of which 55% chose peritoneal dialysis (PD) and 15% chose home hemodialysis (HHD). Rates of HoD choice were similar across the spectrum of socio-economic variables. Of just over half (54.6%) of those choosing to return for more than 1 session, 25.3%, changed their modality preference after the first education session, and nearly all reached a final modality selection by the end of the third visit. Initiation of the CPE program resulted in a 216% growth in HoD census over the same period and resulted in near doubling of HoD prevalence to 38% of all dialysis patients.**

♦ ***Conclusions:*** **Comprehensive patient education improves the choice and prevalence of HoD therapies. We further find that 3 sessions of CPE may provide needed resources for the large majority of subjects for adequate decision-making.**

Perit Dial Int **2017; 37 (5):542–547 epub ahead of print: 25 May 2017**
https://doi.org/10.3747/pdi.2016.00270

KEY WORDS: Predialysis education; home dialysis; peritoneal dialysis; shared decision-making.

More than 90% of all end-stage renal disease (ESRD) patients in the United States (US) receive in-center hemodialysis (IHD) for their renal replacement therapy (RRT), whereas less than 10% receive some form of home dialysis (HoD) therapy (1). When compared with IHD, HoD provides equivalent medical outcomes and may be associated with improved indices of quality of life and financial savings, both for individual patients and the healthcare system (2,3). It has been estimated that merely doubling the current rates of HoD in the US from ~7% to 15% will save the Center for Medicare and Medicaid Services (CMS) over a billion US dollars annually (4). Across the world, a number of industrialized countries have achieved, and maintained, a much larger fraction of their ESRD population on HoD, for a combination of economic and quality-of-life considerations (1).

In the United States, CMS, professional nephrology societies, as well as individual renal physician surveys have indicated that HoD may be suitable for a much larger fraction (25 – 40%) of the prevalent ESRD population (5–8). Targeted initiatives by CMS, (e.g. equalizing monetary incentives for IHD and HoD, recognizing billable chronic kidney disease [CKD] education services, early initiation of Medicare services for HoD, etc.) (6) have led to some improvement in HoD rates in recent times (1). Despite these, HoD continues to be utilized in only about 10% of incident and prevalent ESRD subjects.

Patient education has been shown to improve outcomes in multiple chronic diseases. It is well known that in the US, HoD utilization is higher amongst patients with markers of socio-economic advantage, (e.g. patients that are Caucasians, with higher education, under nephrology care, in urban environments, and with independent living, etc.) (9,10). Comprehensive predialysis education (CPE), also known by many different names in the literature (e.g. multidisciplinary dialysis education, CKD education, predialysis education, etc.) have been shown to bridge this gap and improve patient-oriented selection of dialysis modalities with higher utilization of HoD (in about 50 – 85% of those receiving CPE), in many North American, European, and Asian countries (11–14). However, 2 separate studies examining the outcomes of predialysis education in the US have shown variable and lower rates of HoD choice, likely resulting from variations in protocols and method of delivery of CPE and a likely selection bias (15,16). We report the findings of a retrospective analysis of the initial 22 months of our newly formed CPE clinic at University of

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Received 24 October 2016; accepted 20 February 2017.

Arkansas for Medical Sciences (UAMS) in an unselected cross-sectional population of advanced CKD subjects, especially with reference to its impact on the rates of HoD.

METHODS

We established a CPE clinic at UAMS with an aim to improve patient awareness with reference to advanced CKD and associated comorbidities and promote shared decision-making for their disease management. All patients with stage 4 and 5 CKD, with occasional patients of stage 3b CKD with rapid renal progression under the care of individual nephrologists within the university practice, were offered and encouraged transition to the care of the CPE clinic under a single nephrologist for their routine nephrology care. The final choice for provider selection was made by the individual patients though the medical needs (e.g. administration of erythropoietin and iron infusions when needed) were provided only through the CPE clinic for the entire practice to improve CPE attendance even amongst those who were not followed in the CPE clinic for their care. The CPE clinic included a renal physician, an advanced nurse practitioner (ANP) educator, a renal dietician, and a renal social worker. A pharmacist was inducted in the CPE clinic for the latter half of the study period. Though the protocols for CPE were developed and finalized in the first 6 months of clinic inception, the analysis here includes the entire first 22 months, to maintain the integrity of the findings.

COMPREHENSIVE PREDIALYSIS EDUCATION PROTOCOLS

All patients admitted to the clinic for the first time were seen on new patient protocol, and returning patients were seen on established patient protocol.

New patient protocol required the patients to attend a comprehensive education session lasting nearly a half-day clinic. Patients were encouraged to attend with their family members, spouse, or caregivers. On arrival, patients were provided with the printed material for kidney disease. This was followed by a group lesson in a classroom format by the renal ANP educator, which lasted for a minimum of 1 hour. The participants were encouraged to interact with the educator as well as with other attendees, while care was taken to ensure that no individual patient-specific information was discussed in an open format. The format of the group lesson is highlighted in Table 1. After the group lesson, patients rotated with a renal dietician, a social worker, a trained dialysis nurse well versed in all dialysis techniques, and a renal physician. These discussions were patient-specific, and detailed on the individual needs and questions. Sessions with the dialysis nurse included a 'hands-on' demonstration of home peritoneal dialysis (PD), home hemodialysis (HD), and in-center machine as per the needs and desires of the patients. The visit ended with a detailed session with the renal physician/provider. Provider sessions started with an interview of the individual's family, social, medical, and occupational needs. All previously provided information was reviewed and specific questions addressed. Patients and their caregivers were encouraged to make an 'active choice' for their RRT. Active choice was defined as not only patients choosing the modality, but the ability to discuss the pros and cons of the chosen therapy with reference to their lifestyle with their providers in their own words. Any remaining misconceptions or fears were addressed during this final discussion. The last member of the clinic team recorded final modality choice in a passive manner.

All patients were offered the option to re-attend the new patient protocol based on their choice and otherwise were scheduled to be seen back in the clinic as established patients. Established patient protocol allowed a greater freedom for patients to focus on the areas of their choice with all clinic members available for counseling. Patients choosing not to visit any of the CPE staff were seen by the renal physician for their routine nephrology care. Patient preferences for RRT were noted at each clinic visit. In order to facilitate the analysis, patients leaning towards or resolute about a RRT modality choice were grouped together.

STATISTICAL ANALYSIS

Categorical variables were presented using *n* (%), normally distributed continuous variables were reported as mean ± standard deviation (SD), and non-normally distributed continuous variables were presented as median (range). Chi-square test was applied to examine the patterns between 2 categorical variables with independent measures. Cochran's Q test was used to compare a 2-level categorical variable among repeated measures across all visits. We conducted a multivariate logistic regression analysis to identify the potential determinants for the choice of RRT modality. The patients' age, gender, race, availability and type of insurance, diabetes status, albumin, and the stage of renal disease with reference to Modification of Diet in Renal Disease (MDRD) estimated glomerular filtration rate (eGFR) were included in the model. Joint points and regression slopes were analyzed using Joint point regression program 4.3.1 (National Cancer Institute, Bethesda, MD, USA).

TABLE 1
Outline of the Group CKD Education Session

- Location and structure of kidneys
- Function of kidneys in normal health
  - Clearance functions
  - Non-clearance functions
- What are CKD and stages of CKD
- Impact of CKD/kidney dysfunction on human health
- Health requirements of different stages of CKD
- What is called advanced CKD
- When to initiate RRT
- Different types of RRT, transplantation and conservative care
- Best RRT, is there one or no?
- Lifestyle simulation and outcome discussions
- Questions and Answers

CKD = chronic kidney disease; RRT = renal replacement therapy.

Other statistical tests were conducted using SAS 9.4 (Cary, NC, USA). A *p* value less than 0.05 was considered to be statistically significant.

RESULTS

DEMOGRAPHICS

A total of 108 advanced CKD patients, with an average MDRD eGFR of 18.34 ± 6.5 mL/min were seen in the first 22 months of the CPE clinic. Table 2 shows comparative demographic and biochemical characteristics of the cohort at the time of referral across 4 eventual choices. Despite a universal protocol, a majority of patients were referred to the CPE clinic late in the course of the disease, with late stage 4 (eGFR 16 – 22 mL/min) and stage 5 comprising 74% of the total CPE population. Despite encouraging follow-up, every 2 – 3 months for stage 4 CKD and every month for stage 5 CKD, 49 patients (45.4%) attended only 1 session of CPE before initiation of RRT. The remaining 59 patients (54.6%) had 1.9 ± 1.2 CPE visits, over the following 6.4 ± 5.1 months, with declining numbers at each return.

CHOICE OF DIALYSIS MODALITY

Choice of dialysis was ascertained at the end of each visit. Overall, 75 patients (70%) chose HoD as their final RRT modality. Fifty-nine chose PD, 16 chose home HD, and 24 chose

TABLE 2
Demographic and Laboratory Parameters

Characteristics	All patients *n*=108	Subset choosing HHD *n*=16	Subset choosing PD *n*=59	Subset choosing IHD *n*=24	Undecided *n*=9
Age (years)	56±14	60±17	55±13	52±15	62±17
Weight, lbs Mean±SD	201±52	209±45	193±56	220±46	193±52
Race, *n* (%)					
African-American	66 (61)	9 (56)	37 (63)	17 (71)	3 (33)
White	38 (35)	7 (44)	19 (32)	6 (25)	6 (67)
Others	4 (4)	0 (0)	3 (5)	1 (4)	0 (0)
Female, *n* (%)	61 (43.5)	10 (63)	36 (61)	10 (42)	5 (56)
CKD duration[a] months, median (range)	36 (1–216)	39 (8–216)	36 (1–180)	36 (2–156)	20 (3–85)
Nephrology care, months, median (range)	13 (0–81)	6 (1–71)	15 (0–74)	13 (1–81)	12 (2–45)
Number of CPE visits, mean±SD	2.0±1.3	1.8±1.1	2.1±1.4	2.0±1.1	1.6±0.8
Duration of CPE, month, mean±SD	6.4±5.1	5.6±5.5	7.3±5.5	4.4±3.8	8.1±5.6
Comorbidities, *n* (%)					
Diabetes	61 (56)	11 (61)	33 (56)	12 (57)	4 (40)
CHF	25 (23)	6 (33)	15 (25)	4 (19)	0 (0)
Insurance, *n* (%)					
Medicare	60 (56)	11 (69)	25 (43)	16 (67)	6 (67)
Medicaid	13 (12)	1 (6)	8 (14)	3 (12.5)	0 (0)
Uninsured	19 (17.5)	3 (19)	12 (21)	3 (12.5)	1 (11)
Commercial	20 (18.5)	1 (6)	13 (22)	2 (8)	2 (22)
MDRD eGFR (mL/min)	18.34±6.5	18.75±4.86	18.72±6.86	17.08±6.44	8.11±2.7
Stage of CKD[b]					
Stage 3b	4 (4)	0 (0)	2 (3)	0 (0)	2 (22)
Early stage 4	24 (22)	3 (19)	12 (20)	8 (33)	1 (11)
Late stage 4	40 (37)	9 (56)	23 (39)	6 (25)	2 (22)
Stage 5	40 (37)	4 (25)	22 (37)	10 (42)	4 (44)
Albumin (gm/dL)	3.31±0.53	3.24±0.35	3.31±0.62	3.38±0.40	3.26±0.61
>3	22 (21)	1 (8)	16 (36)	3 (21)	2 (40)
3–3.6	48 (46)	12 (92)	28 (64)	11 (79)	3 (60)

HHD = home hemodialyis; PD = peritoneal dialysis; IHD = in-center hemodialysis; SD = standard deviation; CKD = chronic kidney disease; CPE = comprehensive predialysis education; CHF = chronic heart failure; MDRD eGFR = Modification of Diet in Renal Disease estimated glomerular filtration rate.

Conversion factors for units: serum creatinine in mg/dL to µmol/L, ×88.4; urea nitrogen in mg/dL to mmol/L, ×0.357.

[a] Duration of CKD refers to the known diagnosis of CKD either in the clinical documents or available laboratory records.

[b] Stage 4 CKD was subdivided based on eGFR into early (23–29 mL/min) and late (16–22 mL/min)

IHD, while 8 remained undecided at their last CPE visit, and 1 underwent preemptive renal transplantation (Figure 1). Cochran's Q test shows that the rate of HoD varies significantly from visit 1 through visit 5 ($p < .0001$) (Figure 2). A quarter (25.3%) of those returning for follow-up CPE visits chose to change their modality preferences at least once. Six (33%) of those who originally chose HHD changed their preferences to PD (4) or IHD (2). Two of the 21 who chose IHD changed preferences to go for PD and HHD in 1 instance each, whereas 5 of the 59 (8.4%) patients who chose PD as initial modality later preferred either HHD (2) or IHD (3). Overall, 11 out of the 40 patients (27.5%) who initially chose HoD changed preferences, with nearly half of them converting to IHD. Of the 10 originally undecided patients, 6 continued to remain undecided until the last CPE visit, 1 patient each underwent PD, IHD, HHD, and preemptive transplantation. Multivariate analysis showed that the choice of RRT modality was unaffected by the patients' age, gender, race, availability and type of insurance, diabetes status, albumin, or the stage of renal disease with reference to MDRD eGFR ($p > 0.05$).

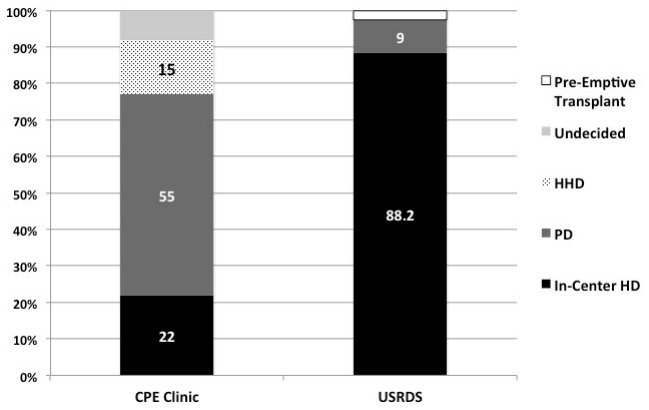

Figure 1 — The cumulative distribution (% of patients) of the final choice of RRT modality on the last CPE visit for each patient in comparison with the contemporary incident USRDS patient modality distribution. HHD = home HD; PD = peritoneal dialysis; HD = hemodialysis; RRT = renal replacement therapy; CPE = comprehensive predialysis education; USRDS = United States Renal Data System.

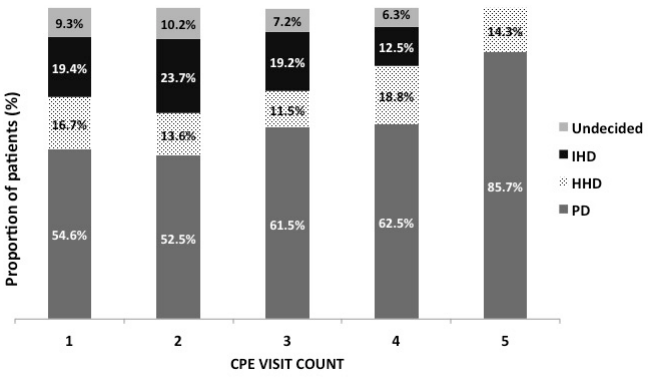

Figure 2 — The choice of RRT modality at the end of each subsequent CPE visit. Preemptive transplantation was performed in 1 patient and was excluded for this chart. An increasing choice for HoD was evident with each successive CPE visit. Fifty-nine patients attended 2 CPE visits, 26 attended 3, 16 attended 4, and 7 patients attended 5 CPE visits. CPE = comprehensive predialysis education; RRT = renal replacement therapy; HoD = home dialysis; IHD = in-center hemodialysis; HHD = home hemodialysis; PD = peritoneal dialysis.

Overall initiation of CPE resulted in growth of HoD census by 216% over the period of the first 22 months (Figure 3). The representative data for long-term (more than 5 years) HoD census at the same university practice is shown in Figure 3 with minimal undulation in the total numbers of patients on HoD, as well as their representation as a fraction of the prevalent ESRD population. We found that the initiation of the CPE program led to a progressive rise in HoD census beyond the first 4 months, with HoD representation rising to 38% of all ESRD patients in the unit by the end of 22 months. A significant joint point was identified at month 5, with a stagnant census for HoD prior to this point (slope β: -0.04 ± 0.32, $p = 0.89$), and significant increase in the slope for HoD census beyond this point (slope β: 0.85 ± 0.07, $p < .0001$).

DISCUSSION

Despite a national focus and mandates from the professional societies, improvements in HoD rates for the management of ESRD have been difficult to achieve in the US. Though multiple factors contribute to low HoD rates, predialysis patient education provided in a comprehensive manner (CPE) by itself has been shown to improve the choice of HoD across the world, especially from centers with well-established HoD programs, with patient preference ranging from 35 to 85% (11–14). However, establishing such programs requires a significant resource allocation and has a low rate of immediate returns, in terms of both financial reimbursements and medical outcome improvements. Due to these factors, based on the authors'

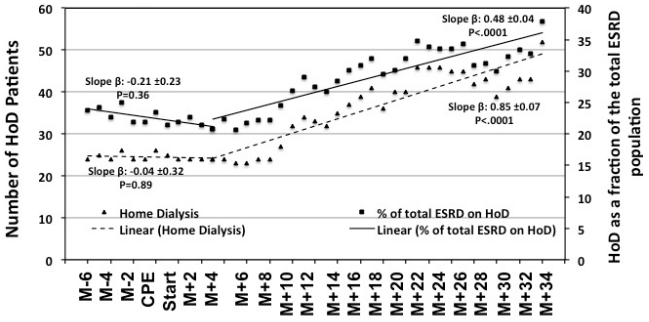

Figure 3 — The impact of initiation of CPE clinic on the census of HoD, and the fractional representation of HoD amongst all prevalent ESRD population within the dialysis unit. The figure shows representative, historical stagnant rates of HoD prior to and up to 6 months following initiation of CPE. The effects of CPE on the HoD census were evident after 6 months of the initiation of a dedicated clinic. The data show that HoD rates of 38% were feasible within 2 years of initiation of the clinic. CPE start: month when CPE clinic was initiated. M±n indicates the month before or after the CPE initiation. HoD = home dialysis; CPE = comprehensive predialysis education; ESRD = end-stage renal disease.

knowledge and given the paucity of published literature from the US, it appears that few institutes within the US offer a 'comprehensive' predialysis education (CPE) to their unselected advanced CKD cohort (15,17).

Our report shows the early impacts of a new CPE program at a university center that had small HoD program to begin with. We find that providing a comprehensive education improves the choice of HoD as well as increases the rates of HoD utilization in an individual practice. We find that 7 out of 10 patients undergoing the CPE choose HoD, with a ratio of PD to HHD being ~3.7:1. These rates are similar to those published from the well-established HoD units providing CPE, predominantly from outside the US. Goovaerts *et al.* from Europe have shown that 'comprehensive education' (i.e. a general education session followed by a one-on-one session with educator) has similar impact on choice of HoD. Thirty-nine percent of their CPE population chose HoD, and 55% chose some form of self-care therapies (including in-center self-care HD) (11). Some investigators have even been able to show similar outcomes even with just a group education session. Mann *et al.* in Canada conducted a randomized study where patients were evaluated for their choices after passive vs active education methods. They found that nearly half of the patients choose self-care RRT with just passive printed education material. The choice of self-care RRT further rose to about 85% after a full education session was provided. Velasco *et al.* examined the outcomes of a system-wide structured education process on uptake of RRT modalities. In this large Spanish cohort where the choice of RRT were between IHD or PD, investigators found that 88.4% of all individuals when educated chose to go on RRT, of which more than half (45%) preferred PD (14). Compared to these, in the only available institutional report of modern times from the US, Liebman *et al.* reported the choice of PD in 48% of those receiving the CPE. However, the patient selection in this cohort was not well defined since the decision for referral for CPE was left to the individual treating physicians resulting in a possible selection bias (18). The investigators also reported that a significant proportion of those choosing HoD ended up on IHD when they reached ESRD and did not report the impact of such measures on the growth of their likely well-established HoD program with reference to launching of the CPE program. In contrast, our results show the impact of a universal CPE on an unselected and prevalent CKD population leading to high rates of HoD choice.

Further, to our knowledge, this is the first report from the US that highlights the outcomes of a CPE program in the initial periods immediately after its establishment, and examines its impact on the actual census of the HoD program within an institute. In this regard, our findings are unique as we show the progressive representation of HoD as a fraction of the prevalent ESRD population within an individual university practice. We show that after a latency, likely due to a natural progression period for newly educated subjects to require the initiation of RRT, CPE led to a progressive rise in our HoD census by 216%, with near doubling of the HoD as a fraction of ESRD care at 38% of prevalent patients within 22 months of initiation. Lacson *et al.* examined the efficacy of a system-wide quality initiative education program provided by one of the large dialysis organizations (LDO), found that the protocol-based education increased the rates of HoD amongst incident ESRD patients (24.5%). However, a much larger non-educated control cohort within the study had very low rates of HoD (3.7%), leading to overall rates of HoD in their population (7%) similar to the national prevalent HoD rates in the United States Renal Data System (USRDS), raising concerns regarding the selection bias and the true efficacy of such system-wide measures (19).

An additional important observation of our study is the insight into the decision-making process for US CKD patients. Based on the authors' awareness as well as the paucity of the available published literature from the US, it appears that a limited number of nephrology programs, outside the LDOs, provide dedicated CPE services to their advanced CKD patients and lack of resources is a major obstacle. The CMS does currently allow for a limited or a 'token' reimbursement for up to 6 sessions of CKD education. However, an evidence-based evaluation of this education strategy has not been conducted thus far. Our study highlights a few concerns with this strategy. First, provision of a comprehensive education session requires significant time and resources. Individual CPE sessions last more than 2 hours in almost all subjects, and close to 3 – 4 hours in a few patients. Such care requires significant resource allocation, and is highly sub-optimally covered by CMS-proposed compensations for individual visits. Second, we found that a large majority of patients (74%) are referred late in the course of CKD, and even for those who are referred, nearly half prefer to come for a single education session. Thus, availing the benefits of 6 educational sessions is impractical for these patients. Finally, even amongst the half (54.6%) of patients that returned for subsequent sessions, we found that only about a quarter changed their RRT modality choice over the subsequent CPE visits, and nearly all but 1 patient had reached the final modality choice by the third CPE visit. We believe that alternate education strategies with higher reimbursement for individual visits, and its impact on improving the provider uptake in establishing CPE programs needs further studies.

Finally, our data show that HoD is not a choice made only by those at the top of the socio-economic privilege. Unlike in the previously published data, we found that age, race, gender, diabetic status, serum albumin or level of renal dysfunction did not have a large impact on eventual choice of HoD. Though retrospective and thus only suggestive, this raises the possibility that the underutilization of HoD may be correctable by dedicated patient education programs.

Overall, together with other reports, our data provide an important reference point to the prevalent patient choice patterns with respect to RRT modalities. Though the physician surveys have suggested a target of 30 – 35% for HoD, ours as well as other available data clearly show the choice of HoD in more than 50% of those receiving CKD education. In addition, our report further shows that such rates can be achieved: 1) both by centers with well-established CPE and HoD programs, as

well as a newly launched program, and 2) across the whole socio-economic spectrum of patients. Together, these data may provide a rationale to reevaluate targets for HoD utilization as a measure for predialysis care within a healthcare infrastructure.

There are few limitations to the findings of our study. We are unable to comment on the true 'choice' to 'accrual' for a modality since the data for true accrual are unavailable for all patients due to loss of follow-up resulting from geographical limitations of a rural university center. However, the significant growth change in our own HoD census indirectly confirms a high congruence between choice and accrual. Our data also do not provide an estimate of cost effectiveness for a CPE program. A true education-based CPE program was found to be cost-effective in the Taiwanese healthcare system when all costs for inpatient and outpatient services were considered (20). Similar opinions have been voiced in other healthcare systems as well (15). Such ascertainments for a US-based system need to be examined in a more targeted financial analysis.

To summarize, we show that CPE increases the choice of HoD in US CKD patients. This is in line with the stated objectives of the payers, providers, and patients. We further show that the targets for HoD are currently underestimated by providers, and the true patient choice for HoD in the presence of an adequate CPE far exceeds the currently targeted goals. Thus, in the absence of a universal 'PD/HoD first approach' that has been ethically considered undesirable by some, a widespread provision of CPE may allow for better rates of HoD. The social and financial implications of such programs, as well as alternates in the care and payment models, need further dedicated prospective studies.

DISCLOSURES

The authors have no financial conflicts of interest to declare.

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