Recruitment and Training for Home Hemodialysis: Experience and Lessons from the Nocturnal Dialysis Trial

Mary Pipkin,*† Paul W. Eggers,‡ Brett Larive,§ Michael V. Rocco,∥ John B. Stokes,¶ Rita S. Suri,** and Robert S. Lockridge, Jr.*† for the Frequent Hemodialysis Network Trial Group

*University of Virginia Nephrology Clinical Research Center, Charlottesville, Virginia; †Division of Nephrology, University of Virginia, Charlottesville, Virginia and Lynchburg Nephrology Physicians, Lynchburg, Virginia; ‡National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, Maryland; §Department of Quantitative Health Sciences, Cleveland Clinic Foundation, Cleveland, Ohio; ∥Wake Forest University School of Medicine, Winston-Salem, North Carolina; ¶Department of Internal Medicine, University of Iowa, and VA Medical Center, Iowa City, Iowa; and **University of Western Ontario, London, Ontario, Canada

Background and objectives: We assessed perceived barriers and incentives to home hemodialysis and evaluated potential correlates with the duration of home hemodialysis training.

Design, settings, participants, & measurements: Surveys were sent to the principal investigator and study coordinator for each clinical center in the Frequent Hemodialysis Network Nocturnal Trial. Baseline data were obtained on medical comorbidities, cognitive and physical functioning, sessions required for home hemodialysis training, and costs of home renovations.

Results: The most commonly perceived barriers included lack of patient motivation, unwillingness to change from in-center modality, and fear of self-cannulation. The most common incentives were greater scheduling flexibility and reduced travel time. The median costs for home renovations varied between $1191 and $4018. The mean number of home hemodialysis training sessions was 27.7 ± 10.4 (11–59 days). Average training time was less for patients with experience in either self-care or both self-care and cannulation. The number of training sessions was unrelated to the score on the Modified Mini Mental Status or Trailmaking B tests or patient’s education level. Training time also did not correlate with the SF-36 Physical Function subscale but did with the modified Charlson comorbidity score and older patient age.

Conclusions: Lack of patient or family motivation and fear of the dialysis process are surmountable barriers for accepting home hemodialysis as a modality for renal replacement therapy. Formal education and scores on cognitive function tests are not predictors of training time.


In the United States in 2009, only 0.8% of people on chronic dialysis were performing home hemodialysis (1), whereas in Canada, the percentage was 2.8% (2). In New Zealand, 25% of dialysis patients perform home hemodialysis (3).

The low utilization rate of this modality in North America is somewhat surprising because there is evidence that home hemodialysis is associated with better outcomes than center dialysis. Woods et al. (4) found that patients who perform hemodialysis at home have lower adjusted mortality rates than patients dialyzing in center. More recent studies have addressed outcomes for patients undergoing nocturnal dialysis, performed five to six nights each week for 6 to 8 hours. Culleton et al. (5) showed improved BP control, reduction of anti-hypertensive medications and regression of left ventricular mass after only 6 months in patients randomized to nocturnal hemodialysis. A recent retrospective analysis found that patients undergoing nocturnal hemodialysis have a survival rate similar to that of patients receiving deceased donor kidney transplant (6).

To further study the feasibility and outcomes of performing overnight home versus thrice-weekly conventional hemodialysis, the National Institutes of Health (NIH, NIDDK) and the Centers for Medicare and Medicaid (CMS) sponsored the Nocturnal Trial component of the Frequent Hemodialysis Network (FHN) Study, thus far the largest multi-center, randomized study on intensive home hemodialysis. The recruitment component of the trial provides a unique opportunity to identify factors that may influence patient participation in home hemodialysis and permits an analysis of factors associated with home hemodialysis training.

Materials and Methods

The FHN Nocturnal Trial was conducted in eight clinical centers in the United States and Canada that had established infrastructures for
training and monitoring home hemodialysis patients. Patients were randomized either to conventional hemodialysis three times per week or nocturnal home hemodialysis six nights per week for 6 to 8 hours. The detailed original protocol for the trial has been previously published (7). Patients randomized into the trial were followed for 14 months. The primary outcomes of the study were left ventricular mass as measured by cardiac MRI and the RAND SF-36 Physical Health Composite. The study was conducted in accordance with the Declaration of Helsinki, and informed consent was given by each patient.

The original recruitment goal for the study was 250 patients but, because of limited recruiting success, the goal was ultimately reduced to 90 patients in December 2008. Of the 118 patients enrolled in the Nocturnal Trial, 87 were randomized: 42 to the conventional arm and 45 to the nocturnal arm. Thirty-one patients dropped out during the baseline recruitment phase (Figure 1). Randomization ended in May 2009, and the follow-up intervention will be complete in May 2010.

Comparison to General ESRD Population

We compared patient demographic and comorbid information collected in the Nocturnal Trial with comparable information from the general ESRD population obtained from the U.S. Renal Data System (USRDS) and the Canadian Organ Replacement Registry (CORR). Characteristics of U.S. dialysis patients not participating in the FHN were derived from the USRDS using standard analysis files (SAFs). Prevalent dialysis patients were defined as of December 31, 2006. Estimates of educational status and functional status of the dialysis population were taken from the Comprehensive Dialysis Study (CDS) conducted by USRDS investigators. The CDS is a sample of 1646 incident dialysis patients from 2005 through 2007 (8).

Assessment of Medical Comorbidities and Mental and Physical Functioning

The modified Charlson comorbidity index combines information from 14 medical conditions designed to predict 1-year mortality among patients with ESRD (9). The Modified Mini-Mental State Exam (3MS) tests global cognitive function including orientation, attention, calculation, language, and short-term memory. Scores range from 0 to 100, with lower scores indicating poorer cognitive function (10). The Trail Making B test is a timed test of executive function, a cognitive domain not assessed with the 3MS. Patients attempt to connect a series of consecutive cues. A patient who was unable to complete the task within 5 minutes was assigned a score of 300s. Higher scores indicate poorer executive function (11). Self-reported physical functioning was assessed using the SF-36 PF subscale. The PF subscale is a self-report of functional status that has been well validated, has good psychometric properties that are subscale specific, and is sensitive to change (12). The scale was scored on a range of 0 to 100 using the RAND scoring method, with higher scores indicating better functional status.

Survey

Questionnaires were sent to the principal investigators and study coordinators at each of the eight participating centers. The questionnaire consisted of 94 questions (Supplemental Appendix). Questions were generally directed toward home hemodialysis, but some specifically targeted nocturnal hemodialysis. Most questions inquired about perceived barriers to home hemodialysis, whereas others explored possible incentives. All questions were scaled (1 = never a barrier, 2 = uncommon barrier, 3 = relatively common barrier, 4 = very common barrier, and 5 = extremely common barrier). Percentages were determined as a fraction of the total responses (six from principal investigators and six from study coordinators) and classified into three groups: (1) factors that were perceived by at least 67% of the respondents as common, (2) factors considered by 33 to 66% of respondents as common, and (3) factors considered by more than 66% of respondents as uncommon. Questions not answered by the survey recipients were coded as no response. For all tabulations, the denominator was 12. Grading of perceived incentives used a similar strategy.

Costs

Home modification costs were collected for categories of (1) water purification systems, (2) electrical and telephone modifications, and (3) plumbing and structural modifications. Because some contractors failed to provide itemized expenses we report only aggregate costs. No patient assumed the cost of renovations, because expenses not born by the dialysis provider were provided by study funds.

Training

All participants trained with the Fresenius 2008 H or K machine. Training time was defined as the total number of dialysis treatments undertaken for instructional purposes, regardless of randomized modality or prior experience. All patients were initially trained in performing at-home hemodialysis; patients randomized to the nocturnal treatment arm received additional training. We were unable to quantify the precise number of sessions specifically devoted to nocturnal dialysis training because of its gradual and integrated nature. One center offered additional instruction in technical issues on nondialysis days. These sessions reflect the heterogeneity of training approaches and were included in the center’s training time totals.

Statistical Analyses

Baseline characteristics were expressed as means ± SD, medians and interquartile ranges, or frequencies (%) as appropriate. Differences in training time among categorical factors were tested using ANOVA when at least 10 observations existed for each category; otherwise, exact Kruskal-Wallis tests were used. Two-group comparisons were made using \( \chi^2 \), \( t \), and exact Wilcoxon signed rank tests as appropriate. Rate differences between two groups within ordered groups with low numbers were tested using an exact Joncheere-Terpsta test. Associations between continuous factors and training time were determined using linear regression. Statistical significance was defined as \( P < 0.05 \) (two sided). All analyses were conducted using SAS v9.1 (SAS Institute, Cary, NC). Exact tests were performed with StatXact v7 (Cytel Statistical Software, Cambridge, MA).

Results

The original protocol (7) was modified in September 2007 to allow the control arm to perform thrice weekly hemodialysis at
home rather than in center. This change reflected our perception that patients interested in nocturnal hemodialysis would more willingly accept being randomized to conventional home hemodialysis therapy. Of the 87 patients randomized, 15 were under the original protocol and 72 were under the revised protocol. Figure 1 shows the reasons for the 31 patients dropping out of baseline. Characteristics of the Nocturnal Trial cohort are described in Table 1.

Survey on Barriers and Incentives to Home Hemodialysis

The most commonly perceived barriers to home hemodialysis (Table 2) included lack of patient motivation and unwillingness to change their present (in center) arrangements. Lack of family support was a commonly perceived barrier; it was also the most common reason enrolled patients reported for dropping out of baseline (Figure 1). The other major barriers related to patient fears of the procedure and a high level of comorbid disease. Less common barriers were age >70 years, inadequate dwelling or water supply, cost of water and electricity, and costs of transportation for training (Table 2).

Four potential barriers were identified as being relatively uncommon: cost of home renovations, monthly transportation costs, age 60 to 69 years, and child care issues. The costs of home renovations were an uncommon barrier, probably because these costs were subsidized by outside sources. The perceived age at which doing home hemodialysis was considered a significant barrier was ~70 years or older.

The perceived incentives for home dialysis (Table 3) included greater scheduling flexibility and reduced travel time. Potential liberalization of dietary constraints was a commonly perceived incentive, but only as applied to nocturnal dialysis patients. Dissatisfaction with current therapy and desire for improved well being were frequently cited as general incentives for doing home therapy.

Costs of Home Renovation

Of the 87 patients randomized, 83 required home renovations, and a cost report was obtained for 75 of these patients (Table 4). Range of costs varied two- to threefold within a single center. The range of median costs between centers was even larger; Lynchburg’s median cost was $1191, whereas Western Ontario’s was $4018. We failed to identify any systematic reasons for the nearly fourfold difference in costs.

Relationship of Randomized Treatment Groups to Training Time

Eight of the 87 randomized patients were excluded from the training time analyses because they either had received home dialysis training before the trial (n = 4) or they were randomized to the in-center arm initially and chose to remain with that modality (n = 4). The training time required for conventional versus nocturnal was not different (P = 0.59). The mean number of training sessions was 27.7 ± 10.4, with a range of 11 to 59

Table 1. Demographics, comorbidities, and education comparisons between randomized FHN nocturnal trial patients and U.S. and Canadian HD patients

<table>
<thead>
<tr>
<th></th>
<th>U.S. HD Patients (USRDSa)</th>
<th>Canadian HD Patients (CORR)</th>
<th>FHN Nocturnal Trial: Randomized Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All (n = 328,041a)</td>
<td>In Nocturnal Trial Units (n = 1533)</td>
<td>All (n = 20,428)</td>
</tr>
<tr>
<td>Male</td>
<td>53%</td>
<td>55%</td>
<td>58%</td>
</tr>
<tr>
<td>Age (years)</td>
<td>61.3 ± 15.0</td>
<td>60.5 ± 15.7</td>
<td>63.7 ± 15.5</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>38%</td>
<td>42%</td>
<td>4%</td>
</tr>
<tr>
<td>Caucasian</td>
<td>55%</td>
<td>55%</td>
<td>69%</td>
</tr>
<tr>
<td>Diabetic</td>
<td>44%</td>
<td>43%</td>
<td>40%</td>
</tr>
<tr>
<td>ESRDS vintage (years)</td>
<td>2.5 (1.0 to 4.9)</td>
<td>2.4 (1.0 to 5.1)</td>
<td>2.7 (1.1 to 5.4)</td>
</tr>
<tr>
<td>Educationa</td>
<td>&lt;High school</td>
<td>20%</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>High school</td>
<td>30%</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>&gt;High school</td>
<td>39%</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
<td>12%</td>
<td>NA</td>
</tr>
</tbody>
</table>

Persons were defined as alive and on in-center hemodialysis as of December 31, 2007. ESRD vintage was computed as the time from the start of first dialysis until December 31, 2007. Age was also computed as of that date. Diabetes was defined as the cause of ESRD from the CMS form 2728.

USRDS, U.S. Renal Data System data, from Standard Analysis Files; CORR, Canadian Organ Replacement Registry (sample included prevalent dialysis patients during 2006); FHN, Frequent Hemodialysis Network Study; NA, data not available.

aEducation data based on the Comprehensive Dialysis Study, a sample of 1646 U.S. incident dialysis patients during 2005 to 2007. Values reported as described in the Methods section.
Table 2. Perceived common barriers to patients electing to choose home hemodialysis

| By greater than 66% of respondents (in descending order of importance) | Lack of motivation | Patients too comfortable in-center | Fear of self-cannulation | Fear of needles falling out/catheter disconnecting (NHD) | Fear of inability to sleep on machine (NHD) | High level of comorbid disease | Fear of family/partner support | Fear of machine | Fear of inability to learn procedures | By greater than 33 to 66% of respondents (in descending order of importance) | Age 70 to 79 years | Training too long and intense | Burden of dialysis/burn-out-patient/ partner (NHD) | Inadequate dwelling | Fear of intradialytic hypotension/hurting self | Increased water and electricity bills | Fear of needles falling out or catheter disconnecting (CHD) | Low literacy | Fear of not being monitored by professionals | Transportation costs for training | Inadequate water supply |
| NHD, specific to nocturnal hemodialysis; CHD, specific to conventional home hemodialysis. |

Table 3. Perceived common incentives by >66% of responders (in descending order of importance)

<table>
<thead>
<tr>
<th>Flexible scheduling</th>
<th>Flexible prescription</th>
<th>Less travel to dialysis units</th>
<th>More liberal diet (NHD)</th>
<th>Partner encouragement</th>
<th>Influence of other home dialysis patients</th>
<th>More privacy</th>
<th>Putative improvement in well being</th>
<th>Dissatisfied with current therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHD, specific to nocturnal hemodialysis.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

days. This lack of a difference could relate to the wide variability of training times needed for individual patients.

Relationship of Access Type and Prior Training to Training Time

We hypothesized that patients who had a catheter, had experience in self-care centers, or practiced self-cannulation would require less training time than those without such experience. Figure 2A shows the average training time for patients using a catheter was marginally less than patients using an AV fistula. Figure 2B shows that patients who had experience in self-care required less training than patients with no prior experience. Those who had experience in both self-care and self-cannulation required fewer training sessions than those with no prior experience or experience in self-cannulation only \((P = 0.017 \text{ and } 0.058, \text{ respectively})\).

Relationship of Tests of Cognition and Education on Training Time

Many care providers might assume that patients who score well on tests of cognitive function or who have more education would be able to complete home hemodialysis training more quickly than patients with lower cognitive performance or less education. Figure 2C shows that scores on the Modified Mini Mental Status test did not correlate with the number of sessions needed to complete home training. Performance on the Trail-making B test also did not correlate with training time (data not shown, \(P = 0.51\)). The majority of patients randomized to this trial had education beyond high school (Table 1). However, there was no difference in the number of training sessions for those who did not have education beyond high school compared with those who did \((P = 0.72)\). These data show that using tests of cognitive function or educational level are not likely to provide robust predictions on how long patients will take to complete training in home hemodialysis.

Relationship of Physical Function, Comorbidity, and Age with Training Time

There was no association between the score on the SF-36 Physical Function subscale and training time (data not shown, \(P = 0.27\)). However, the modified Charlson comorbidity score did correlate directly with the number of sessions needed to complete the training \((P = 0.005)\). In addition, age was positively associated with training time (Figure 2D). Using linear regression, it seemed that, on average, three additional training sessions were required for each decade increase in age. Inspection of the individual data, however, suggests that this relationship may not be linear. In addition, there was a wide range of training time required for people older than 60 years.

Discussion

These results report a systematic evaluation of our efforts to recruit patients into a randomized trial of nocturnal dialysis. We conducted a two-stage recruiting strategy: recruit patients to home hemodialysis and then recruit them to the randomized trial. The barriers and incentives to home hemodialysis that we identified are similar to those reported by others (13). It is important to note that these results represent the perceptions of recruiters to the study and not a direct survey of patients. The study coordinators did keep records on the reasons for patient refusal, but the responses were not collected in a sufficiently systematic format to allow direct analysis. Thus, we assessed patients’ perceived barriers and incentives using a questionnaire (Supplemental Appendix) designed to capture aggregate impressions of the recruiters. Because the respondents were experienced and specially trained in recruiting patients to
home dialysis, they can not be considered “typical.” Neverthe-
less, we believe the design of the study and this analysis rep-
resents a reliable assessment of common barriers to patients
entering either nocturnal or conventional home hemodialysis.

Commonly reported barriers include patients becoming too
comfortable in center, lack of confidence in their ability to
conduct home hemodialysis, and fear of self-cannulation. Sev-
eral authors have noted that such barriers can be overcome
with more thorough education and preparation as patients
approach the need for dialysis (14–18). Others have focused on
the substantial technical barriers to learning home hemodialy-
sis, a situation that might also be alleviated through augmented
education (19,20). Interestingly, we did not find that entering
into a randomized trial was perceived as a major barrier to
recruitment.

### Types of Barriers to Doing Home Hemodialysis

We divided the barriers into two major categories: situational
and psychologic. Situational barriers include inadequate hous-
ing or water or inadequate family support. Such barriers can be
difficult or impossible to overcome, essentially prohibiting pa-
tients from doing home hemodialysis, even if they have the

### Table 4. Costs of home renovation by center

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Minimum</th>
<th>25th percentile</th>
<th>Median</th>
<th>75th percentile</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>75</td>
<td>575</td>
<td>1099</td>
<td>1329</td>
<td>1900</td>
<td>4603</td>
</tr>
<tr>
<td>Lynchburg Nephrology</td>
<td>33</td>
<td>575</td>
<td>975</td>
<td>1150</td>
<td>1300</td>
<td>1575</td>
</tr>
<tr>
<td>University of Iowa</td>
<td>8</td>
<td>850</td>
<td>1213</td>
<td>1868</td>
<td>3116</td>
<td>3640</td>
</tr>
<tr>
<td>Wake Forest University</td>
<td>6</td>
<td>600</td>
<td>750</td>
<td>998</td>
<td>1300</td>
<td>1448</td>
</tr>
<tr>
<td>University of Toronto</td>
<td>10</td>
<td>919</td>
<td>1337</td>
<td>1470</td>
<td>1588</td>
<td>1618</td>
</tr>
<tr>
<td>University of Western Ontario</td>
<td>11</td>
<td>1376</td>
<td>3373</td>
<td>4018</td>
<td>4201</td>
<td>4603</td>
</tr>
<tr>
<td>Humber River (Toronto)</td>
<td>7</td>
<td>1341</td>
<td>1890</td>
<td>2000</td>
<td>2098</td>
<td>2369</td>
</tr>
</tbody>
</table>

Costs reported in native U.S. and Canadian currencies because differences during this time were <10%. Data unavailable from 12 randomized patients.
desire. Psychologic barriers, on the other hand, can in many instances be overcome by focused strategies. These psychologic barriers fall into two general categories: (1) lack of patient/family motivation and (2) fear of the dialysis process. Of these, lack of motivation constituted the most uniformly perceived barrier to attempting home hemodialysis. Study recruiters came to appreciate that patients who had settled into their dialysis routine were much less willing to train in home hemodialysis than those who were relatively new to the process. Thus, although it is certainly possible to recruit prevalent patients, focusing on patients of shorter vintage produced a higher yield (Table 1).

A second set of psychologic barriers falls into the category of “fears.” Table 2 lists eight specific fears perceived as relatively common by most recruiters. In general, such fears are not supported by the available data; certainly, the safety and competency fears are generally not supported (21). Addressing these fears early in the process of evaluating and treating CKD might be one strategy to reduce their influence on the patient’s decision.

We highlight a strategy to overcome one fear—self-cannulation—that is a significant barrier for some patients. At some centers, patients learn self-cannulation in-center under the supervision of a trained nurse or technician. Mastering this skill often empowers patients with a sense of control over their health care and gives them the confidence. The buttonhole technique, in which the same access site is cannulated with duller needles, could further encourage self-care as a segue into home hemodialysis. There are other strategies to address fears such as concern of needles falling out or the catheter disconnecting (21).

Role of Cognition, Educational Status, Comorbidities, and Age on Training Time

In contrast to some commonly held preconceptions, we found that performance on neither two tests of cognitive function nor educational achievement correlated with training time. Thus, these measures have little value in predicting how long it will take individuals to learn the hemodialysis procedure. We also note that failure to learn the procedure was never identified as a reason for dropping out of baseline (Figure 1). We interpret these data to indicate that cognitive impairments that would preclude learning home dialysis are probably easily identified by routine assessment and require no sophisticated testing.

In contrast to cognition and education, comorbidities did associate with training time. Although the patients’ perceived physical function did not correlate with training time, the Charlson comorbidity score did. We do not have enough patient numbers to adequately assess the major comorbidities that contribute to this association, but it is no surprise that sicker patients might take longer to learn home hemodialysis.

Our data show that older patients, in general, require more training to learn home hemodialysis, but there is great variability in patients older than 60 years (Figure 2D). The factor of age also seems to influence the perception of study recruiters on the likelihood of their willingness to consider home hemodialysis (Table 2). Motivation, comorbidities, perceived physical and mental capacity, and the extra physical effort needed to conduct home dialysis may all play varying roles in an older individual’s decision and capacity to undertake this modality.

This study, despite having only moderate statistical power to detect differences, has identified factors that contribute to patients’ willingness to consider home hemodialysis and their ability to learn the procedure quickly. These factors, particularly the modifiable ones, may become important in developing more effective methods for treating patients with ESRD. Effecting a major change in therapy—from primarily a center based to a home-based service—will require rethinking the way we offer the options for patients with ESRD. Proactively addressing tractable psychologic barriers may pay substantial dividends for some patients. In addition, developing strategies to reduce the psychologic and physical barriers to learning home dialysis might enhance health providers’ ability to provide more effective therapies for ESRD.

Acknowledgments

We thank Susan Sherer for assistance with the data analysis. Funding for this study was received from the National Institutes of Health (NIH; Grants DK66597 and DK066480), Centers for Medicare and Medicaid Services, Fresenius Medical Care, the Renal Research Institute, Satellite Health Care, NKF of Iowa, and a grant from the NIH Foundation.

Disclosures

None.

References

8. Kutner NG, Johansen KL, Kaysen GA, Pederson S, Chen