

# Home Hemodialysis Patients Using 2008K@home™ Achieve Greater Standardized Kt/V With Fewer Weekly Treatments Compared to Patients Using NxStage® System One™

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#### Introduction

- The prevalence of home hemodialysis (HHD) in the United States has grown over the last decade. The United States Renal Data System (USRDS) Annual Data Report for 2012 reports that HHD patients comprised 1.3% of the prevalent dialysis patient population in 2010, compared to 0.6% in 2001.<sup>1</sup>
- HHD regimen options include conventional (≤3 times per week) schedules, daily dialysis, and nocturnal dialysis. Such flexibility may offer a better fit with the lifestyle and employment needs of patients compared to in-center hemodialysis (ICHD).
- Studies in matched cohorts have demonstrated reduced mortality rates and longer survival in HHD patients.<sup>2–4</sup> In addition, short daily dialysis at home has been associated with improved quality of life compared to conventional ICHD.<sup>5–7</sup>

### Objective

This retrospective, comparative effectiveness study of HHD patients within a large dialysis organization compares outcomes for patients using the NxStage<sup>®</sup> System One<sup>™</sup> and Fresenius 2008K@home<sup>™</sup> systems.

#### Methods

- Patients included in the analysis were ≥ 18 years of age and received HHD for at least 30 days between January 1, 2009 and June 30, 2010. Patients were included from the first full month in which they received HHD that fell within the study time frame. Patients were followed-up for 12 months.
- Patients were classified into intent-to-treat (ITT) assignment based on the ordered dialyzer/filter type\* in the first month of the study. 2008K@home patients were then matched to NxStage System One patients on a 1:1 ratio via a propensity score matching process (N = 127 for each group).
- After propensity score matching, 2008K@home patients were stratified on observed number of treatments/week into those dialyzing ≤ 3x/week (N = 46) and those dialyzing > 3x/week (N = 81), based on treatment frequency in the first 60 days of the study. Expected treatment frequency for all System One patients was ≥ 5/week.<sup>8</sup> The observed number of treatments/week and mean time per treatment over the entire study were calculated for each group from the recorded number of treatments/month and number of minutes/month on dialysis.
- Standardized Kt/V (stdKt/V) was calculated from equilibrated urea Kt/V (eKt/V) and mean time per treatment, as described by Leypoldt et al.9
- Data were analyzed using generalized linear mixed models (GLMM). Mean estimates
  for dialysis treatment and laboratory measures were obtained for each group in each
  month of the study. Mean estimates for the entire follow-up period are presented for
  each group. Disposition of patients at the conclusion of the study and hospitalizations
  over the follow-up period were also assessed.

\*A prescribed dialyzer of NxStage indicated a NxStage machine. Any dialyzer other than NxStage was taken as an indicator of a 2008K@Home machine. However, some NxStage machines have been fitted with an adapter that allows the use of non-NxStage dialyzers. These patients would be mis-classified. It is unknown if, and at what frequency, this may have happened in the present analysis.

#### Results

- System One patients received less than the expected ≥5 treatments per week, **Table 1**.
- StdKt/V was greater for 2008K@home patients, compared to System One patients (p < 0.0001). In addition a greater percentage of patients in the 2008K@home groups achieved stdKt/V > 2.0 than in the System One treatment group (p < 0.001), **Table 1.**
- 2008K@home ≤3x/week patients were more likely to remain on HHD after 1 year than patients in other treatment groups (p < 0.0001). No significant differences in reasons for censoring were detected,</li>
   Table 2.

Table 1: Dialysis Treatment Measures

	2008K@home ≤3x/week	2008K@home >3x/week	System One	P-value
	Mean (SEM) (N = 46)	Mean (SEM) (N = 81)	Mean (SEM) (N = 127)	(Omnibus)
Expected no. of treatments per week	≤3	> 3	≥5	
Observed no. of treatments per week	2.8 (0.1)	4.1 (0.1)	4.4 (0.1)	< 0.001
Time per treatment (hrs)	4.16 (0.15)	3.62 (0.11)	2.82 (0.09)	< 0.001
Total treatment time per week (hrs) <sup>a</sup>	10.91 (0.67)	14.39 (0.53)	12.12 (0.42)	< 0.001
URR (mg/dL) <sup>a,b</sup>	71.5 (1.5)	55.8 (1.1)	41.9 (0.9)	< 0.001
StdKt/V <sup>a,b</sup>	2.03 (0.08)	2.50 (0.06)	1.81 (0.05)	< 0.001
Adequacy (% of patients with stdKt/V > 2.0) <sup>a</sup>	56.0 (6.2)	79.9 (4.9)	44.7 (3.9)	< 0.001

Abbreviations: hrs, hours; SEM, standard error of mean; URR, urea reduction ratio.

aData for months 9–12 only; bUUR is a per-treatment parameter; stdKt/V reflects accurately the total treatment per week with each machine/device.

Table 3: Hospitalizations

	2008K@home ≤3x/week Mean (SEM) (N = 46)	2008K@home >3x/week Mean (SEM) (N = 81)	System One  Mean (SEM) (N = 127)	P-value (Omnibus)
Hospitalization events	1.50 (0.26)	0.96 (0.20)	1.41 (0.16)	0.14
Days in hospital	11.10 (2.39)	6.93 (1.80)	10.10 (1.44)	0.27

Abbreviations: SEM, standard error of mean.

- No statistically significant differences between groups in number of hospitalizations or days spent in hospital were detected, Table 3.
- 2008K@home ≤3x/week patients had significantly lower serum albumin levels than those in other groups (3.81 g/dL versus 4.09 g/dL and 4.06 g/dL for 2008K@home > 3x/week and System One patients, respectively; p = 0.014). No significant differences between groups in hemoglobin, serum calcium, serum phosphorus, parathyroid hormone, or normalized protein catabolic rate were observed, Table 4.

Table 2: Final Disposition of Patients After 1 Year

	2008K@home ≤3x/week	2008K@home >3x/week	System One	P-value
	N (%)	N (%)	N (%)	(Omnibus)
Same home modality	33 (71.74)	38 (46.91)	76 (59.84)	
Opposite HHD machine	1 (2.17)	13 (16.05)	2 (1.57)	< 0.001
ICHD	3 (6.52)	12 (13.81)	22 (17.33)	
Censored	9 (19.57)	18 (22.22)	27 (21.26)	
Transplant	1 (11.11)	8 (44.44)	12 (44.44)	
Died	7 (77.78)	7 (38.89)	8 (29.63)	0.140
Other reason	1 (11.11)	3 (16.67)	7 (25.93)	
Overall drop-out rate	5 (10.9)	28 (34.6)	31 (22.4)	0.012

Abbreviations: HHD, home hemodialysis; ICHD, in-center hemodialysis.

<sup>a</sup>No information on patients switching from 2008K@home ≤3x/week to >3x/week was available. <sup>b</sup>Drop-out rate is sum of "Opposite HHD machine," "ICHD," and "Censored—Other reason."

Table 4: Laboratory Measures

	2008K@home ≤3x/week	2008K@home >3x/week	System One	P-value
	Mean (SEM) (N = 46)	Mean (SEM) (N = 81)	Mean (SEM) (N = 127)	(Omnibus)
Serum albumin (g/dL)	3.91 (0.05)	4.09 (0.04)	4.06 (0.03)	0.014
Serum calcium (mg/dL)	9.1 (0.08)	9.1 (0.06)	9.0 (0.05)	0.177
Serum phosphorus				
(mg/dL)	5.0 (0.13)	5.4 (0.10)	5.3 (0.08)	0.064
Normalized protein				
catabolic rate (g/kg/day)	0.96 (0.05)	1.02 (0.04)	1.10 (0.04)	0.071
Parathyroid hormone				
(pg/mL) <sup>a</sup>	287.1	270.2	315.1	0.376
Hemoglobin (g/dL)	11.4 (0.16)	11.6 (0.12)	11.4 (0.10)	0.398

Abbreviations: PTH, parathyroid hormone; SEM, standard error of mean.

<sup>a</sup>PTH was log transformed. Means are presented from back-transformed data therefore SEM not available.

## Summary/Conclusions

- Patients using the Fresenius 2008K@home system at either frequency (≤3x/week or >3x/week) achieved higher stdKt/V than patients using NxStage System One. Patients dialyzing using System One did not achieve the expected treatment frequency of ≥5 times per week.
- Laboratory values were generally equivalent among treatment groups, although 2008K@home ≤3x/week patients had lower serum albumin concentrations than the other groups (3.81 g/dL versus 4.09 g/dL and 4.06 g/dL for 2008K@home > 3x/week and System One patients, respectively).
- No statistically significant differences between groups were detected in number of hospitalizations or hospitalized days.
- 2008K@home ≤3x/week patients were more likely to remain on HHD after 1 year than patients in other treatment groups (10.9% drop-out rate, versus 34.6% and 22.4% for for 2008K@home
- > 3x/week and System One patients, respectively).
- A limitation of this analysis is that determination of HHD machine type used was made from the dialyzer/filter type ordered.
- A randomized clinical trial may be warranted to confirm the findings of this retrospective analysis.

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