HOME HEMODIALYSIS

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DISCLOSURES

No Financial conflicts. No financial ties to NxStage.
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HOME HEMODIALYSIS TEAM

- Dr. Amy Hogan - HHD Program Director - Clifton Park - DCI
- Shari Meola - Operations Director - DCI (HHD 1998)
- Christine Lansing – Home Program Coordinator (HHD 1998)
- Pasqualena Meyer - Technical Manager
- Donna Vargo – HHD trainer
MORTALITY RATE

- In-center Hemodialysis
  - 1 year: 22%
  - 2 years: 34%
  - 3 years: 43%
  - 5 years: 58%

- Dialysis vs. General Population
  - Ages 40-44: life span of 11 years vs. 37 years
  - Ages 60-64: life span of 5-6 years vs. 20 years

1. USRDS 2017 Annual Data Report. Vol 2. Table 5.3 Adjusted survival by treatment modality and incident cohort year (year of ESRD onset).
2. USRDS 2017 Annual Data Report. Vol 2 Table 5.4 Expected remaining lifetime (years) by age, sex, and treatment modality of prevalent dialysis patients and transplant patients, and the general U.S. population, 2013
Over 41% of all deaths were cardiovascular-related, with nearly identical percentages in hemodialysis and peritoneal dialysis patients.¹

Chapter 1, Figure 2: Distribution of primary cause of death in hemodialysis patients, 2011 to 2013.¹


AdvancingDialysis.org
PROJECTED DIALYSIS POPULATION GROWTH

Dialysis 2013: 468,386

Projected Growth 2013 to 2025: 181,006 (+38.6%)

Dialysis 2025: 649,392

Data source: USRDS 2015 ADR Reference table D.1; Projection simple auto regression with annual growth 2.5-3%
2025 Dialysis State Predicted Utilization

- 85% Continued In-center Prescription Rates
- 650k Patients
- +3,100 Centers
- 40% Increase in Dialysis Centers
- +Nephrologists
- +Staff

Shortage
5-YEAR PATIENT SURVIVAL

- **40%**
  - 5-year survival
  - In-center HD

- **50%**
  - 5-year survival
  - Peritoneal Dialysis

- **58%**
  - 5-year survival
  - More Frequent HHD*

- **73%**
  - 5-year survival
  - Deceased Donor Transplant

**Conventional HD Patients**
- 88%
- 420,000+

**PD Patients**
- 10%
- 45,000+

**HHD Patients**
- 2%
- 8,000+

**Transplant Patients**
- 73%
- 205,000+

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U.S. Renal Data System, USRDS 2015 Annual Data Report: Table 6.3. Adjusted survival (%) by (a) treatment modality and incident cohort year (year of ESRD onset), and (b) age, sex, race, and primary cause of ESRD, for ESRD patients in the 2008 incident cohort (initiating ESRD treatment in 2008)

Abbreviation: ESRD, end-stage renal disease.

*Data source: NxStage patient data on file.
HOME HEMODIALYSIS (HHD)

- Conventional HHD (3 times per week)
- More frequent HHD (3.5/4/5/6/7 times per week)
  - Using conventional equipment
  - Using specifically designed HHD equipment
- Nocturnal HHD (up to 8+ hours at least every other night)
HOME HEMODIALYSIS
ESRD NETWORKS
2005 VS. 2015: +377%

Patients on December 31

- NxStage receives specific home indication
- Introduction of the bundled payment


1,529 1,787 2,557 3,371 4,145 4,836 5,844 6,395 7,203 7,811 8,044 8,531
RUBIN DIALYSIS CENTER – EXPERIENCE
1998-2014

100,477 TX as of 7/31/2014!
(including extended, overnight, and short daily therapies)

BIG Congratulations
Rubin Home Team!!!

September 2005
START
Census 2009-2014
Home Therapies Saratoga/Clifton Park Rubin Dialysis Centers

Number of patients at beginning of year
Number of patients trained during year
Number of Patients at end of year
Deaths per year
Cumulative Incidence of Mortality and Kidney Transplant among Nxstage Training Graduates

At Rubin Dialysis Center, 2010-2014, with follow-up through December 31, 2015.

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Kidney Transplant</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Months</td>
<td>4.6</td>
<td>5.3</td>
</tr>
<tr>
<td>24 Months</td>
<td>5.4</td>
<td>9.8</td>
</tr>
<tr>
<td>36 Months</td>
<td>10.6</td>
<td>12.4</td>
</tr>
<tr>
<td>48 Months</td>
<td>13</td>
<td>12.4</td>
</tr>
<tr>
<td>60 Months</td>
<td>14.5</td>
<td>14.2</td>
</tr>
</tbody>
</table>

Source: Nxstage
GROWTH POTENTIAL FOR SELF-CARE

Patients able to do self care

Patients who should be on self care

Patients who considered themselves able to do self-care, but chose not to

Current Self Care Penetration

“The advent of dramatically improved machines designed to be extremely user-friendly means as many as 40% of patients could safely dialyze at home”

Allen Nissenson, MD
October 2005

Lebedo (EDTA 2000) Survey of 6000 renal professionals
Mendelssohn (AJKD 2001) Survey of 240 U.S. nephrologists
McLaughlin (AJKD 2003) Survey of 173 patients
HOME HD EQUIPMENT:

<table>
<thead>
<tr>
<th>Specific home HD indication</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific nocturnal HD indication</td>
<td>Yes -</td>
</tr>
<tr>
<td>Dimensions (inches)</td>
<td>15h x 15w x 18d (cycler)</td>
</tr>
<tr>
<td>Weight (lbs)</td>
<td>~ 75 (cycler)</td>
</tr>
<tr>
<td>Water system</td>
<td>Sterile pre-bagged fluid or compact D.I.</td>
</tr>
<tr>
<td>Water needs</td>
<td>None (bag system); Low (D.I. system)</td>
</tr>
<tr>
<td>User interface</td>
<td>Simple, push-button controls &amp; LED readout</td>
</tr>
<tr>
<td>Portability</td>
<td>High</td>
</tr>
<tr>
<td>Treatment options</td>
<td>Short, long, varying frequencies</td>
</tr>
<tr>
<td>Special features</td>
<td>Simple, drop-in cartridge; no significant plumbing/ electrical changes; service swap maintenance; ability to travel</td>
</tr>
</tbody>
</table>

Photos © NxStage Medical, Inc.
Intended as general overview only; contact company representatives for full details.
Many of the most commonly reported symptoms among hemodialysis patients and care partners were identified as being more important than life expectancy.  

Symptoms identified as more important included fatigue, drops in blood pressure, and cramping.

Chapter 5, Figure 1:3
Prevalence of commonly reported symptoms in a cohort of 550 hemodialysis patients.


MORE FREQUENT HEMODIALYSIS DEMONSTRATED CLINICAL BENEFITS

AJKD. November 2016
Volume 68, Issue 5, Supplement 1, S1-S58.
THE CUMULATIVE INCIDENCE OF INTRADIALYTIC HYPOTENSION WAS SIGNIFICANTLY LOWER WITH INTENSIVE HEMODIALYSIS IN BOTH OF THE FHN TRIALS COMPARED TO CONVENTIONAL HEMODIALYSIS.¹

Incidence of levels I, II, and III intradialytic hypotension for intensive versus conventional hemodialysis in the FHN Daily Trial and the FHN Nocturnal Trial.¹

Symptoms of intradialytic hypotension were classified into 3 categories: those that led to lowering of the UF rate or reduced blood flow (Level I); those that led to the administration of saline, but not to lowering of the UF rate (Level II); and those that led to both the administration of saline and lowering of the UF rate (Level III).

AdvancingDialysis.org

### DAILY HD IMPROVES BLOOD PRESSURE CONTROL
#### SUMMARY OF 41 STUDIES

<table>
<thead>
<tr>
<th>Parameter Measured</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Blood Pressure</td>
<td>Reduced by 9.7% to 14%</td>
</tr>
<tr>
<td>Systolic Blood Pressure</td>
<td>Reduced by 4.9% to 16.3%</td>
</tr>
<tr>
<td>Diastolic Blood Pressure</td>
<td>Reduced by 4.6% to 12.5%</td>
</tr>
<tr>
<td>Antihypertensive Medications</td>
<td>From 20% to 85% of patients completely discontinued the use of antihypertensive drugs</td>
</tr>
<tr>
<td></td>
<td>Almost all other patients decreased the number of pills and/or types of antihypertensive medications needed</td>
</tr>
</tbody>
</table>

Source: Summary of 41 studies on impact of more frequent dialysis on hypertension. Bibliography and tabulated study findings available upon request via NxStage Medical, Inc.
Control: 7.3 hrs
Daily HD: 0.6 hrs
Nocturnal HD: 0.2 hrs

*Different from Baseline @ p < 0.05  ○ Between-group difference @ p < 0.05

Translates into over 18 additional hours of “recovered time” per week

Study design: 45 patient prospective, matched-control
Peter Crooks, MD and Medical Director:
“Not only do patients report feeling significantly better with the regular dialysis home treatment allows, but hospitalizations due to complications from kidney failure, even while on dialysis, were halved for Kaiser patients on the home regimen - from 14 to 7 days of hospitalization a year. Most of these hospitalizations are due to heart conditions linked to or worsened by kidney failure.”*


Reductions in hospital-days per year from an expected 14.3 to an actual of 8.3 (-40%).
SPECIFIC CLINICAL EVIDENCE / DATA
At-home short daily hemodialysis improves the long-term health-related quality of life

Fredric O. Finkelstein\textsuperscript{1}, Brigitte Schiller\textsuperscript{2}, Rachid Daoui\textsuperscript{3}, Todd W. Gehr\textsuperscript{4}, Michael A. Kraus\textsuperscript{5}, Janice Lea\textsuperscript{6}, Yoojin Lee\textsuperscript{7}, Brent W. Miller\textsuperscript{8}, Marvin Sinsakul\textsuperscript{9} and Bertrand L. Jaber\textsuperscript{10}, on behalf of the FREEDOM Study Group

\textsuperscript{1}Yale University School of Medicine, New Haven, Connecticut, USA; \textsuperscript{2}Satellite Healthcare, San Jose, California, USA; \textsuperscript{3}Hortense & Louis Rubin Dialysis Center, Clifton Park, New York, USA; \textsuperscript{4}Virginia Commonwealth University, Richmond, Virginia, USA; \textsuperscript{5}Indiana University Medical School, Indianapolis, Indiana, USA; \textsuperscript{6}Emory University, Atlanta, Georgia, USA; \textsuperscript{7}Brown University, Providence, Rhode Island, USA; \textsuperscript{8}Washington University School of Medicine, St Louis, Missouri, USA; \textsuperscript{9}Rush University Medical Center, Chicago, Illinois, USA and \textsuperscript{10}St Elizabeth's Medical Center, Tufts University School of Medicine, Boston, Massachusetts, USA

Patients with chronic kidney disease treated by in-center conventional hemodialysis (3 times per week) have significant impairments in health-related quality of life measures, which have been associated with increased morbidity and mortality. FREEDOM is an ongoing prospective cohort study measuring the potential benefits of at-home short daily (6 times per week) hemodialysis. In this interim report we examine the long-term effect of short daily hemodialysis on health-related quality of life, as measured by the SF-36 health survey. This was administered at baseline, 4 and 12 months after initiation of short daily hemodialysis.

The impaired health-related quality of life (HRQOL) of patients with chronic kidney disease treated by conventional three times weekly hemodialysis (HD) is well documented\textsuperscript{1-6} and has been an area of major concern for patients, their families, and nephrologists. The Center for Medicare and Medicaid Services now mandates that dialysis facilities in the United States perform an annual measurement of HRQOL for dialysis patients, preferentially using the Kidney Disease Quality of Life-36 (KDQOL-36) questionnaire with additional instruments as clinically indicated (http://www.cms.hhs.gov/ cpmproject). A major challenge for nephrologists is how to
### FREEDOM Study Overview

<table>
<thead>
<tr>
<th>Freedom</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sponsor</strong></td>
</tr>
<tr>
<td><strong>Design</strong></td>
</tr>
<tr>
<td><strong>Size</strong></td>
</tr>
<tr>
<td><strong>Primary Endpoint</strong></td>
</tr>
<tr>
<td><strong>Secondary Endpoints</strong></td>
</tr>
<tr>
<td><strong>Estimated data availability</strong></td>
</tr>
</tbody>
</table>

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1 Following Rehabilitation, Economic, and Everyday Dialysis Outcome Measures
**FREEDOM STUDY INTERIM FINDINGS - RECOVERY TIME**

**Statistically significant improvement in post-treatment recovery time**

- Study patients on short daily HHD with NxStage showed significant improvement in post-treatment recovery time compared to their own in-center baseline.
- Other studies have found similar results:
  - Lindsay (2006) found reduction from ~6 hours in-center to ~1 hour on short daily HHD.
- May result in a day of quality time back to patients each week.

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## RECOVERY TIME
### PATIENT IMPACT

### Comparative Treatment Times (hours)

<table>
<thead>
<tr>
<th></th>
<th>In-center</th>
<th>Short Daily HD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel to center</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Preparation</td>
<td>.25</td>
<td>.5</td>
</tr>
<tr>
<td>Treatment</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Wrap-up</td>
<td>.25</td>
<td>.25</td>
</tr>
<tr>
<td>Travel from center</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Recovery</td>
<td>7.7</td>
<td>1.1</td>
</tr>
<tr>
<td>Hours / Tx</td>
<td>14.2</td>
<td>4.85</td>
</tr>
<tr>
<td>Tx / week</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Hours / week</td>
<td>~ 43</td>
<td>~ 29</td>
</tr>
</tbody>
</table>

- Patients may gain back ~ 14 quality waking hours per week with short daily HD
- Based on common time required for various treatment elements
FREEDOM STUDY INTERIM FINDINGS - DEPRESSION

Statistically significant reduction in depressive symptoms

- Study patients on short daily HHD with NxStage showed significant improvement in Beck Depression Inventory (BDI) scores compared to their own in-center baseline.

- BDI: validated & widely used measure of depressive symptoms

- BDI score >10 indicates mild depressive symptoms

- Numerous studies have shown association between depressive symptoms & dialysis patient mortality & hospitalization

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FREEDOM STUDY INTERIM FINDINGS
QUALITY OF LIFE

Statistically significant improvement in physical and mental functioning

- Study patients on short daily HHD with NxStage showed significant improvement in physical component summary (PCS) and mental component summary (MCS) scores compared to their own in-center baseline

- SF-36 PCS & MCS: validated & widely used measures of physical & mental functioning

- Validated QOL measures, such as SF-36 PCS & MCS, have been shown to have an inverse association with dialysis patient mortality & hospitalization

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Impact of At-home Short Daily Hemodialysis on Restless Legs Symptoms and Sleep Disturbances

Bertrand L. Jaber,* Brigitte Schiffer,† John M. Burckan,* Rachid Daou,‡ Michael A. Kraus,§ Yooyin Lee,‖ Brent W. Miller,* Isaac Teitelbaum,* Amy W. Williams,** and Fredric O. Finkelstein*** on behalf of the FREEDOM Study Group

Summary

Background and objectives Restless legs syndrome (RLS) and sleep disturbances are common among in-center hemodialysis patients and are associated with increased morbidity/mortality.

Design, setting, participants, & measurements The FREEDOM study is an ongoing prospective cohort study investigating the benefits of home short daily hemodialysis (SDHD) (6 times/week). In this interim report, we examine the long-term effect of SDHD on the prevalence and severity of RLS, as measured by the International Restless Legs Syndrome (IRLS) Study Group rating scale, and sleep disturbances, as measured by the Medical Outcomes Study sleep survey.

Results 235 participants were included in this report (intention-to-treat cohort), of which 127 completed the 12-month follow-up (per-protocol cohort). Mean age was 52 years, 55% had an arteriovenous fistula, and 40% suffered from RLS. In the per-protocol analysis, among patients with RLS, the mean IRLS score improved significantly at month 12, after adjustment for use of RLS-related medications (18 versus 11). Among patients with moderate-to-severe RLS (IRLS score ≥15), there was an even greater improvement in the IRLS score (23 versus 13). The intention-to-treat analysis yielded similar results. Over 12 months, there was decline in the percentage of patients reporting RLS (35% versus 26%) and those reporting moderate-to-severe RLS (59% versus 43%). There was a similar and sustained 12-month improvement in several scales of the sleep survey, after adjustment for presence of RLS and use of anxiolytics and hypnotics.

Conclusions Home SDHD is associated with long-term improvement in the prevalence and severity of RLS and sleep disturbances.

COMPARATIVE TRANSPLANT AND SURVIVAL RATES

Source: NxStage Home Patient Database; PD literature (Guo, Mujais, Kidney Int 2003 and 2006); 2007 USRDS Annual Data Report
WHO IS A GOOD CANDIDATE FOR HOME HEMODIALYSIS?

- Patients who are tolerating in center hemodialysis poorly with hypotension, cramps, prolonged post dialysis symptoms, depression, restless leg syndrome sleep disturbance, Patients with CHF, noncompliance with fluid and dietary restriction, valvular heart disease, low EF’s.

- People who are failing PD.

- People with failing transplants.

- People who have to travel long distances to dialysis.

- People who want to work, study, care for families.

- There is no medical comorbidity that precludes being trained for home hemodialysis

- We even trained a 300 lbs female patient and her husband (had mild Dementia, was a carpenter and was accessing her button holes under her guidance )- The patient did very well.
WHAT MAKES OUR PROGRAM SUCCESSFUL

• Dedicated staff willing to bend over and backward to help these patients and think outside the box to trouble shoot and make it work
• Accepting a challenge that not every one is 100% able to do everything and finding ways to work around it.
• The trainers are willing to train the patients at the time of day that works for the patients to accommodate theirs lives.
• Give it a try and go for it and never turn a patient away
• An open dialogue relationship with the nephrologists
Experience the difference- Dialyzing patients 5 days a week, at the HHD unit. Most of the patients transit to HHD.

All patients with HHD prescriptions of 5 to 6 days/week for the 2 months after completing the initial training (increase retention, patient become more confident and comfortable with cannulation and Nx Stage machine) then change the HHD prescription as needed.

Different HHD prescriptions tailored to the need and lifestyle of the patients.
WHAT MAKES OUR PROGRAM SUCCESSFUL

- Offer the patients the options to come to HHD unit for dialysis when needed if sign of burn out or partner is not available (trip, illness …)

- Prefer to use AVF, but ok to use tunneled catheter for short daily or longer treatment such as nocturnal HHD

- Do not use AVG for nocturnal HHD, OK to use for short daily HHD.

- Teaching appropriate surveillance to patients, informing them of sign of sepsis so that if they have any signs, they immediately notify staff.

- If there is any sense of granulated tissue/redness etc. at the button holes site, immediately stop using it and create new ones
WHAT MAKES OUR PROGRAM SUCCESSFUL

• Staff must inspect the vascular access site at least monthly. If patient can not come in to the monthly HHD clinic, utilize technology and send picture of access to the team.

• Occasional group meetings with staff member to review safe, proper technique and infection control such as not opening the syringes/needles and leaving them around or having animals in the room when cannulating.

• Certify the patient or the partner after they complete 6 weeks training (sense of accomplishment, control and reducing the risk of helplessness syndrome).
MOISTURE SENSOR TO DETECT BLOOD LEAK AT THE ARTERIAL OR VENOUS NEEDLE - LOUD SOUND IF LEAK
STOCKINETTE – COVER AND PROTECT
HOME DIALYSIS TODAY
QUESTIONS ?