Home Dialysis
Coming to a Home near You

John A. Sweeny
NANT
Annual National Symposium
Tuesday – March 8th, 2011
Initial Home Hemodialysis

- Home HD was begun to reduce the cost of in-hospital HD in the 60s and early 70’s
- Stanley Shaldon introduced overnight home HD in October of 1964. (3x/week, 6 – 8 hours/treatment)
- By 1972 there were 7,500 ESRD patients in the US with 35% of them at home
- With the start of the Medicare ESRD Program, the number of home patients began to decline until by 2002 the total number of US patients was 1,758 (0.57% of the total patient population)

Why the decline in home HD?

- The Medicare ESRD program is an entitlement program which meant that many patients not able to dialyze at home could still receive treatment.
- The funding was for a treatment was quite high resulting in the proliferation of dialysis facilities thereby reducing the transportation time to obtain a treatment.
- For-profit dialysis units were not interested in home HD.
- Most Nephrologists had minimal experience with chronic renal failure, much less the advantages of home HD.
- Medicare reimbursement for training Home HD patients was minimal.
  - It would take about two years to recover training costs.
  - An effective home training program needed 12 -15 patients.

## USRDS Dialysis Patients

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center HD</td>
<td>280,473</td>
<td>291,632</td>
<td>302,899</td>
<td>314,097</td>
<td>326,671</td>
<td>338,539</td>
<td>350,617</td>
</tr>
<tr>
<td>Center Self HD</td>
<td>271</td>
<td>193</td>
<td>184</td>
<td>138</td>
<td>102</td>
<td>142</td>
<td>157</td>
</tr>
<tr>
<td>Home HD</td>
<td>1,761</td>
<td>1,910</td>
<td>2,053</td>
<td>2,230</td>
<td>2,601</td>
<td>3,225</td>
<td>3,826</td>
</tr>
<tr>
<td>CAPD</td>
<td>11,659</td>
<td>11,366</td>
<td>10,992</td>
<td>10,857</td>
<td>10,482</td>
<td>9,940</td>
<td>9,649</td>
</tr>
<tr>
<td>CCPD</td>
<td>13,705</td>
<td>14,433</td>
<td>14,790</td>
<td>15,164</td>
<td>15,589</td>
<td>16,247</td>
<td>16,868</td>
</tr>
<tr>
<td>Dialysis Total*</td>
<td>308,898</td>
<td>320,498</td>
<td>331,871</td>
<td>343,449</td>
<td>356,381</td>
<td>369,140</td>
<td>382,343</td>
</tr>
</tbody>
</table>

* Total includes dialysis patients who’s dialysis therapy was unknown
# Top 10 Providers - 2010

<table>
<thead>
<tr>
<th>PROVIDER</th>
<th># PATIENTS</th>
<th>HD</th>
<th>HHD</th>
<th>PD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresenius Medical Care N.A.</td>
<td>132,381</td>
<td>123,119</td>
<td>581</td>
<td>8,681</td>
</tr>
<tr>
<td>DaVita Inc.</td>
<td>120,400</td>
<td>108,700</td>
<td>2,000</td>
<td>9,700</td>
</tr>
<tr>
<td>Dialysis Clinic Inc.</td>
<td>13,350</td>
<td>12,127</td>
<td>67</td>
<td>1,156</td>
</tr>
<tr>
<td>Renal Advantage Inc.</td>
<td>12,000</td>
<td>10,799</td>
<td>396</td>
<td>805</td>
</tr>
<tr>
<td>DSI Renal Inc.</td>
<td>7,868</td>
<td>7,345</td>
<td>91</td>
<td>432</td>
</tr>
<tr>
<td>Liberty Dialysis LLC</td>
<td>6,100</td>
<td>5,372</td>
<td>127</td>
<td>601</td>
</tr>
<tr>
<td>American Renal Associates</td>
<td>5,800</td>
<td>5,350</td>
<td>30</td>
<td>420</td>
</tr>
<tr>
<td>U. S. Renal Care</td>
<td>5,508</td>
<td>5,174</td>
<td>94</td>
<td>240</td>
</tr>
<tr>
<td>Satellite Health Care</td>
<td>4,317</td>
<td>3,396</td>
<td>169</td>
<td>752</td>
</tr>
<tr>
<td>Innovative Dialysis Systems</td>
<td>3,911</td>
<td>3,523</td>
<td>15</td>
<td>373</td>
</tr>
</tbody>
</table>
### Home Dialysis – Top 10 Providers

<table>
<thead>
<tr>
<th>YEAR</th>
<th>HD</th>
<th>INC./% INC.</th>
<th>PD</th>
<th>INC./% INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>2,321</td>
<td>-----</td>
<td>20,474</td>
<td>-----</td>
</tr>
<tr>
<td>2009</td>
<td>2,836</td>
<td>515/22 %</td>
<td>20,690</td>
<td>216/1 %</td>
</tr>
<tr>
<td>2010</td>
<td>3,569</td>
<td>733/26 %</td>
<td>23,159</td>
<td>2469/12 %</td>
</tr>
</tbody>
</table>
Why renewed interest in HHD?

• The ESRD mortality rate in the US is high (24.4 deaths/100 patient years – USDRS - 2008)
• Modeling the dialysis dose using Kt/V hasn’t helped
  – International Outcomes and Practice Study
  – 1991 Kt/V = 1.11
  – 2002 Kt/V = 1.52
• Therapy complications remain high
  – Hypertension
  – Malnutrition
  – Congestive Heart Failure
  – Bone and mineral disorders
• Thrice weekly treatments cause high fluctuations in uremic toxins and fluid volume

Survival – Hemodialysis vs. Transplant

• Study done over 8 years
  – 172 patients received an allograft from a living related donor
  – 112 patients received a cadaveric transplant
  – 125 patients were on home hemodialysis

• Transplant survival rates after one year:
  – Parental = 84.2%
  – Sibling = 89.5%
  – Cadaver = 68.7%

• Survival rates for HD at one and two years respectively:
  – Home hemodialysis patients = 88.5% and 77.8%
  – In center patients = 92.9% and 86.1%

Clinical Benefit of More Frequent HD

Cardiovascular Effects
Nutritional Effects
Mineral Metabolism
Hematologic Effects
Effects on Sleep
Quality of Life
Hospitalization Rates
Impact on Survival
Cost Effectiveness
Patients desiring additional HD

- Quality of life improvement
- Liberalize diet
- Disabling complications
  - Unstable BP
  - Severe cramping
  - Congestive heart failure
  - Hyperphosphatemia
- Stay at home
- Transplantation not possible
- Obese
- Vascular Access
- Severe sleep apnea
- Work during the daytime

Patient Mortality
Does where you dialyzer matter?

• Report from the Center for Advancing Health/ Health Services Research Journal – Lead Author: Yi Zhang, PhD

• The study involved 34,914 Medicare patients, from 3,601 non-hospital based centers in 2004

• Comparisons were done between the five largest for-profit chains and non-chain for–profit and nonprofit facilities

• Analysis showed that mortality rates were 19% and 24% higher for the top 2 chains than for patients at a medium-size nonprofit chain

• Overall, mortality was 13% higher when comparing non-profit to profit facilities

• No explanation for these results were given.

PD survival better than HD

- Researchers matched 6,337 patient pairs from 98,875 starting dialysis in 2003
- Cumulative survival probabilities:

<table>
<thead>
<tr>
<th>Months on Tx</th>
<th>PD</th>
<th>HD</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>85.5%</td>
<td>80.7%</td>
<td>0.01</td>
</tr>
<tr>
<td>24</td>
<td>71.1%</td>
<td>68.0%</td>
<td>0.01</td>
</tr>
<tr>
<td>36</td>
<td>58.1%</td>
<td>56.7%</td>
<td>0.25</td>
</tr>
<tr>
<td>48</td>
<td>48.4%</td>
<td>47.3%</td>
<td>0.50</td>
</tr>
</tbody>
</table>

- There was no statistical difference if comparisons were done beginning 90 days after dialysis initiation
- Hemodialysis had better survival among subgroups with cardiovascular disease and diabetes

Patient Urea Dynamics

BUN Generation Rate vs. Protein Catabolic Rate

BUN Generation Rate (mg/minute) vs. Protein Catabolic Rate (g/kg/day)
Toxin Fluctuation over one Week
(Three treatments weekly)

**Patients's BUN for the Week**

- **BUN in mg/dL**
  - 0
  - 20
  - 40
  - 60
  - 80
  - 100
  - 120

- **Time in hours**
  - 0
  - 12
  - 24
  - 36
  - 48
  - 60
  - 72
  - 84
  - 96
  - 108
  - 120
  - 132
  - 144
  - 156
  - 168

**Patient**

**Normal**
Patient Toxin Fluctuations over one Week

7 - 103-minute Treatments per week

BUN (mg/dL)

SUN  MON  TUE  WED  THU  FRI  SAT

50.0  55.0  60.0  65.0  70.0  75.0  80.0
Dialysis Frequency Effect on Standard Kt/V

- End of treatment patient weight = 85 kg
- Patient height = 178 cm
- Patient age = 60 years
- Weigh loss per week = 4.0 kg
- Weight loss per treatment = 4.0 kg ÷ Tx per week
- Single pool Kt/V for the week = 3.9
- Individual treatment Kt/V = 3.9 ÷ Tx per week
- 3 Standard stdKt/Vs calculated:
  - Leypoldt Fixed-volume Standard Kt/V
  - FHN UF-corrected Standard Kt/V
  - SAN (surface-area-normalized) Standard Kt/V

www.hdcn.com/calcf/ley.htm
# Dialysis Frequency Effect on Standard Kt/V

<table>
<thead>
<tr>
<th>Treatments per Week</th>
<th>Treatment Length (minute)</th>
<th>Weight loss/ Tx (kg)</th>
<th>Single Pool Kt/V</th>
<th>LFV stdKt/V</th>
<th>FHN stdKt/V</th>
<th>SAN stdKt/V</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>360</td>
<td>2.0</td>
<td>1.95</td>
<td>1.74</td>
<td>1.81</td>
<td>1.98</td>
</tr>
<tr>
<td>3</td>
<td>240</td>
<td>1.33</td>
<td>1.30</td>
<td>2.12</td>
<td>2.18</td>
<td>2.38</td>
</tr>
<tr>
<td>4</td>
<td>180</td>
<td>1.0</td>
<td>0.98</td>
<td>2.33</td>
<td>2.38</td>
<td>2.60</td>
</tr>
<tr>
<td>5</td>
<td>144</td>
<td>0.8</td>
<td>0.78</td>
<td>2.44</td>
<td>2.48</td>
<td>2.71</td>
</tr>
<tr>
<td>6</td>
<td>120</td>
<td>0.67</td>
<td>0.65</td>
<td>2.49</td>
<td>2.52</td>
<td>2.76</td>
</tr>
<tr>
<td>7</td>
<td>103</td>
<td>0.57</td>
<td>0.56</td>
<td>2.51</td>
<td>2.54</td>
<td>2.77</td>
</tr>
</tbody>
</table>

LFV = Leypoldt Fixed Volume, FHN = Frequent Hemodialysis Network, SAN = Surface Area Normalized

[www.hdcn.com/calcf/ley.htm](http://www.hdcn.com/calcf/ley.htm)
Increasing Clearance effect on final Urea

URR Changes with Increasing K

Each Interval = 15 Minutes

BUN (mg/dL)
URR during a treatment

Patient's Treatment Urea Reduction

1st half Urea reduction

2nd half Urea reduction

TIME (minutes)
# URR Treatment Comparison

## 1st Half vs. 2nd Half

<table>
<thead>
<tr>
<th></th>
<th>K = 200 (mL/min)</th>
<th>K = 225 (mL/min)</th>
<th>K = 250 (mL/min)</th>
<th>K = 275 (mL/min)</th>
<th>K = 300 (mL/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>spKt/V</td>
<td>1.0805</td>
<td>1.2154</td>
<td>1.3504</td>
<td>1.4855</td>
<td>1.6205</td>
</tr>
<tr>
<td>Urea Reduction 1st Half (mg/dL)</td>
<td>31.4</td>
<td>34.5</td>
<td>37.4</td>
<td>40.1</td>
<td>42.6</td>
</tr>
<tr>
<td>Urea Reduction 2nd Half (mg/dL)</td>
<td>18.3</td>
<td>18.8</td>
<td>19.0</td>
<td>19.1</td>
<td>19.0</td>
</tr>
<tr>
<td>1st Half % of Total Reduction</td>
<td>63.2%</td>
<td>64.7%</td>
<td>66.3%</td>
<td>67.8%</td>
<td>69.2%</td>
</tr>
</tbody>
</table>
Conventional HD vs. Nocturnal HD

- Study used 21 patients who had been on conventional HD
- Nocturnal HD was done thrice weekly for 8 hours
- Comparison: CHD - 12 months vs. NHD - 12 months
- Results:
  - Albumin level > 3.5 g/dL: 97% (NHD) vs. 86% (CHD)
  - Phosphate level < 5.5 mg/dL: 62% (NHD) vs. 46% (CHD)
  - Mean std Kt/V: 2.8 (NHD) vs. 2.5 (CHD)
  - Epogen use decreased by 62% after 12 months on NHD
  - Patients reported significant improvement in quality of life
- Drawback: Recruiting/Maintaining RN staff

Dodd et al., A nocturnal in-center hemodialysis pilot program: logistic issues and improved clinical outcomes, American Society of Nephrology and meeting, Denver, 2010
Nocturnal Home HD: 3 Year Experience

• Over three years, 12 patients were started on NHHD
• The therapy parameters
  – Overnight - 8-10 hours, 6-7 times per week
  – Blood Flowrate = 300 mL/min. using internal jugular catheters
  – Dialysate flowrate = 100 mL/min
  – Dialyzer = Fresenius F40 (0.7 m²), Nightly Kt/V = 0.99
• Clinical results
  – Pruritus, nausea, postdialytic symptoms and lack of energy decreased or disappeared
  – Appetite increased
  – Daily BP meds decreased from 2.67 to 1.67
  – All patients off phosphate binders, 2 given supplements
  – No change in hemoglobin levels or EPO use

Nocturnal Home HD: 3 Year Experience

• Vocational Rehabilitation
  – Before nocturnal HD:
    • 2 – retired, 2 – disabled, 3 – unemployed, 2 – full time, 3 – part time
  – After nocturnal HD:
    • 2 – retired, 2 – disabled, 6 – full time, 2 – part time, 1 – looking for work

• Patient biochemistry removal per week

<table>
<thead>
<tr>
<th>CHEMICAL</th>
<th>Nocturnal HD (mmol)</th>
<th>Conventional HD mmol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urea</td>
<td>1856 ± 413</td>
<td>1636 ± 301</td>
</tr>
<tr>
<td>Creatinine</td>
<td>63.75 ± 31.78</td>
<td>60.04 ± 44.16</td>
</tr>
<tr>
<td>Phosphate</td>
<td>150 ± 47</td>
<td>82 ± 22</td>
</tr>
<tr>
<td>β₂ Microglobulin</td>
<td>52.13 ± 10.6</td>
<td>12.14 ± 2.09</td>
</tr>
</tbody>
</table>

Daily HHD vs. In-center HD

- Study used 13 patients, all of whom having been on dialysis at least 2.3 years
- Patients were studied initially in center being dialyzed 3 times per week for 2 months.
- Patients then began DHHD dialyzing 6x per week for 6 months
- The DHHD sessions were adjusted to yield a weekly dialysis dose Kt/V equivalent to the therapy patients received in-center

Daily HHD vs. In-center HD

• Study results:
  – Quality of life improved markedly
  – BP normalized in hypertensive patients
  – Antihypertensive medications reduced considerably
  – No hospitalizations for any patient during the study
  – Metabolic changes were small
  – Phosphate binders were decreased slightly

• Authors of study concluded this therapy was best for patients with…
  – Heart failure
  – Uncontrollable hypertension
  – Non-compliant fluid intake
  – Severe dialysis induced symptoms

The NxStage® Freedom Study

- Following Rehabilitation Economics and Everyday-Dialysis Outcome Measurements study
- Compares traditional, thrice-weekly in-center HD to more frequent home HD
- 500 short daily HHD patients matched to 5,000 in-center HD patients from the US Renal Data System
- Measured parameters:
  - Recovery time
  - Depressive symptoms
  - Sleep quality
  - Mortality rate
  - Quality of life
  - Restless legs syndrome
  - Anti-hypertensive medication use

http://www.nxstage.com/freedomstudy/index.cfm
NxStage® Freedom Study – Depression Score

**FREEDOM Study**

- Patients serve as their own control, completing recovery time data at baseline (in-center therapy) and after 4, 12, and every subsequent 6 months on HHD
  - Baseline BDI scores did not differ significantly between patients who dropped out (11.5 ± 9.0) and those who completed 12-month follow-up (12.6 ± 10.1), P=NS
- BDI is a validated and widely used measurement instrument for depressive symptoms
- BDI score of 10 or higher may indicate mild depressive symptoms and, per study protocol, requires MD assessment for signs of clinical depression
  - On average, FREEDOM patients moved from above this threshold on in-center therapy to below it on HHD
- Improvements in depressive symptoms seen at 4 months were maintained at 12 months
- Improvements were even more dramatic (~50% improvement at 12 months) for patients with higher BDI at baseline
- BDI scores >15 have been found to be highly correlated with diagnosis of depression

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http://www.nxstage.com/freedomstudy/index.cfm
NxStage® Freedom Study – Recovery Time

FREEDOM Study

Recovery Time In Hours

(P<0.0001; n=65)

- Patients serve as their own control, completing recovery time data at baseline (in-center therapy) and after 4, 12, and every subsequent 6 months on HHD.

- FREEDOM findings echo those of prior studies assessing recovery time for HHD patients compared to in-center baseline.
  - A 2006 publication by Lindsay in London, Ontario, found reduction from nearly 6 hours on in-center to under 1 hour on short daily HHD.

- Recovery time improvements seen at 4 months were maintained at 12 months.

Distribution of Time to Recovery (TTR)

(ε=0.005; n=65)

- At in-center baseline, only 16% of patients had post-treatment recovery time <60 min.

- At 12-month follow-up, 64% of patients had post-treatment recovery time <60 min.

- % Patients with TTR >60 min.
- % Patients with TTR <60 min.

http://www.nxstage.com/freedomstudy/index.cfm
The Water Toxin Issue
(something to think about)

• There is no such thing as truly pure water
• Toxins can diffuse across dialyzer membrane (think heavy metals)
• Diffusion is based on concentration, not flowrate
• The longer the patient is on dialysis, the longer the patient is exposed to toxins
• Once a heavy metal is in your body there’s a good chance it’s there for a long time
• The question: If dialysis time doubles, should safe toxin levels be halved?
The new Medicare PPS - Impact on Home Dialysis

- PPS = Perspective Payment System
- Nothing complicated here… it’s just 935 pages long!
- The bottom line is that a treatment will be reimbursed at $229.63
- Included are all supplies, labor, equipment, lab fees, as well as medications
- Home dialysis training
  - $33.38 per treatment (was $20.00)
  - Up to 25 treatments for HD
  - Up to 15 treatments for PD
  - Centers must opt in at 100% for the new regulations

The new Medicare PPS - Impact on Home Dialysis

- **Quality Incentive Program (QIP)**
  - Quality Indicators: high and low hemoglobin levels and urea reduction ratio
  - Reimbursement reduced 2% to facilities with poor quality indicators
- **Medications**
  - Data suggest that well dialyzed patients use less ESAs (erythropoiesis stimulating agents)
  - More dialysis implies less itching which means less antipruritic drugs
  - Drugs to treat fluid overload should also be decreased
  - Patients who cannulate themselves have fewer access problems and hence use fewer drugs to help keep the access open
  - The end result? Decreased drugs + fixed reimbursement = higher profits = higher promotion of home therapies

The new Medicare PPS - Impact on Home Dialysis

- Frequency of dialysis
  - Reimbursement is for 3 treatments per week
  - Physician must justify addition medical need for more Tx’s
- Method II reimbursement
  - Previously the supplier of equipment and supplies was paid $1,491 a month and the center received $121
  - The new figure will be $229.63 x 13 = $2985.19 which will go directly to the provider. The provider pays the supplier.
  - Remember, the larger amount includes medications which if the home patient uses less of, could be a good deal for the provider.

Nephrology News and Issues Survey

Question; What percentage of dialysis patients do you think could receive their care at home?

220 responses:
- 16 said 5% (7.08% of votes cast)
- 35 said 10% (15.93% of votes cast)
- 33 said 20% (15.04% of votes cast)
- 42 said 30% (19.03% of votes cast)
- 94 said >30% (42.92% of votes cast)

Weighted average using >30% to be 40%: 23%

Nephrology News & Issues, February 2009, p. 28
Future Developments

• Home Dialysis Plus – received $50 million dollars June 16th 2010 from Warburg Pincus to develop a new portable dialysis system enabling frequent treatments

• The FDA has approved an Investigational Device Exemption for a home hemodialysis system developed by Baxter International and DEKA Research and Development

• The global dialysis equipment market is expected to grow at an annual rate of 7% and reach $8.9 billion by 2016

• Revenue for dialysis centers in the US is expected to grow 4% to 6% annually

• Growth in US patients should be 5% annually driven by
  – Increasing prevalence of diabetes and hypertension
  – Rapidly aging population
  – Shortage of kidney donors
Christopher Blagg on treatment choices
(in increasing order of benefit)

- In-center thrice-weekly four hour treatments
- Peritoneal Dialysis
- Thrice-weekly overnight HD in a facility
- Thrice-weekly HD at home, preferably overnight
- Alternate night overnight HD at home (6-8 hours)
- 5/6 times per week short HD at home (2-3 hours)
- 5/6 times per week overnight HD at home

“It is certainly significant that when asked what treatment they would prefer for themselves if they had kidney failure (and a transplant was not feasible) most Nephrologists would opt for home HD five or six nights a week”