

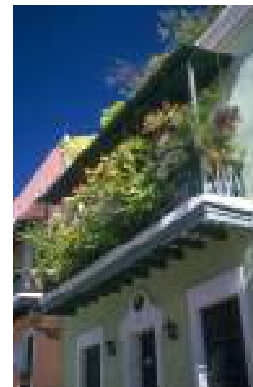
# Home Hemodialysis: Key Trends and Advancements

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## Today we'll discuss

- Trends influencing a movement towards increased use of more frequent, home hemodialysis (HHD)
- Clinical and patient QOL benefits of HHD
- Key technology innovations that can make HHD more accessible & practical for more patients



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## Before centers, dialysis was at home



Drake-Willock 4002 with Kill Dialyzer: Mid-1960's



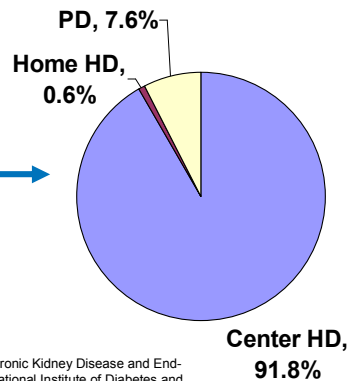
Milton Roy Model A: 1964

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## Home hemodialysis: then and now

- In 1973, fully 40% of patients were doing hemodialysis at home
- Today, less than 10% of the dialysis population is at home and less than 1% of patients are doing home HD<sup>1</sup>



<sup>1</sup> U.S. Renal Data System, USRDS 2007 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2007

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## A natural question: *Why did Home HD (HHD) decline?*

- **Economic disincentives**
- **More, and more complex, patients**
- **Increased usage of PD**
- **Machines not designed for home**
- **Limited awareness of new HHD options**



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## An even better question: *Why are so many patients in-center, when...*

- ***...the patient population is continuing to grow***
- ***...there is a nursing shortage***
- ***...in-center HD 3-times a week imitates the kidney's function least***
- ***...in-center HD has the most restricted diet & fluids***
- ***...schedules & symptoms limit patients' work and activities***

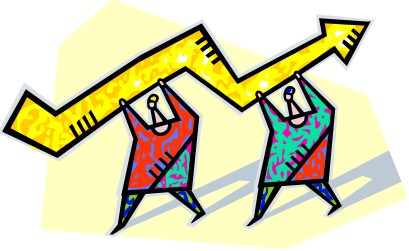


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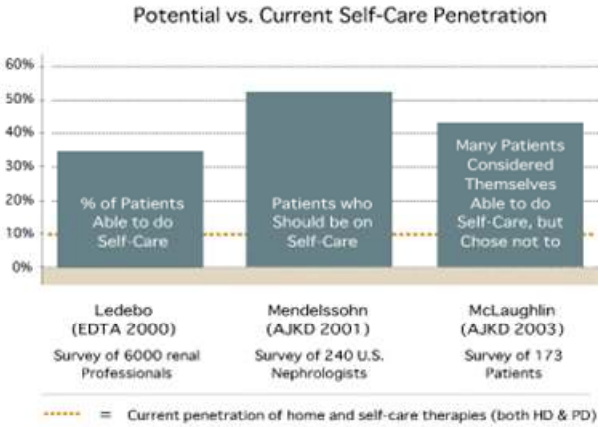
# Renewed interest in home HD

- Patient and clinician interest
- Interest in new more frequent and/or longer HD modalities
  - Hard to offer these in center
- Advances in technology
- Information on the web



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# Professional, physician, and patient interest

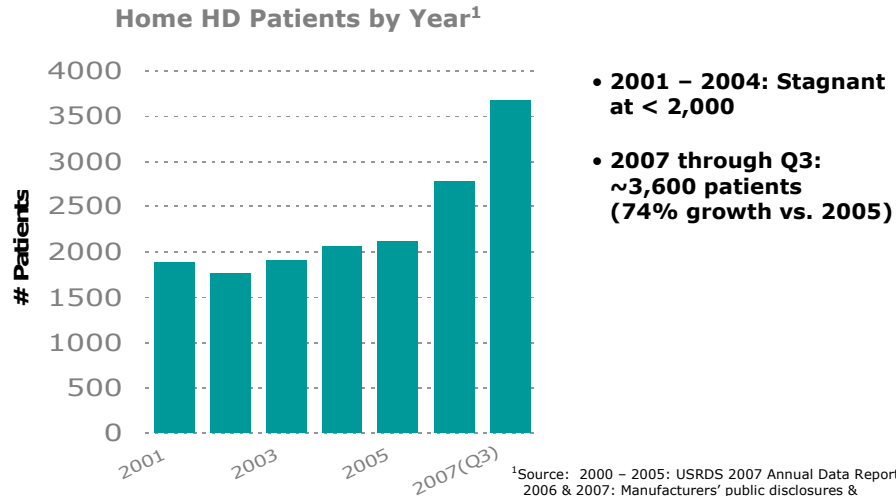


“The advent of dramatically improved machines designed to be extremely user-friendly means as many as 40% of patients could safely dialyze at home”

*Allen Nissenson, MD  
October 2005*

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## Home HD back on a growth trajectory



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## Longer and/or more frequent HD: Short Daily HHD

- 2-1/2 to 3 hours, 5-6 days/week
- Self-scheduled; easy to fit in short treatments
- Training 2-3 weeks
- Few diet/fluid limits, symptoms
- Trained partner needed
- Uses any vascular access
- Single cannulator; access may last longer

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## Longer and/or more frequent HD: Nocturnal HHD\*

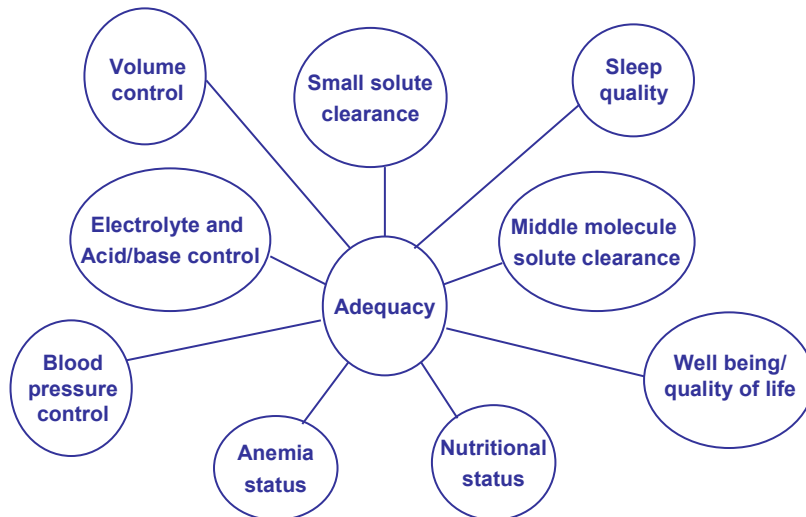
- 7-8 hours, 3-6 nights/week
- Training usually 4-8 weeks
- Very few diet or fluid limitations
- Few symptoms during or between sessions
- Trained partner needed
- Uses any vascular access
- Single cannulator; access may last longer

\* There are currently no systems specifically indicated for nocturnal hemodialysis. NxStage is currently undergoing an FDA IDE Clinical Trial for this specific indication.

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## Clinical benefit of more frequent HD: More than just adequacy



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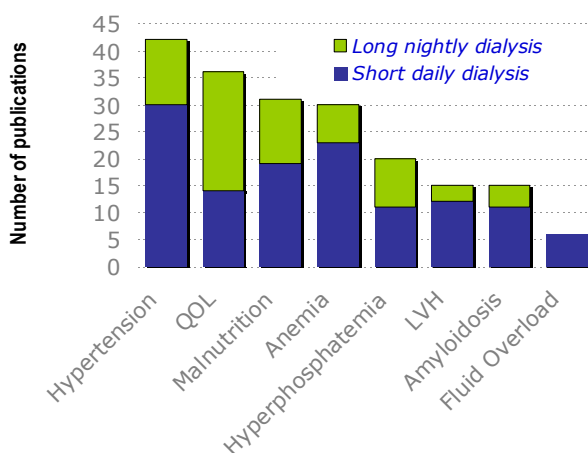
## Clinical benefits of more frequent & home therapy have been seen in the following:

- Health benefits of more frequent HD<sup>1</sup>,
  - Regression of LVH
  - Reduced hypertension
  - Reduced fluid overload
  - Improved anemia status
  - Improved nutritional status
  - Improved B2M/plasma levels / reduced amyloid disease
  - Improved phosphate/renal osteodystrophy status
- Quality of life benefits
  - Improved treatment tolerance
  - Increased flexibility, freedom (including travel),
  - Increased control over treatment of disease

<sup>1</sup>Source: Benefits of Daily Dialysis: Summary of Literature; Available from NxStage Medical, Inc. upon request.  
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## Clinical literature supports the benefits of more frequent dialysis



- Growing acceptance as standard clinical practice

- Large and growing body of literature supporting more frequent & home therapy
- Multiple references in *K/DOQI Cardiovascular Guidelines 2005*

Source: Analysis of 94 original published articles published since 1996. See "Benefits of Daily Dialysis" booklet (NxStage, 2005)

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## Further recent clinical support

- **Effect of Frequent NHD vs. CHD on LV Mass & Quality of Life**
  - Culleten BC et al: JAMA 298: 1291 – 1299; 2007
  - Found:
    - Statistically significant LV Mass reduction (8%) with NHD
    - Statistically significant reduction in BP Meds with NHD
    - Relevant KDQOL indicators significantly improved with NDH
- **Association between high ultrafiltration rates and mortality in uremic patients on regular dialysis**
  - Movilli et al; NDT 2007; Sept 21
  - Found association of high ultrafiltration rates with higher mortality
  - More frequent HD results in lower UF rates

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## What patients want

"Dialysis must become **easier** so patients can **administer treatment to themselves**. Machines would be **portable** with their own filters...Equipment would run on **normal current**, and necessities like sodium bicarbonate, dialysate, etc. would be packaged as **single-use** and in **disposable** containers for ease of transport and clean-up.



Call me a dreamer, but making dialysis easier and more portable can make patients capable of living a **normal life**. Dialysis is all about the **freedom** to live."

*A Patient, Rosemead, CA  
Family Focus, The Renal Community's Newspaper (1/03)*

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## The ideal HHD system would combine...

### The best attributes of **PD**:

- **Simple** procedure
- **Portable** equipment
- **No infrastructure** modifications
- **Daily** therapy
- **Bagged, sterile fluids** for flexibility & ability to **travel**
- **Low utility costs** (water, electricity)
- Maintenance by **service swap**

### With the best of **HD & online fluid systems**:

- **Greatly reduced delivery & storage**
- **No handling & disposal of bags** required
- **Increased treatment simplicity**
- Prescription **flexibility** to meet the needs of **wide patient range**
- **Wide range of treatment regimens** available
- Any **vascular access**

*...in a system designed to overcome the tradeoffs of each*

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## Available home HD technologies



Fresenius 2008K

B Braun Dialog +



NxStage System One with PureFlow SL



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## Modified traditional systems



Photos © Fresenius Medical Care and B. Braun. Intended as general overview only; contact company representatives for full details.

|                            |  |
|----------------------------|--|
| <b>Dimensions (inches)</b> | ~ 60h x 20w x 25d  |
| <b>Weight (lbs)</b>        | 160 - 185  |
| <b>Water system</b>        | Online R.O.  |
| <b>Water needs</b>         | High   |
| <b>Electricity needs</b>   | Dedicated outlet   |
| <b>User interface</b>      | Touch-screen, menu-driven LCD                                    |
| <b>Portability</b>         | Low  |
| <b>Treatment options</b>   | Short, long, varying frequencies                                 |
| <b>Special features</b>    | Touch-screen, menu-driven LCD interface; definable user profiles |

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## A key home HD advancement: NxStage<sup>®</sup> System One<sup>™</sup>



Photo © NxStage Medical, Inc. Intended as general overview only; contact company representatives for full details.

|                                     |  |
|-------------------------------------|--|
| <b>Dimensions (cycler - inches)</b> | 15h x 15w x 18d  |
| <b>Weight (cycler - lbs)</b>        | ~ 75   |
| <b>Water system</b>                 | Compact D.I. or sterile pre-bagged fluid   |
| <b>Water needs</b>                  | Low (D.I. system)<br>None (bag system)   |
| <b>Electricity needs</b>            | Any standard grounded outlet   |
| <b>User interface</b>               | Simple, push-button controls & LED / LCD readouts  |
| <b>Portability</b>                  | High   |
| <b>Treatment options</b>            | Short, extended, varying frequencies   |
| <b>Special features</b>             | Simple, drop-in cartridge; no significant plumbing/electrical changes; service swap maintenance; ability to travel |

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## PureFlow SL™: A unique dialysate preparation system



- Accessory to the System One cycler
  - Compact dialysate batch production system
- Simplifies treatments
  - Reduced size & complexity vs. traditional water systems
  - No significant home modifications needed
  - Reduced storage needs vs. bagged systems
- Aids in treatment flexibility
  - Treatment type, length, fluid volume
  - Treatment schedule
  - Treatment location
- Maintains System One portability
  - Modular
  - Allows use at home or on road

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## PureFlow SL: How it works



- PureFlow SL uses tap water, which is simply connected in one of 3 ways:
  - At the faucet
  - Under the sink
  - At a washer connection
- Dialysate is prepared in advance
  - 40L, 50L, or 60L 'batch'
  - Batch will provide 1-3 treatments, depending on prescription
- Preparation process takes approximately 7 hours
  - Tap water flows through DI purification pack to become ultrapure
  - Ultrapure water mixes with sterile-filtered dialysate concentrate
- Disposable supplies include:
  - Purification pack (lasts on average 4-8 weeks, up to 12 weeks)
  - Dialysate sack

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## Two packages for flexibility

### SL package (home use)



### Express package (on the road)



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## How the NxStage therapy works

### *Drop-in cartridge*



Cartridge drops into cyclor, then is automatically primed

### *Easy therapy concept*



Dose = dialysate volume; therapy complete when prescribed volume has been delivered

### *Remove, discard when done*

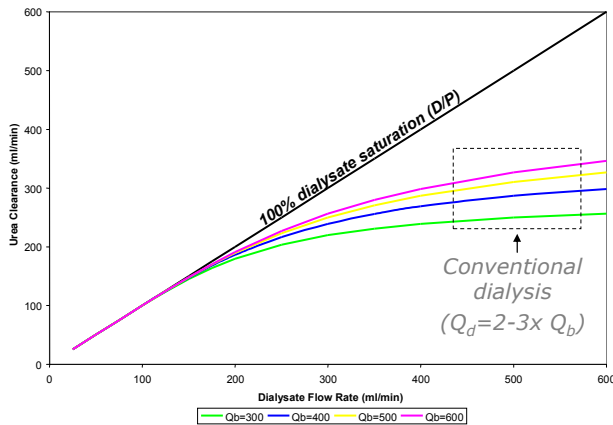


Daily supplies are thrown away; simply wipe down after treatment

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## How the therapy works Turning conventional hemodialysis...

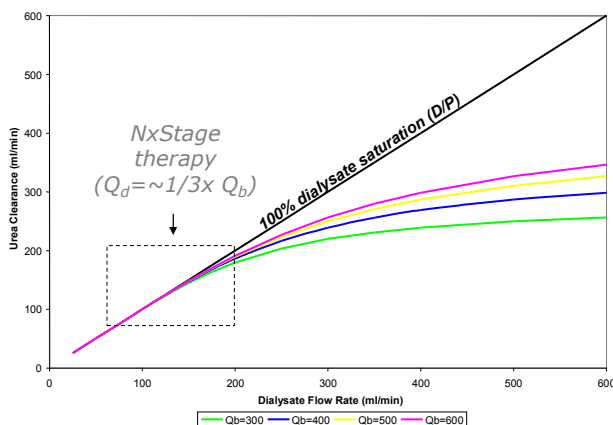


- Water is free, use lots
  - Time and frequency fixed due to in-center constraints
  - Maximize clearance vs. efficiency ( $\Downarrow$  D/P)
  - Run dialysate as quickly as possible
  - **Reliant on high volumes of on-line generated fluid and infrastructure**

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## How the therapy works ...on its head

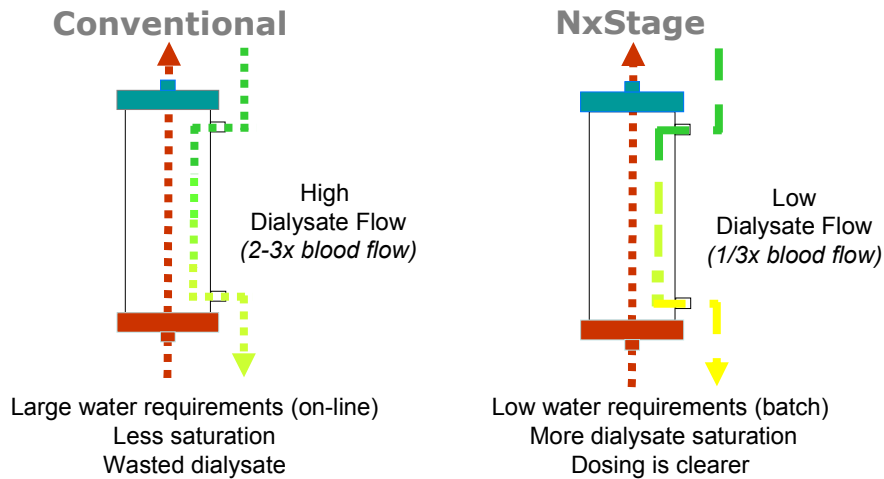


- Dialysate used to its fullest
  - Ratio of dialysate flow to blood flow turned upside down:
    - From: 2 to 3x
    - To: approx. 1/3
  - Dialysate fully saturated ( $\Uparrow$  D/P)
  - Therapy schedule, time adjusted to meet objectives
  - **Allows use of lower fluid volumes & bags (for travel)**

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## Another view of the therapy: “Upside-down dialysis”



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## How NxStage therapy is prescribed

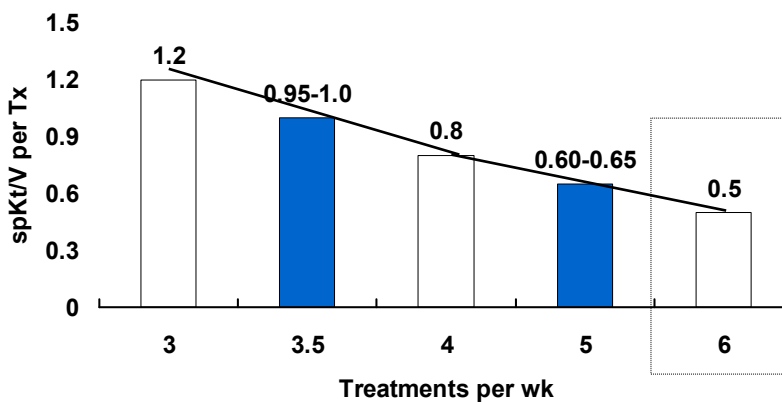
- The doctor prescribes the best dialysis therapy for each patient, based on his/her size and clinical needs
  - *How frequently*
  - *How long*
  - *How much and what kind of dialysate*
  - *What he/she should weigh after treatment*
- To date, most doctors have prescribed “daily” (5 or more times per week) therapy
  - *A “typical” prescription is 6 days per week, 2.5-3 hours per session, 20 to 30 liters of dialysate per session.*



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## Prescribing the therapy: 2006 K/DOQI Kt/V per HD session

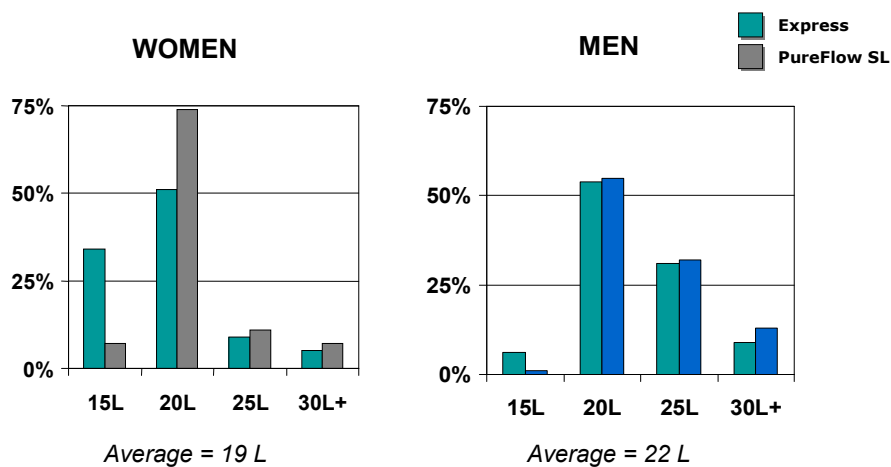


Source: KDOQI Clinical Practice Guidelines 2006 Updates. Defined to achieve stdKt/V > 2.0. Blue bars represent extrapolation not in K-DOQI guidelines.

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## Prescribing the therapy: Fluid volumes per 6x weekly session



Data as of November 2007

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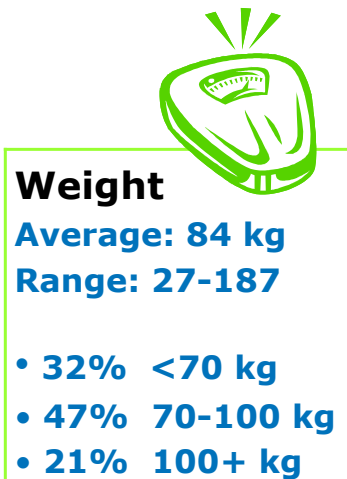
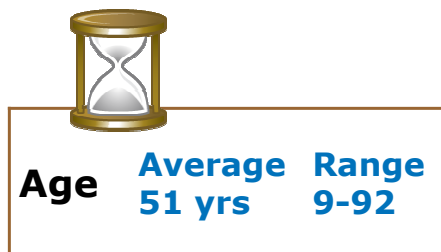
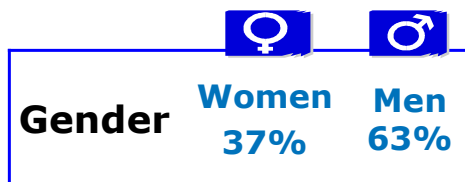
## Therapy time comparisons

|                          | <i>In-center HD</i>             | <i>NxStage home-care</i> | <i>CAPD (4 exch.)</i> | <i>CAPD (5 exch.)</i> |
|--------------------------|---------------------------------|--------------------------|-----------------------|-----------------------|
| Times/week               | 3                               | 6                        | 7                     | 7                     |
| Travel to                | 1 hour                          | --                       | --                    | --                    |
| Preparation              | 1/4 hour                        | 1/2 hour                 | 1/4 hour              | 1/4 hour              |
| Treatment                | 3 1/2 hours                     | 2 1/2 to 3 hours         | 1/2 hour              | 1/2 hour              |
| Wrap-up                  | 1/4 hour                        | <1/4 hour                | <1/4 hour             | <1/4 hour             |
| Travel from              | 1 hour                          | --                       | --                    | --                    |
| Recovery                 | can be high                     | --                       | --                    | --                    |
| <b>Total weekly time</b> | <b>18 hours + recovery time</b> | <b>19 to 22 hours</b>    | <b>22 hours</b>       | <b>29 hours</b>       |

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## NxStage patient characteristics



Data as of December 31, 2007

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## NxStage therapy data

### Access Type

- AV Fistula 63%
- AV Graft 14%
- Catheter 23%



### Sessions/Week



- 6-7 83%
- 4-5 16%
- 3-3.5 <1%

Data as of December 31, 2007

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## NxStage home indication study

- |                     |   |
|---------------------|---|
| Objective           | <ul style="list-style-type: none"> <li>• To demonstrate the NxStage System One is as safe and effective on a per treatment basis in the home setting as in the in-center setting</li> </ul>   |
| Type of study       | <ul style="list-style-type: none"> <li>• 32 patient, crossover study of NxStage hemodialysis therapy in the center vs. at home at 6 clinical sites                             <ul style="list-style-type: none"> <li>- 8 weeks in center</li> <li>- 2 weeks "wash-out"</li> <li>- 8 weeks at home</li> </ul> </li> </ul> |
| Primary endpoints   | <ul style="list-style-type: none"> <li>• Efficacy: dose delivery</li> <li>• Safety: adverse events</li> </ul>   |
| Secondary endpoints | <ul style="list-style-type: none"> <li>• Quality of life, system utility, training time, Kt/V</li> </ul>  |
| Clinical Sites      | <ul style="list-style-type: none"> <li>• Indiana University (Kraus), Satellite Healthcare (Coplon), University of Vermont (Solomon), Wake Forest University (Burkart), University of Iowa (Hegeman), South Valley Dialysis (Kleinman)</li> </ul>  |

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## Efficacy and dose delivery

|                             | Conventional                  | In-Center NxStage                | Home NxStage                     |
|-----------------------------|-------------------------------|----------------------------------|----------------------------------|
| <b>Frequency</b>            | <b>3 times weekly</b>         | <b>6 times weekly</b>            | <b>6 times weekly</b>            |
| <b>Time (hr)</b>            | <b>3.7 ± 0.7</b>              | <b>2.8 ± 0.6</b>                 | <b>2.8 ± 0.6</b>                 |
| <b>Dialysate Volume (L)</b> | <b>n/a</b>                    | <b>18.8 ± 2.9</b><br>(12.5-24.0) | <b>19.2 ± 3.0</b><br>(12.5-24.0) |
| <b>Dry Weight (kg)</b>      | <b>81 ± 15</b><br>(49-107)    | <b>82 ± 15</b><br>(48-112)       | <b>79 ± 17</b><br>(49-115)       |
| <b>spKt/V</b>               | <b>1.7 ± 0.3</b><br>(1.2-2.4) | <b>0.53</b><br>(CI: 0.50-0.57)   | <b>0.54</b><br>(CI: 0.51-0.57)   |
| <b>stdKt/V</b>              | <b>2.4</b>                    | <b>2.3</b>                       | <b>2.3</b>                       |

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## Safety and adverse events

|   | In-Center NxStage<br>(per 100 tx) | Home NxStage<br>(per 100 tx)    |                       |
|---|-----------------------------------|---------------------------------|-----------------------|
| <b>Adverse Events</b>                     | <b>5.31</b><br>(3.58 - 7.88)      | <b>2.14</b><br>(1.26 - 3.66)    | <b><i>p=0.007</i></b> |
| <b>Anticipated Treatment Observations</b> | <b>27.21</b><br>(16.54 - 44.75)   | <b>20.15</b><br>(9.84 - 41.26*) | <b><i>p=0.16</i></b>  |

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## NxStage home indication study: *Improvements in daily dialysis at home*

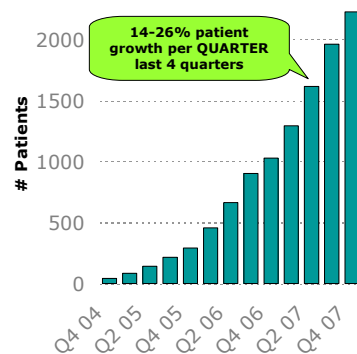
- Published
  - **A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease**
    - Kraus, et al; Hemodial Int. 2007 Oct;11(4):468-77
- Adverse Events, Home versus In-Center
  - Adverse events/100 treatments were significantly lower Home versus In-Center (2.1 vs. 5.3, P=0.007)
- Rapid reduction in BP and BP Meds (retrospective)
  - Mean systolic lower by 23.9 mmHg (P<0.0001)
  - Mean diastolic lower by 6.9 mmHg (P=0.01)
  - Mean pulse pressure lower by 17.1 mmHg (P<0.0006)
  - **83% patients reduced hypertensive med dose**
    - **33% eliminated hypertensive med requirements completely**

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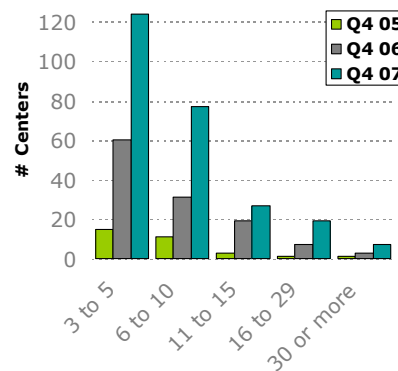
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## Usage of NxStage is growing quickly

### Strong NxStage Patient Growth



### Centers increasing HHD depth



Data as of December 31, 2007

# Patients

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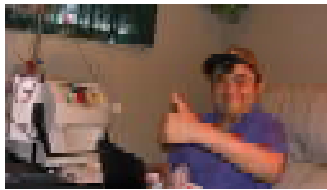
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## NxStage patient experience



- Over 2,482 patient years experience to date

- Tenure of active patients:
  - 1,360 patients at 6+ months
  - 711 patients at 1+ years
  - 144 patients at 2+ years
  - 22 patients at 3+ years
  - 2 patients at 4+ years



Data as of December 31, 2007

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## What's on the horizon?

- Renewed focus and interest in home HD from a manufacturer perspective:
  - Fresenius acquired Renal Solutions
  - Baxter partnering with DEKA, who owns Akysis IP
  - XCorporeal is developing a 'wearable' device
- Renewed focus and interest by providers, managed care companies, and CMS:
  - Fewer hospitalizations and lower overall costs than in-center HD<sup>1, 2, 3</sup>
  - Medicare bundling concept may benefit home dialysis therapies, especially home HD
- Home HD will continue to grow...the future is exciting!

<sup>1</sup> Dr. Peter Crooks, Medical Director-Kaiser Permanente Southern California: Quote in *San Mateo County News* (San Mateo, CA); 2/24/08

<sup>2</sup> "Kaiser Permanente launches HOME FIRST dialysis initiative", *Nephrol News Issues*. 2005 June; Vol. 19 No. 7: 36, 76.

<sup>3</sup> "Home Dialysis: The Future is Now", Borg D, et al. 28<sup>th</sup> ADC Abstracts; *Hemodialysis International*, Vol. 12 No. 1, 2008.

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## Home HD program best practices



- Commitment to successful initiation requires:
  - The **desire** to market and build a program
    - A **champion physician**
    - **Nursing enthusiasm** and patience
    - Administration's **leadership** and **vision**
  - A willingness to build **community among patients** – they are part of something special
    - Clinic visits
    - Get-togethers

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## More best practices

- Dedicated, enthusiastic, head training nurse
- Engaged & accessible nephrologist
- Strong cooperation on patient selection/care
- Good use of adult learning concepts
- Committed training resources – people, space, tools
- Assure patient & partner readiness

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## More best practices

- Adaptable training plan
- Support in transitioning home
- Clear expectations for patient & partner
- Patient support & community building efforts
- Patient awareness efforts once program foundation is established

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## Conclusions

- More frequent, home HD is gaining more visibility and is growing once again
  - Patients and clinicians are realizing the clinical and lifestyle benefits of more frequent hemodialysis
  - New technologies are making home HD a reality for more patients and future technologies are exciting
  - Payers and providers are seeing the benefits of offering more frequent, home HD
- Home HD programs can be successful with a committed staff, established policies, and good practices
- The future is bright for continued HHD growth

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