

# **Home Dialysis**

## **Coming to a Home near You**

**John A. Sweeny**

**NANT**

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# 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 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

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

\* Total includes dialysis patients who's dialysis therapy was unknown

# Top 10 Providers - 2010

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

# Home Dialysis – Top 10 Providers

YEAR	HD	INC./% INC.	PD	INC./% INC.
2008	2,321	-----	20,474	-----
2009	2,836	515/22 %	20,690	216/1 %
2010	3,569	733/26 %	23,159	2469/12 %

# 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%

Edmund G. Lowrie, M.D., et al, *Survival of Patients Undergoing Chronic Hemodialysis and Renal Transplant*, N Engl J Med 1973; 288:863-867



# 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.

“New Study cites higher mortality rate among for-profits” , Nephrology News and Issues, Vol 24, Issue 13, Jan 2011, p. 11.

# PD survival better than HD

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

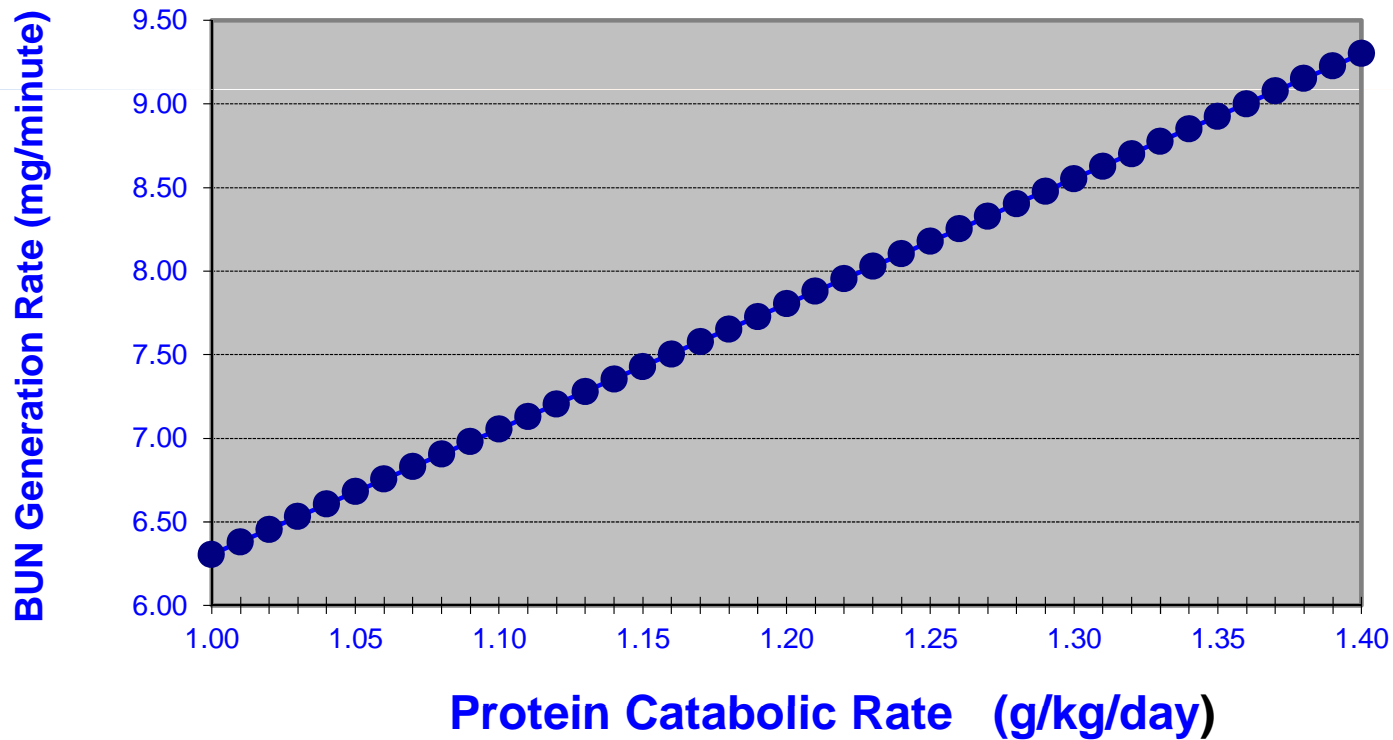
Months on Tx	PD	HD	P
12	85.5%	80.7%	0.01
24	71.1%	68.0%	0.01
36	58.1%	56.7%	0.25
48	48.4%	47.3%	0.50

- 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

PD survival better than HD patients, Journal of the American Society of Nephrology, abstract in Nephrology News and Issues, Vol 25 No 10, December 2010, p 20

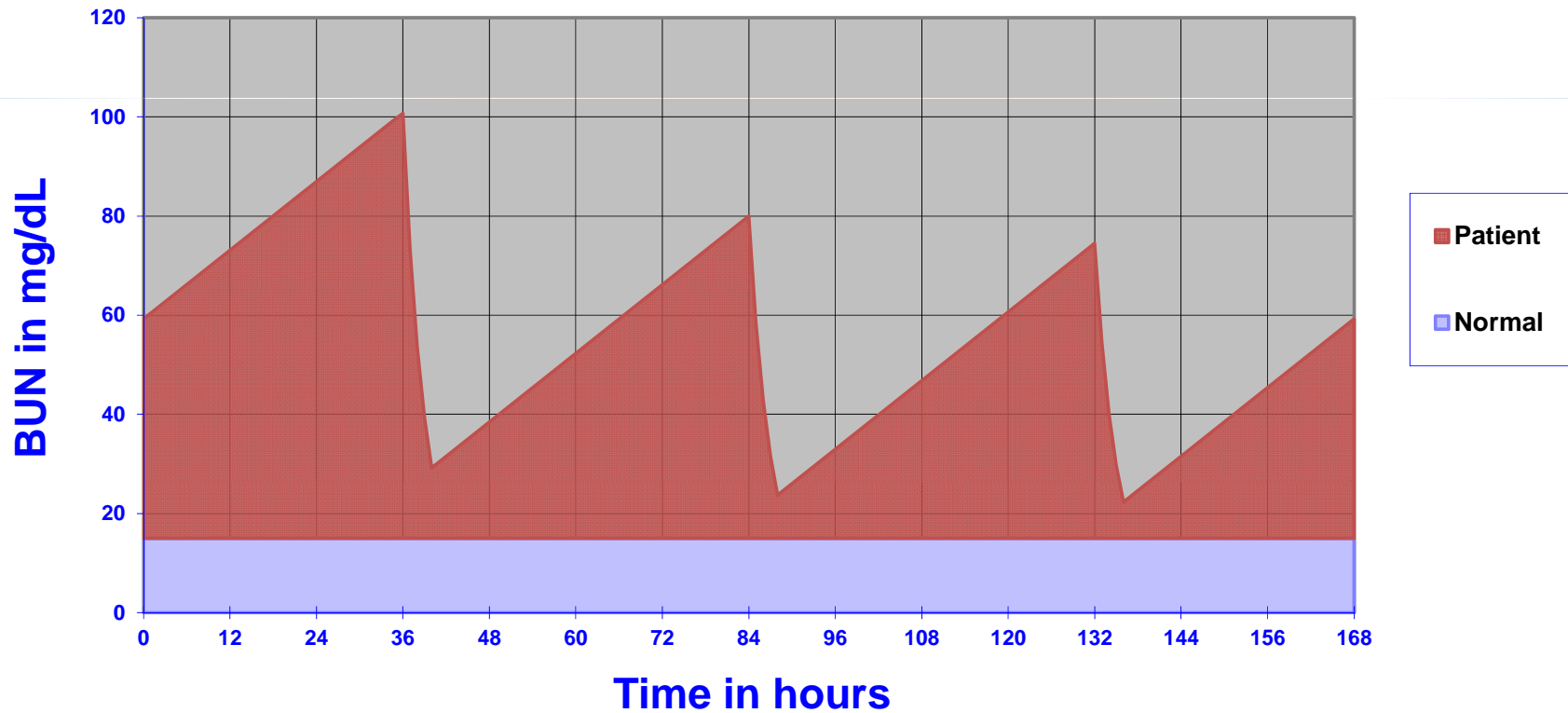
# Patient Urea Dynamics

**BUN Generation Rate vs. Protein Catabolic Rate**

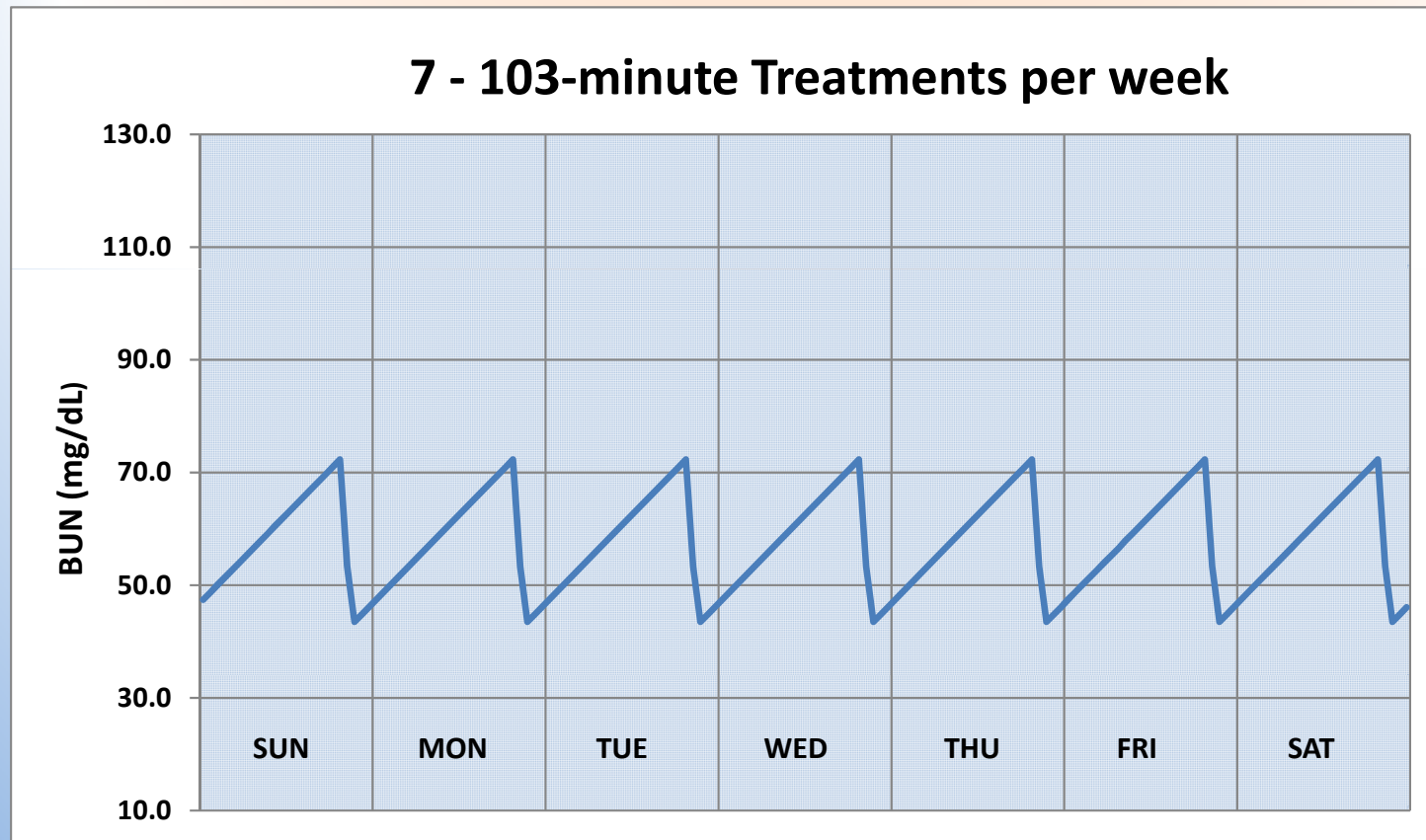


# Toxin Fluctuation over one Week (Three treatments weekly)

## Patients's BUN for the Week



# Patient Toxin Fluctuations over one Week





# Dialysis Frequency Effect on Standard Kt/V

- End of treatment patient weight = 85 kg
- Patient height = 178 cm
- Patient age = 60 years
- Weight loss per week = 4.0 kg
- Weight loss per treatment =  $4.0 \text{ kg} \div \text{Tx per week}$
- Single pool Kt/V for the week = 3.9
- Individual treatment Kt/V =  $3.9 \div \text{Tx per week}$
- 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](http://www.hdcn.com/calcf/ley.htm)

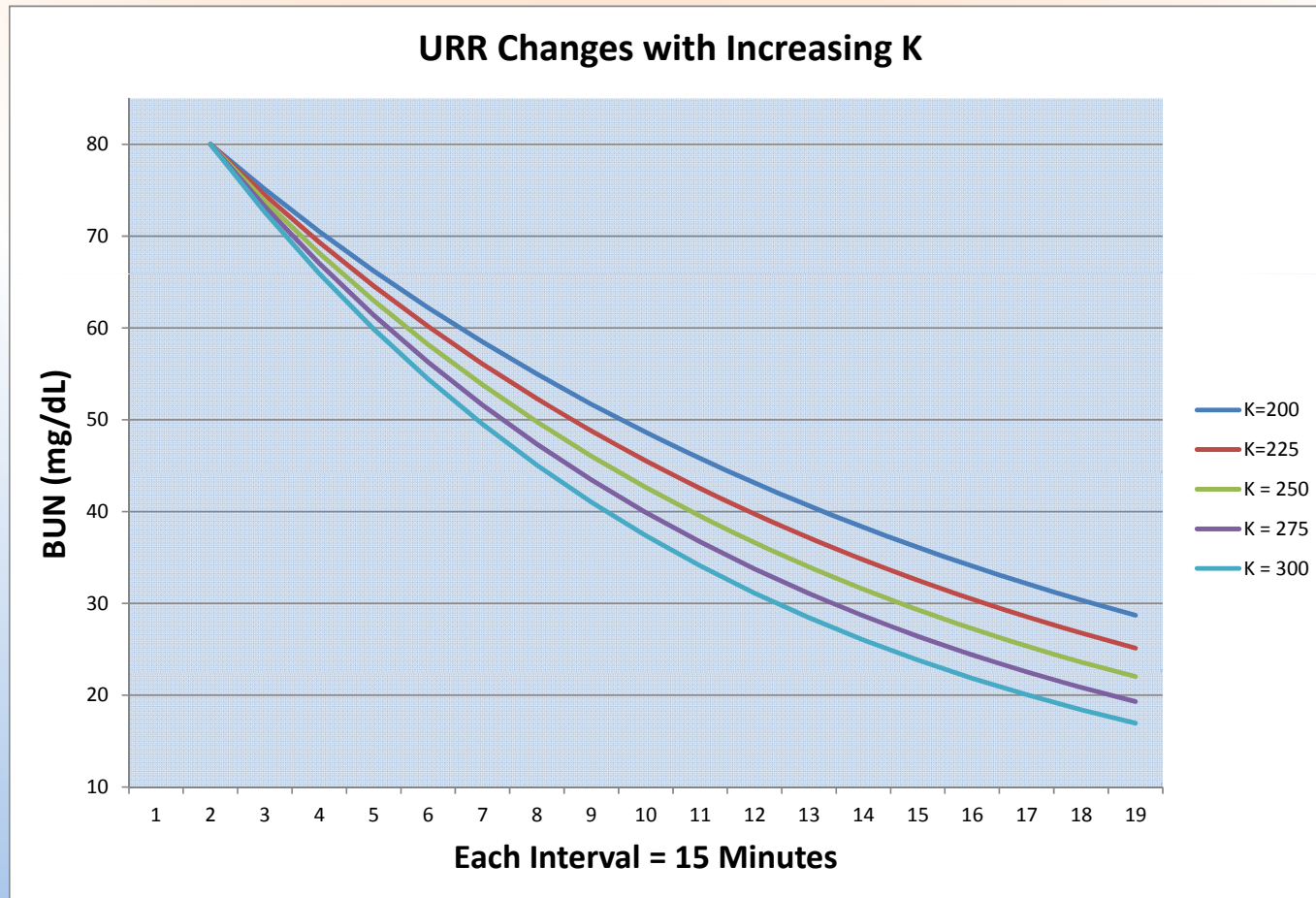
# Dialysis Frequency Effect on Standard Kt/V

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

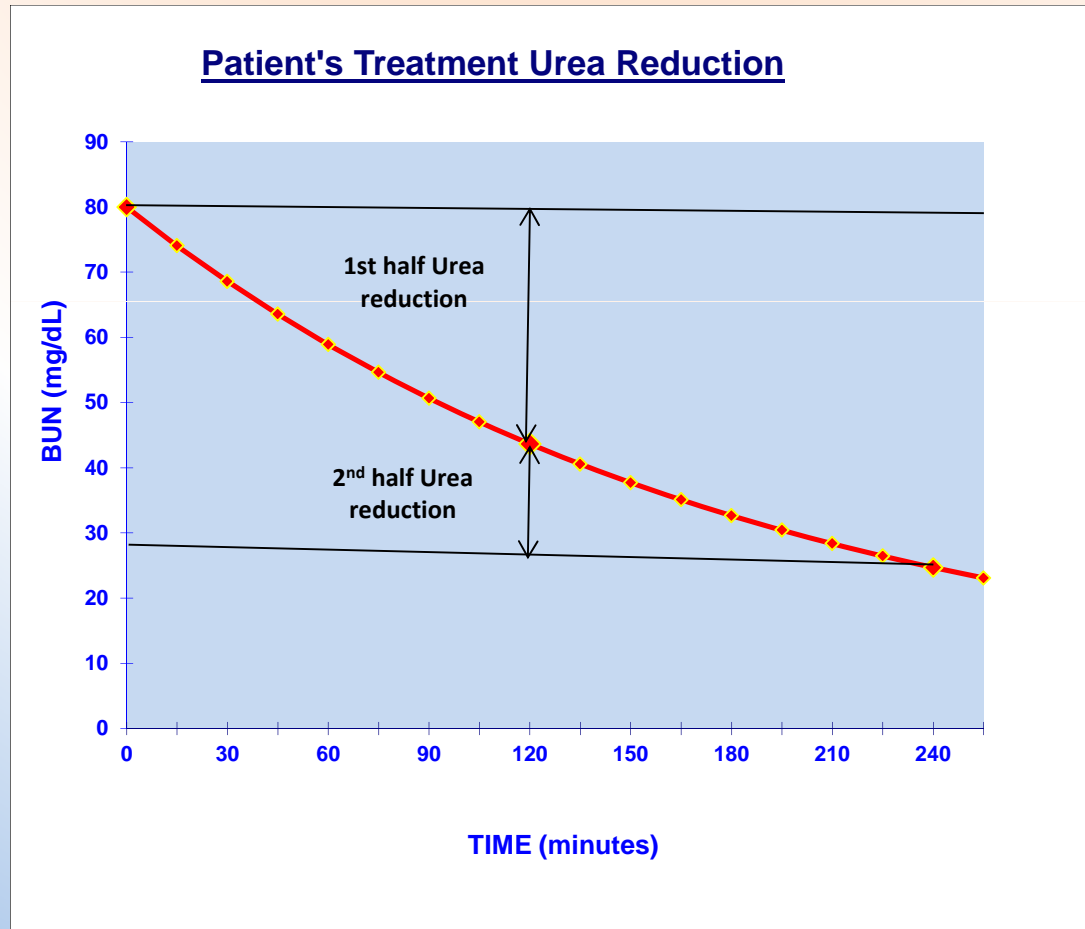
LFV = Leypoldt Fixed Volume, FHN = Frequent Hemodialysis Network, SAN = Surface Area Normalized

[www.hdcn.com/calcf/ley.htm](http://www.hdcn.com/calcf/ley.htm)

# Increasing Clearance effect on final Urea



# URR during a treatment



# URR Treatment Comparison

## 1<sup>st</sup> Half vs. 2<sup>nd</sup> Half

	K = 200 (mL/min)	K = 225 (mL/min)	K = 250 (mL/min)	K = 275 (mL/min)	K = 300 (mL/min)
spKt/V	1.0805	1.2154	1.3504	1.4855	1.6205
Urea Reduction 1 <sup>st</sup> Half (mg/dL)	31.4	34.5	37.4	40.1	42.6
Urea Reduction 2 <sup>nd</sup> Half (mg/dL)	18.3	18.8	19.0	19.1	19.0
1 <sup>st</sup> Half % of Total Reduction	63.2%	64.7%	66.3%	67.8%	69.2%

# 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 m<sup>2</sup>), 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

CHEMICAL	Nocturnal HD (mmol)	Conventional HD mmol
Urea	1856 ± 413	1636 ± 301
Creatinine	63.75 ± 31.78	60.04 ± 44.16
Phosphate	150 ± 47	82 ± 22
$\beta_2$ Microglobulin	52.13 ± 10.6	12.14 ± 2.09

Pierratos A., et al; Nocturnal Hemodialysis: Three-Year Experience; J of Am Soc of Neph; Vol 9, Issue 5, May 1998; pp. 858-868

# 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<sup>®</sup> Freedom Study

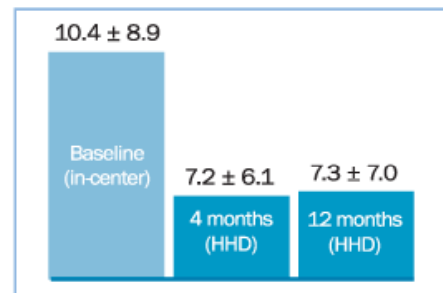
- **F**ollowing **R**ehabilitation **E**conomics and **E**veryday-**D**ialysis **O**utcome **M**easurements study
- Compares traditional, thrice-weekly in-center HD to more frequent home HD
- 500 short daily HHD patients matched to 5,000 in-center HD patients from the US Renal Data System
- Measured parameters:
  - Recovery time
  - Sleep quality
  - Quality of life
  - Anti-hypertensive medication use
  - Depressive symptoms
  - Mortality rate
  - Restless legs syndrome

# NxStage® Freedom Study – Depression Score

## FREEDOM Study

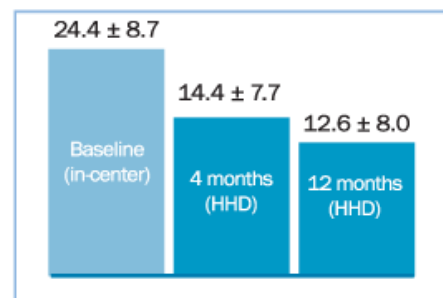
### Beck Depression Inventory Score

(P=0.0005; n=68)



### Beck Depression Inventory Patients with BDI >15 at Baseline

(P=0.0001; n=14)



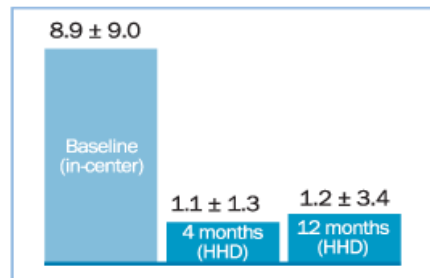
- Patients serve as their own control, completing recovery time data at baseline (in-center therapy) and after 4, 12, and every subsequent 6 months on HHD<sup>3,4</sup>
  - Baseline BDI scores did not differ significantly between patients who dropped out (11.5 ± 9.0) and those who completed 12-month follow-up (12.6 ± 10.1), P=NS<sup>1</sup>
- BDI is a validated and widely used measurement instrument for depressive symptoms<sup>5-8</sup>
- 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<sup>1</sup>
- Improvements in depressive symptoms seen at 4 months were maintained at 12 months<sup>1</sup>
- Improvements were even more dramatic (~50% improvement at 12 months) for patients with higher BDI at baseline<sup>1</sup>
- BDI scores >15 have been found to be highly correlated with diagnosis of depression<sup>9</sup>

# NxStage<sup>®</sup> Freedom Study – Recovery Time

## FREEDOM Study

### Recovery Time in Hours

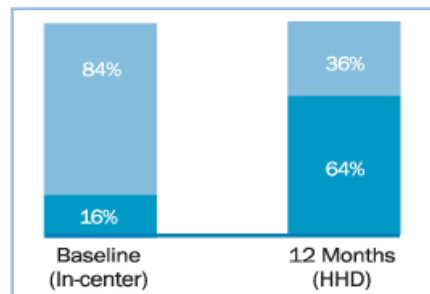
(P<0.0001; n=55)



- 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<sup>3,4</sup>
- 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<sup>5</sup>
- Recovery time improvements seen at 4 months were maintained at 12 months<sup>1</sup>

### Distribution of Time to Recovery (TTR)

(P<0.0001; n=55)



- At in-center baseline, only 16% of patients had post-treatment recovery time <60 min.<sup>1</sup>
- At 12-month follow-up, 64% of patients had post-treatment recovery time <60 min.<sup>1</sup>

■ % Patients with TTR ≥ 60 min.  
■ % Patients with TTR < 60 min.



# 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  $\$229.63 \times 13 = \$2985.19$  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%

# Future Developments

- Home Dialysis Plus – received \$50 million dollars June 16<sup>th</sup> 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”*