

**ESRD Modalities:  
Questions for 2011  
and Beyond**

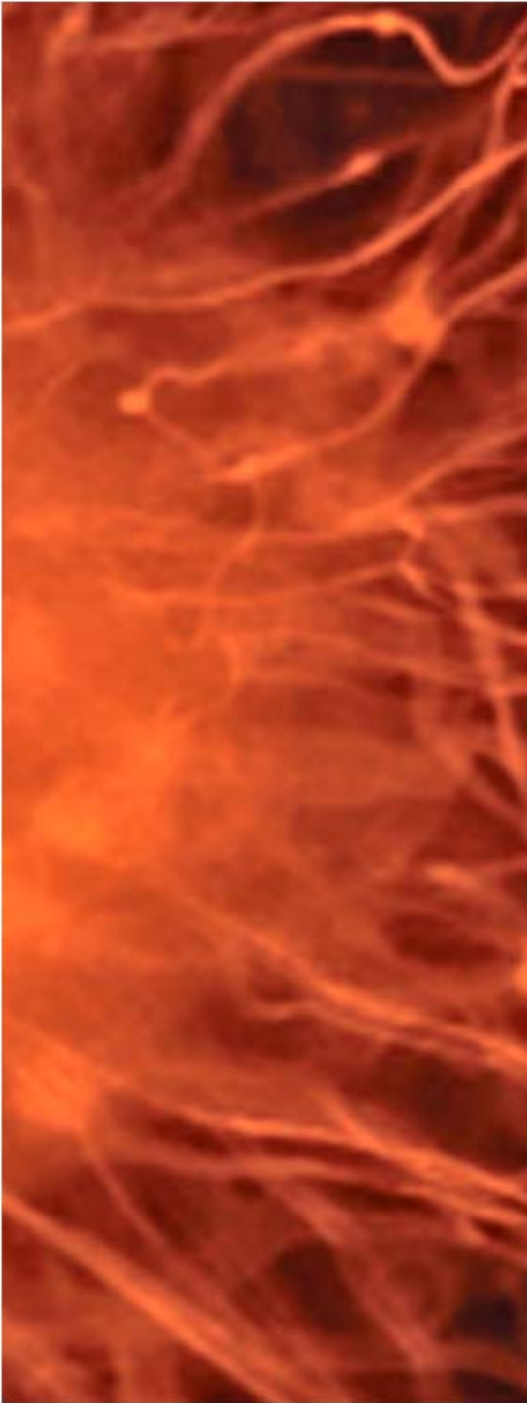
# Disclosures

- Amit Sharma MD, FACP, FASN, President of Boise Kidney and Hypertension
  - Liberty Dialysis (Consultant)
  - Fresenius (Consultant)
  - Amgen (Consultant)
  - AMAG (Consultant)
  - Genzyme (Consultant)
  - Abbott (Consultant)
  - Nephrian (Consultant)

# Objectives:

## “Just the Facts on Modalities”

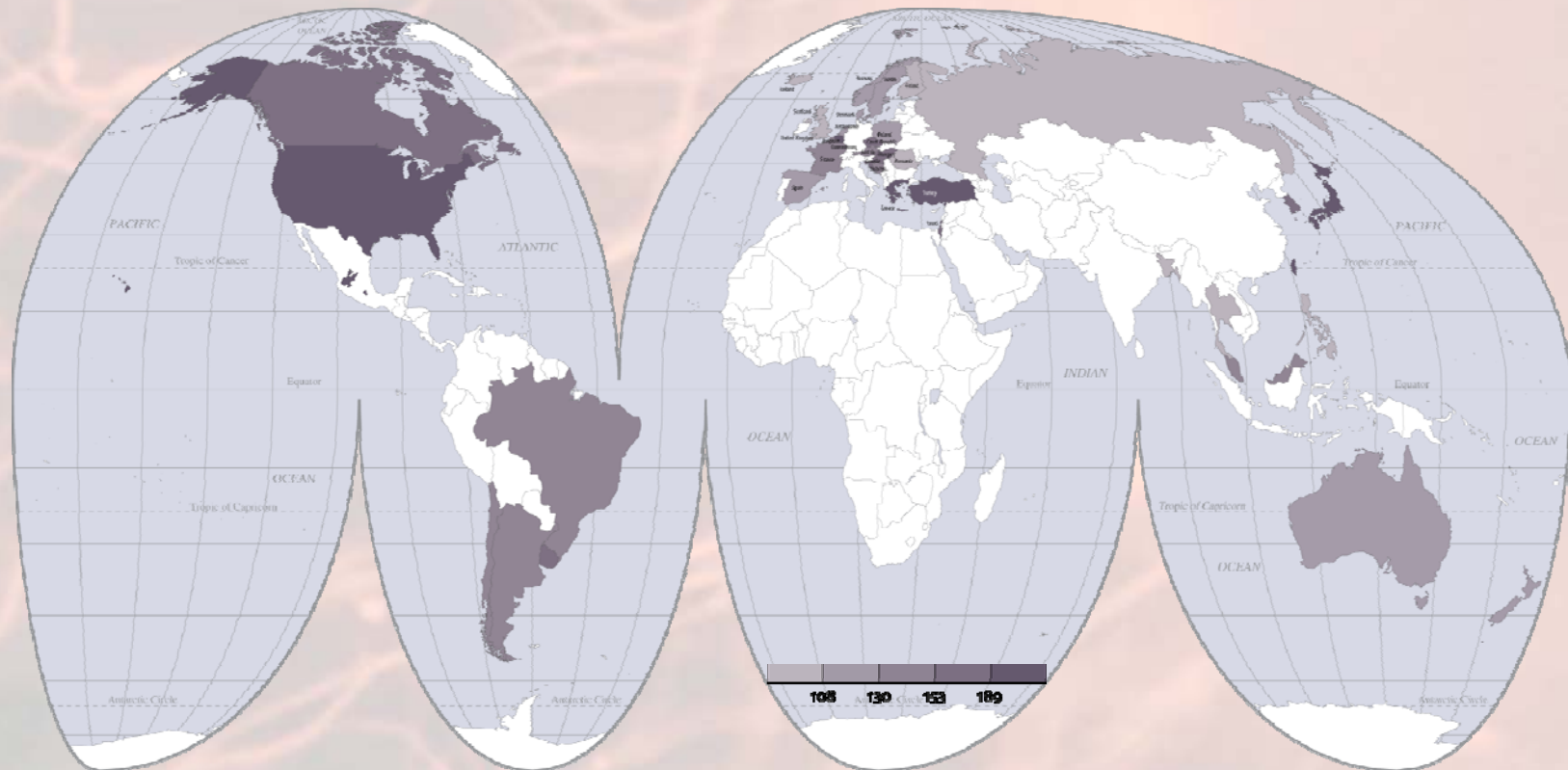
- Review Epidemiology in End Stage Renal Disease Modalities: Worldwide and United States
- Understand the Implications of the New Bundled Environment for Policy and Implementation of Best Practices
- Review the current Medical Literature on Modalities
- Predict the Potential Trends for Modalities for this Decade



Question one:  
What is the Worldwide  
Experience with Renal  
Replacement Therapy?



# Geographic variations in the incidence (per million population) of ESRD, 2008



Data presented only for those countries from which relevant information was available. All rates are unadjusted. Data from Bangladesh, Brazil, Czech Republic, Japan, Luxembourg, & Taiwan are dialysis only. Latest data for Hungary are for 2007. Data for France include 18 regions in 2008. **USRDS 2010**

# Incident rates per million population of reported ESRD in 2008

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|                         |     |
|-------------------------|-----|
| ● Morelos (Mexico)      | 557 |
| ● Jalisco (Mexico)      | 400 |
| ● Taiwan                | 384 |
| ● United States         | 362 |
| ● Japan (dialysis only) | 288 |
| ● Canada                | 164 |
| ● France                | 146 |
| ● Australia             | 116 |

# Percentage of incident patients with ESRD due to diabetes 2008

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- Morelos (Mexico) 59.8%
- Malaysia 55.8%
- Jalisco (Mexico) 54.6%
- United States 43.8%
- Canada 34.2%
- France 22.5%
- Australia 34%

# Prevalent rates per million population of reported ESRD in 2008

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|                 |       |
|-----------------|-------|
| ● Taiwan        | 2,311 |
| ● Japan         | 2,126 |
| ● United States | 1,752 |
| ● Canada        | 1,096 |
| ● France        | 1,052 |
| ● Australia     | 803   |



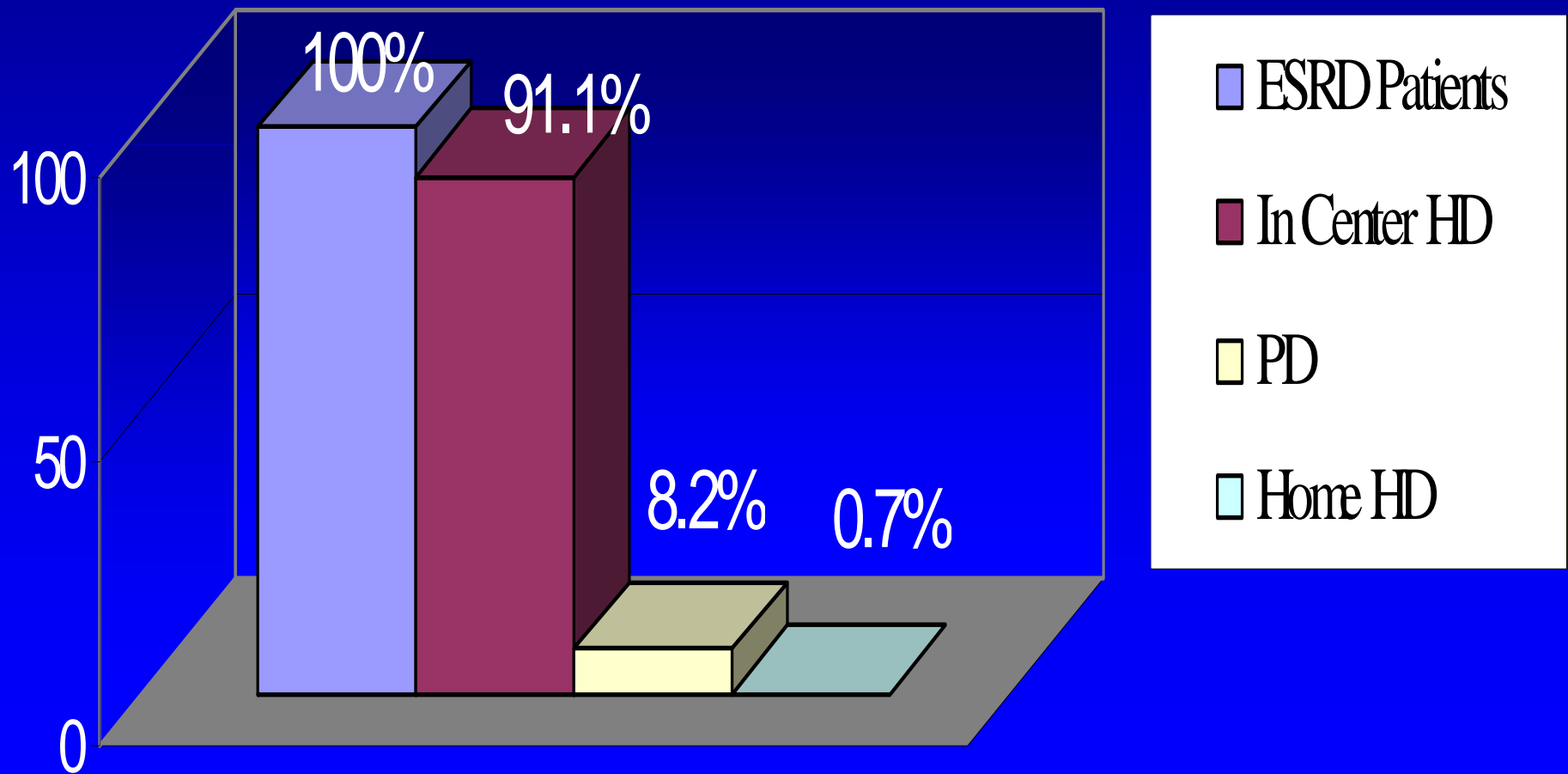
# Percentage of dialysis patients by modality in 2008

|               | In center | Peritoneal | Home HD |
|---------------|-----------|------------|---------|
| Taiwan        | 90.7%     | 9.3%       | 0%      |
| Japan         | 96.9%     | 3.1%       | 0.04%   |
| United States | 92%       | 7%         | 1%      |
| Canada        | 78.3%     | 18.4%      | 3.3%    |
| France        | 87.8%     | 10.9%      | 1.3%    |
| Australia     | 68.6%     | 22%        | 9.4%    |
| New Zealand   | 48.1      | 36%        | 15.6%   |

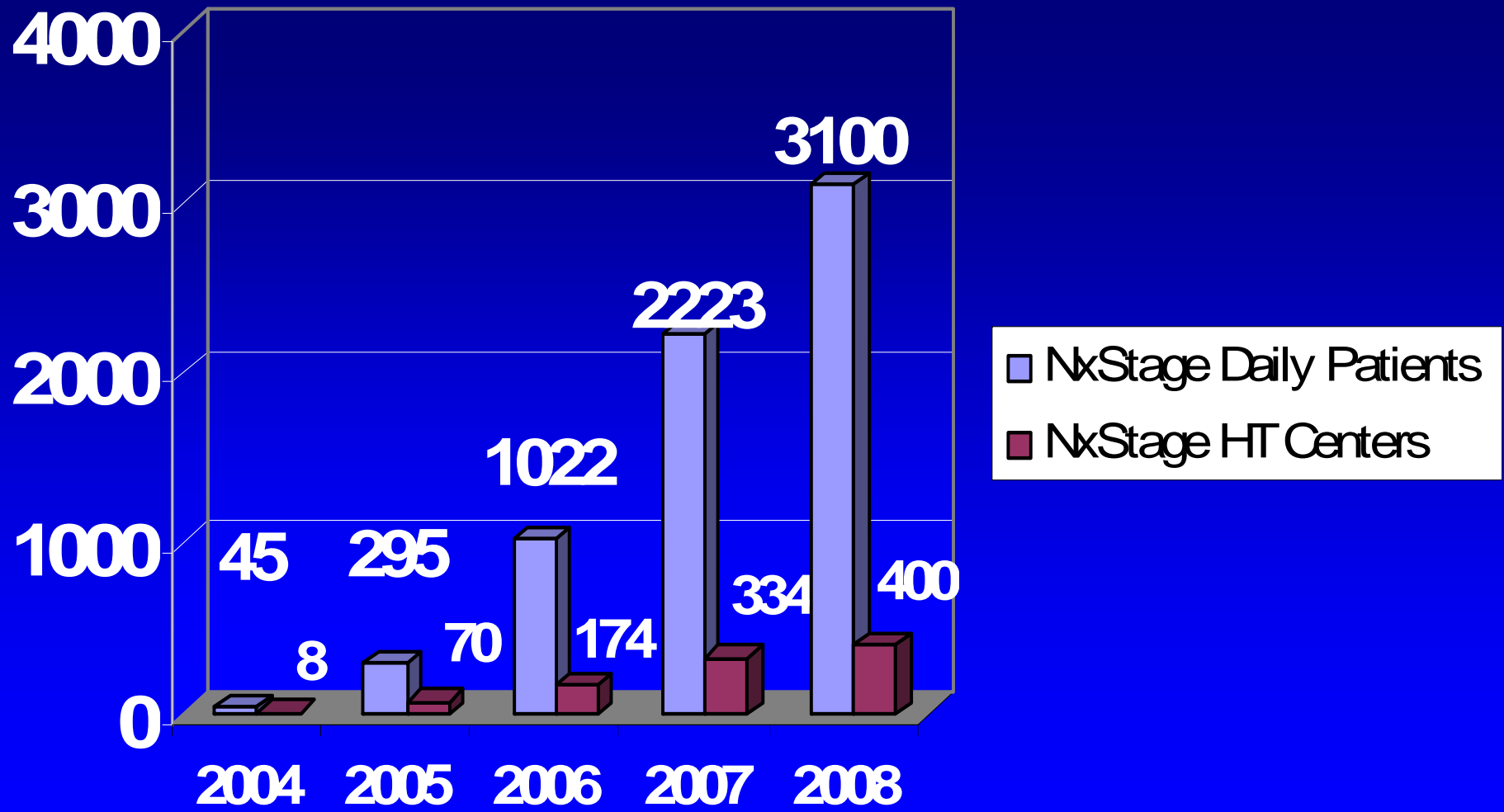


**What is happening  
concerning renal  
replacement modalities in  
the US?**

# US Network Data 2006

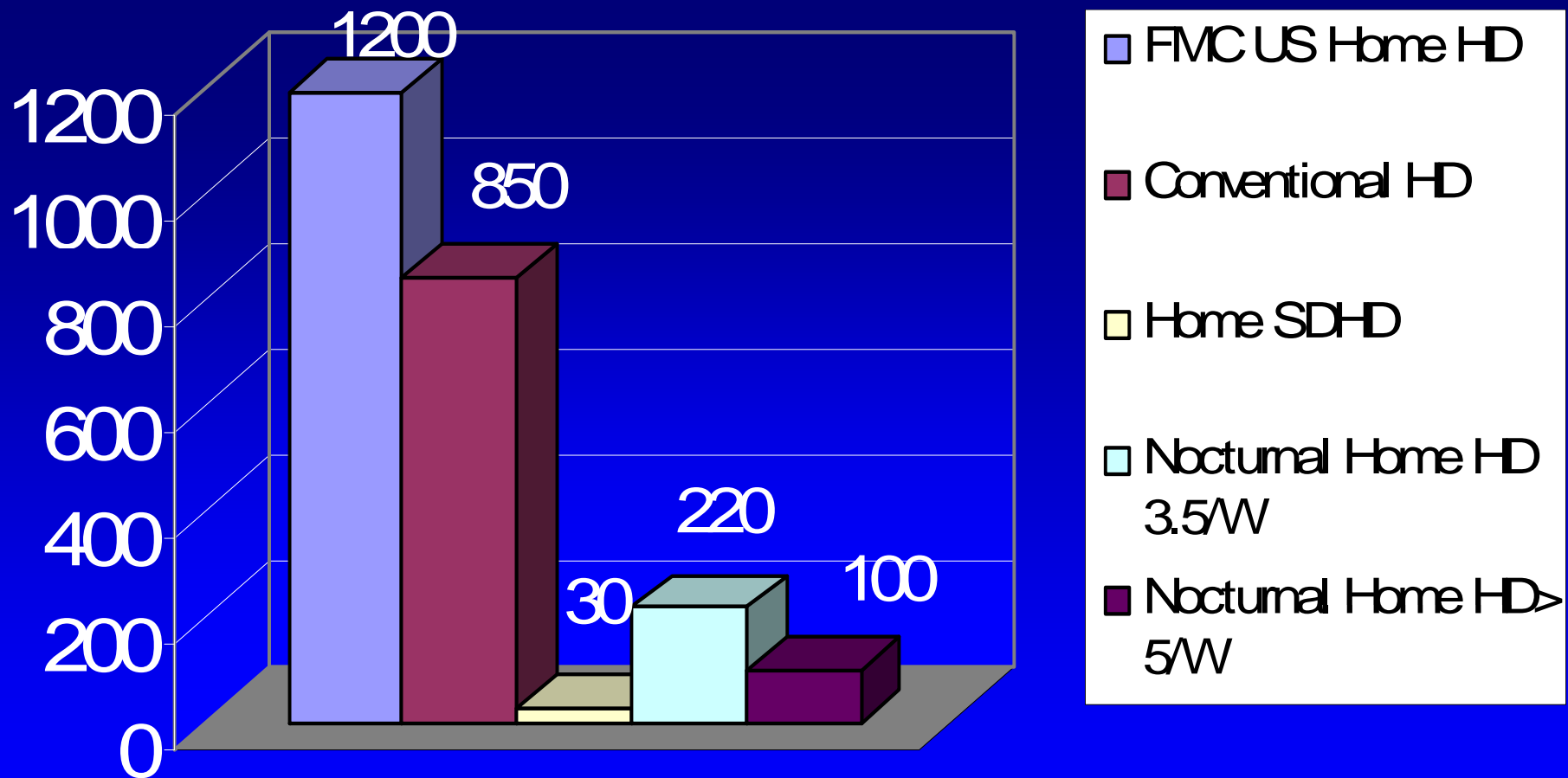


# NxStage Growth 2004 to 2008

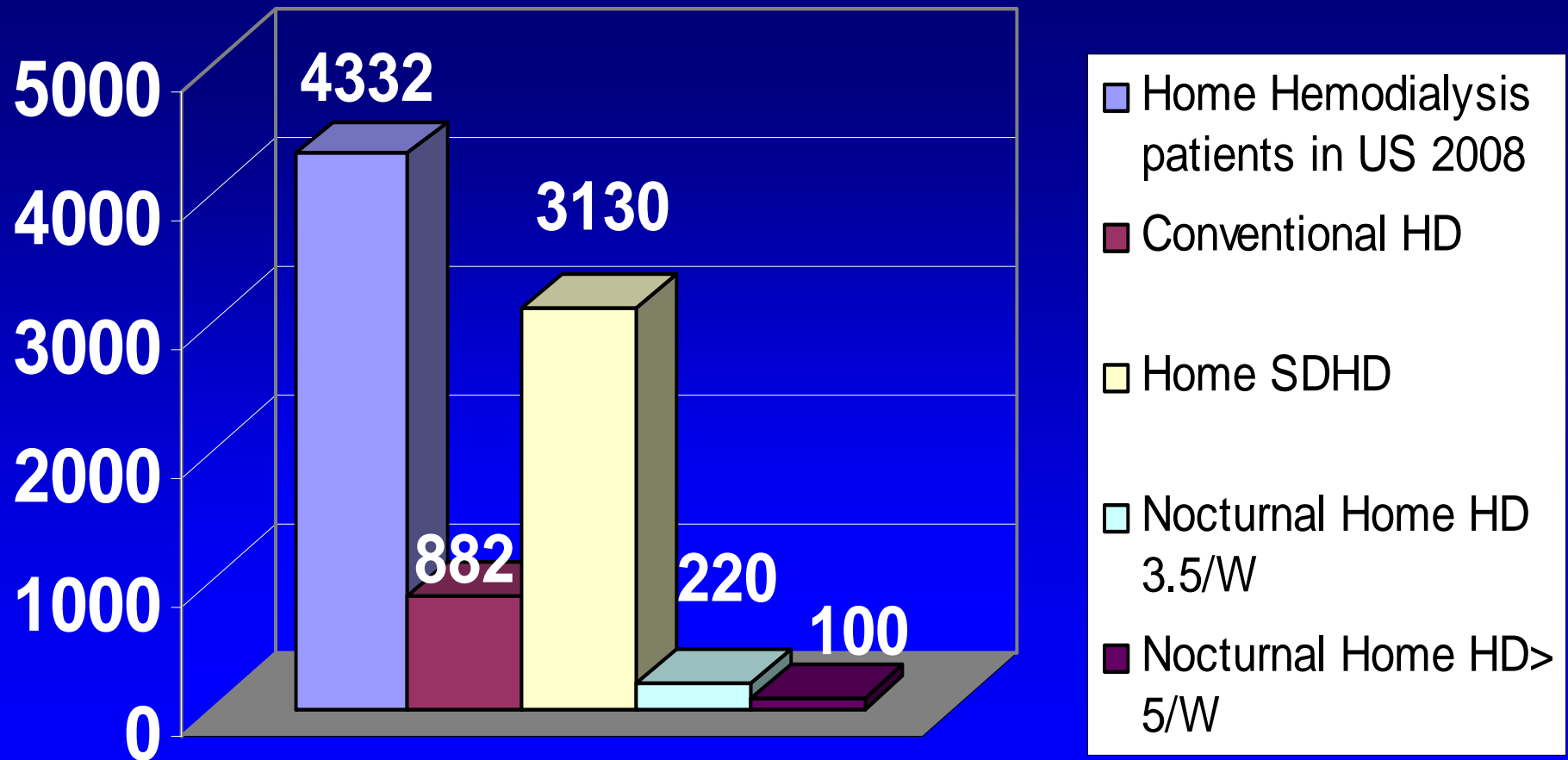




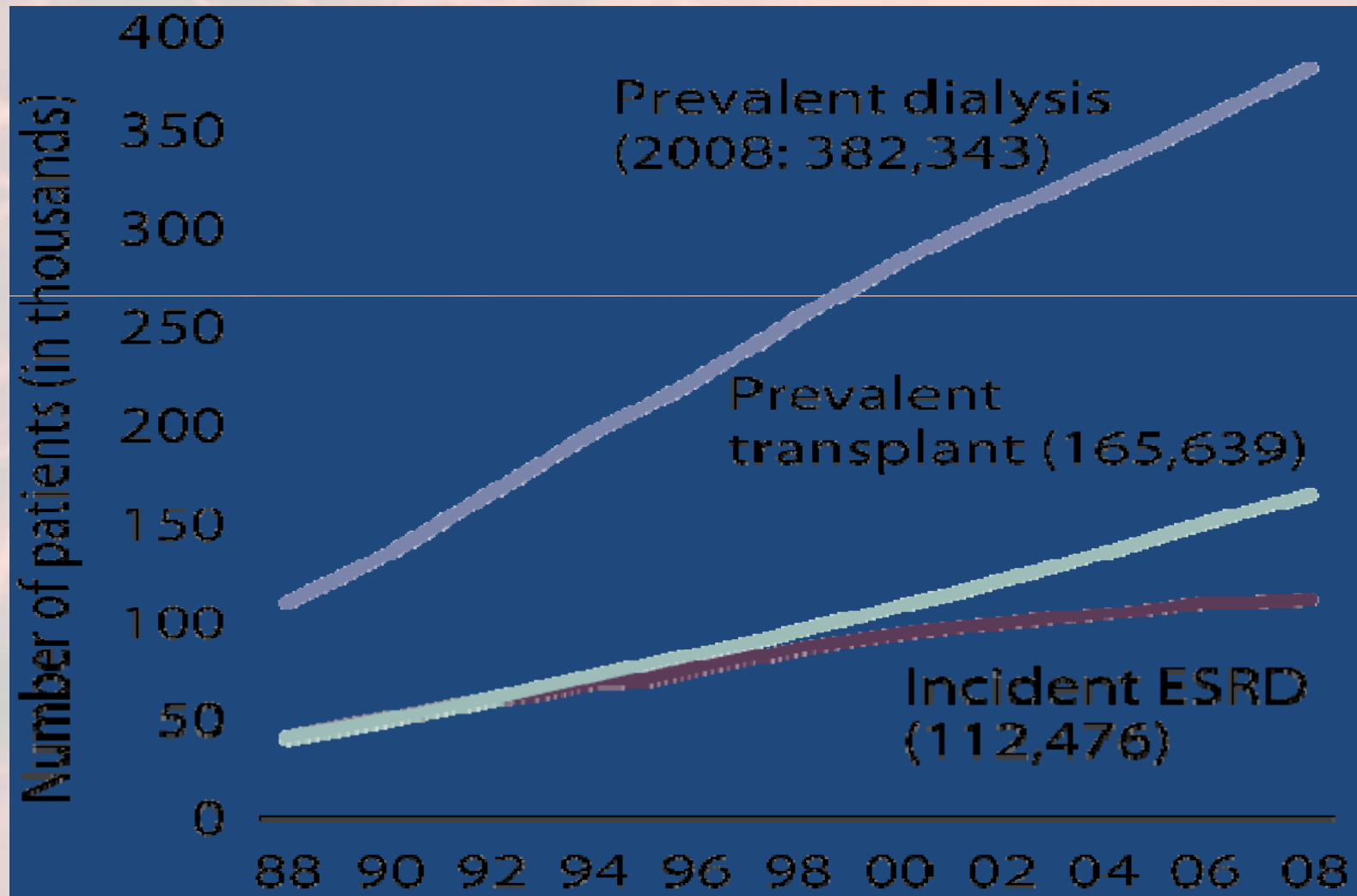
# US Fresenius Home HD 2008



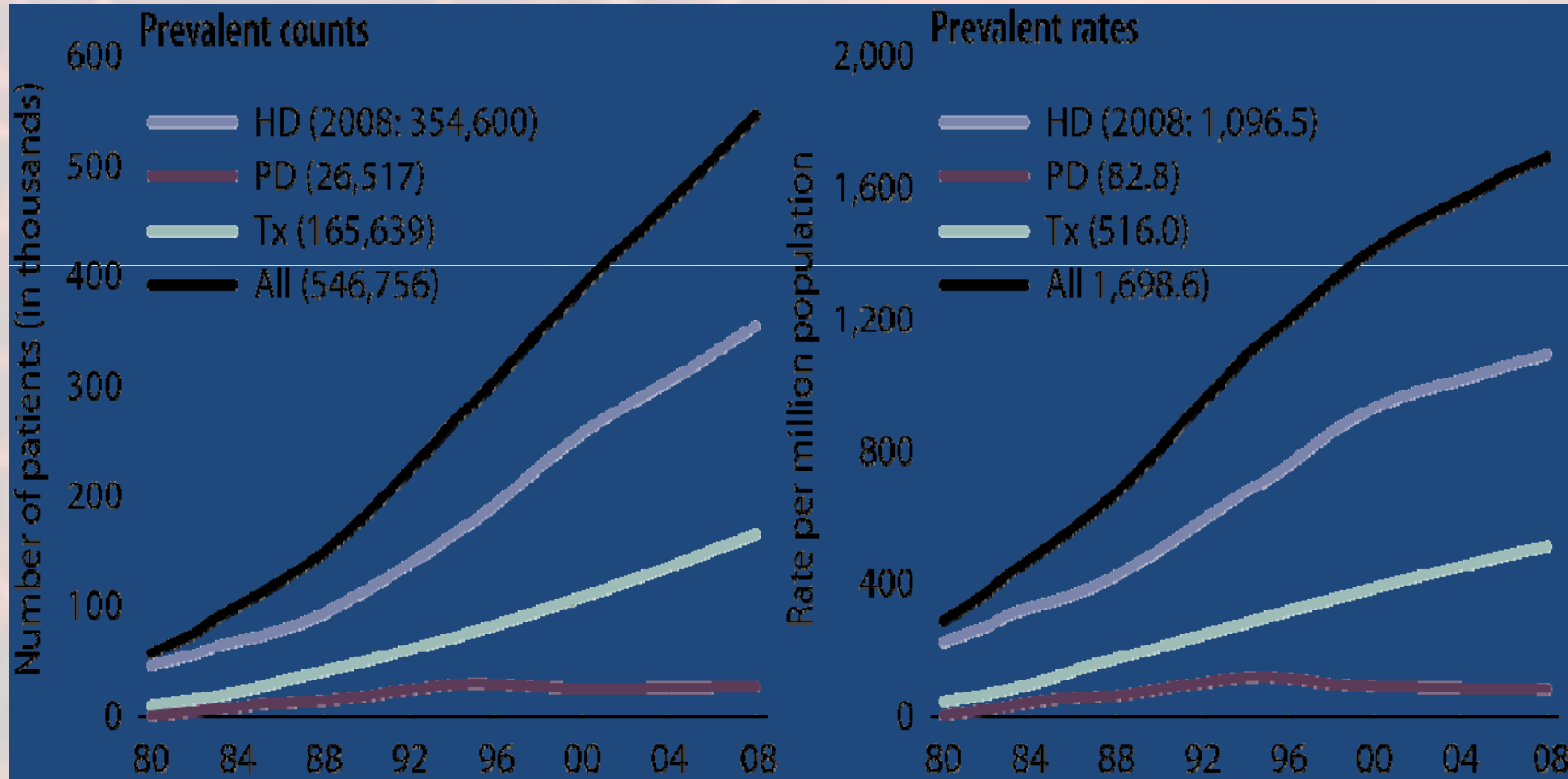
# Home Hemodialysis Patients in US 2008



# Patient counts by modality 12-31-08



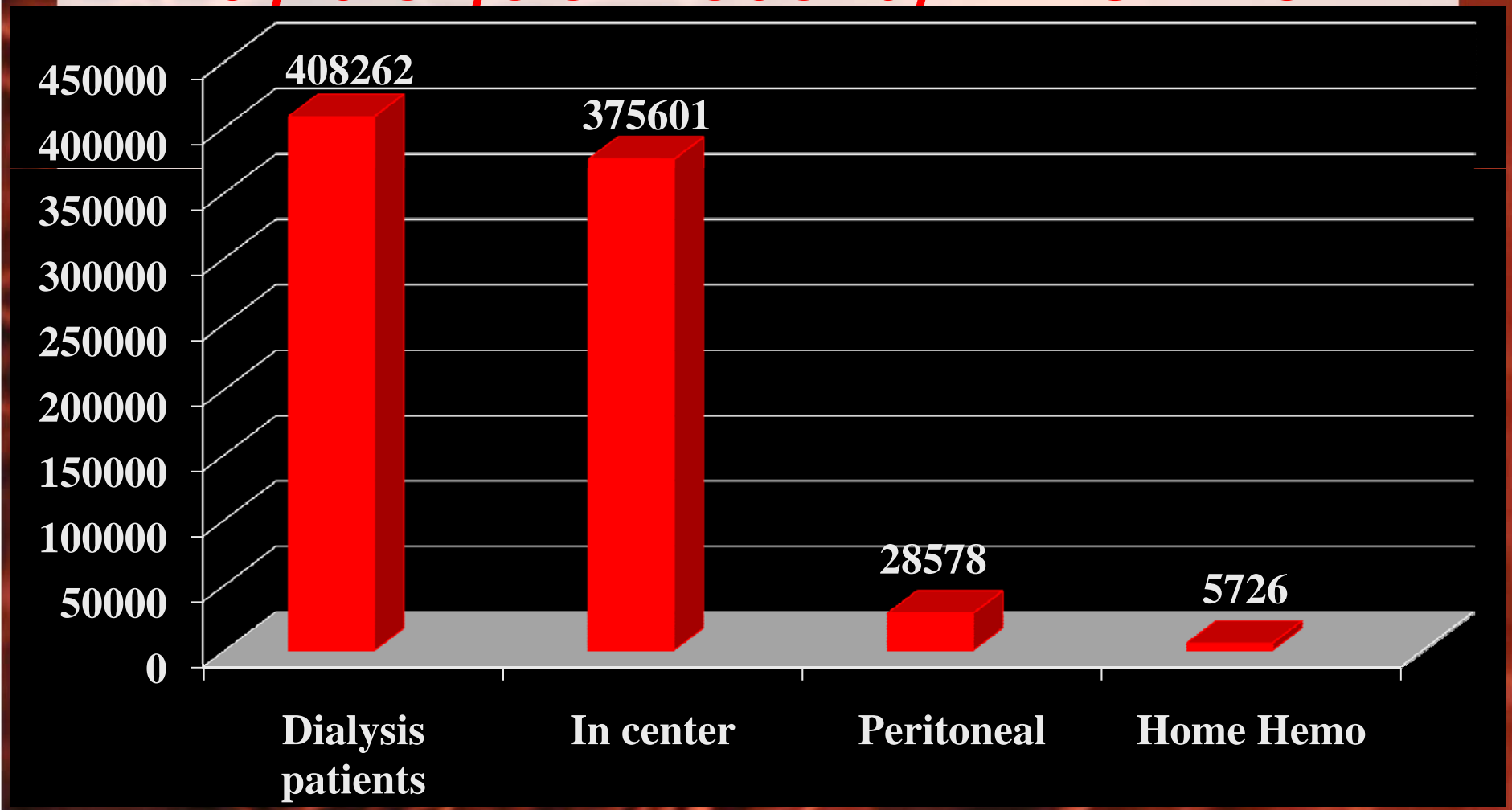
# Prevalent ESRD patient counts & rates by modality 12-31-08



December 31 point prevalent ESRD patients; excludes those with unknown modality. Rates adjusted for age, gender, & race. **USDRS 2010**



# Estimated prevalent patient counts in US by dialysis modality 12-31-10





**Will the bundle change  
where we are going?**

**“WE BELIEVE THAT BY PROVIDING ONE BASIC PAYMENT RATE UNDER THE ESRD PPS FOR BOTH PD AND HD, FACILITIES WILL HAVE A POWERFUL FINANCIAL INCENTIVE TO ENCOURAGE THE USE OF HOME PD AMONG DIALYSIS PATIENTS WHERE FEASIBLE”**

**DEPARTMENT OF HEALTH AND HUMAN  
SERVICES  
CENTERS FOR MEDICARE & MEDICAID  
SERVICES, 42 CFR PART 410, 413 AND 414,  
[CMS-1418-F], RIN 0938-AP57; PAGE 448**

# The Bundle: Payment for home HD

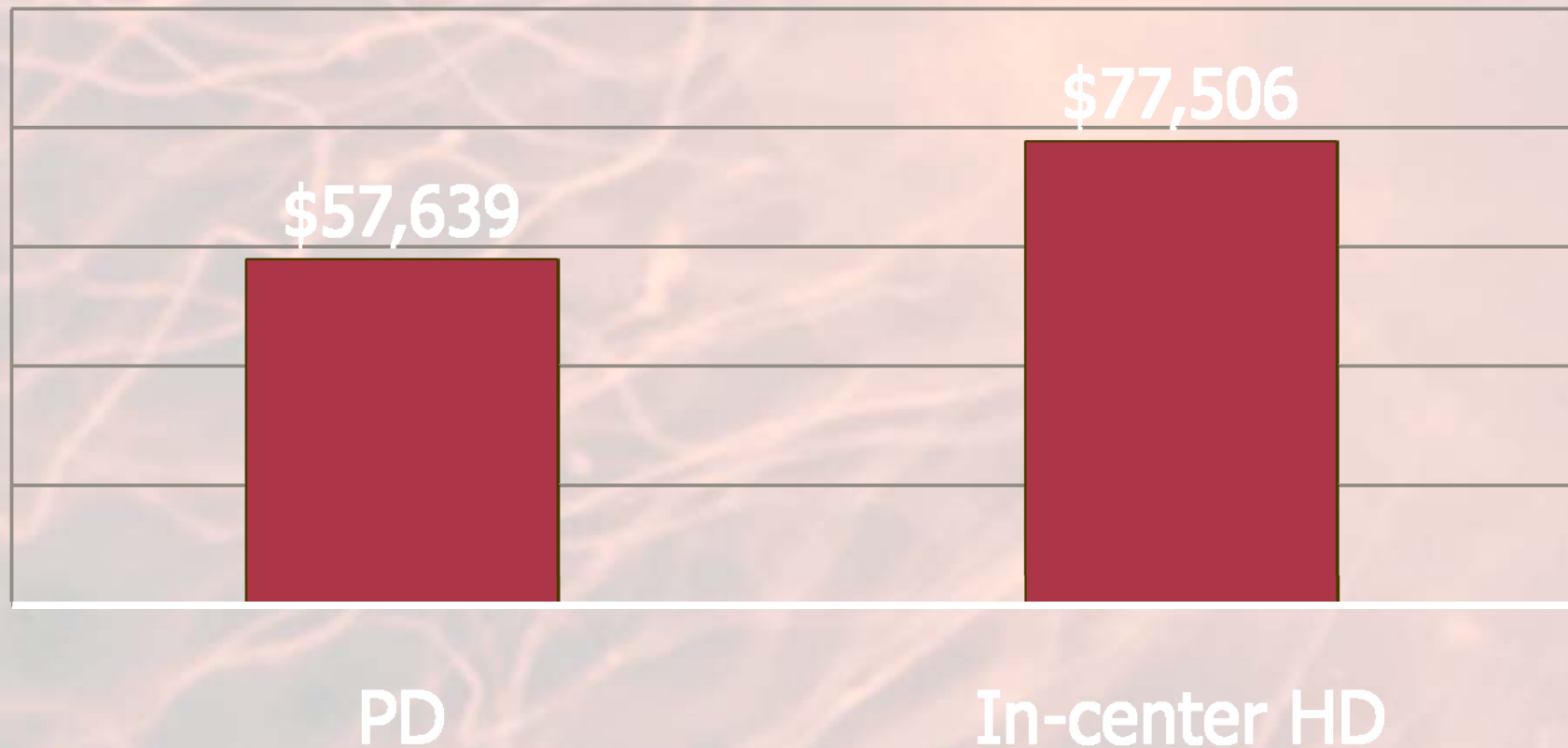
- The bundle rule did not change the rules on payment by CMS for hemodialysis treatments at home
- The rule still states that CMS will pay for three treatments per week, more with medical justification



# The Bundle: Payment for PD

- PD will continue to be paid for at the in-center HD equivalent rate
- *“Because we want to encourage home dialysis, in which PD is currently the prevailing mode of treatment, we are proposing an ESRD PPS which does not rely on separate payment rates based on modality. By establishing prospective payment rates that are higher for PD patients ..... we believe home dialysis will be encouraged for patients able to use PD.”*

# Annual Dialysis Patient Medicare Expenditure 2008: PD vs. in-center HD



USRDS 2010 Annual Data Report Volume 2 Figure 11.7

# Dialysis Costs per "Treatment Equivalent"

|                        | <b>CAPD</b>   | <b>CCPD</b>   | <b>NxStage</b> | <b>In Center<br/>HD</b> |
|------------------------|---------------|---------------|----------------|-------------------------|
| Pharmaceuticals        | 21.10         | 21.10         | 24.63          | 63.30                   |
| ESAs                   | 15.27         | 15.27         | 22.42          | 41.02                   |
| Salaries &<br>Benefits | 26.68         | 26.68         | 26.68          | 65.70                   |
| Medical Supplies       | 66.36         | 92.62         | 112.25         | 27.11                   |
| <b>Total</b>           | <b>114.14</b> | <b>140.40</b> | <b>163.55</b>  | <b>156.11</b>           |

## The Bundle: Home modalities training

- Reimbursement for home dialysis training is included in the final rule
- \$33 additional per training treatment
- 25 training sessions for home HD, 15 for PD



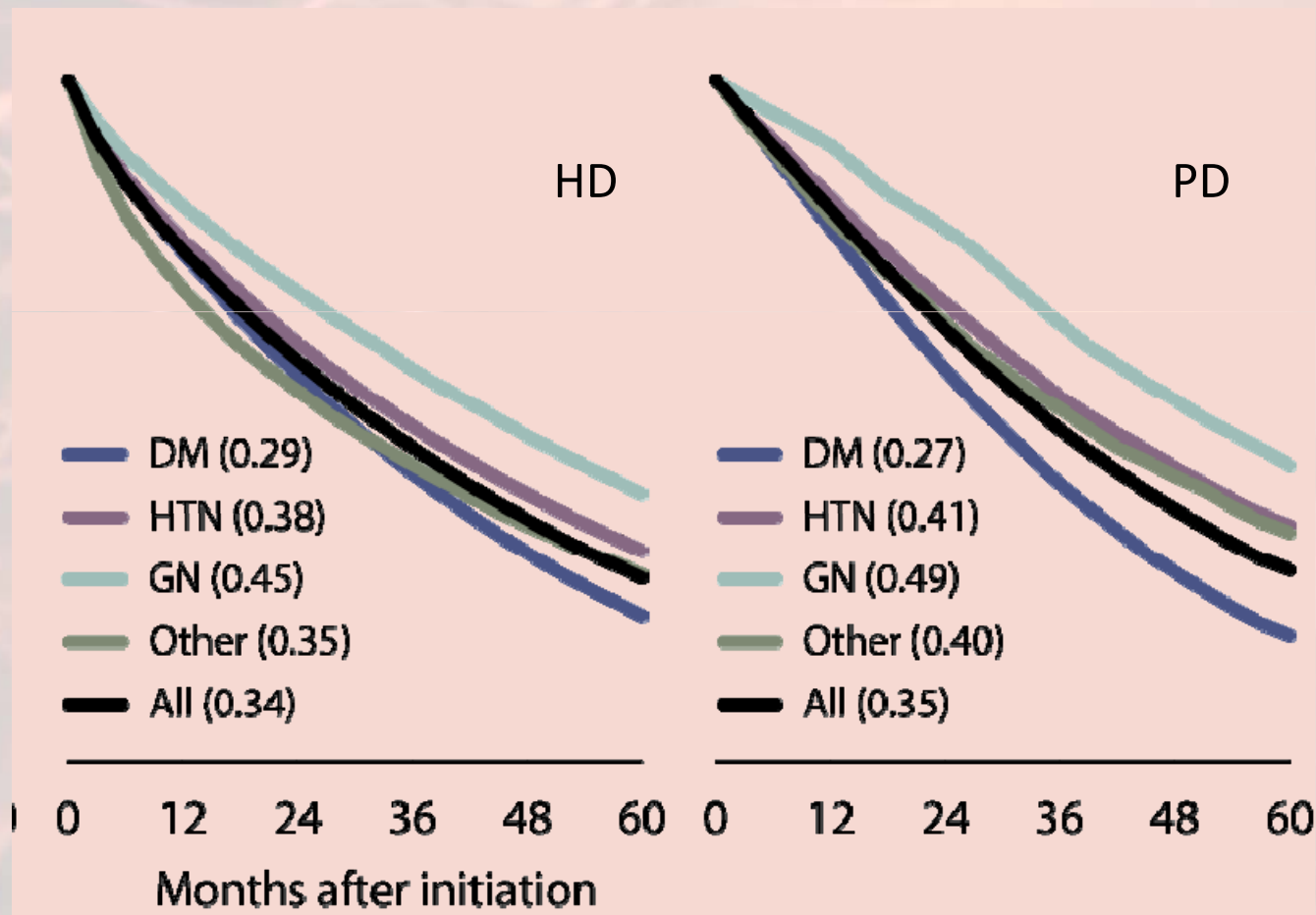
# Home Dialysis Technician

- Phlebotomy, lab processing, and scheduling
- PET and Kt/V collections and tracking
- Supply and inventory management
- Patient scheduling and assessments
- Combined clinical and secretarial functions for small facilities

A microscopic image of a neural network, showing a dense, interconnected web of orange and red fibers. The fibers are thin and thread-like, with some larger, more complex structures that could be cell bodies or synapses. The overall appearance is that of a complex, branching network.

**Modality Outcomes ?**

# Five-year survival of patients commencing treatment in 1999-2003, by modality & primary diagnosis



USRDS 2010 Annual Data Report Volume 2 Figure 6.7



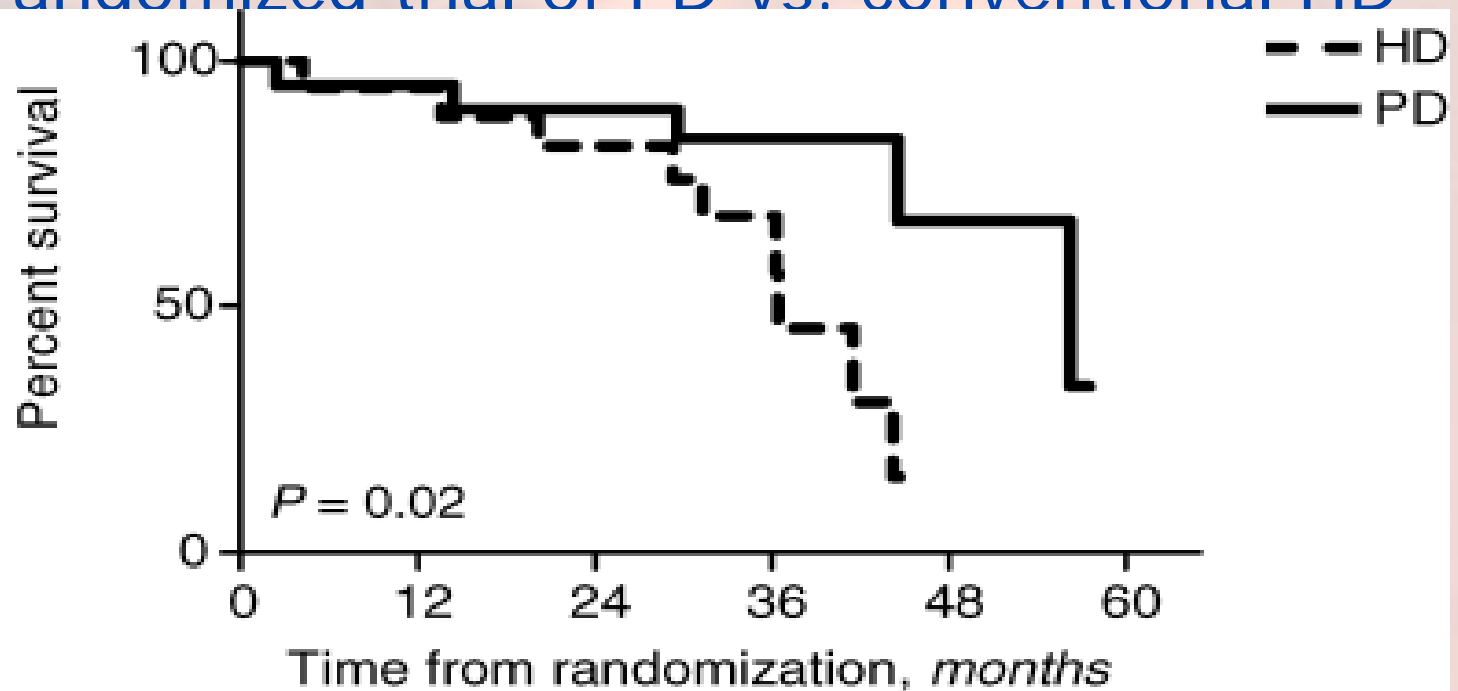
Patient survival (Propensity-matched): 6,337 matched patient pairs from USRDS database

|           | PD    | HD    |
|-----------|-------|-------|
| 12 months | 85.8% | 80.7% |
| 24 months | 71.1% | 68.0% |
| 36 months | 58.1% | 56.7% |
| 48 months | 48.4% | 47.3% |

Weinhandl et al JASN 21: 499-506, 2010



## A randomized trial of PD vs. conventional HD



Number at risk

|    |    |    |    |    |   |   |
|----|----|----|----|----|---|---|
| HD | 18 | 16 | 12 | 6  | 0 | — |
| PD | 20 | 19 | 18 | 12 | 2 | 0 |

Survival of patients randomized to HD and PD

# Randomized study of nocturnal vs. conventional HD

- 52 patients randomized to conventional in-center HD or 5-6 nights per week nocturnal HD
- Primary outcome: Change in LV mass by MRI after 6 months

|          | LV Mass g/m <sup>2</sup> |                 |                          |
|----------|--------------------------|-----------------|--------------------------|
|          | Nocturnal HD             | Conventional HD | Between-group Comparison |
| Baseline | 92.4 (26.6)              | 101.8 (50.6)    | -9.4 (-34 to 15.2)       |
| Exit     | 85.3 (23.2)              | 102.8 (46.1)    | -17.5 (-39.8 to 4.6)     |
| Change   | -7.1 (12.4)              | 1.0 (14.1)      | -8.1 (-16.2 to -0.1)     |

# NIH FHN Study

- Short daily HD study
  - 6 days per week in-center vs. 3 days per week in-center
- Nocturnal HD study
  - 6 nights per week in the home vs. 3 days per week in-center.
- Each study needed to randomize 250 patients
  - Short daily study randomized 245 patients
  - Nocturnal study randomized 87 patients

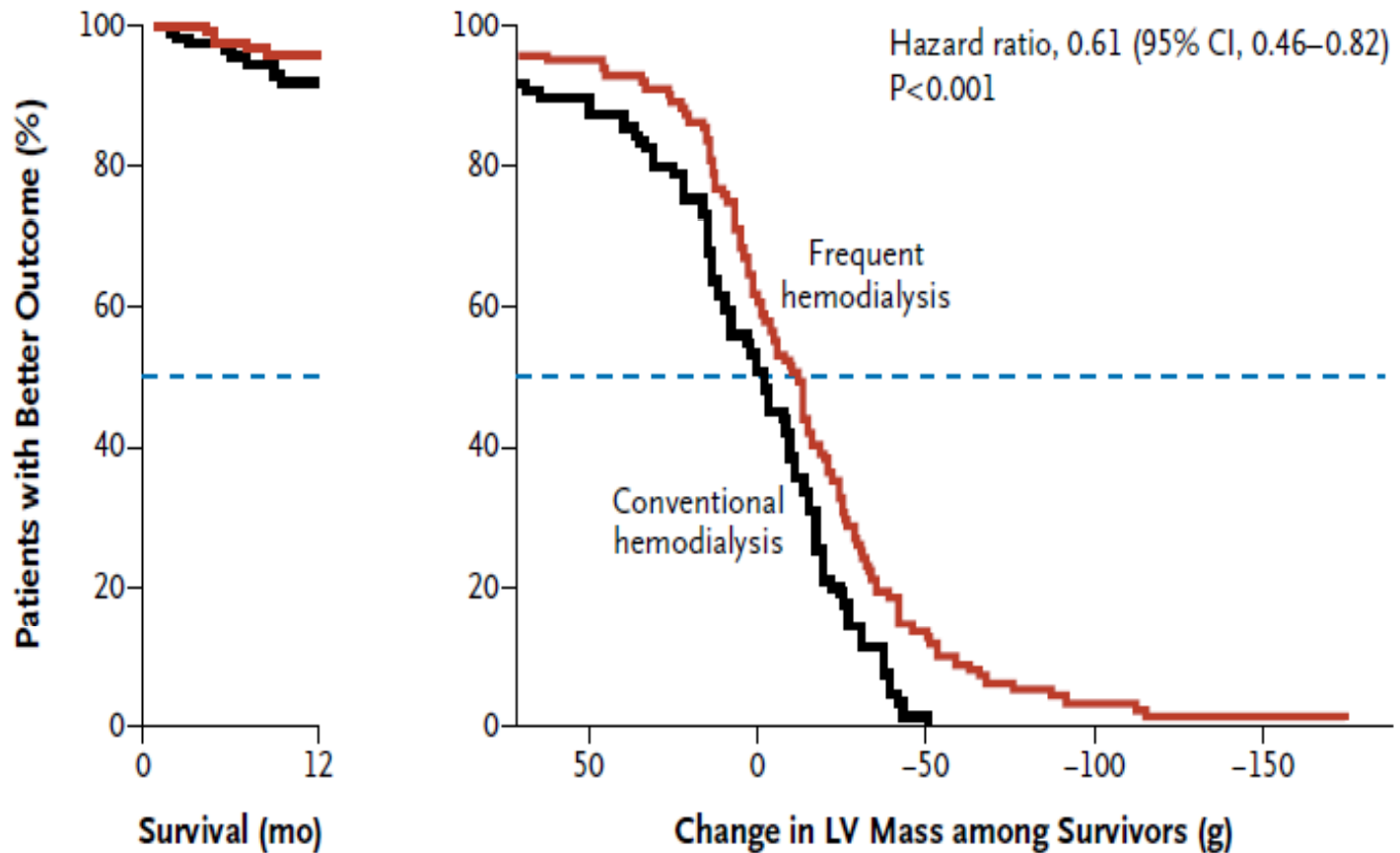
# NIH Study Results

- Each study had 2 combined end-points
  - Mortality plus decreased LV mass
  - Mortality plus improvement in Physical Health Component of the SF-36 Health Survey
- Short daily was positive for both end-points ( $p < 0.001$  and  $p = 0.007$ )
- Given the failure to achieve the required patient enrollment, no conclusions can be made from the nocturnal study



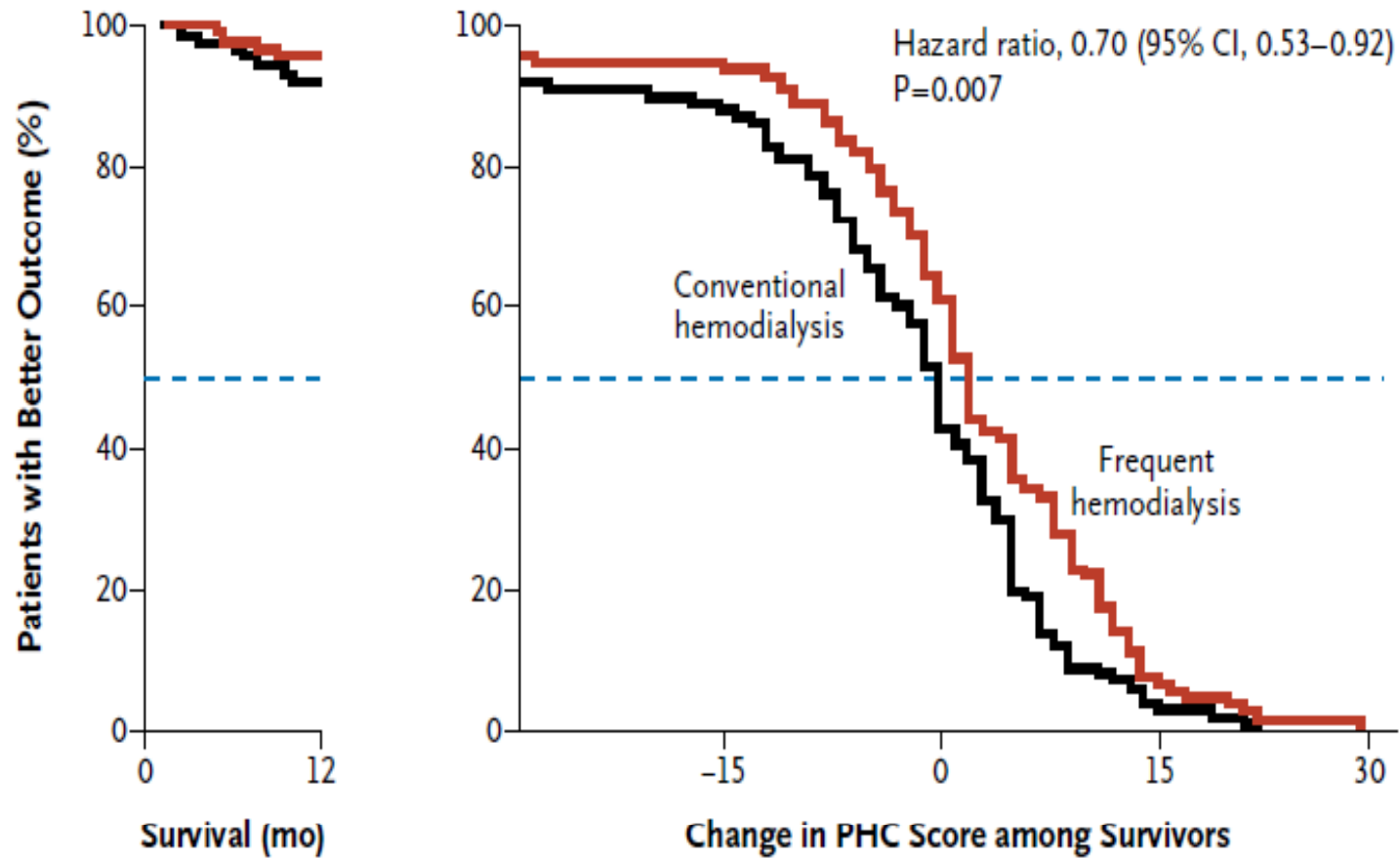
# Co-primary Outcome: Death or change in LV mass

**A** Death or Change in LV Mass



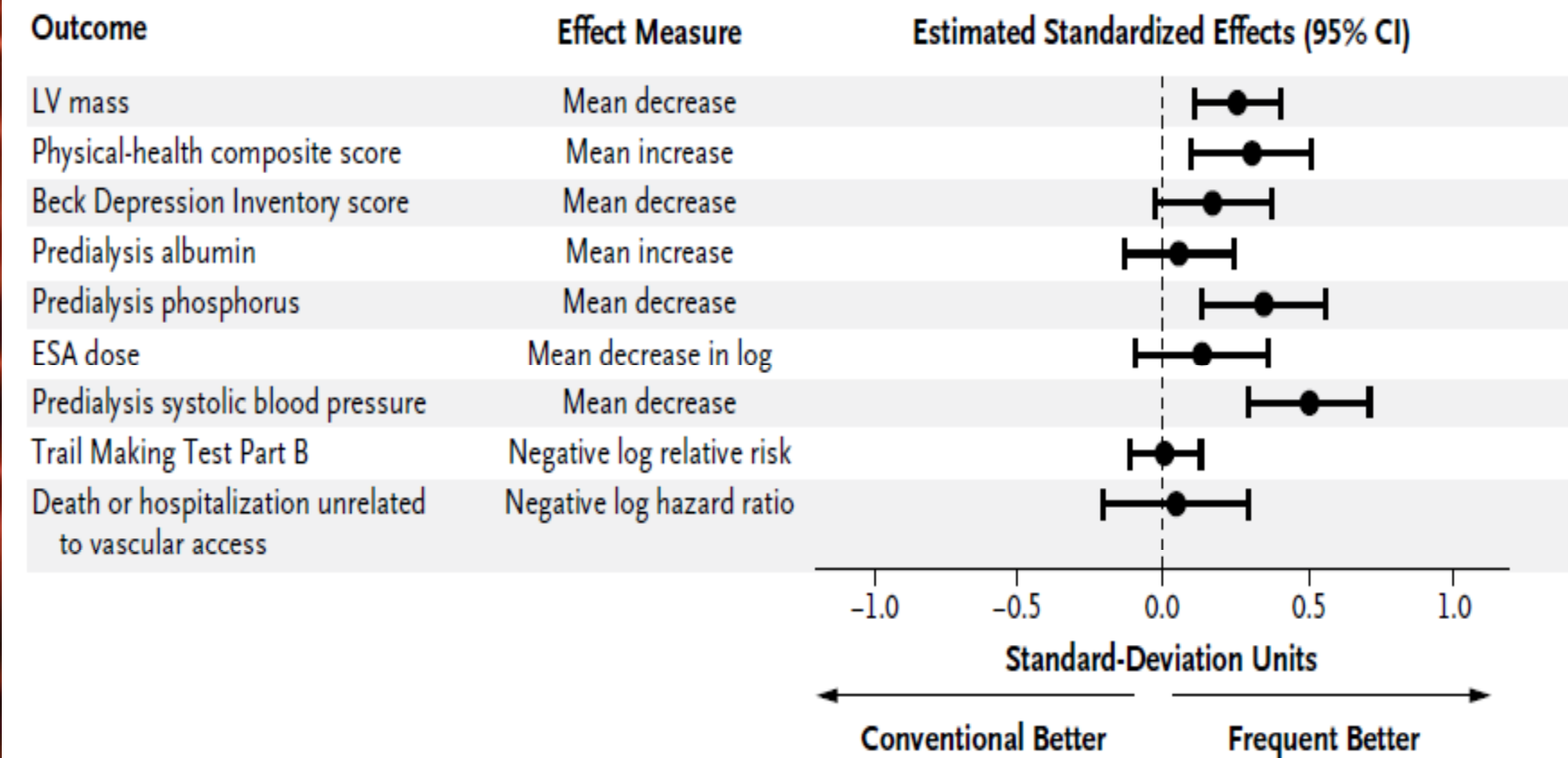
# Co-primary Outcome: Death or change in PHC score

**B** Death or Change in PHC Score



# Secondary Outcomes

## C Main Secondary Outcomes



# FREEDOM Study

Jaber B, Finkelstein F, Glickman J et al: Scope and Design of the Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements (FREEDOM) Study. Am J Kidney Dis. Sept, 2008

- Designed to examine the impact of changing from conventional HD or PD to 6x/week home HD using the NxStage HD machine
- Cohort study of 500 patients starting NxStage 6x/week HD (Medicare as primary insurance carrier)
- Dose of dialysis with NxStage was targeted to be a single pool daily KT/V of 0.5, which corresponds to a standardized KT/V of 2.1 per week for each patient
- Standard medical parameters monitored
- Follow-up of at least 12 months

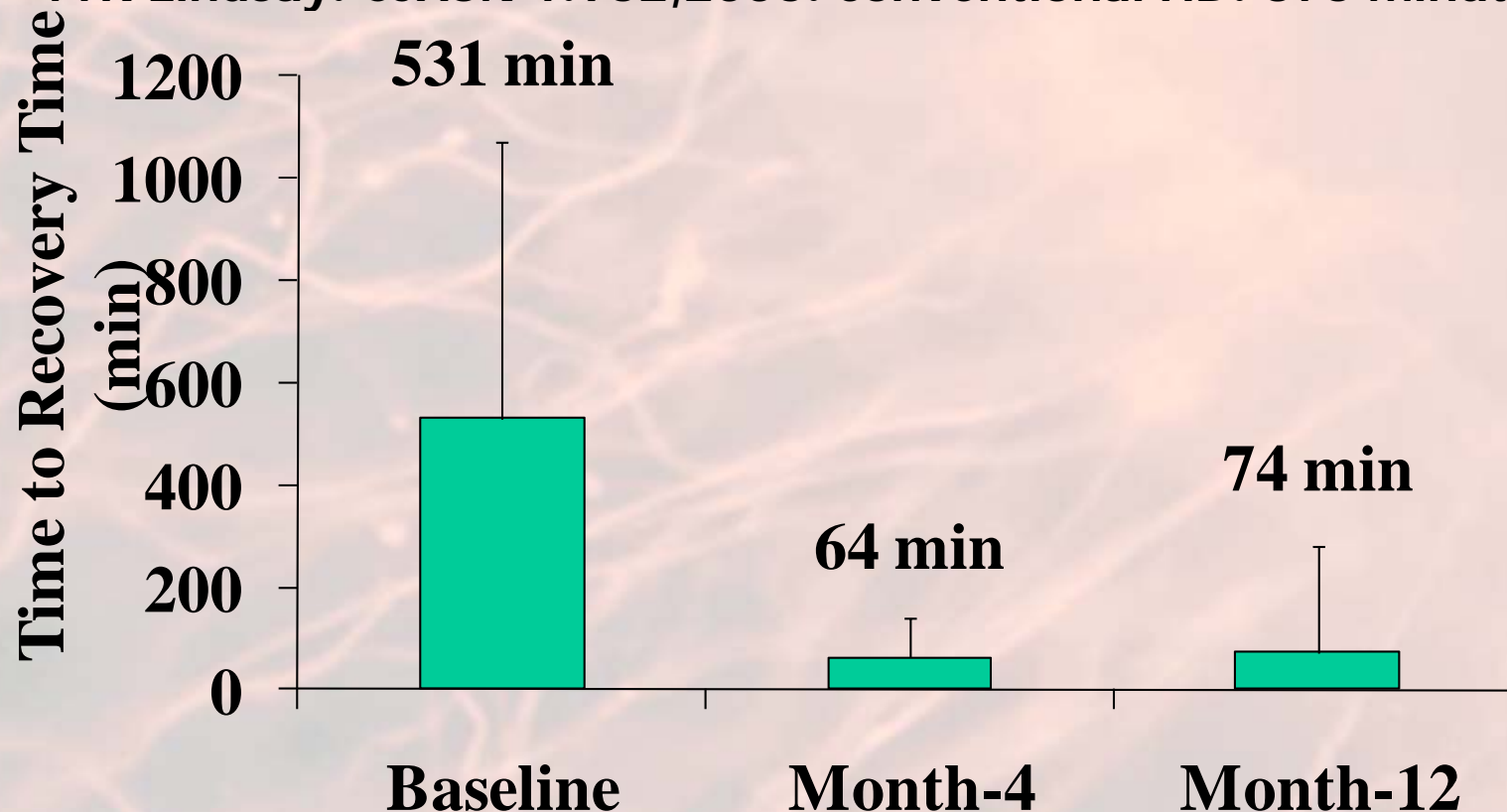


# FREEDOM STUDY

- Hospitalizations and costs tracked
- Hospitalizations and costs to be compared to matched HD patients treated thrice-weekly in 10:1 ratio (n=5,000) from the USRDS database
- Focus on quality of life issues measuring a variety of parameters/domains at baseline, 4 months, 12 months and then at 6-month intervals

# Time-To-Recovery (N=55: pts for whom enrollment & month 4 & month 12 data are available)

TTR Lindsay: CJASN 1:952,2006: conventional HD: 375 minutes



P < 0.0001 by ANOVA

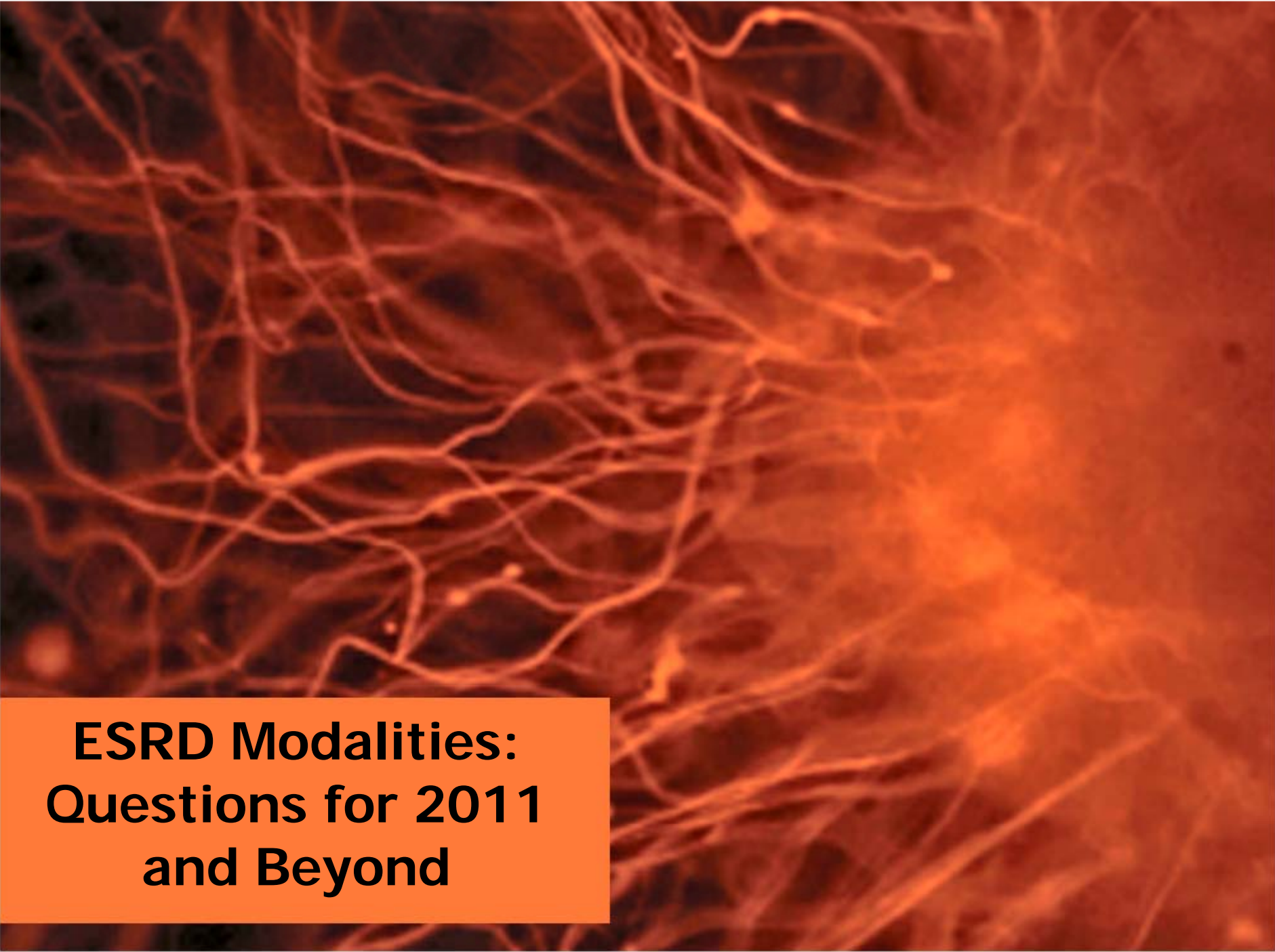
# FREEDOM SUMMARY

- Significant Improvement in post treatment recovery time
- Significant improvements in depressive symptoms
- Significant improvement in validated quality of life parameters
- Significant Reduction in Mortality Risk

# Conclusion

- There is suggestive evidence that the outcome with frequent HD is superior to that of PD
- A definitive conclusion would require a randomized controlled trial



A microscopic image showing a dense network of thin, branching fibers, likely neurons or axons, stained in shades of orange and red. The fibers are interconnected, forming a complex web. The background is dark, making the glowing fibers stand out.

**ESRD Modalities:  
Questions for 2011  
and Beyond**