

Informed Consent

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What is informed consent?

Definition of informed consent

- Informed consent is a legal condition whereby a person can be said to have given consent based upon a clear appreciation and understanding of the facts, implications and future consequences of an action. In order to give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts at the time consent is given. Impairments to reasoning and judgement which would make it impossible for someone to give informed consent include such factors as severe mental retardation, severe mental illness, intoxication, severe sleep deprivation, Alzheimer's disease, or being in a coma.

American Medical Association Definition of informed consent

- It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.

American Medical Association Definition of informed consent

- In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:
 - The patient's diagnosis, if known;
 - The nature and purpose of a proposed treatment or procedure;
 - The risks and benefits of a proposed treatment or procedure;

American Medical Association Definition of informed consent

- (Continued), should disclose and discuss with your patient:
 - Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
 - The risks and benefits of the alternative treatment or procedure; and
 - The risks and benefits of not receiving or undergoing a treatment or procedure.

American Medical Association definition of informed consent

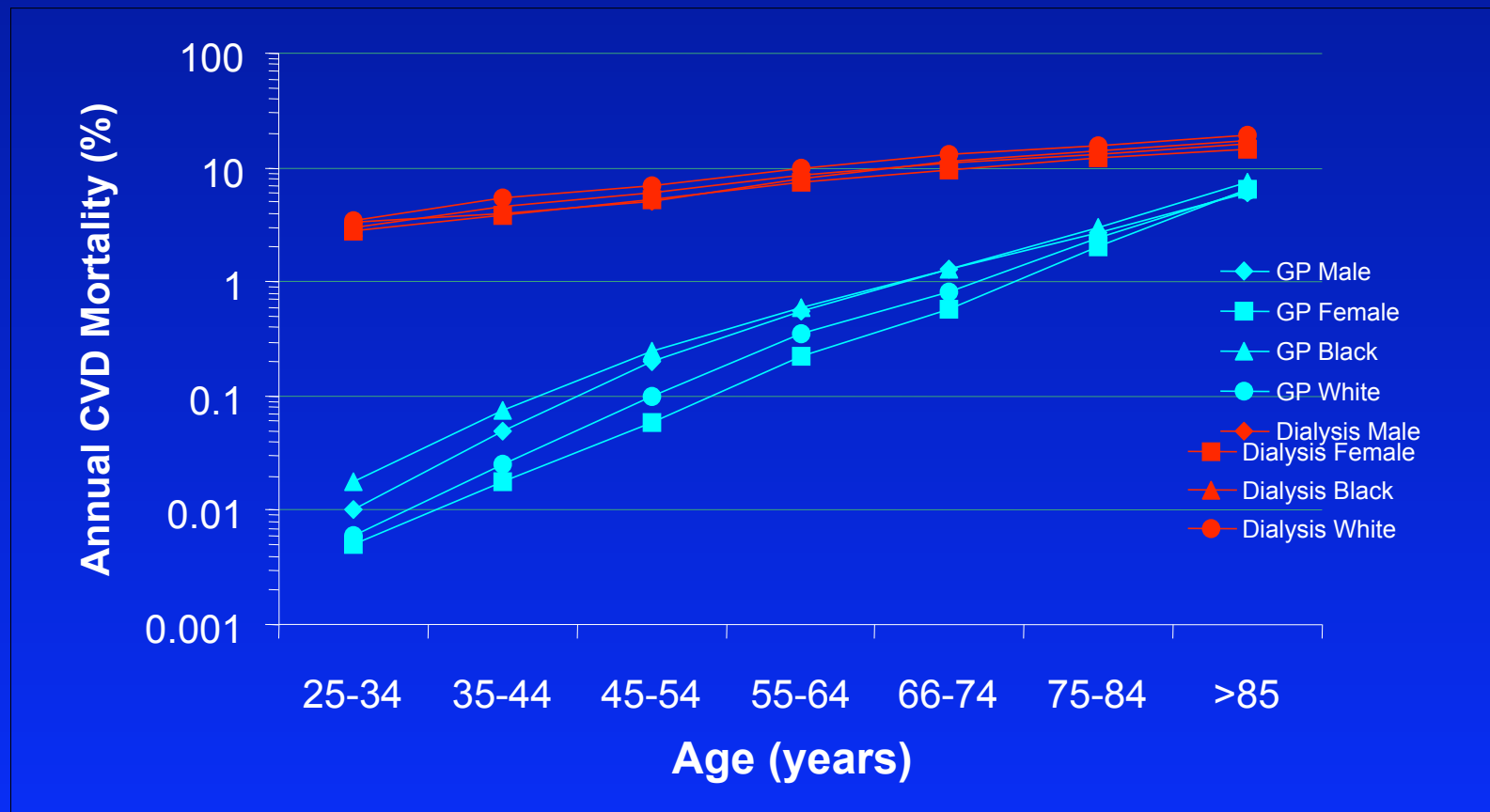
- In turn, the patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.
- This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states.

American Medical Association definition of informed consent

- Providing the patient relevant information has long been a physician's ethical obligation, but the legal concept of informed consent itself is recent.

**What do I tell my patients when I
talk about modality options?**

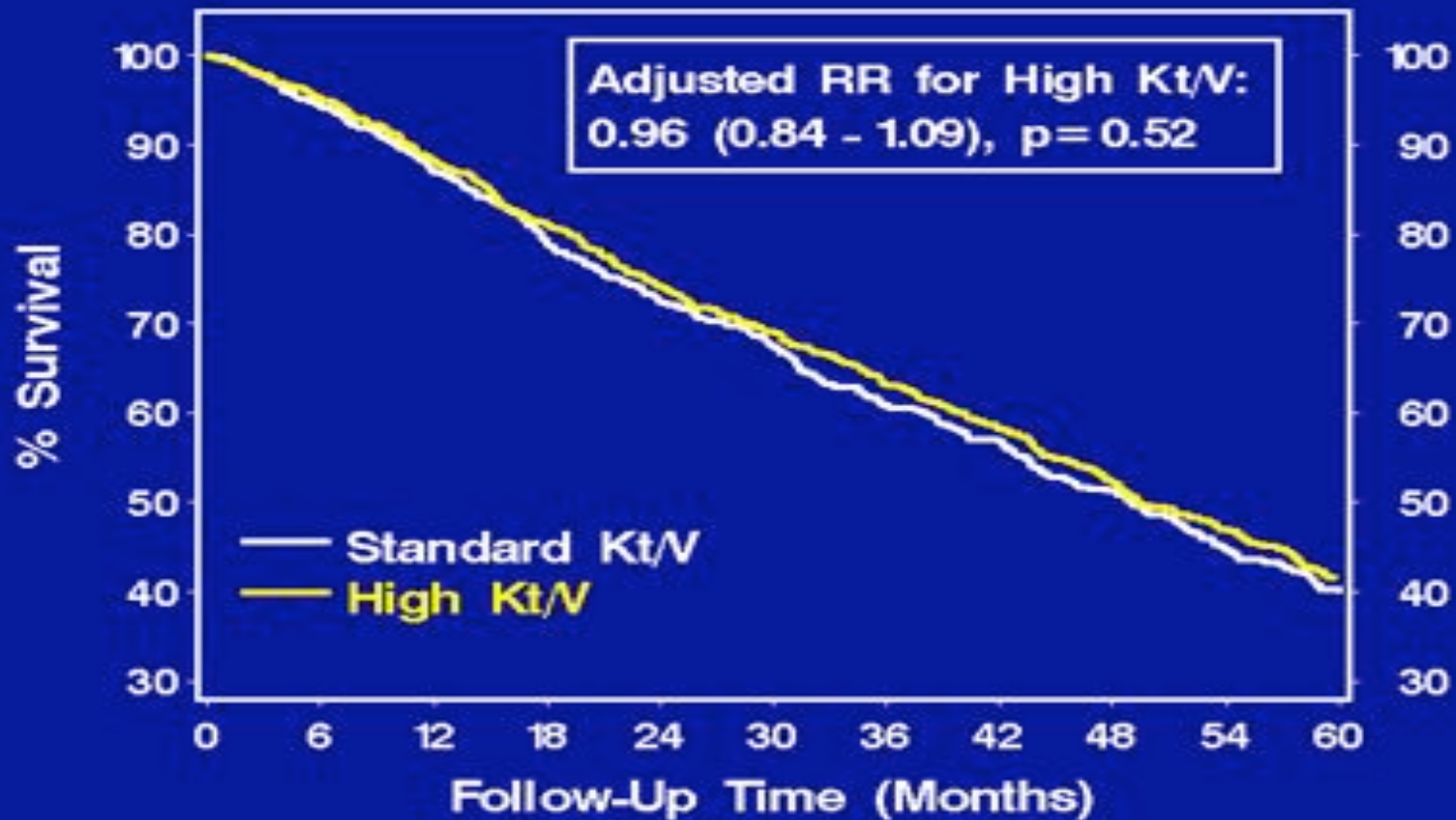
Cardiovascular disease mortality general population vs ESRD patients



GP = General Population.

Foley RN, et al. *Am J Kidney Dis.* 1998;32:S112-S119.

HEMO Study: Survival by dose group



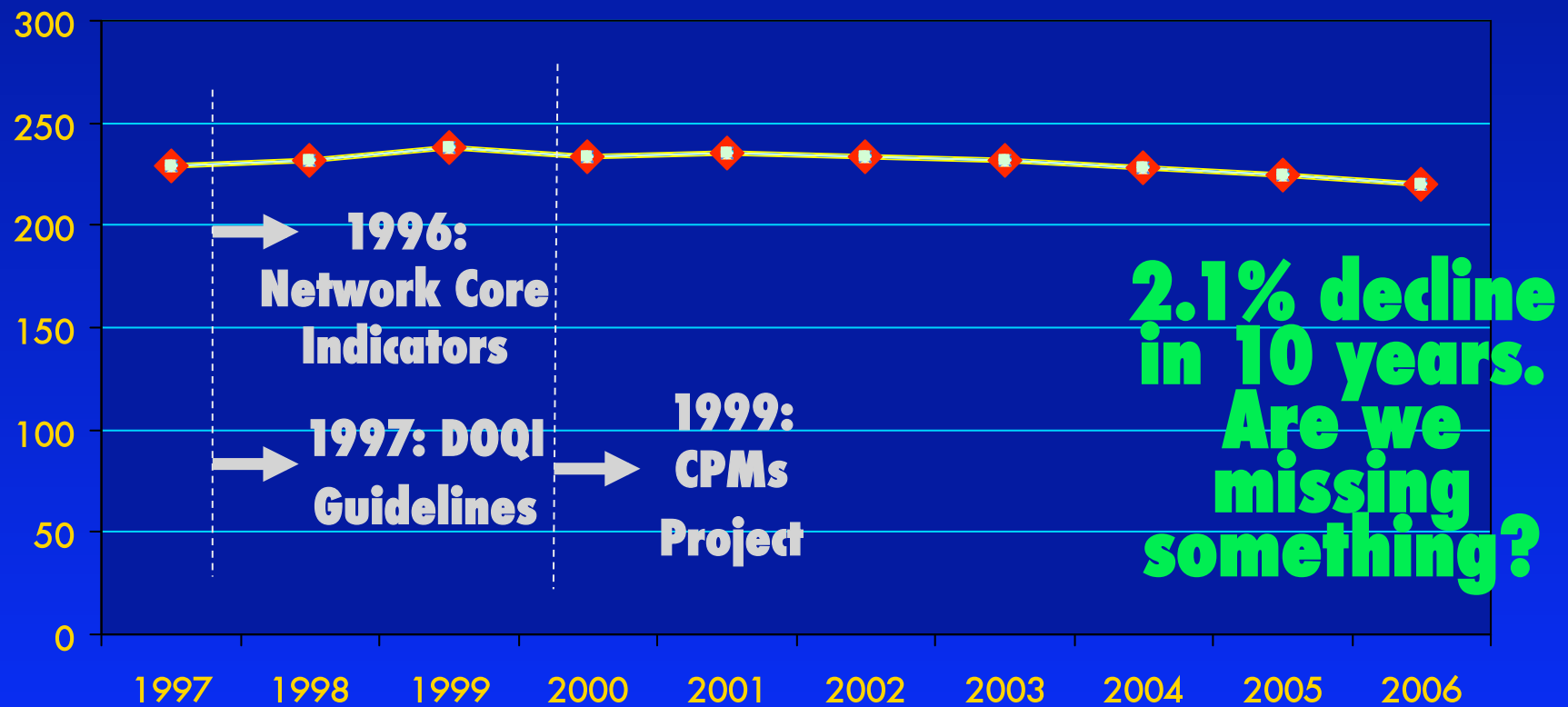
Eknoyan et al, N Eng J Med 2002

The ADEMEX Study

- Prospective, randomized, controlled trial
- Evaluated outcome of peritoneal patients looking at **KT/V of 1.75 vs. 2**
- Study showed that there was no significant improvement with outcomes of patients with a standard weekly KT/V of 1.75 vs. 2

J Am Soc Nephrol 13:1307-1320, 2002

Adjusted Annual Mortality Rate Per 1000 life years on dialysis: 1997-2006



USRDS 2008 Annual Data Report, Table H4

Period prevalent patients by age, gender, race, ethnicity, primary diagnosis, vintage

Adjusted five-year survival, by modality & primary diagnosis: 1997-2001

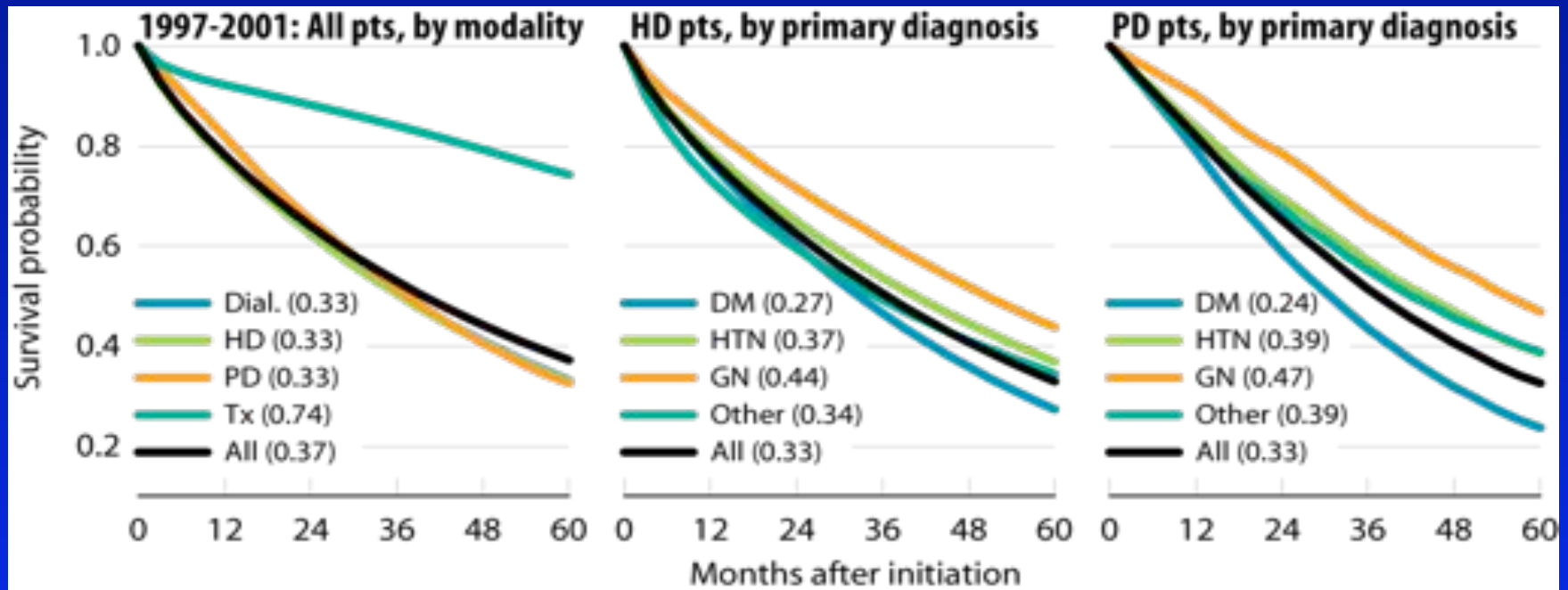
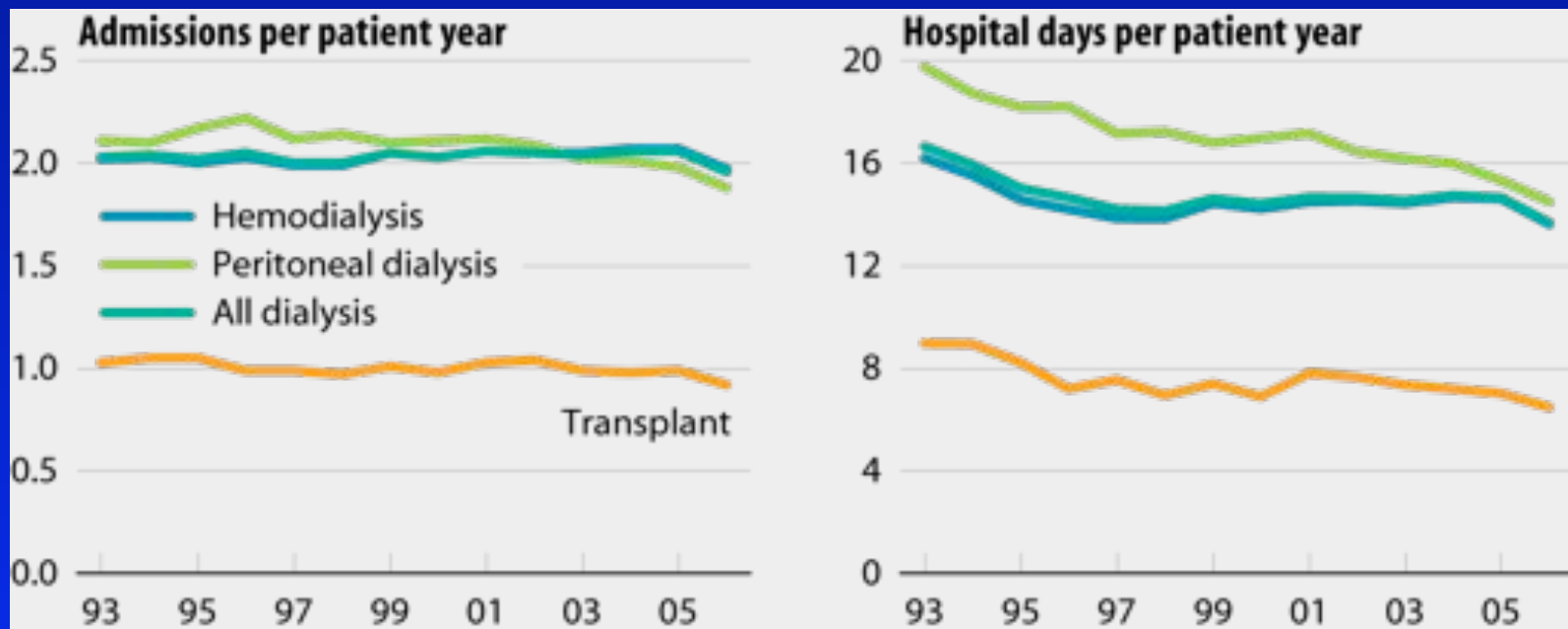


Figure 6.10 (Volume 2) incident dialysis patients & patients receiving a first transplant in the calendar year. All probabilities adjusted for age, gender, & race; overall probabilities also adjusted for primary diagnosis. All ESRD patients, 2005, used as reference cohort. Five-year survival probabilities noted in parentheses. Dialysis patients followed from day 90 after initiation; transplant patients followed from the transplant date.

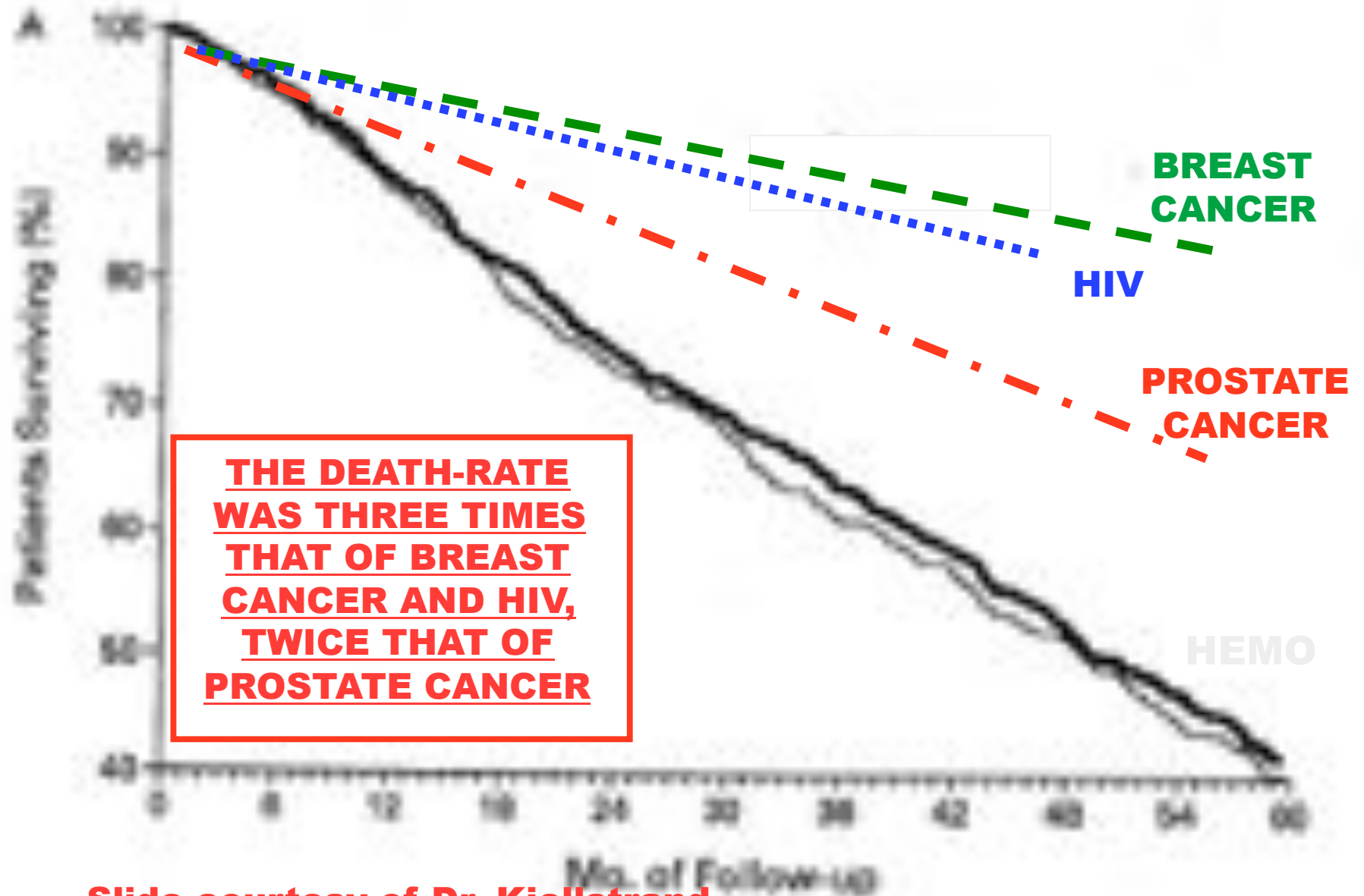
The 2008 USRDS Annual Data Report (ADR) Reference Tables

Adjusted admissions & days by modality

Figure 6.3 (Volume 2)



Period prevalent ESRD patients; rates adjusted for age, gender, race, & primary diagnosis. ESRD patients, 2005, used as reference cohort. **The 2008 USRDS Annual Data Report (ADR) Reference Tables**



Slide courtesy of Dr. Kjellstrand

Withdrawal & hospice status, by age

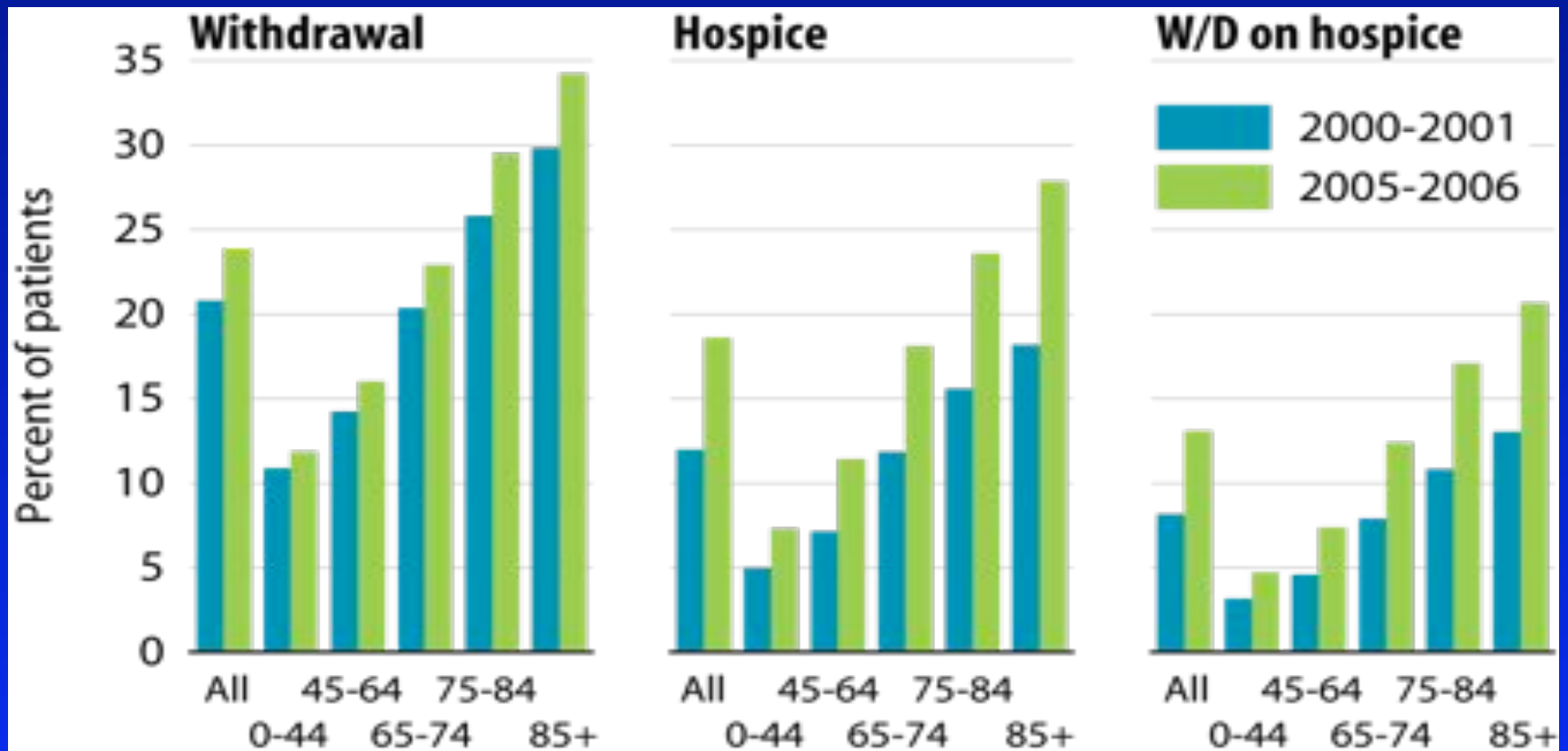
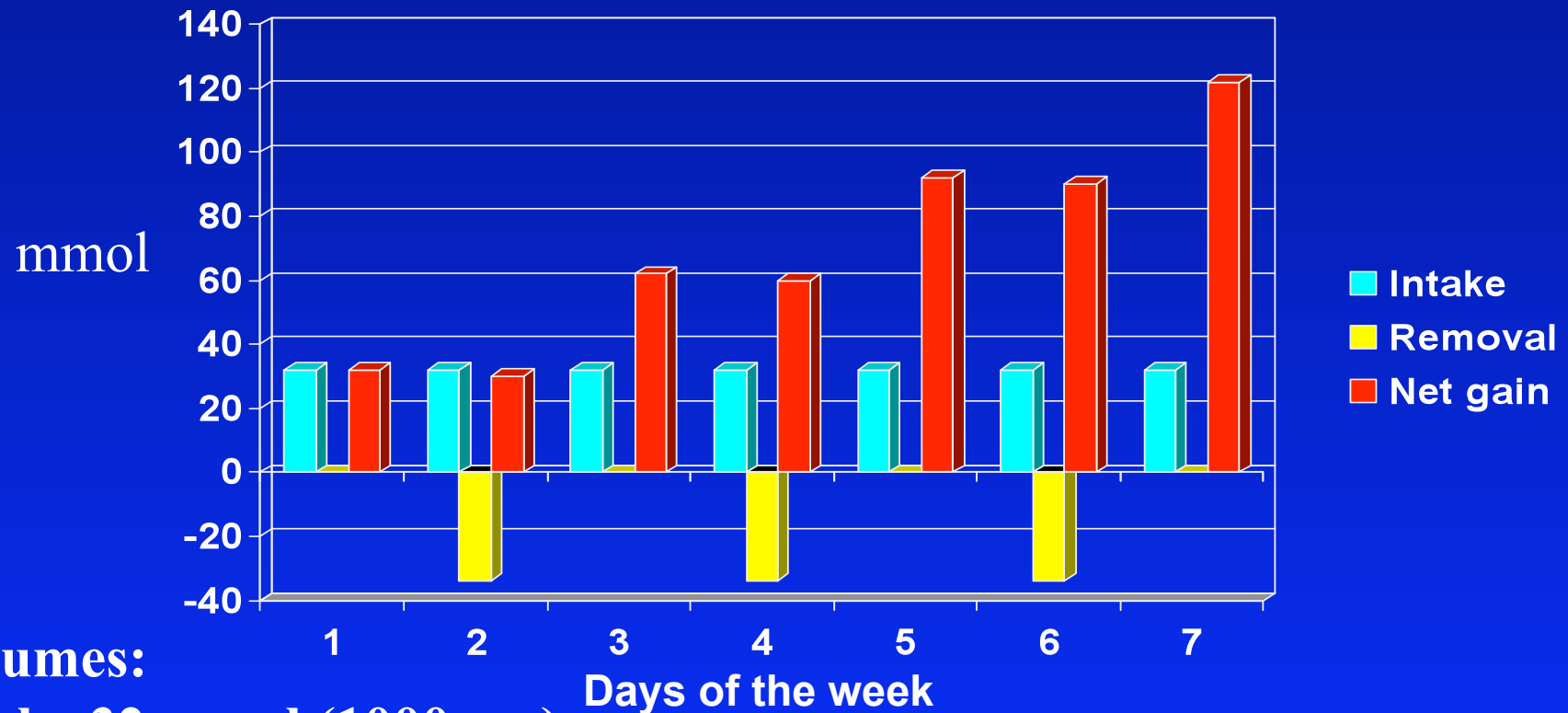


Figure 6.18 (Volume 2) incident & prevalent ESRD patients dying in 2000–2001 or 2005–2006. **The 2008 USRDS Annual Data Report (ADR) Reference Tables**

Phosphorous balance - CHD



Assumes:

Intake 32 mmol (1000 mg)

Removal 34 mmol

3 Day/wk x 4 hr

Adapted: *Kidney Int*, 67 S95. 2005 pp 28-32
Slide courtesy of Dr. Glickman

Sudden deaths in dialysis patients

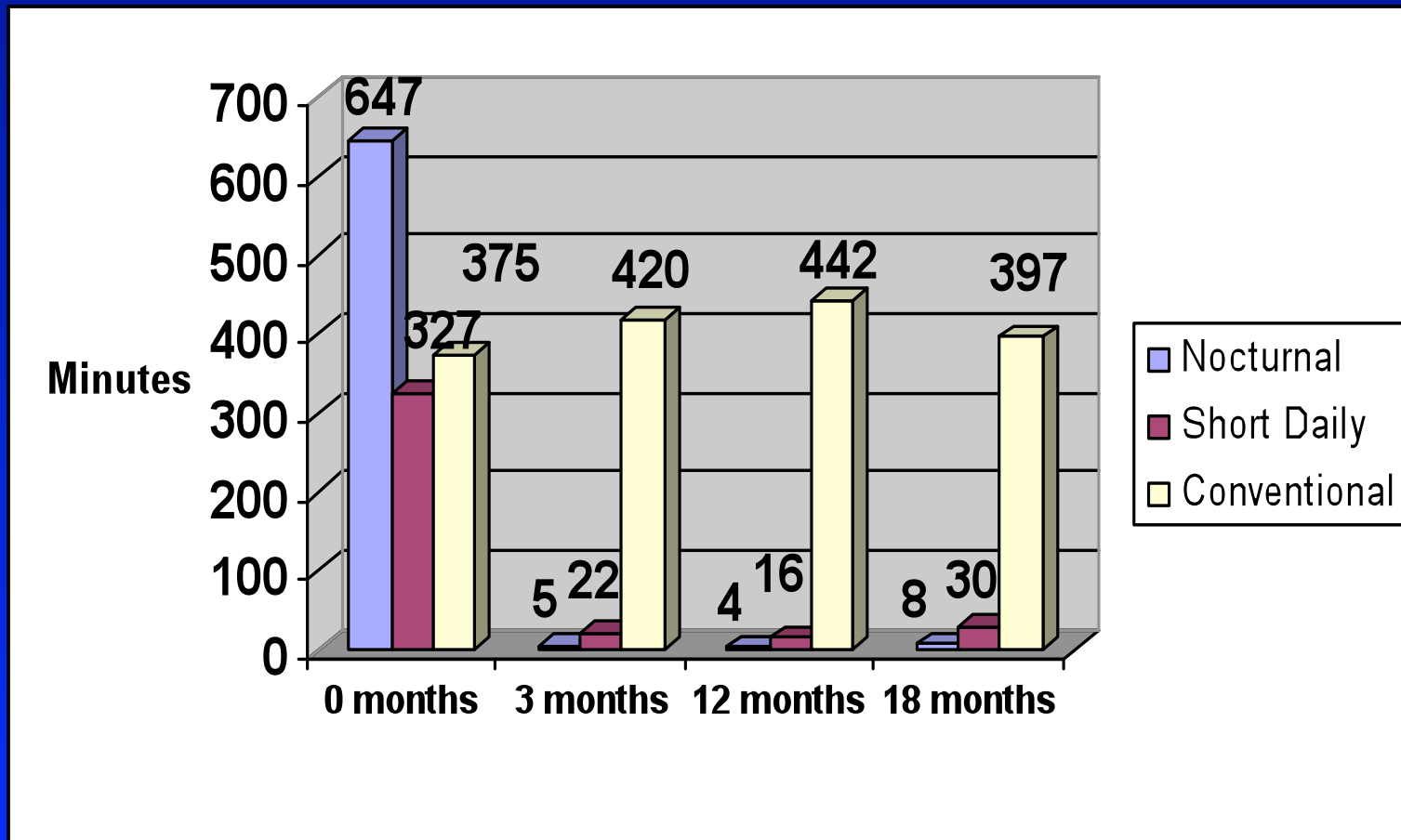
- Sudden and cardiac deaths are most common on Mondays and Tuesdays
- For Monday, Wednesday, Friday patients, 20.8% of sudden deaths occur on Monday compared to 14.3% expected ($P = 0.002$) - a 45% increase in mortality
- For Tuesday, Thursday, Saturday patients, 20.2% of cardiac deaths occur on Tuesday compared to 14.3% expected ($P = 0.0005$).
- There is an even distribution of sudden and cardiac deaths throughout the week in peritoneal dialysis patients

Bleyer AJ, Russell GB, Satko SG: Sudden and cardiac death rates in hemodialysis patients. Kidney Int. 1999;55:1553-1559

Side effects occur during and after conventional hemodialysis in 15 to 50% of treatments

- Hypotension
- Nausea and vomiting
- Headaches
- Cramping
- Washed out feeling after dialysis

Minutes to recovery from dialysis



Heidenheim et al AJKD 2003

Estimated CKD Stages Provided by Each RRT Modality

Modality	Controls PO4	Controls Fluid	CKD Stage
In-center HD (3x/week)	—	—	5
CAPD/APD	—	In some	5
Conventional home HD (3x/week)	—	—	5
NxStage Short Daily	—	Yes	5
Conventional Short Daily	—	Yes	4
Nocturnal ≥ 5 /week	Yes	Yes	3
Transplant	Yes	Yes	≥ 3

What does each modality offer the patient?

What each modality offers

- **Conventional in center**
- Dialyze 3 days a week for 3.5 to 4.5 hours
- Will not control fluid
- Will not control phosphorous (must take binders)
- Blood Flow rate 300 to 400
- Dialysate Flow rate 500 to 800
- Offers a clearance of less than 15% (100% is normal)
- Fixed dialysis schedule
- Travel (in center dialysis treatment arranged by facility)

What each modality offers

- **Peritoneal Dialysis CAPD and CCPD (without residual renal function)**
- Will not control fluid
- Will not control phosphorous (must take binders)
- Offers a clearance of less than 15% (100% is normal)
- Training time 1-2 weeks
- Schedule may be flexible
- Ability to travel with equipment

What each modality offers

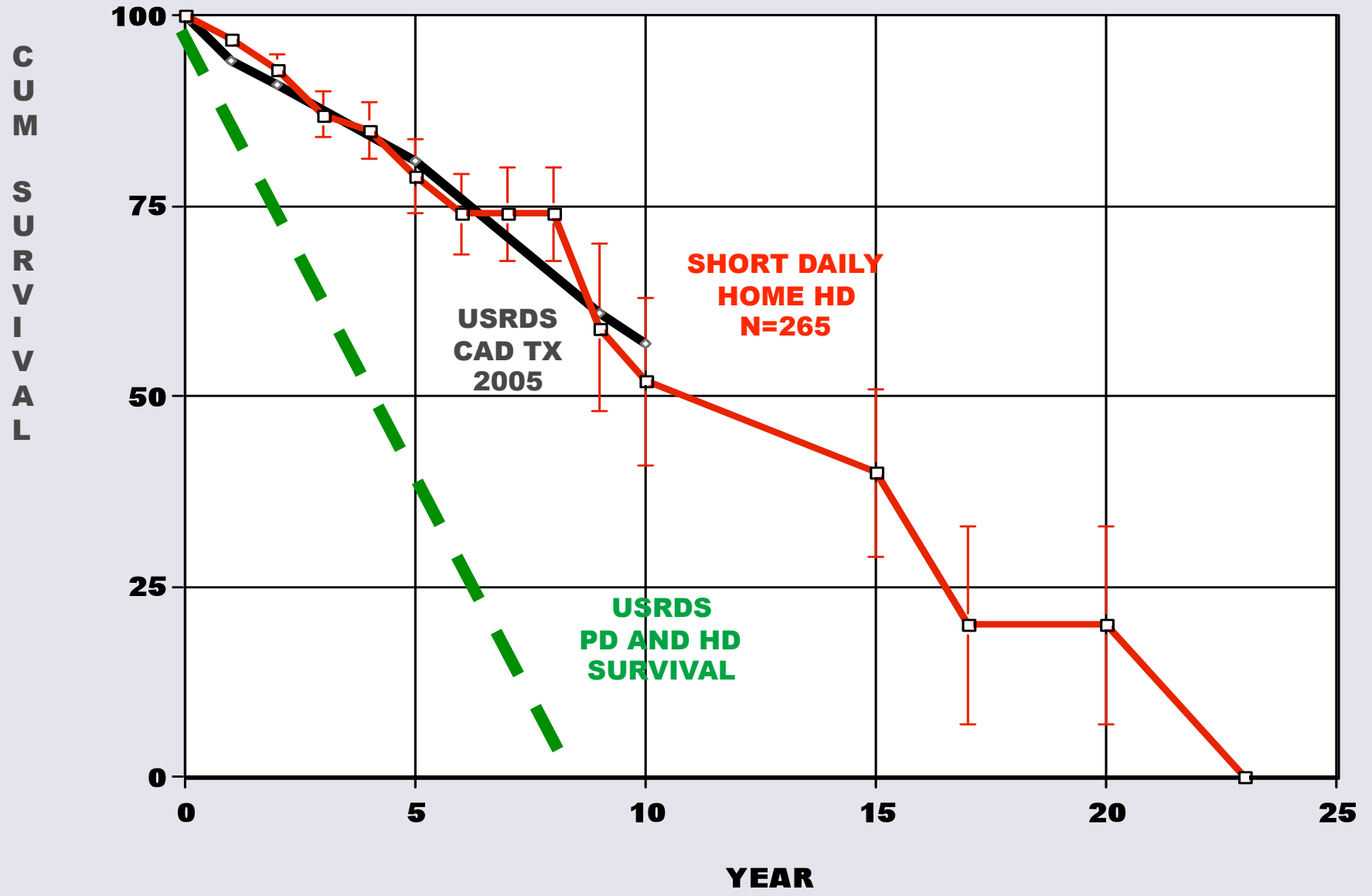
- **Short Daily using NxStage**
- Dialyze 5 or 6 days a week for 2.5 to 4 hours
- Will control fluid (reduced B/P meds)
- Will not control phosphorous (must take binders)
- Blood Flow rate 300 to 400
- Dialysate Flow rate 90 to 125 (20-30 liters)
- Offers a clearance of 15% (100% is normal)
- Training time 3 to 4 weeks
- Flexible schedule - Ability to travel with equipment

What each modality offers

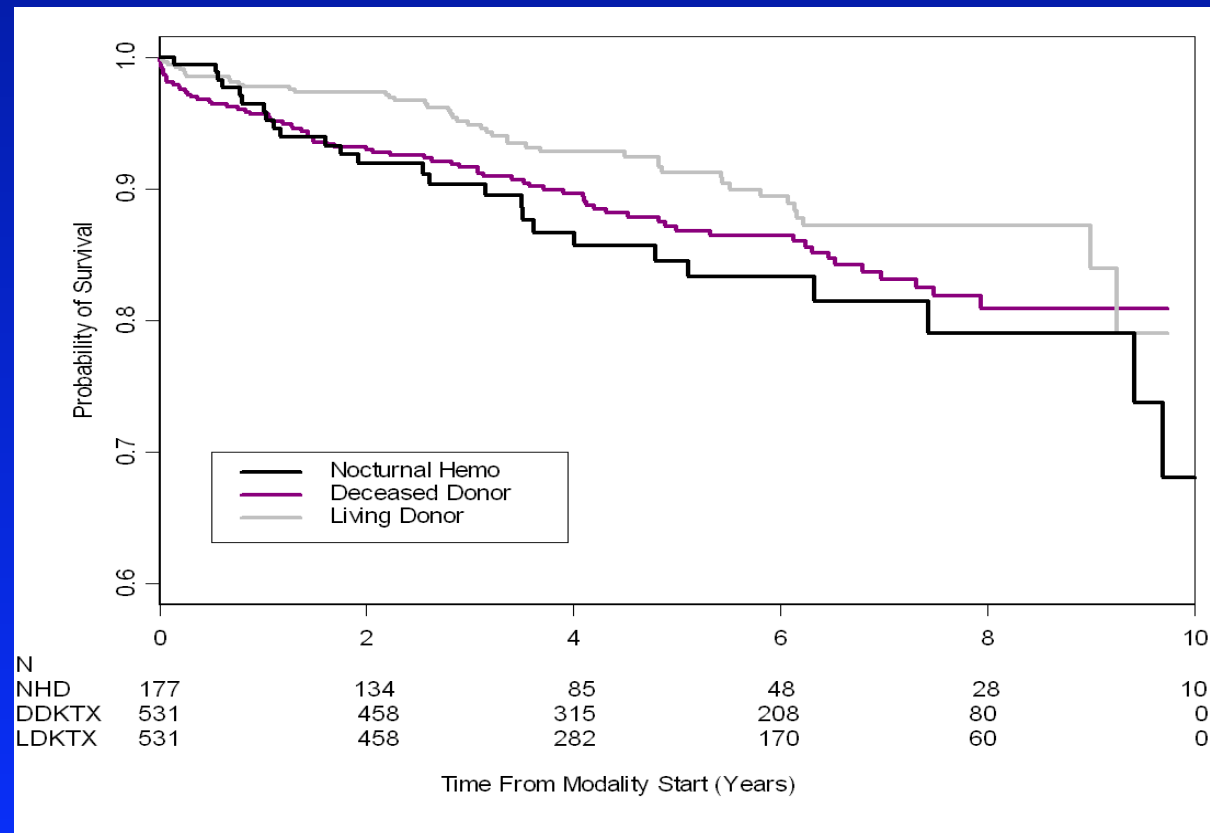
- Nocturnal with traditional machine
- Dialyze 5 nights a week for 7 hours
- Will control fluid - Will control phosphorous (off binders and reduced B/P meds)
- Blood Flow rate 200 to 300
- Dialysate Flow rate 200 to 300
- Offers a clearance of 30% or greater (100% is normal)
- Training time 6-8 weeks
- Flexible schedule - Travel (in center dialysis treatment arranged by facility)

What each modality offers

- **Transplant**
- Will control fluid
- Will control phosphorous (off binders)
- Medications to prevent rejection
- Offers a clearance of 30% or greater (100% is normal)
- Freedom to travel



No difference in survival between patients treated with deceased donor transplantation and nocturnal hemodialysis. *Pauly et al. ATC Abstract 1598, AJT 8 (Suppl. 2), 2008.*



How do you feel?

- Do you think this is what informed consent should be like?
- What type of informed consent did you have?
- Did this informed consent scare you or did it give you hope?
- How would you change the informed consent presented here? Leave out or add information?
- When should patients hear about informed consent?
- Do you think you can take population outcomes and apply to individual patients?

Do all patients receive the same informed consent?

- An elderly patient with Alzheimer's disease
- A fifteen year old starting dialysis
- A patient with multiple co morbid conditions with limited life expectancy
- A transplant candidate on the waiting list
- A homeless patient
- A person working full time with a college education
- A person with less than a fifth grade education

Timing for informed consent

- When patient is educated about CKD?
- When patient is educated about different access options?
- When patients go to Treatment Choice Seminars?
- When after starting renal replacement therapy should informed consent be presented to the patient?
- Should informed consent be repeated and if so how often?

Who provides informed consent education to the patient?

- CKD nurse educator
- Dietitian
- Social worker
- Dialysis nurse
- Physician Assistant
- Nephrologist