Important Lessons from the DOPPS:

Implications for quality improvement

Budapest Nephrology School
August 29, 2008

nephrolife
A Complete Kidney Care Centre

HR Humber River
REGIONAL HOSPITAL

VELUT ÆVO ARBOR

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Outline

1) General Aspects of Quality of Health Care
2) Quality of Dialysis Care
3) Measuring Dialysis care
4) DOPPS data
5) The Davita Quality Index
6) The DOPPS derived Practice Risk Score
7) PRS and DSI

To Err is Human

Building a Safer Health Care System (I of M 1999)

- Estimated 44,000 to 98,000 deaths per year in USA due to errors in hospital care
  - That is about 100 deaths per day who die from injuries caused by care, and not from disease
- Serious medication errors occur in 7 of 100 hospital admissions

Quality in the USA

- Only 50% of patients receive recommended preventive care
- 70% receive recommended acute care
- 30% receive contraindicated care

Kizer, KW. JAMA 286; 1213 – 17: 2001.

Institute of Medicine, 2001

Between the health care we have
and the care we could have
lies not just a gap,
but a chasm.

Crossing the Quality Chasm:
A New Health Care System for the 21st Century

- Institute of Medicine, 2001
- New system must be evidence based
- New system is driven by quality in all aspects
- A systems oriented approach to health care delivery

Goals

- Safety
  - Rather than being an individual responsibility, safety should be considered as a system and built into all policies
- Effective
- Patient centeredness
- Timely
- Efficient
- Equity

Changes

- Improved use of information systems
  - Supports QI, research, education, and accountability
  - Eliminate hand written notes by 2010
- Utilization of multidisciplinary teams
- Guidelines
- Performance and outcome measures to improve quality and accountability
- Reimbursement methods may be barriers to change

The yawning chasm between what we know and what we do for patients is no longer news; indeed, the repeated evidence is somewhat numbing. We are far less sure what to do next.

S Jencks

Dialysis remains a half way technology

- Survival is only 1/3 that of age adjusted peers
- Quality of life is compromised
  - Modalities are burdensome
- Morbidity remains high
- All modern methods are imperfect
- Funding for innovation is difficult to secure
- Moving expensive new ideas from research to practice is difficult
  - Eg. Funding of home HD

Our primary challenge:

Dialysis growth leads to impersonal care

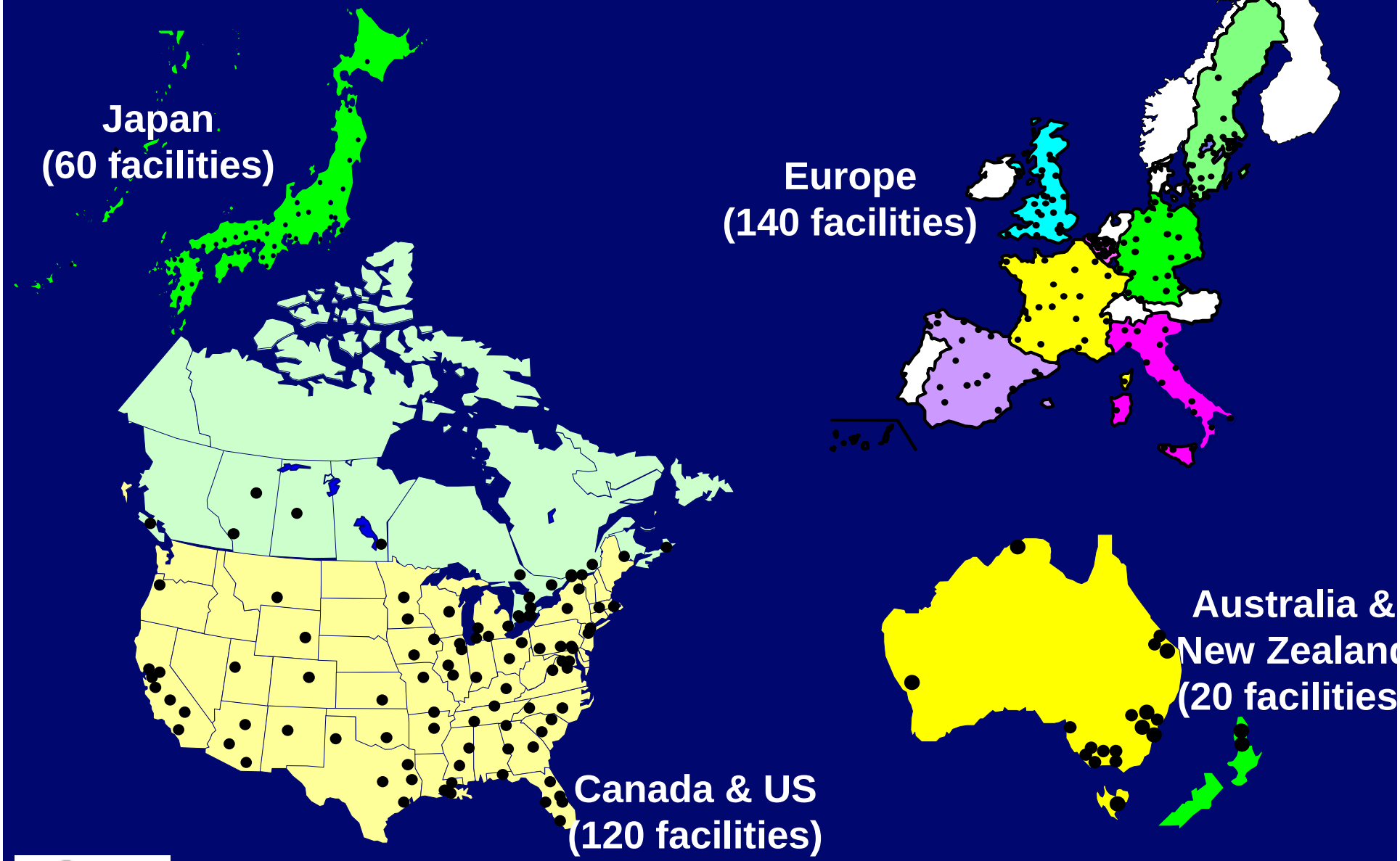
- Small units that deliver personalized, individualized care may be ideal
- HR crisis makes this impossible
- Units will grow larger and therefore more impersonal with time
- But, bigger units have better patient outcomes

DOPPS

- Longitudinal study of HD patients and practices in 12 countries
- Conducted in three phases: I (1996-2001); II (2002-2004); III (started in 2005; currently ongoing)
- Represents ~ 70% of the global HD population
- Wide variety of data collected both from health care providers and patients
- Goal: Identify HD practice patterns associated with improved outcomes to improve patient longevity

DOPPS

DOPPS sites



Randomly selected after stratification by unit type and region

Table 1. Comparisons of Key Features Between Randomized Controlled Trials and Observational Studies

Feature	Controlled Trials	Observational Studies
Number of hypotheses	Usually only 1 or 2	Many
Cost per hypothesis	Very high	Low to moderate
Sample size	Often marginal	Less restricted
Study of poor treatment	Ethically not feasible	Feasible via representative sample study
Study of medications	Ideally suited	Confounding by indication*
Study of trends	Limited	Feasible
Causality	Yes (for positive findings)†	Correlation, suggestive only
Representativeness	Limits due to selection criteria	Feasible
Statistical adjustment	Usually not required	Always required

*Results showing benefit associated with medication use despite this confounding are of great interest

†Negative findings may be difficult to interpret because high cost usually limits the sample size

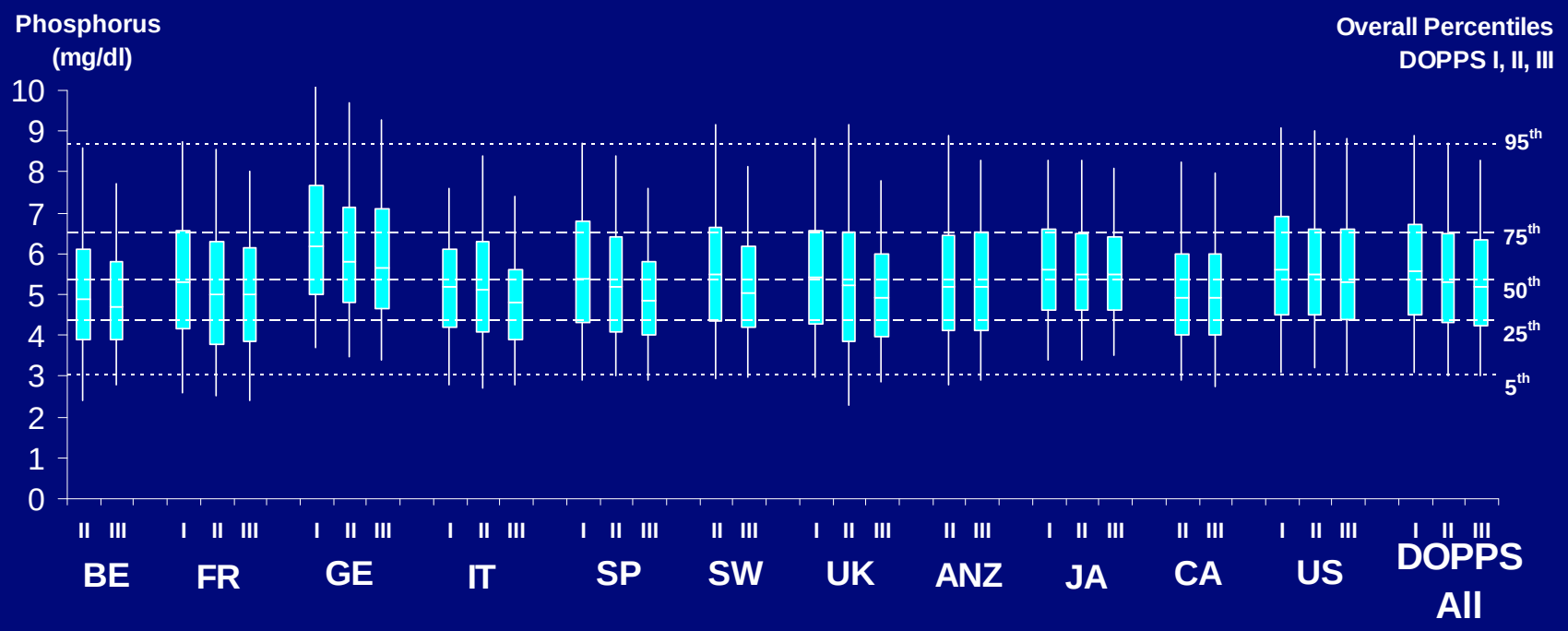
DOPPS

Port FK and Eknoyan G. *Am J Kidney Dis* 44:S1-S6, 2004

Searching for needles in haystacks

Serum Phosphorus Distributions

Among Patients on HD > 180 days



Box-plots with weighted 5th, 25th, median, 75th, 95th percentiles by country and phase of DOPPS.

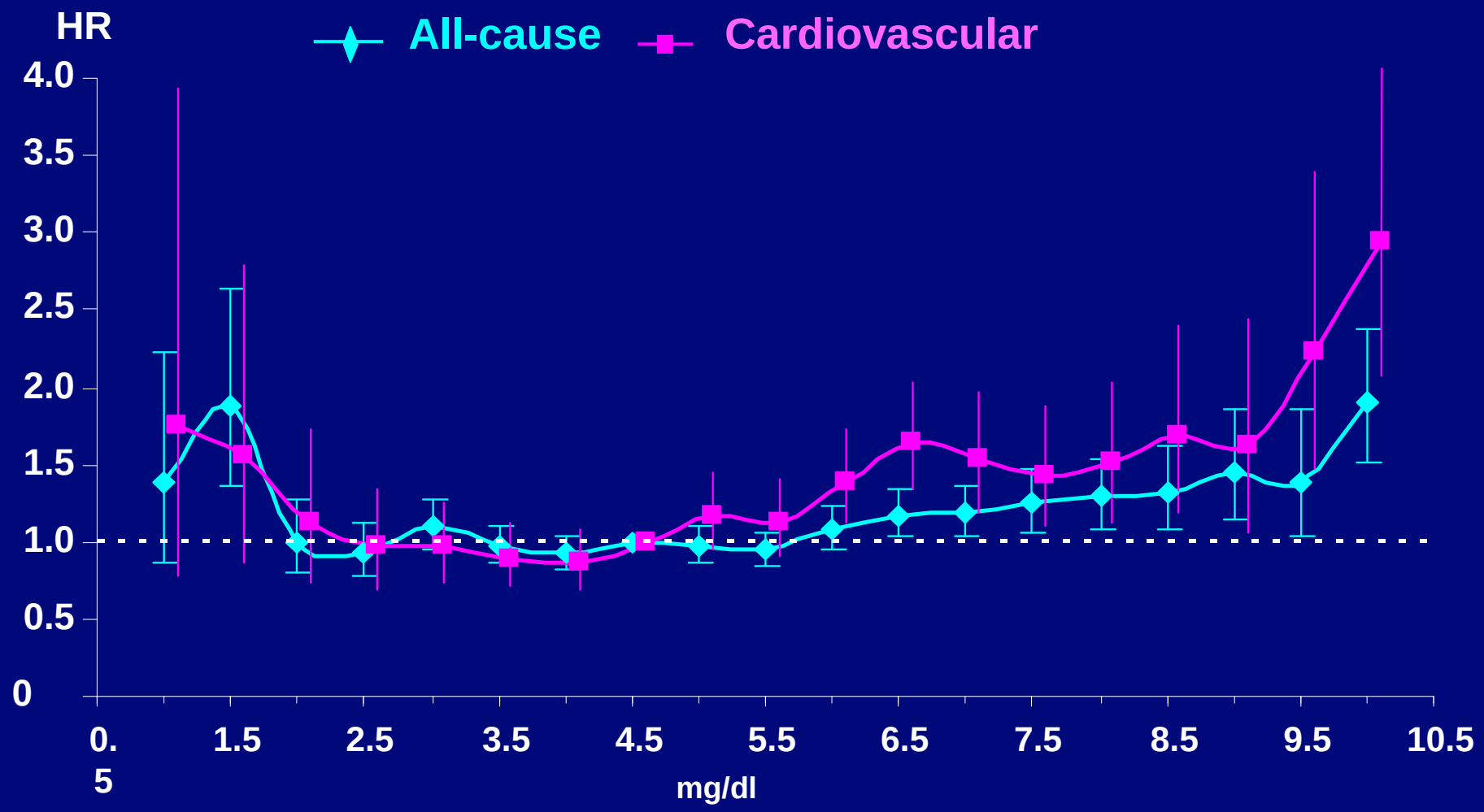
Horizontal lines indicate these percentiles for serum phosphorus: 5th=3.0 mg/dL; 25th=4.3 mg/dL; 50th=5.4 mg/dL; 75th=6.5 mg/dL; 95th=8.7 mg/dL for the overall DOPPS study sample (n=25,375).

BE= Belgium, FR=France, GE=Germany, IT=Italy, SP=Spain, SW=Sweden, UK=United Kingdom, ANZ= Australia-New Zealand, JA=Japan, CA=Canada, US= United States

Tentori et al. AJKD 2008

Mortality Risk by Phosphorus Categories

Among Patients on HD > 180 days



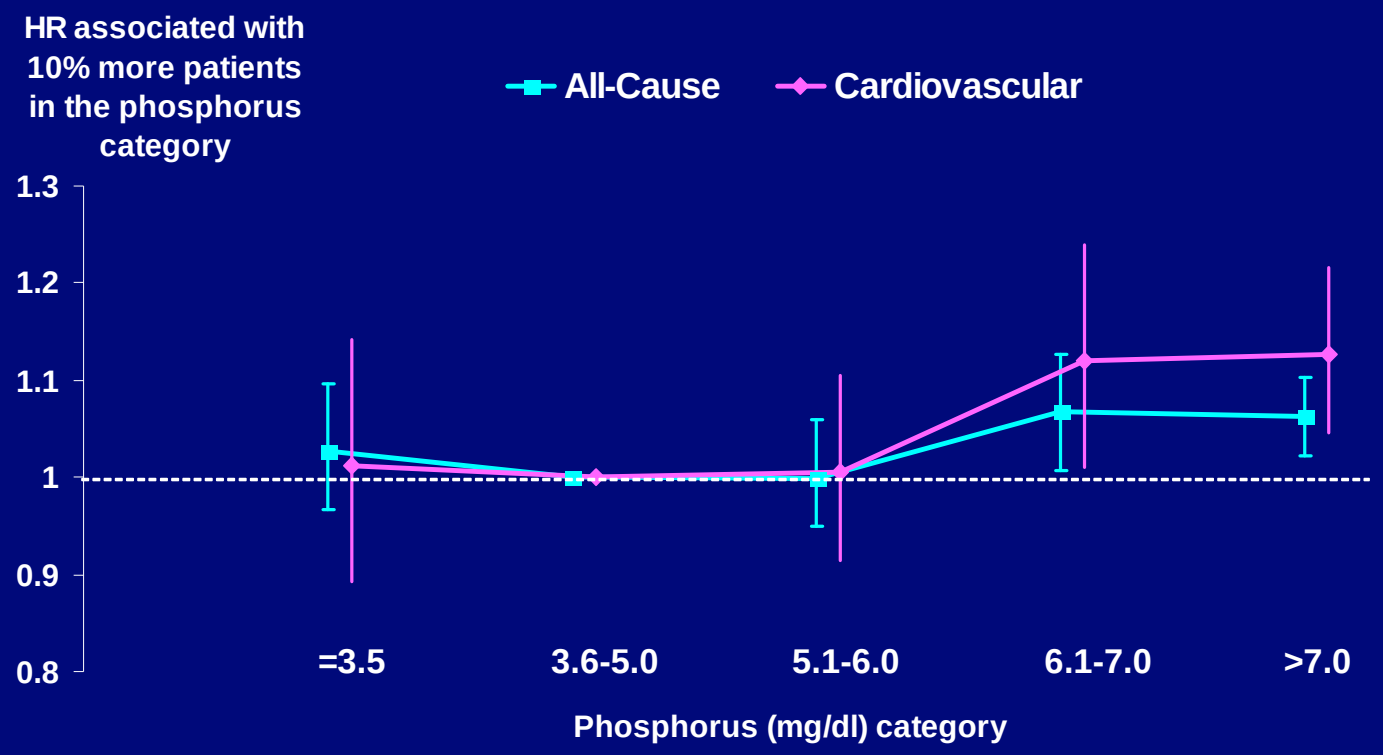
Cox models used all DOPPS (n=25,529) and adjusted for age, sex, race, BMI, years on ESRD, 13 comorbid conditions, facility clustering. Hazard ratios and 95% confidence intervals (whiskers) for all-cause (events n=5,857) and cardiovascular mortality (*n* events=1,930)

DOPPS

Tentori et al. AJKD 2008

Facility-Level Phosphorus and All-cause Mortality

Among Patients on HD > 180 days



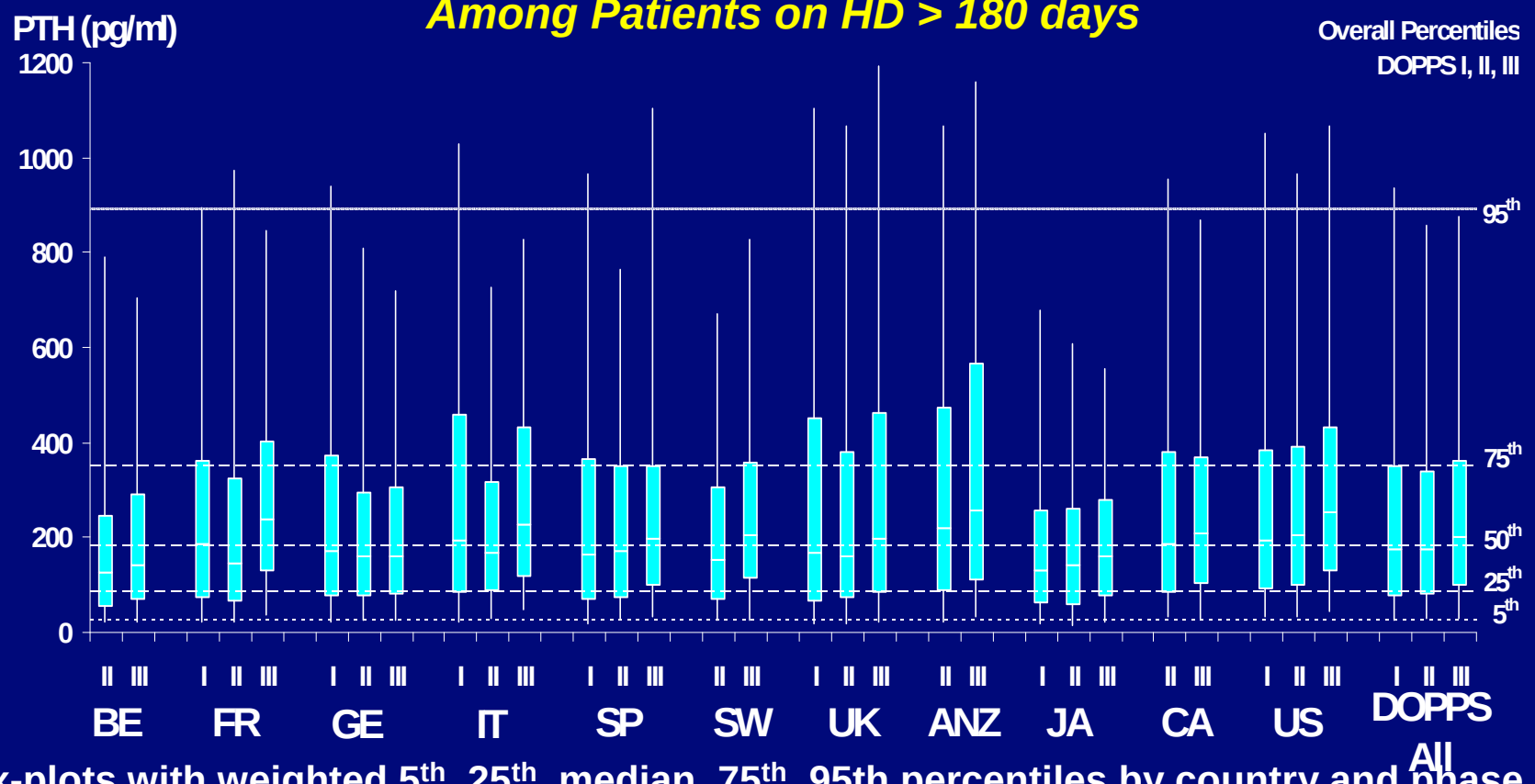
Hazard ratios and 95% confidence intervals (whiskers) for all-cause (events n=5,857) and cardiovascular mortality (events n=1,930). Models (n=20,561) were stratified by study phase and region and adjusted for facility clustering effect; baseline patient age, sex, race, BMI, time on ESRD, 13 comorbid conditions, hemoglobin, albumin, normalized protein catabolic rate, single-pool Kt/V, prior parathyroidectomy, and vitamin D prescription; the percentage of patients at a facility with serum calcium ≤8.5, 8.6-10, and >10 mg/dL; and the percentage of patients at a facility with serum PTH ≤100, 101-300, 301-600, and >600 pg/mL.

DOPPS

Tentori et al. AJKD 2008

PTH Distributions

Among Patients on HD > 180 days



Box-plots with weighted 5th, 25th, median, 75th, 95th percentiles by country and phase of DOPPS.

Horizontal lines indicate these percentiles for PTH: 5th=28 pg/mL; 25th=83 pg/mL; 50th=177 pg/mL; 75th=342 pg/mL; 95th=831 pg/mL for the overall DOPPS study sample (n=25,375).

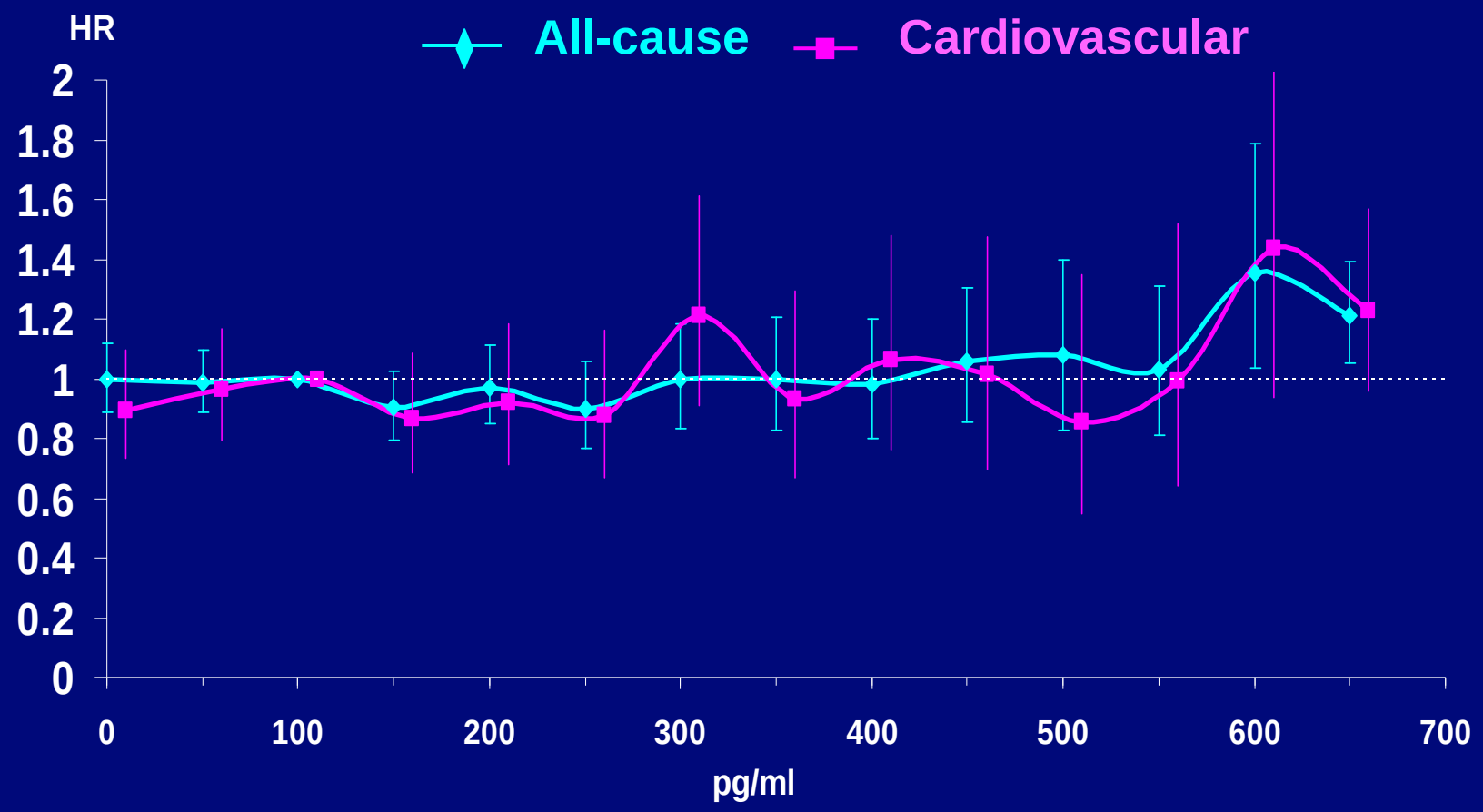
BE= Belgium, FR=France, GE=Germany, IT=Italy, SP=Spain, SW=Sweden, UK=United Kingdom, ANZ= Australia-New Zealand, JA=Japan, CA=Canada, US= United States

DOPPS

Tentori et al. AJKD 2008

Mortality Risk by PTH Categories

Among Patients on HD > 180 days



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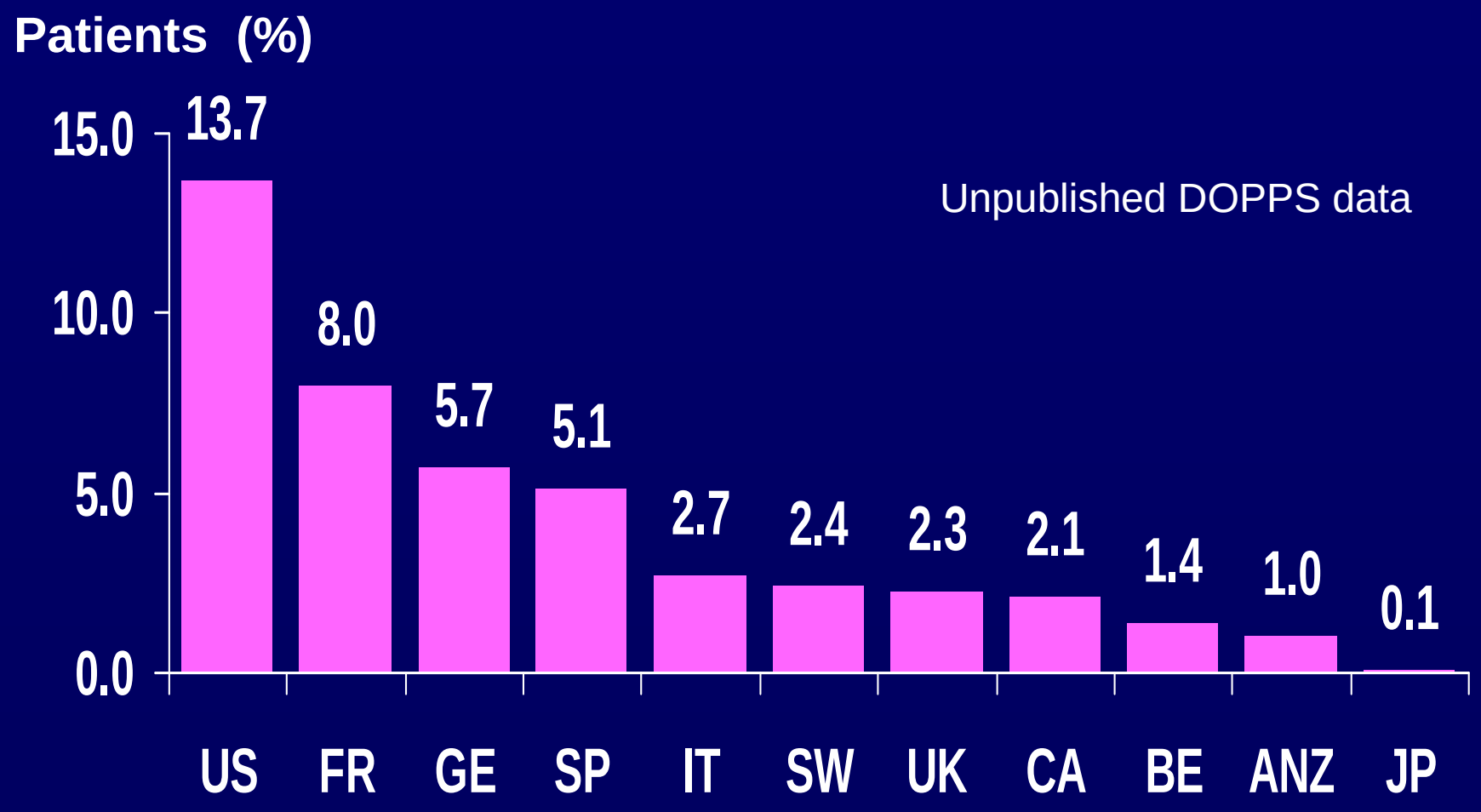
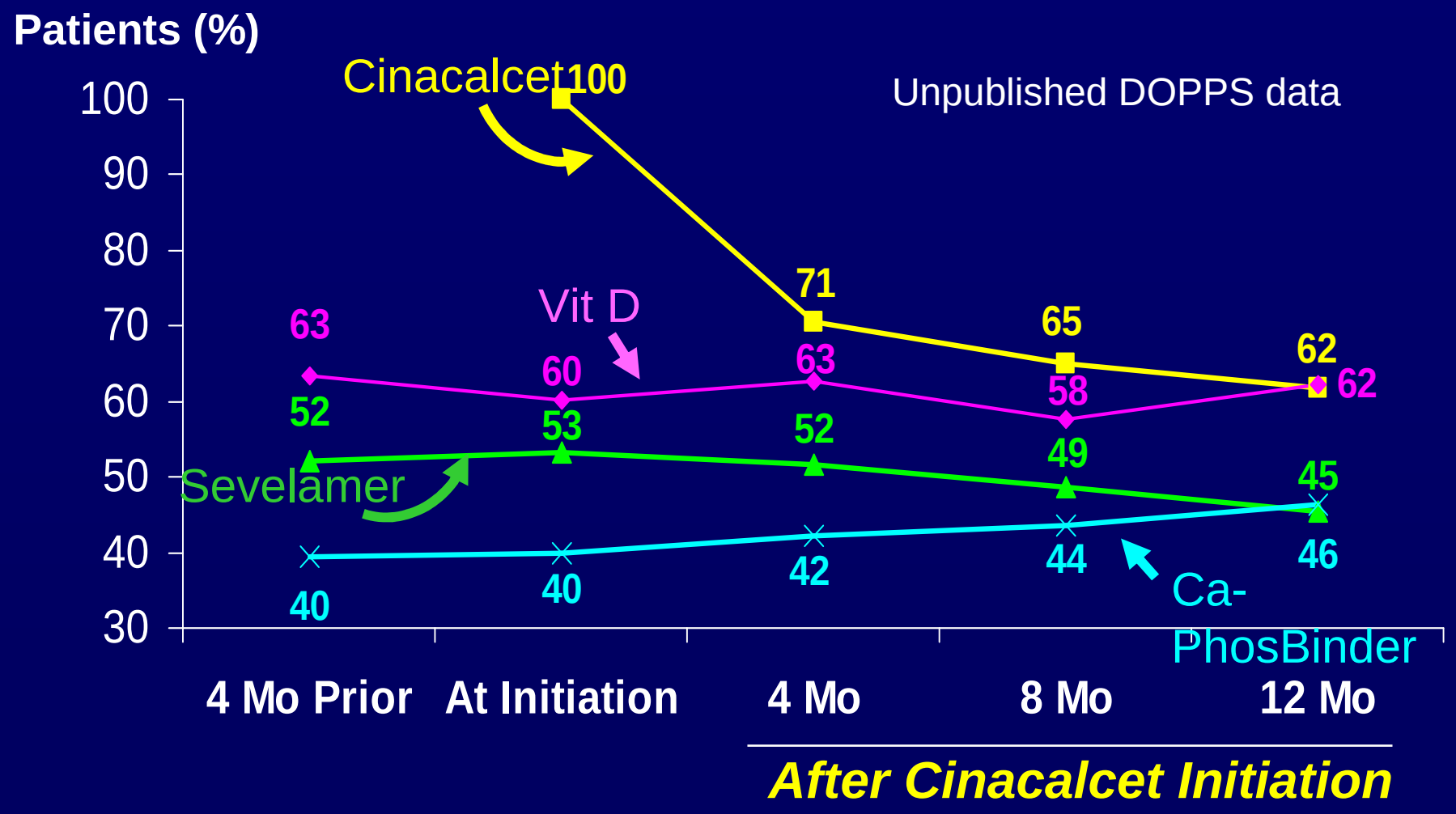
Tentori et al. AJKD 2008

Prevalence of Cinacalcet Use, by Country: DOPPS 3



DOPPS 3 (2005-2007), prevalent cross-section (n=8224).

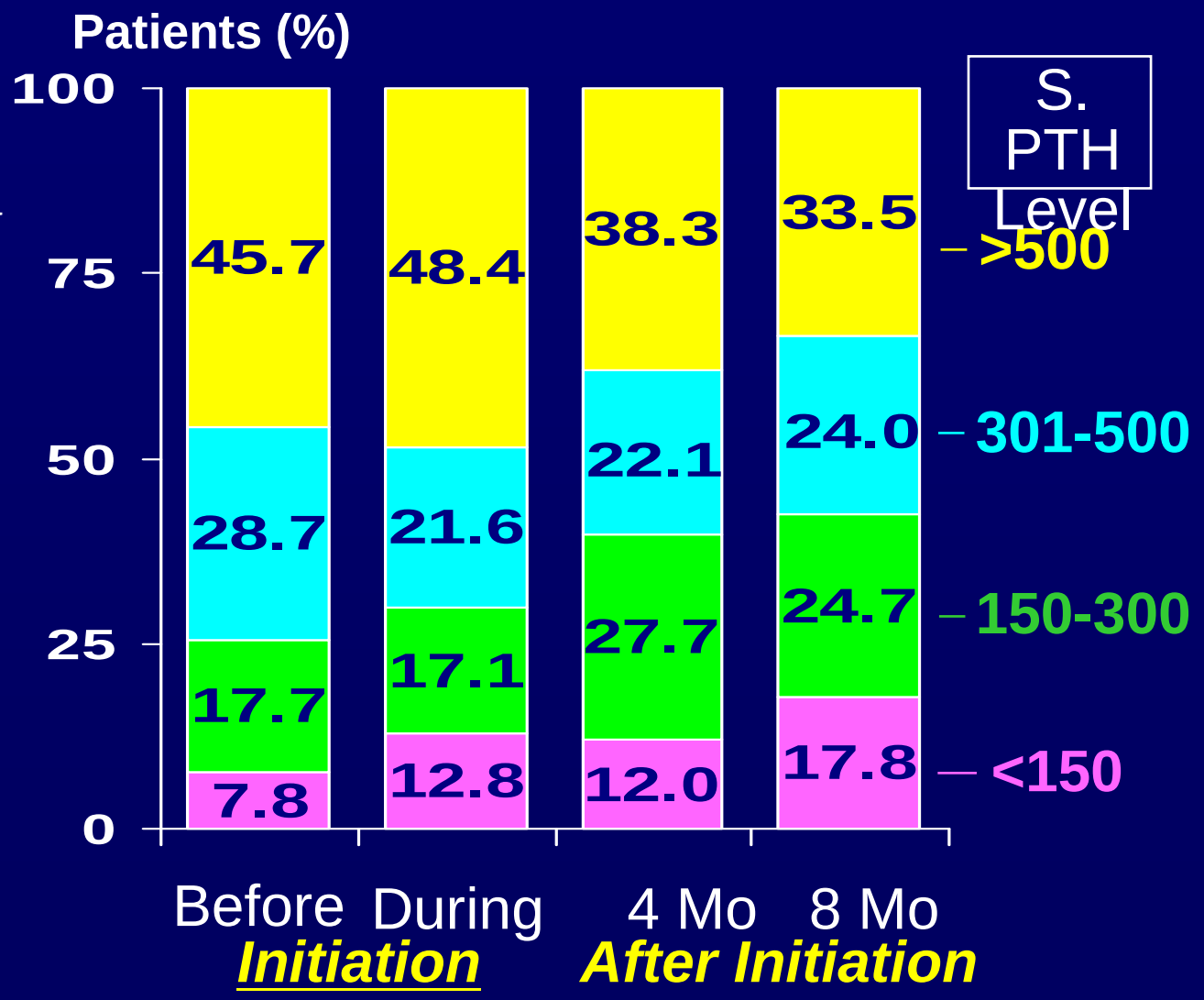
MBD Medication Use Before vs After Cinacalcet Therapy is Initiated: DOPPS 3



n=306 DOPPS III patients at time of initiating cinacalcet therapy AND having follow-up data for at least 8 months AFTER cinacalcet initiation

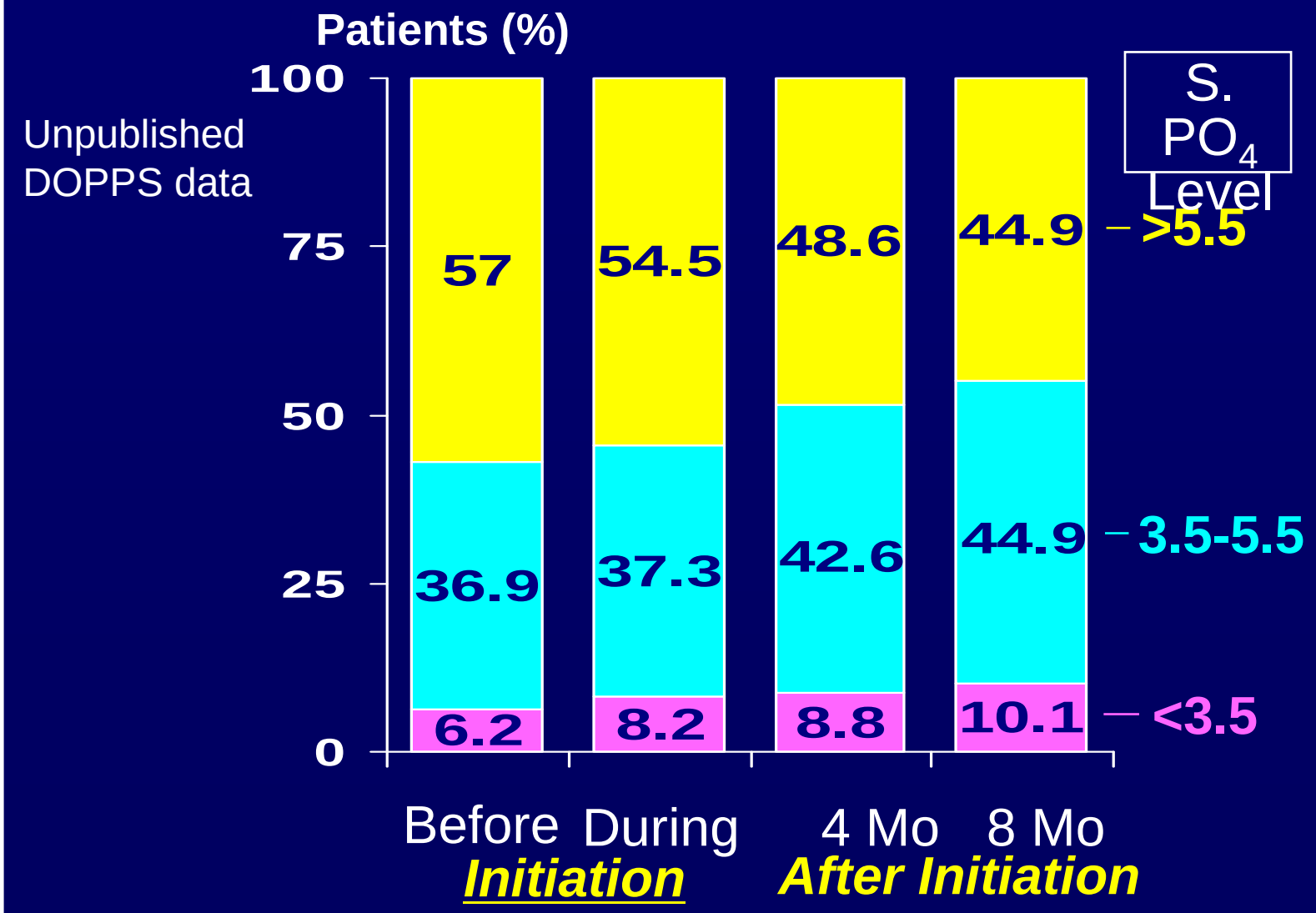
Serum PTH Levels Before vs After Initiation of Cinacalcet Therapy: DOPPS 3

Unpublished DOPPS data



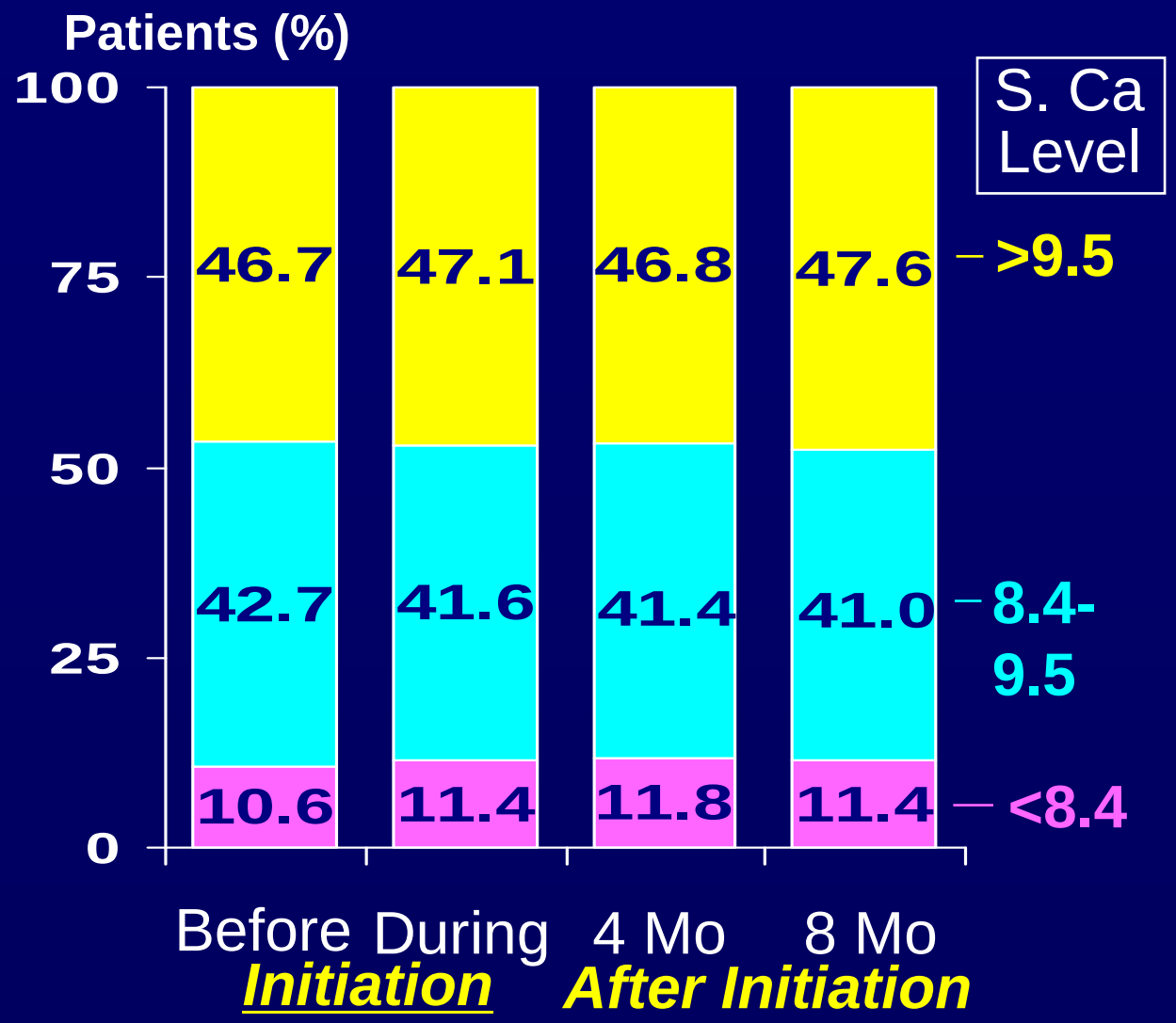
n=306 DOPPS III patients at time of initiating cinacalcet therapy AND received cinacalcet for at least 8 months AFTER cinacalcet initiation

Serum Phosphorus Levels Before vs After Initiation of Cinacalcet Therapy: DOPPS 3



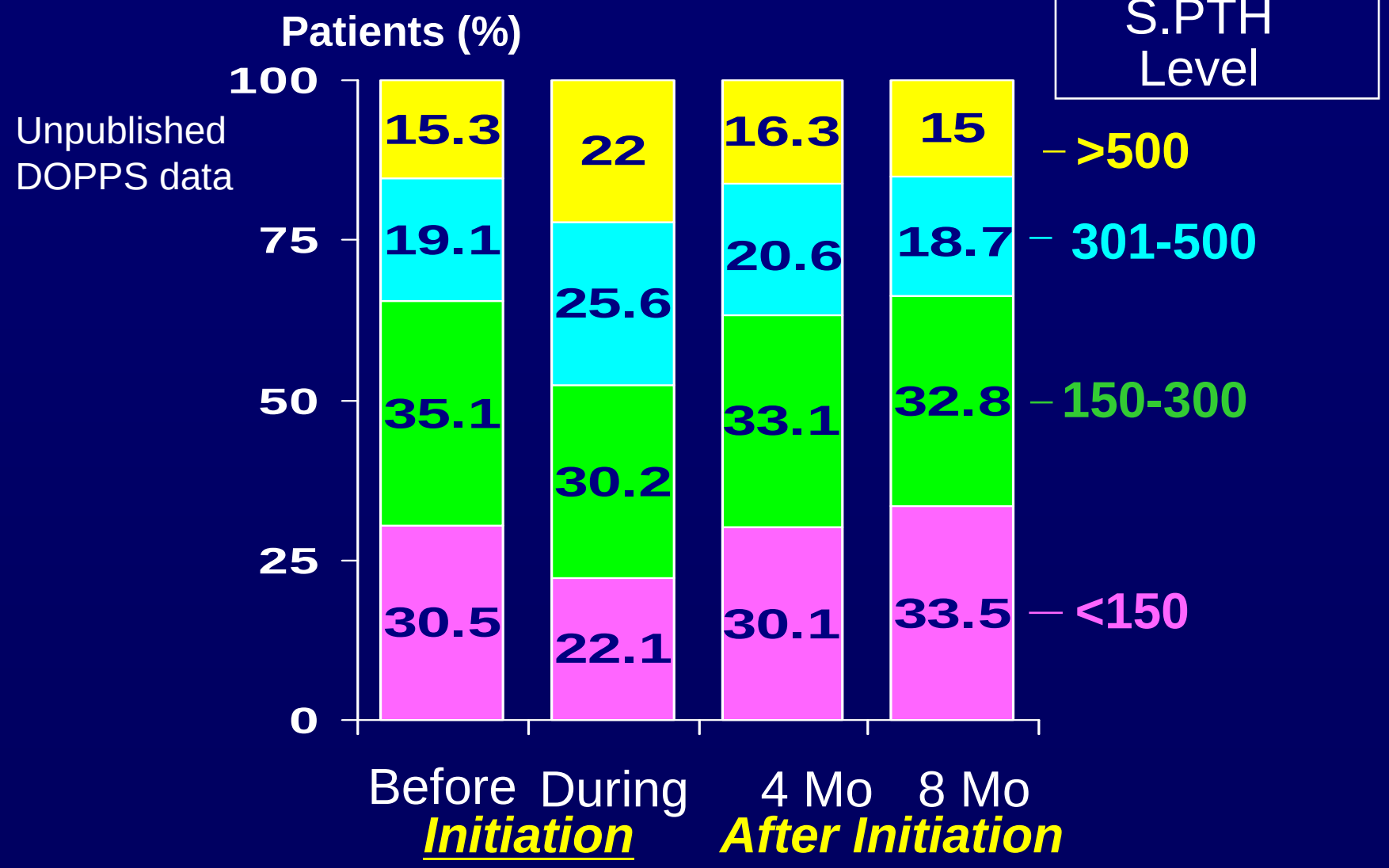
n=306 DOPPS III patients at time of initiating cinacalcet therapy AND received cinacalcet for at least 8 months AFTER cinacalcet initiation

Serum Calcium* Levels Before vs After Initiation of Cinacalcet Therapy: DOPPS 3



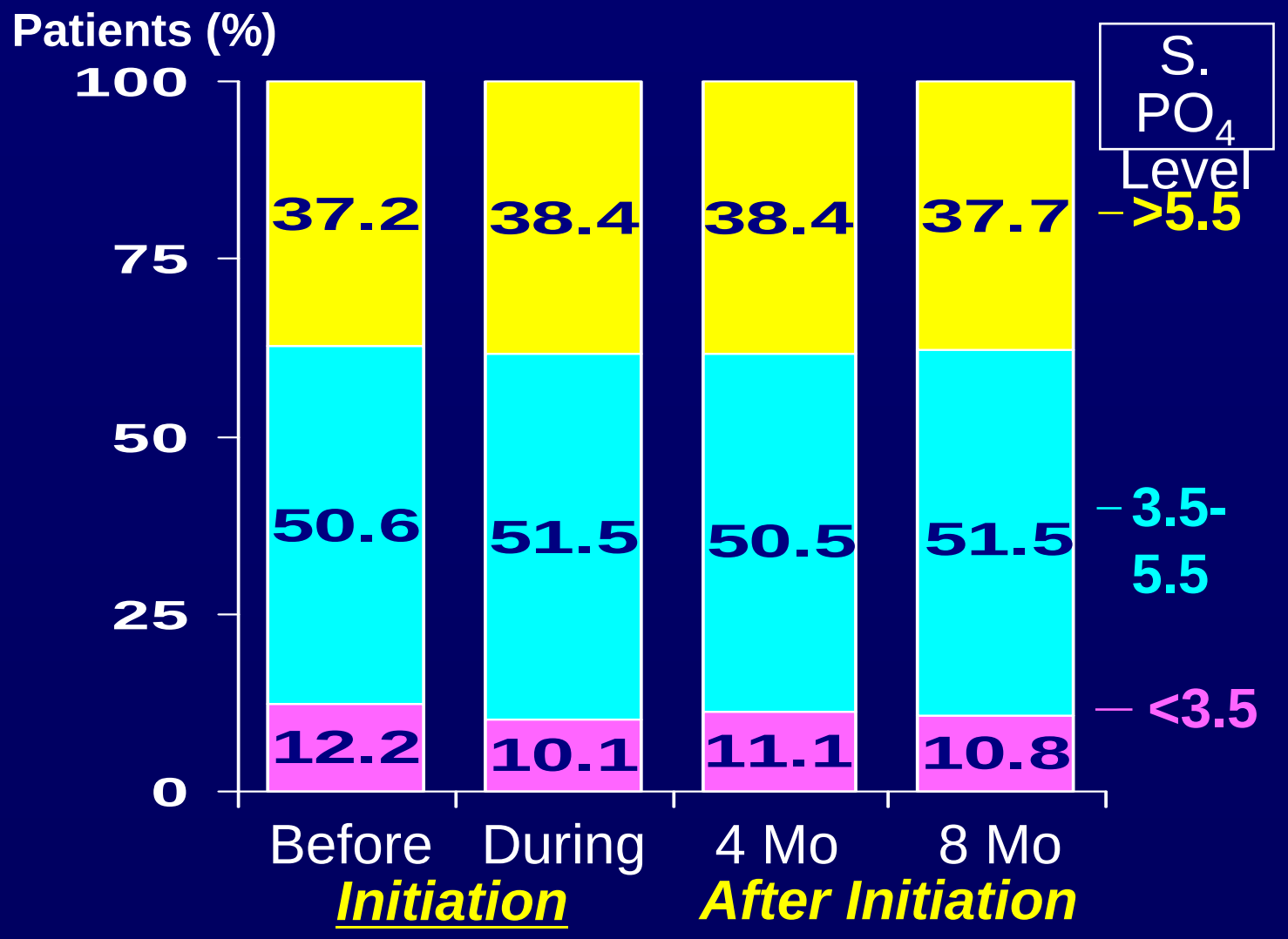
n=306 DOPPS III patients at time of initiating cinacalcet therapy AND received cinacalcet for at least 8 months AFTER cinacalcet initiation;
*albumin-corrected

Serum PTH Levels Before vs After Initiation of Vitamin D Therapy: DOPPS 3



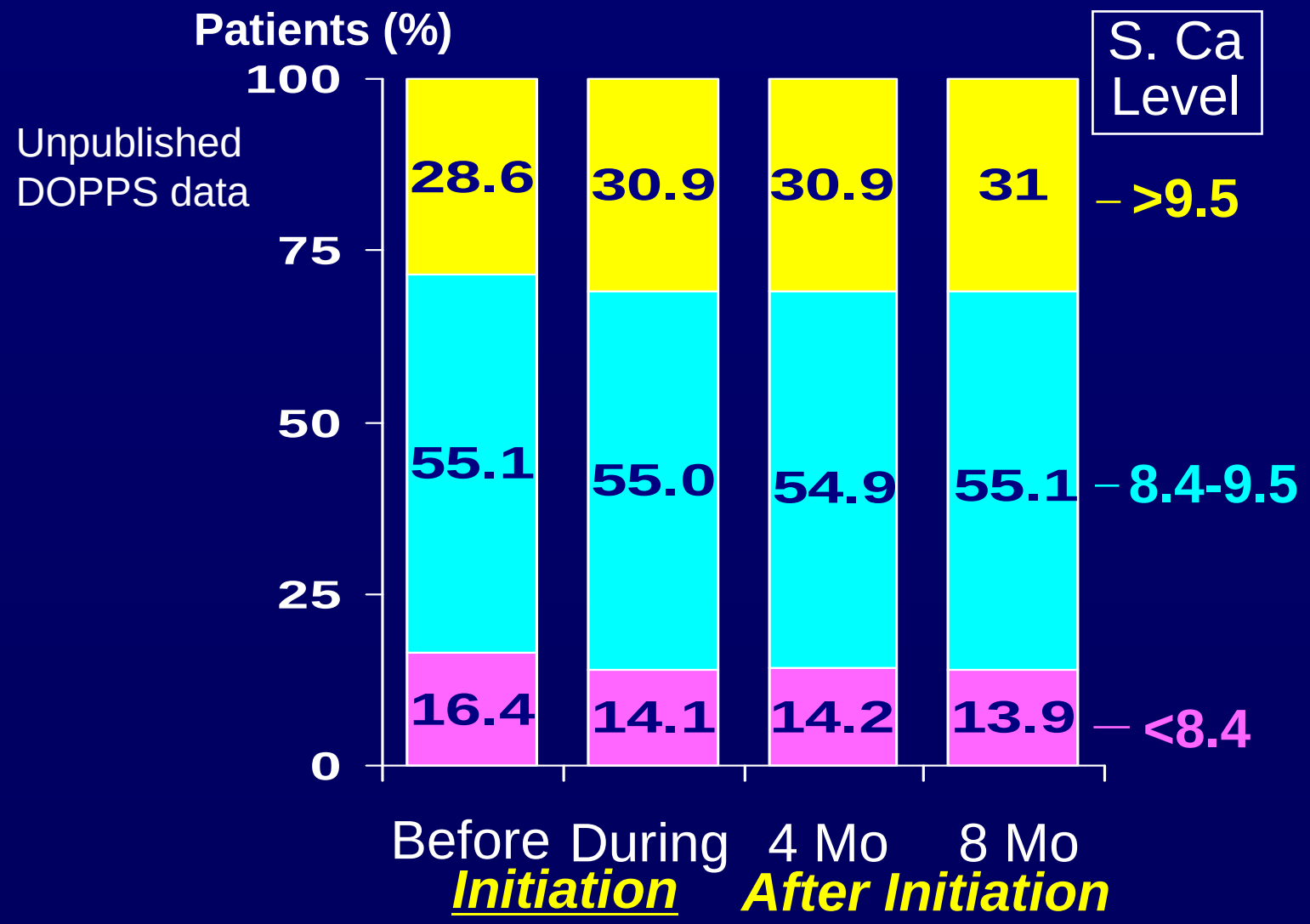
n=786 DOPPS III patients at time of initiating vitamin D therapy AND received vitamin D for at least 8 months AFTER initiating Vitamin D therapy

Serum Phosphorus Levels Before vs After Initiation of Vitamin D Therapy: DOPPS 3



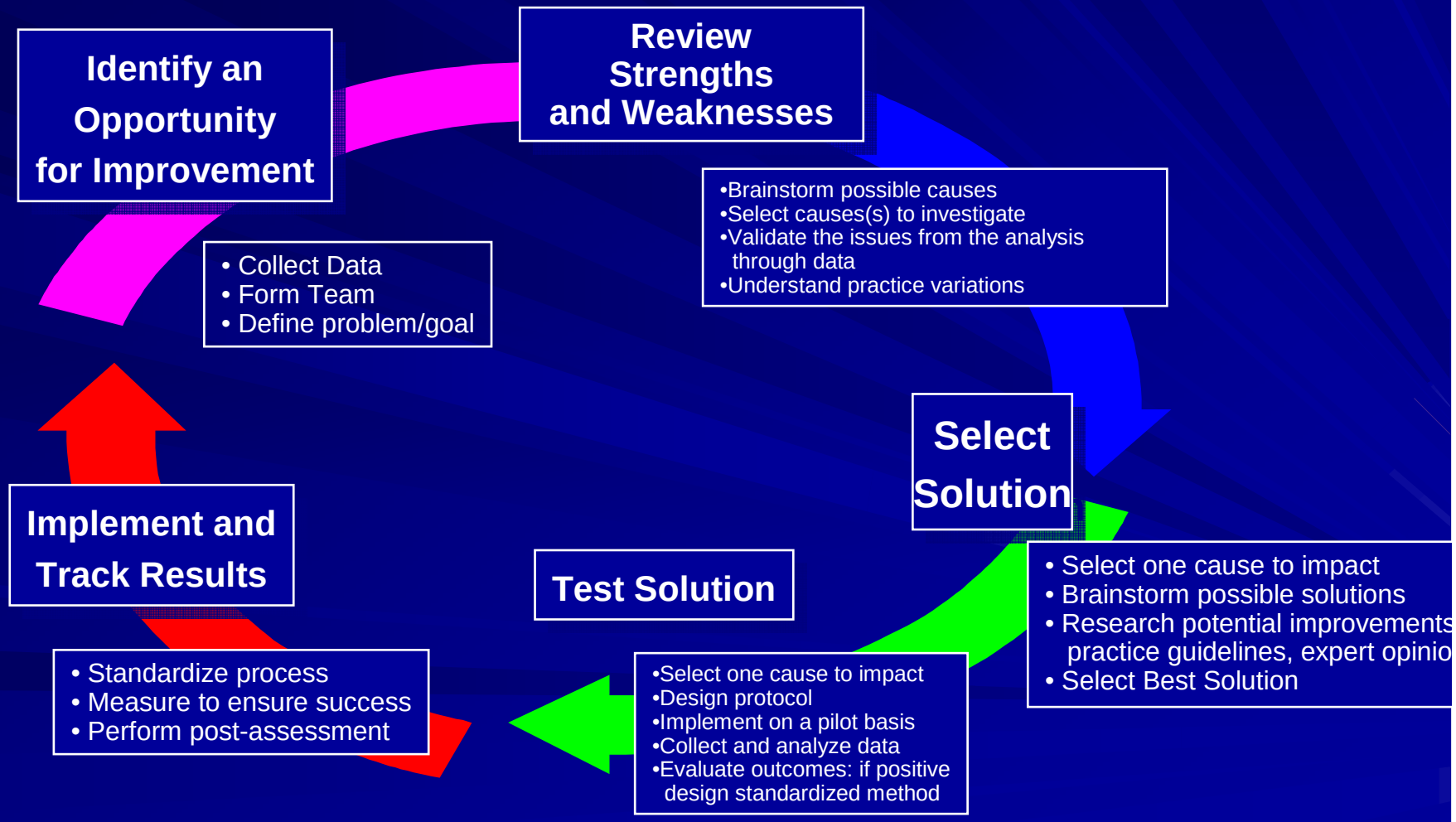
n=786 DOPPS III patients at time of initiating vitamin D therapy AND received vitamin D for at least 8 months AFTER initiating Vitamin D therapy

Serum Calcium* Levels Before vs After Initiation of Vitamin D Therapy: DOPPS 3



n=786 DOPPS III patients at time of initiating vitamin D therapy AND received vitamin D for at least 8 months AFTER initiating Vitamin D

What is Continuous Quality Improvement (C.Q.I.)?



What is PDCA?

A Simple, Effective Approach to Get to the Source of Process Problems

Plan:

Develop a Plan to Improve

- Identify the opportunity for improvement
- Document the present process
- Create a vision of the improved process
- Define the scope of the improvement effort

Do:

Carry out the Plan

- Pilot the proposed changes on a small scale, with customers and over time

Check:

Study the Results

- Observe what you learned about the improvement of the process

Act:

Adjust the process, based on new knowledge

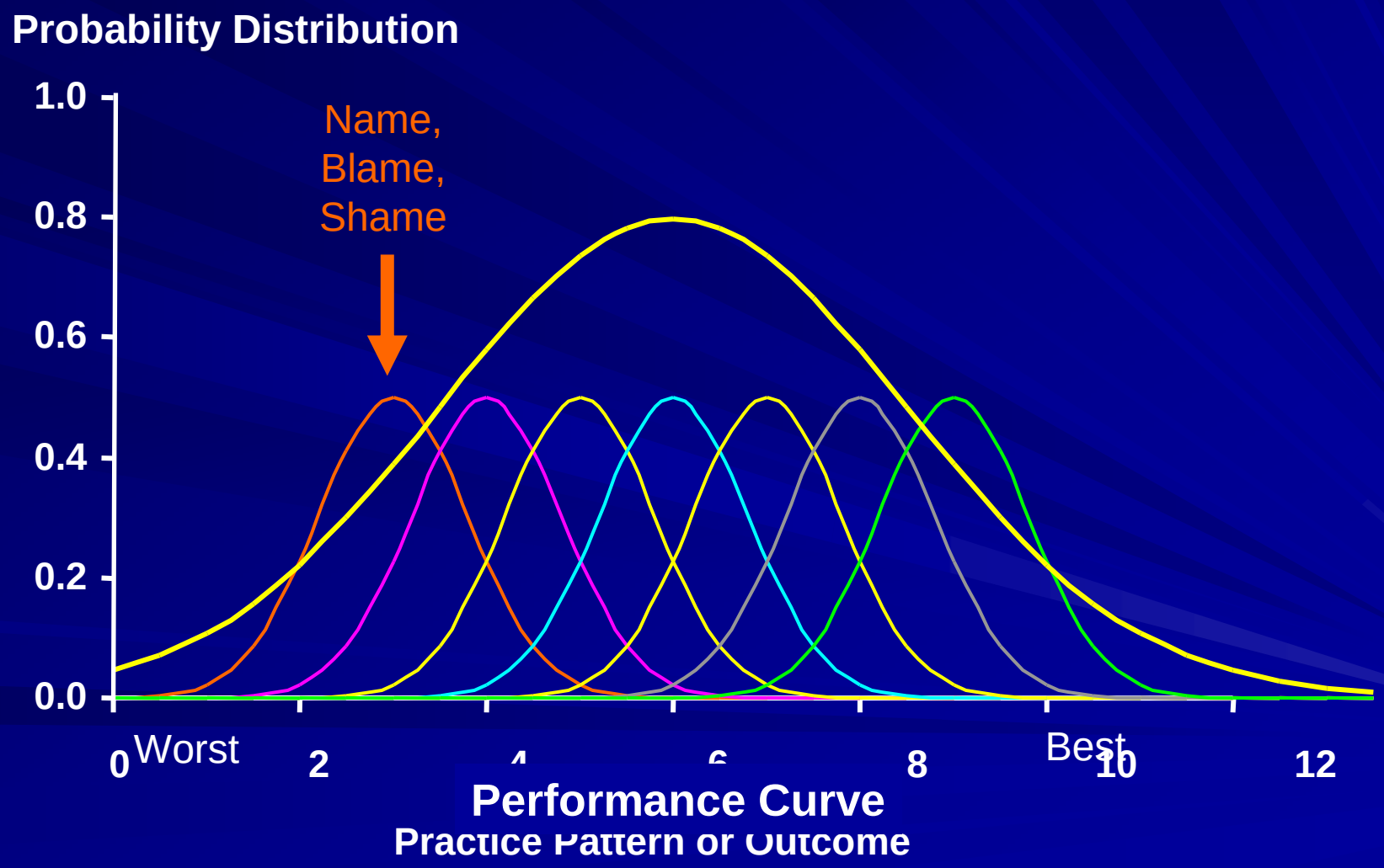
- Operationalize the new mix of resources Repeat the Cycle on the next opportunity

QUALITY

THE RACE FOR QUALITY HAS NO FINISH LINE-
SO TECHNICALLY IT'S MORE LIKE A DEATH MARCH.

www.despair.com

CQI Approaches (1)
Focus on individuals



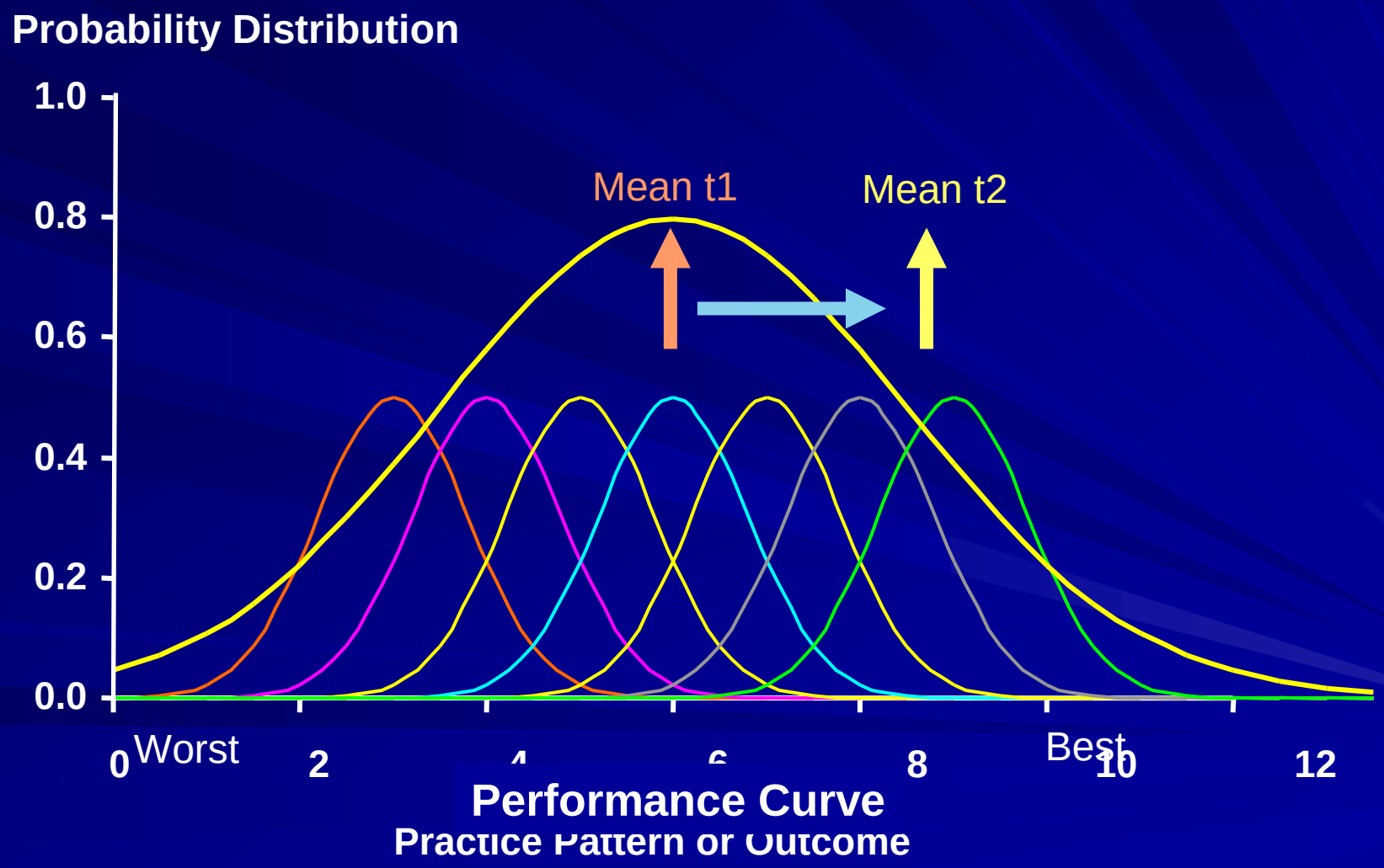
BLAME

THE SECRET TO SUCCESS IS KNOWING WHO TO BLAME FOR YOUR FAILURES.

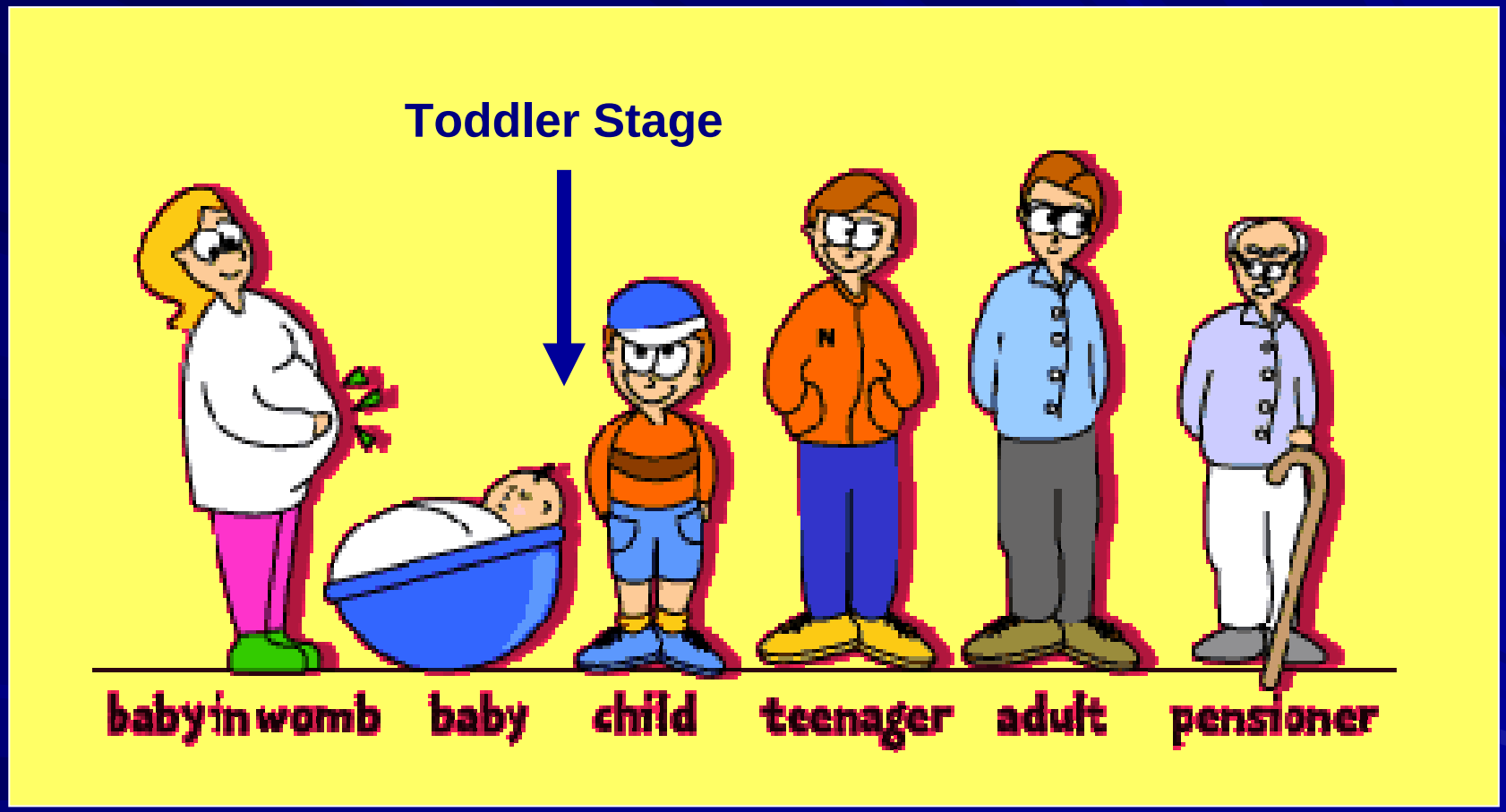
www.despair.com

CQI Approaches (2)

Focus on the team, the system, and the process of care

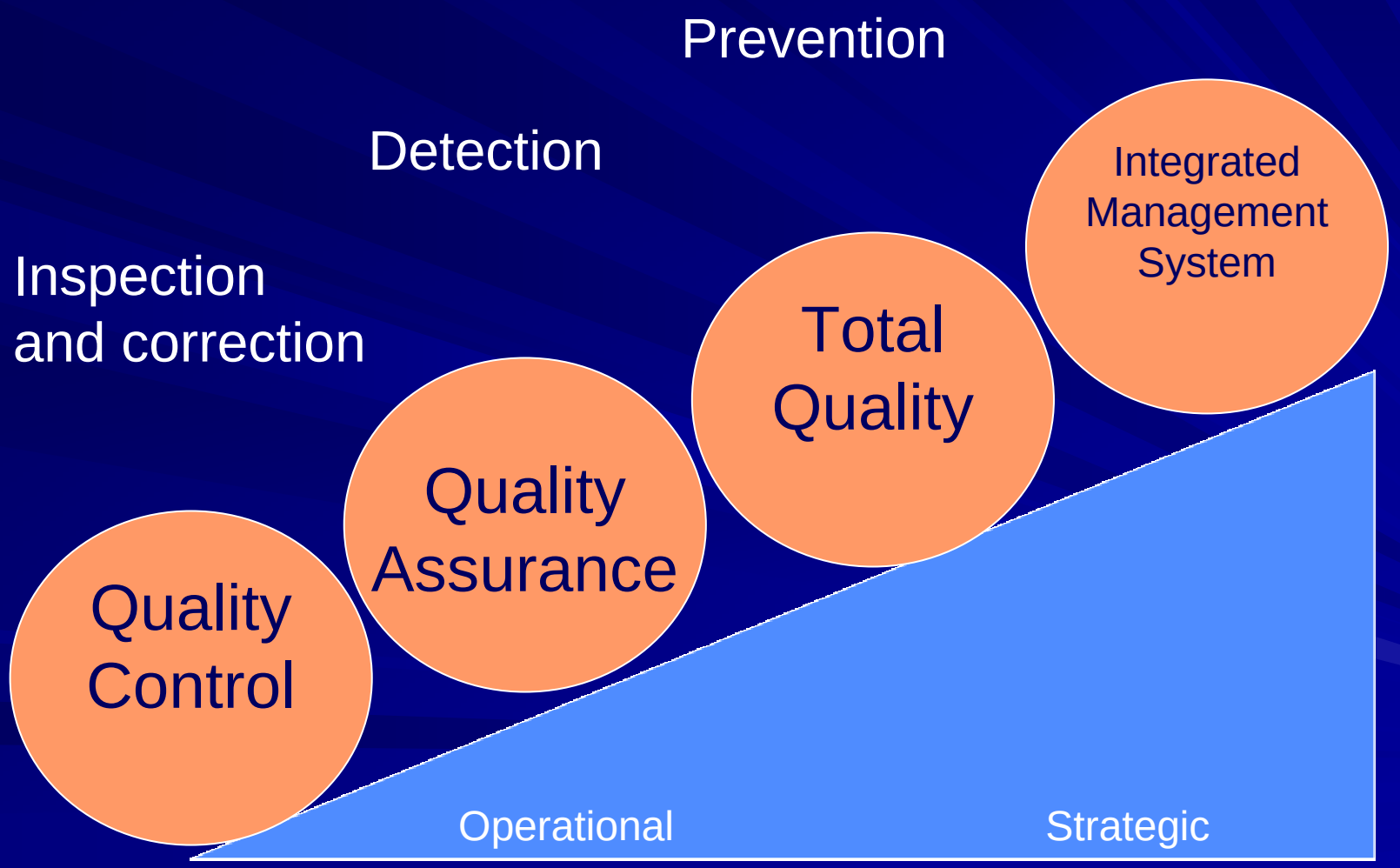


Where are we at?

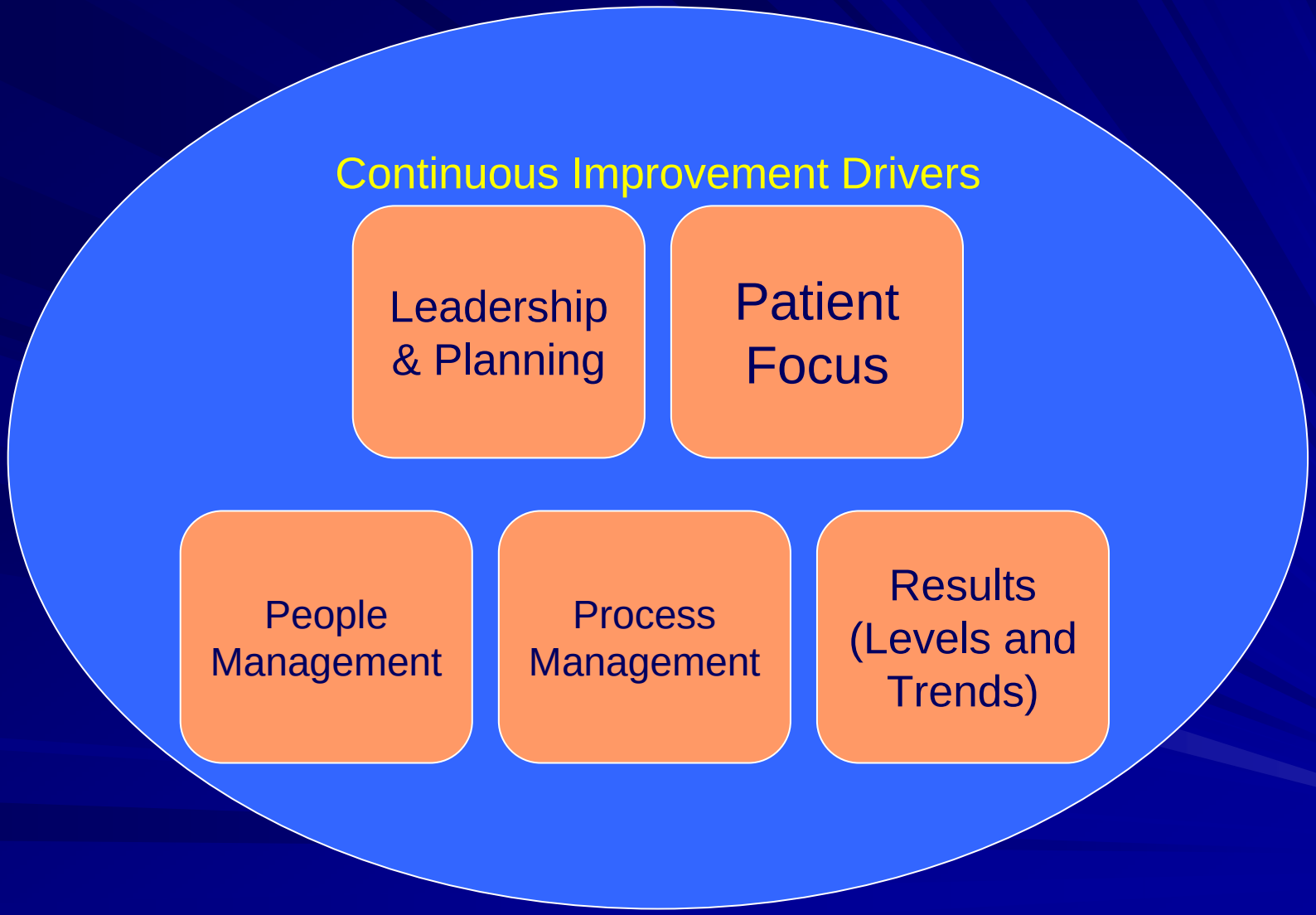


NB: Most hospital departments and other specialty areas are at the infant stage.

Evolution

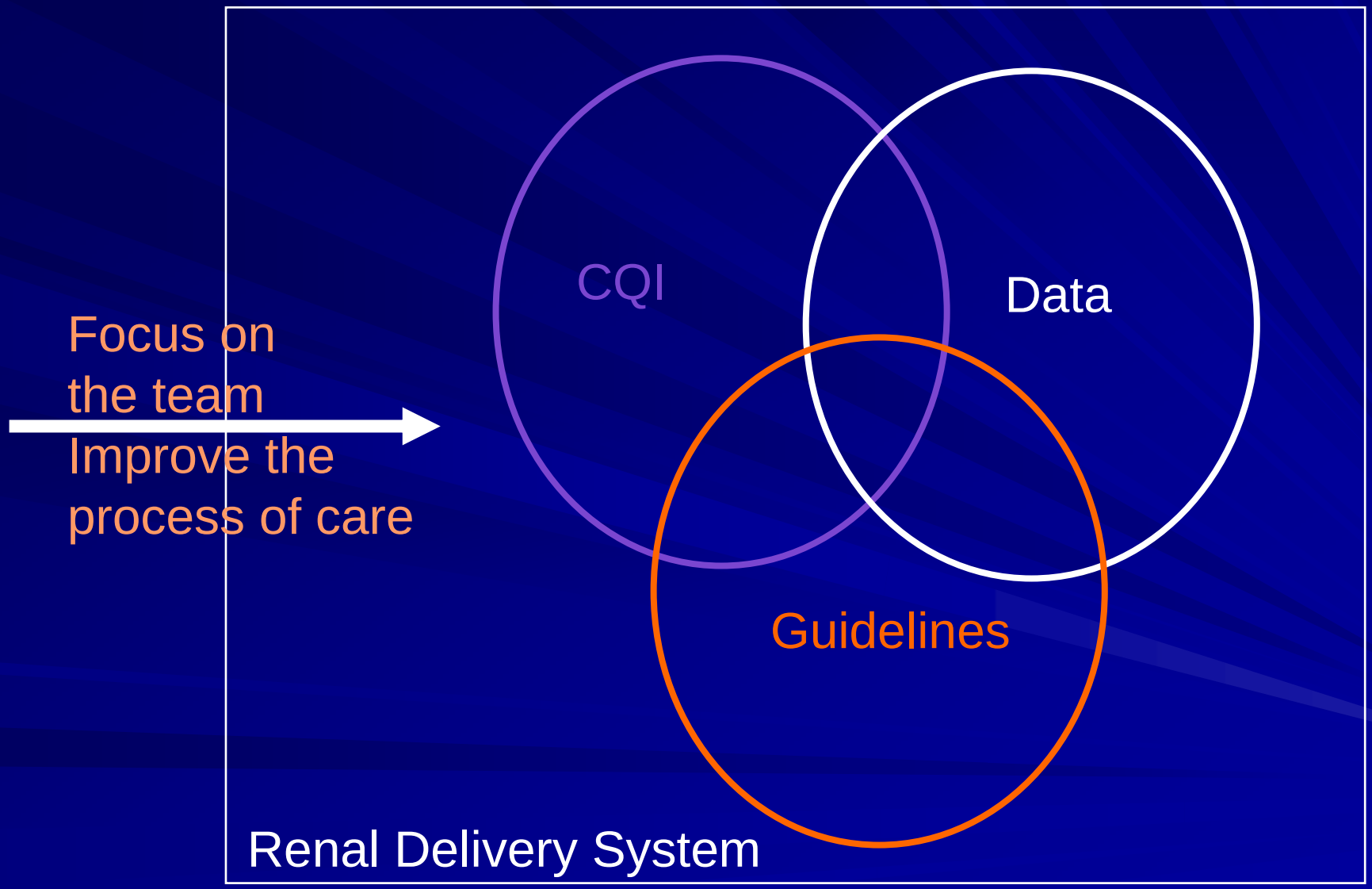


Perry and associates



Perry and Associates

Optimization of Renal Care



Federal Express

- Error rate is 1: 1,000,000
- What is the error rate in health care or dialysis settings?

The future of dialysis?

We can only manage things better if we think in a different way

Tensions

- How do we reconcile the empowerment of the autonomous and expert clinician operating within the powerful doctor – patient relationship with the clear imperative to improve hemodialysis care systems and processes in a factory like manner?
- Perhaps by quantifying patient satisfaction and psychosocial elements of care

Mendelssohn and Benaroia. NDT March 2008

Lessons from the US Dialysis Industry

- 1990 – for profit facilities were felt to compromise quality of care for cost containment
- 1995 – for profit chains take control
- 2005 – Davita buys Gambro
- 2006 – Fresenius buys RCG
- 2006 – DSI enters the picture
  - For profit chains are now leading the industry in CQI
  - Independents cannot invest in software and infrastructure, cannot achieve economies of scale and are a doomed species

Standard Quality Indicators

- Kt/V or URR
- Hemoglobin
- Calcium and phosphorus

- Most units can report on these at least
- Some can report on more than this
- These are unidimensional, and do not tell the whole story about quality in a facility

Quality of Care in the USA

- 15 years ago, America recognized that mortality outcomes were poor, and there was concern that quality was compromised by the for profit industry
- Dramatic change has occurred
  - Annual facility reports
  - ESRD networks mandated to improve care
  - Self interest of providers
  - USRDS report, CPM report

Quality in the USA

- Information flows to and from facilities, chains, networks, USRDS and to the public
- This is mandated and linked to reimbursement
- Public accountability
  - www.cms.hhs.gov/dialysisfacilitycompare
- Objective evidence of success
  - Fistula first initiative
  - KDOQI
  - DOPPS

Some is not a number, Soon is not a time

DM Berwick

2006 ANNUAL REPORT
ESRD CLINICAL PERFORMANCE MEASURES PROJECT

OPPORTUNITIES
TO IMPROVE CARE FOR
IN-CENTER HEMODIALYSIS
AND PERITONEAL DIALYSIS PATIENTS

JANUARY 2007

Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Clinical Standards & Quality
Baltimore, Maryland

Data on adult and pediatric in-center hemodialysis patients are from October–December 2005

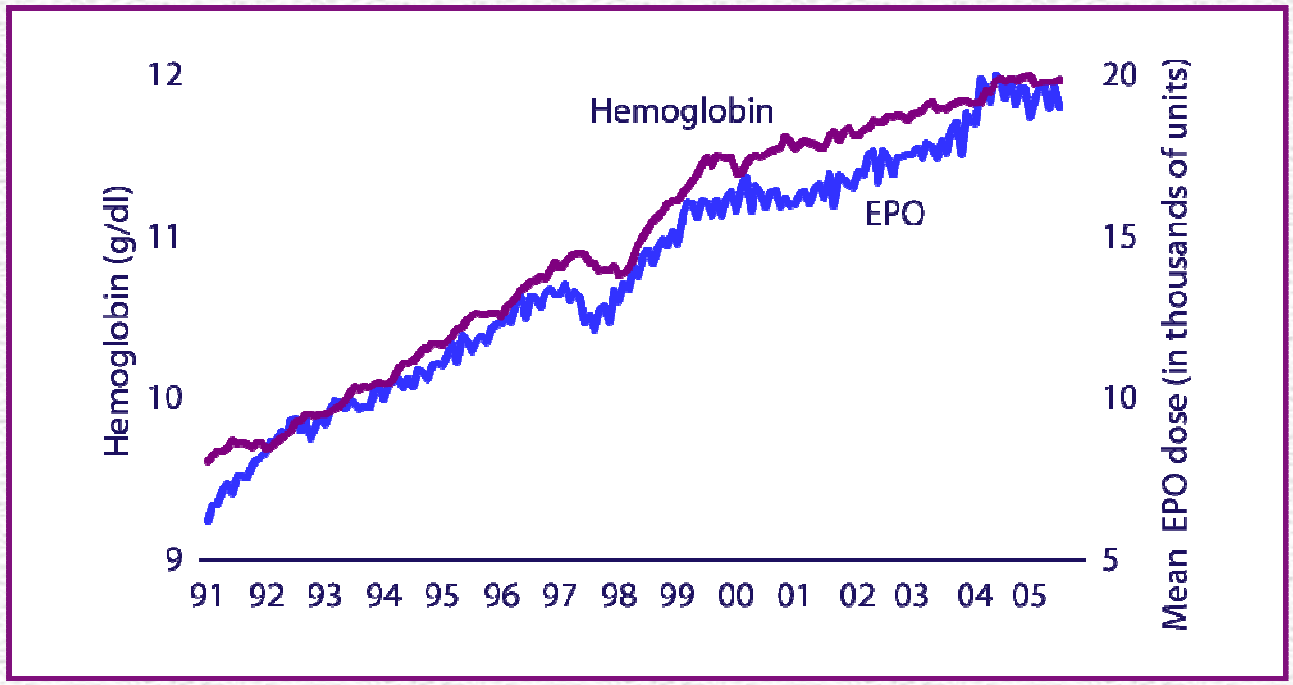
Data on adult and pediatric peritoneal dialysis patients are from October 2005–March 2006

USRDS

- 2007 report is published
- 12 chapters, one entirely devoted to quality indicators, with 51 slides
- Trends since 1991
- 2007 reports focuses on anemia management, HbA1C, lipids, diabetic eye exams, comprehensive diabetic care, vaccinations, vascular access
- Another whole chapter on CVD

Mean monthly hemoglobin & mean EPO dose per week

Figure 5.3

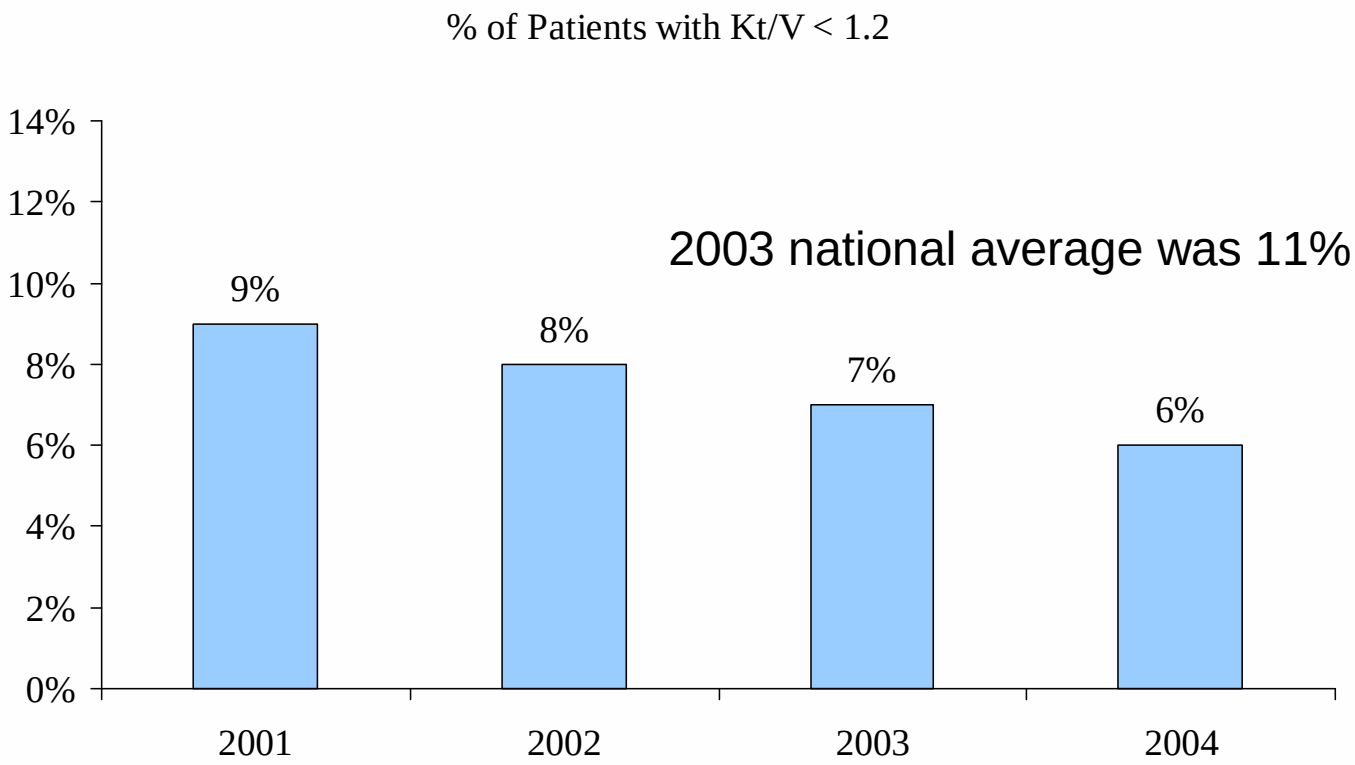


Period prevalent dialysis patients with EPO claims; monthly hemoglobin includes all claims with a hematocrit value between 10 & 50; weekly EPO dose includes all claims for patients with an average number of administrations per month of ≤ 20. EPO doses prior to are adjusted for inpatient days.

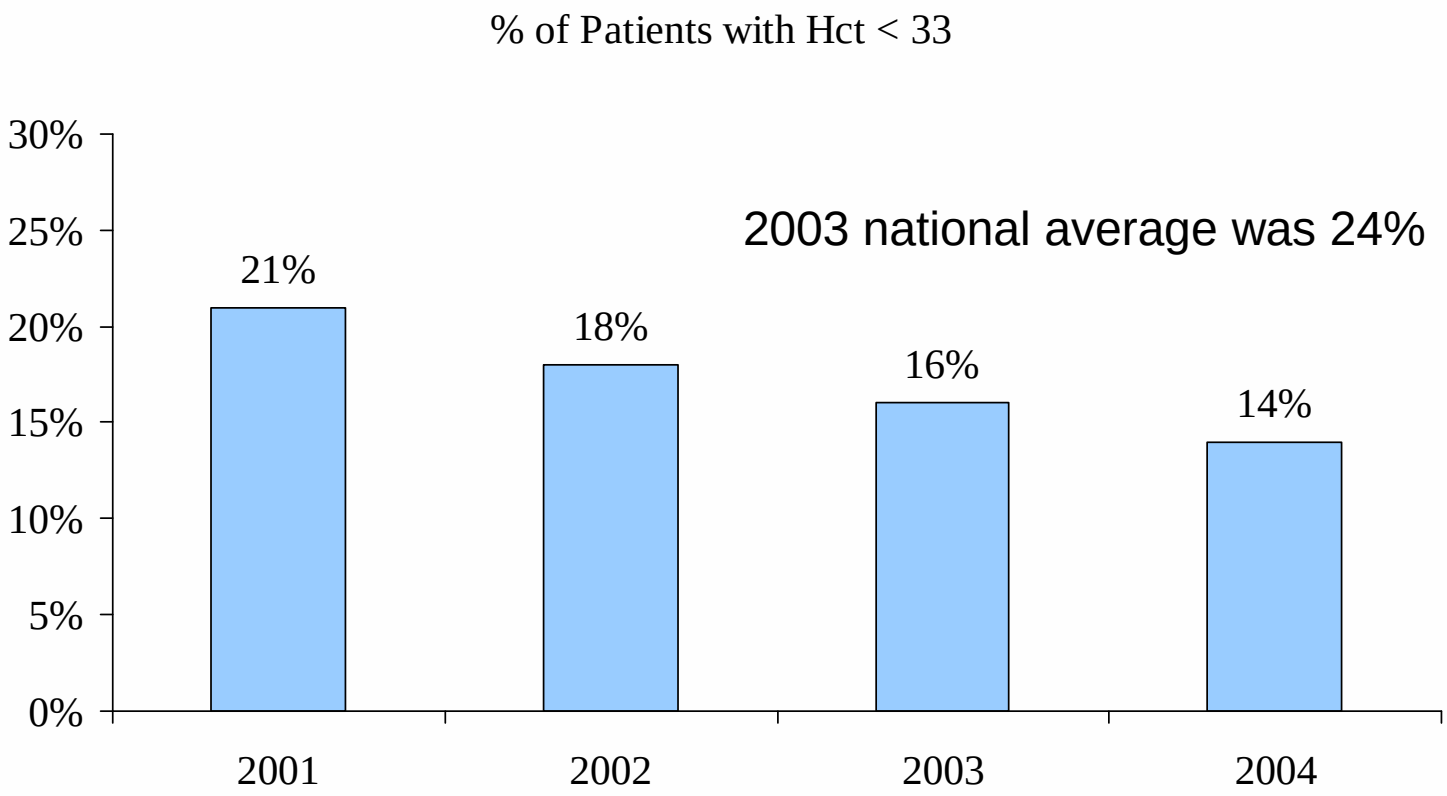
USRDS

Guidelines
should not be set into stone!

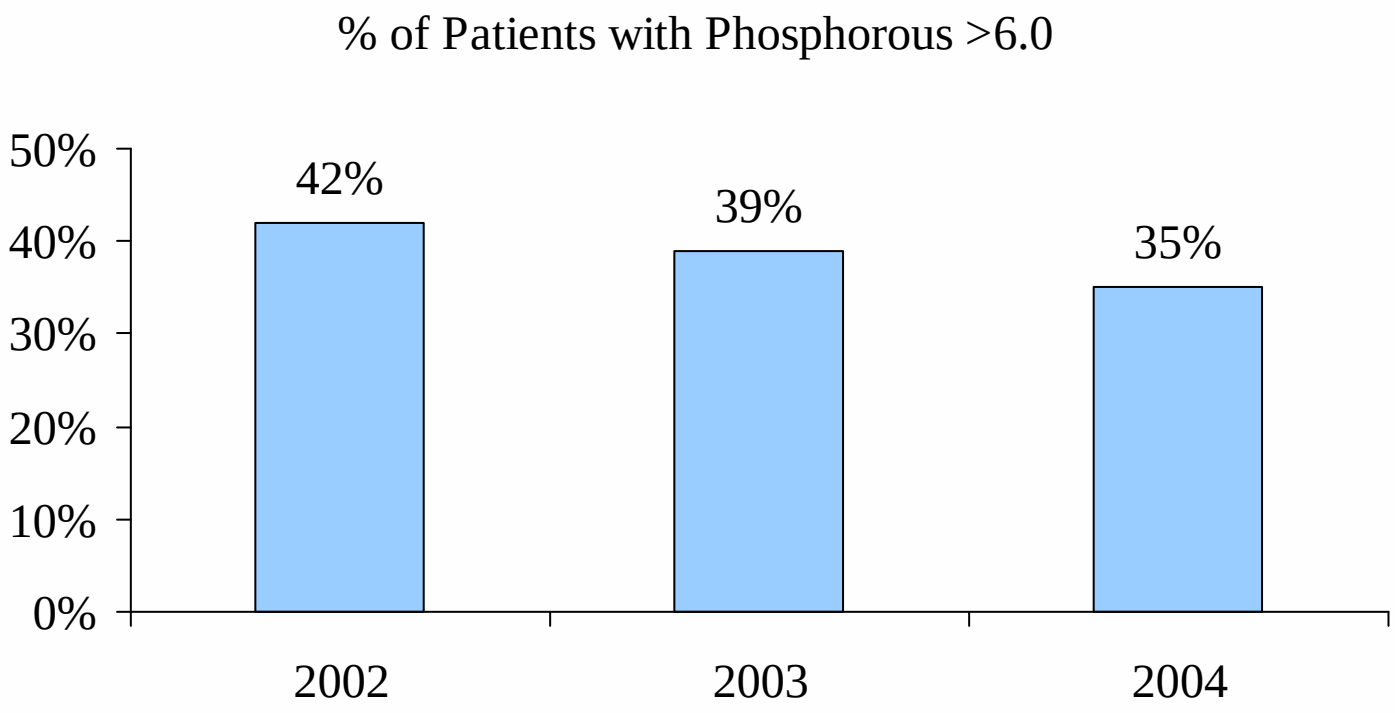
DaVita Clinical Outcomes – Adequacy



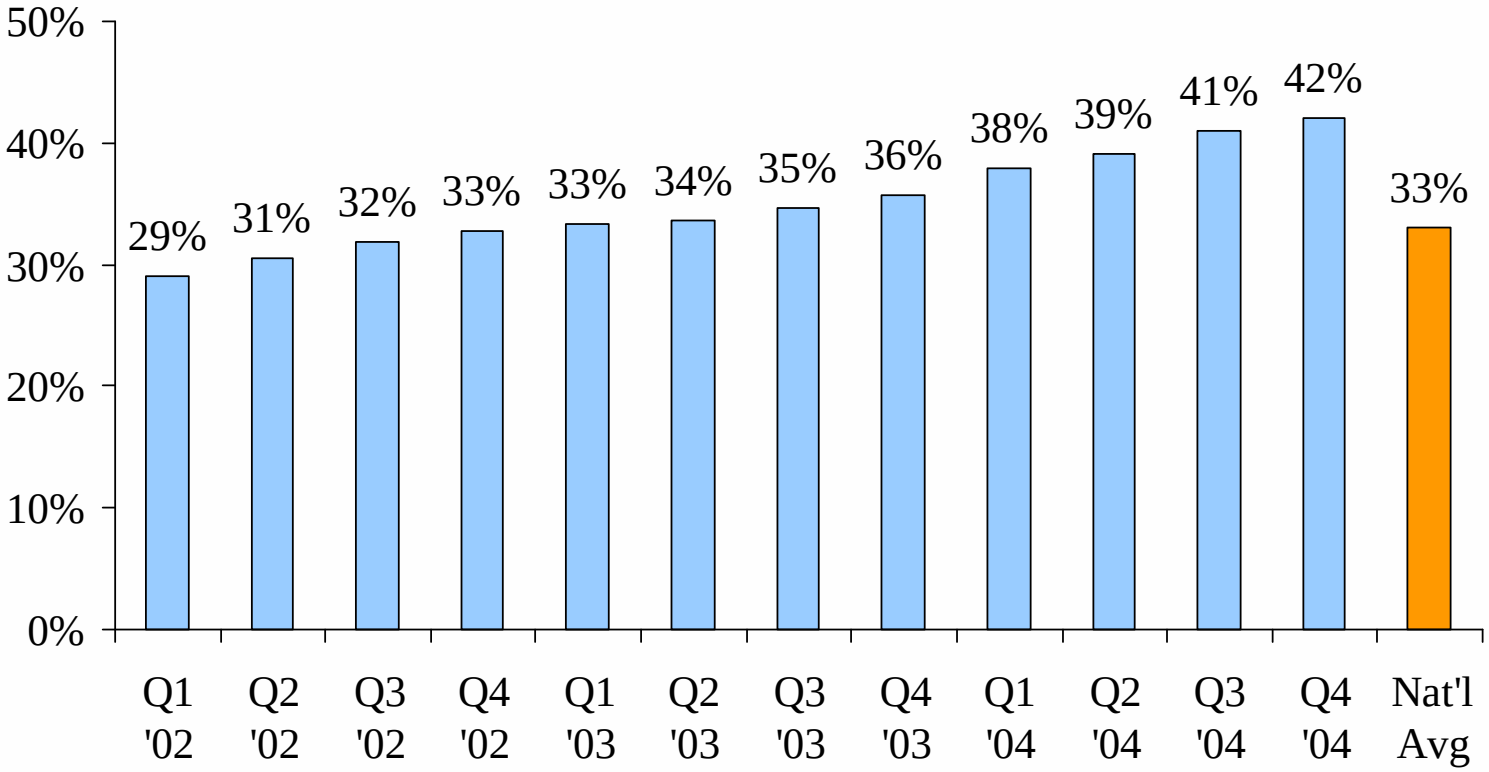
DaVita Clinical Outcomes – Anemia Mgmt



DaVita Clinical Outcomes – Phosphorous



DaVita Fistula Access



DaVita Quality Index (DQI)

Function of:

- Kinetics (Kt/V)
- Anemia (Hgb x 3)
- Albumin
- Phosphorous
- PTH
- Mortality (SMR)
- Vascular Access

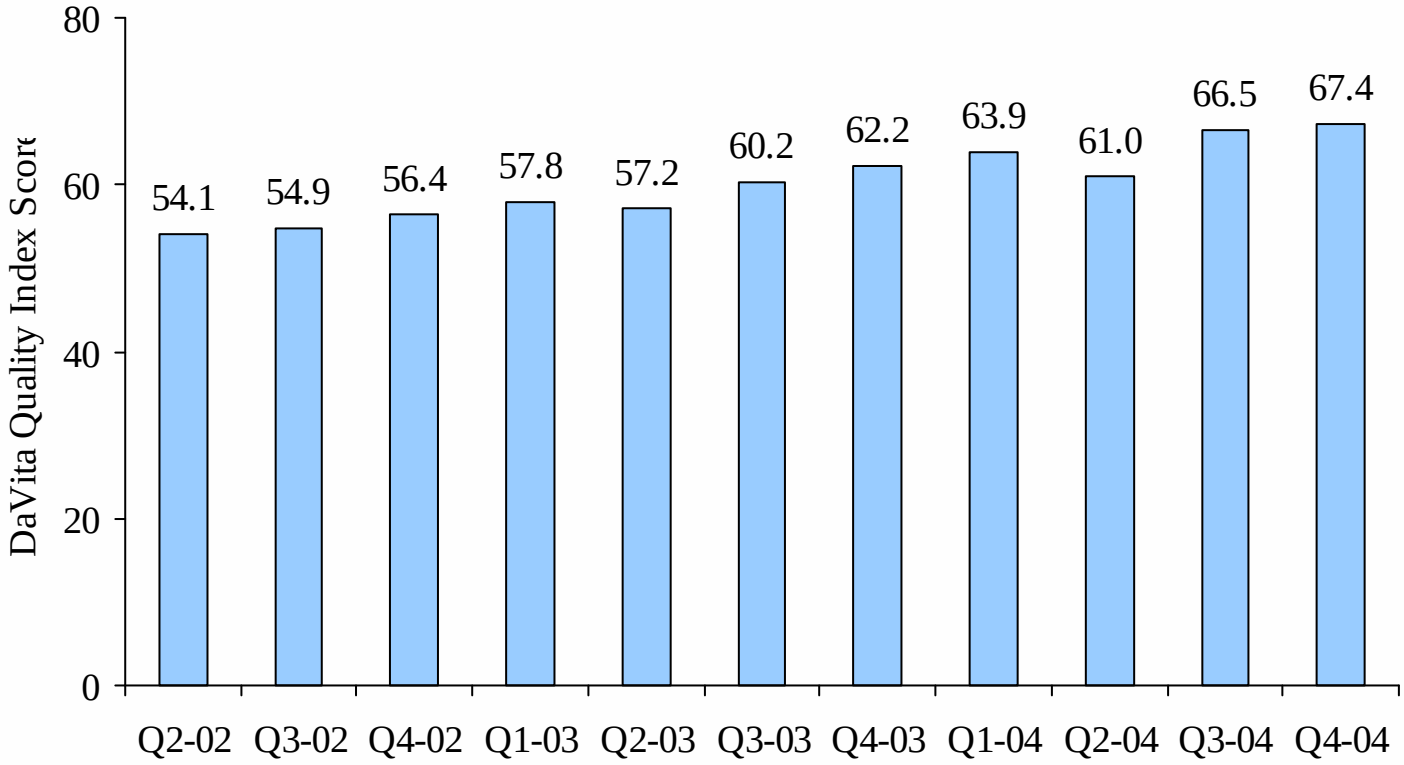
Emphasis on Aggregation of Standardized Measures

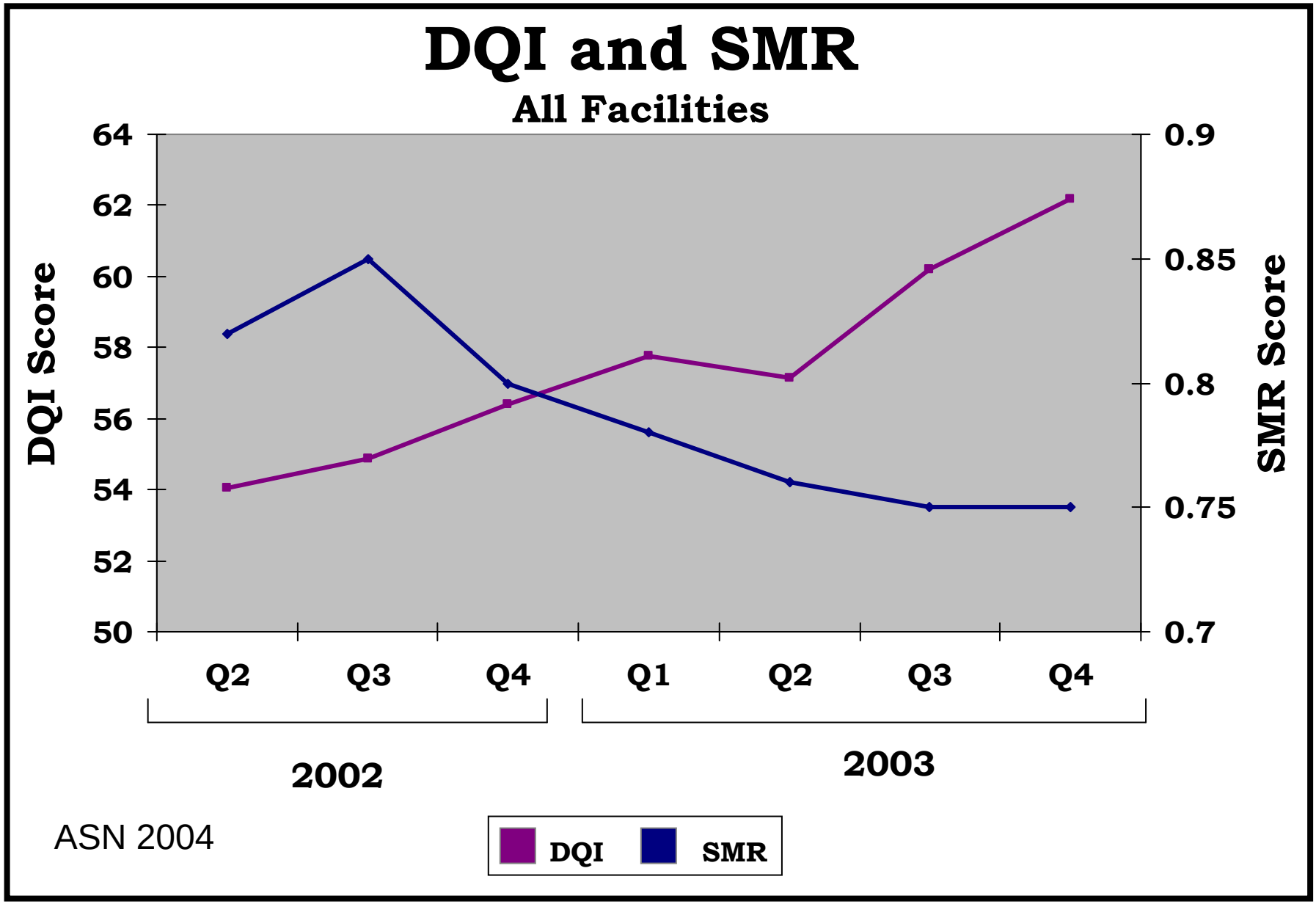
DaVita Quality Index Formula

1. Kinetics (Kt/V) – 20 points
   - % above 1.4 less below 1.2
2. Anemia (Hgb x 3) – 20 points
   - % above 33 less below 33
3. Albumin – 15 points
   - % above 4.0 less below 3.0
4. Phosphorous – 15 points
   - % below 6.0 (*15) less above 8.0 (*10)
5. PTH – 15 points
   - % below 300 less above 800
6. Mortality (SMR) – 5 points
   - 1 minus SMR
7. Vascular Access – 10 points
   - 1 minus % catheters, no score if >50% catheters

90 days in the system

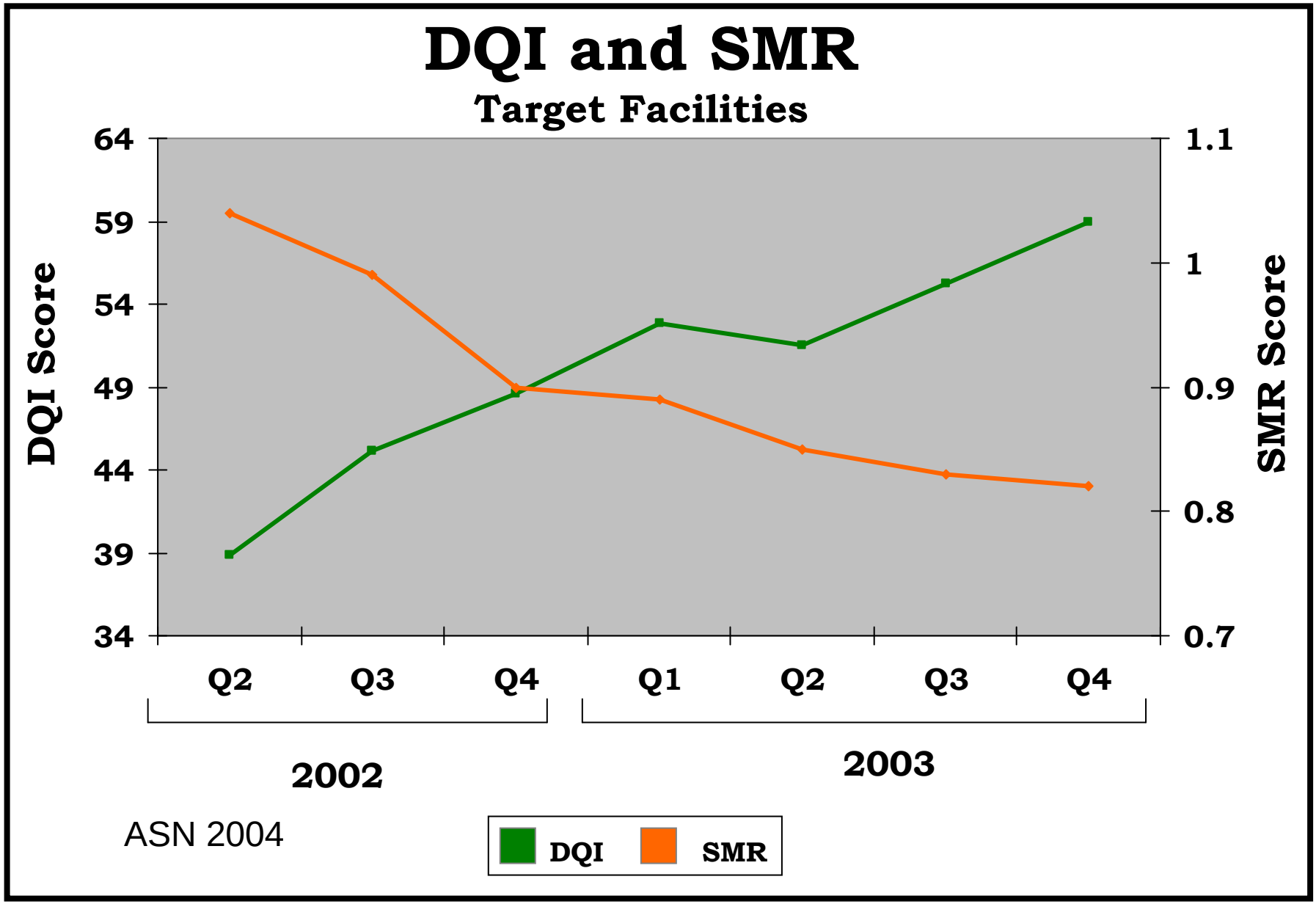
DaVita DQI Trajectory




DQI and SMR
All Facilities
DQI Score
SMR Score
64
62
60
58
56
54
52
50
0.9
0.85
0.8
0.75
0.7
Q2
Q3
Q4
Q1
Q2
Q3
Q4
2002
2003
DQI
SMR

ASN 2004

58 poorest performing facilities with DQI < 45, SMR 1.04, were closely monitored



ASN 2004

DQI…DaVita Quality Index Adjusted formulas 2005

A summary of the DaVita Quality Index (DQI) scoring system

Indicators	Formula	Points
Kt/V	(% ≥1.4 x 15) minus (% <1.2 x 15)	= points earned of 15 possible
– Weighting reduced from 20 points		
Hgb x3	(% ≥33 x 15) minus (% <33 x 15)	= points earned of 15 possible
– Weighting reduced from 20 points		
PTH	(% 50-150 x 15) minus (% ≥400 x 15)	= points earned of 15 possible
– Range adjusted (<300 or > 800)		
Phosphorus	(% ≤6.0 x 20) minus (% ≥8.0 x 10)	= points earned of 20 possible
– Increased weighting from 15 points		
Albumin	(% ≥4.0 x 10) minus (% <3.0 x 10)	= points earned of 10 possible
– Weighting reduced from 15 points		
SMR	(1 – SMR) x 5	= points earned of 5 possible
CVC	(1 – % CVC) x 10 plus (1 + % FIS) x10)	= points earned of 20 possible
– Rewards for fistulas are added, increased weighting from 10 points		

- *if %CVC is ≥50%, then 0 points are scored*

Davita Quality Index
Strengths

- I love the concept!
  - An index to describe quality
  - An environment that nurtures and rewards staff based on quality
  - Used in > 600 facilities
  - Allows for sequential internal and external comparisons
  - It seems to work well as a driver of CQI, and improved patient outcomes

Davita Quality Index
Weaknesses

- I hate the execution of it!
  - Many of the formulas and targets are arbitrary, opinion based and counterintuitive
  - Only based loosely on KDOQI
  - SMR should not be part of it, SMR may be a tool for validation
  - We can do better!

I have no doubt that technically, we could reduce injuries to patients by 99% or more, saving tens of thousands of lives every year. But the changes required to get there are so profound that most hospitals and clinics will not find their own way.

DM Berwick

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Amgen provides unrestricted funding to support this investigator initiated project

A New Approach

A Practice – Related Risk Score (PRS): A DOPPS Derived Aggregate Quality Index for Hemodialysis Facilities

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NDT advance access

DOPPS

Aggregate Index Development

- Elements should be based on modifiable practices
- Should be measurable
- Should have well defined relationships to outcomes
- Should make sense to busy clinical staff

DOPPS

Table 1:Facility Measures Included in PRS

- % patients with Kt/V ≥ 1.2
- % patients with Hgb ≥ 11 g/dl
- % patients with Albumin ≥ 4.0 g/dl
- % patients with catheters

Based on a prevalent cross-section of DOPPS I patients. Also tested but not significant: calcium, phosphorus, calcium-phosphorus product, treatment time, shortened treatments, multivitamin use, vaccination

DOPPS

Variables examined and rejected

1) calcium
2) phosphorus
3) calcium phosphate product
4) treatment time
5) shortened treatments
6) multivitamin use
7) vaccination

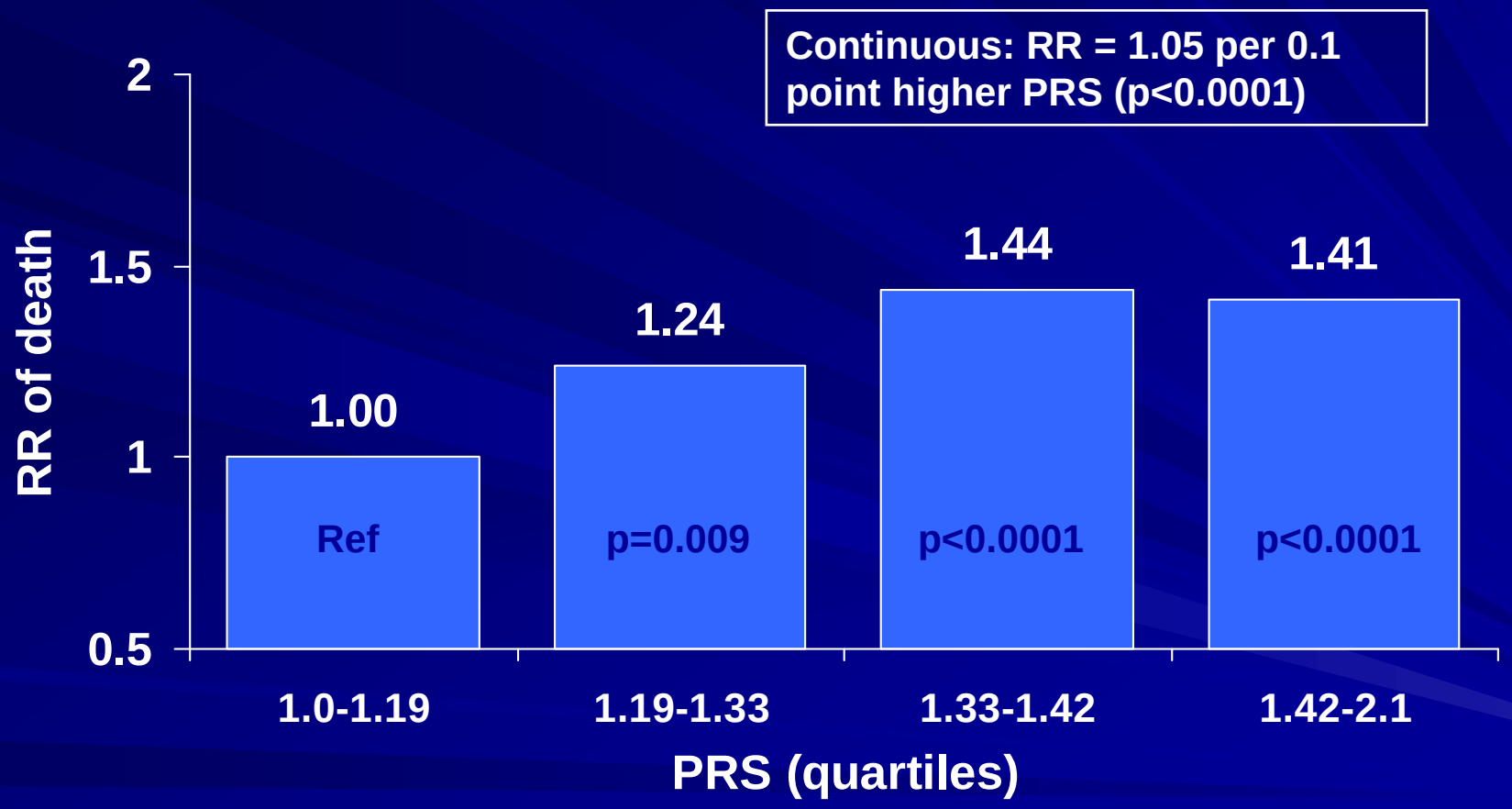
DOPPS

Table 2: Calculating PRS Based on Facility Model Results

Facility Factor	N facilities	RR* Death	Example Facility
Kt/V ≥1.2, 0-40%	15	1.46	
Kt/V ≥1.2, 40-60%	49	1.33	a
Kt/V ≥1.2, 60-80%	99	1.06	
Kt/V ≥1.2, 80-100%	113	1.00	
Hgb ≥11 g/dl, 0-20%	67	1.26	
Hgb ≥11 g/dl, 20-60%	191	1.18	
Hgb ≥11 g/dl, 60-100%	47	1.00	a
Cath use, 20-100%	61	1.13	
Cath use, 10-20%	63	1.12	a
Cath use, 0-10%	182	1.00	
Alb ≥4.0 g/dl, 0-20%	68	1.18	
Alb ≥4.0g/dl, 20-40%	87	1.06	
Alb ≥4.0 g/dl, 40-100%	127	1.00	a
Example: Total Score = 1.33 * 1.00 * 1.12 * 1.00 = 1.49			

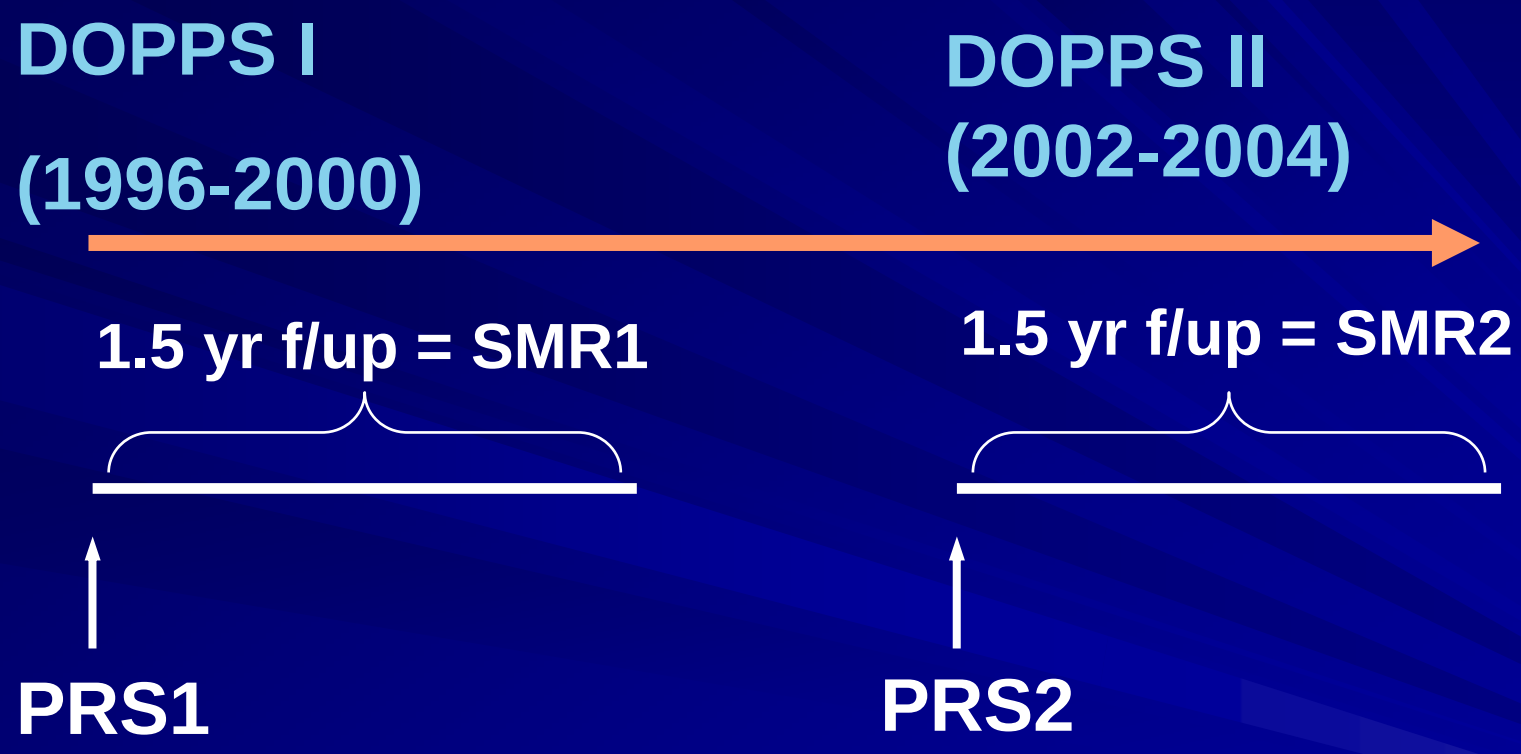
*RRs based on Cox model adjusting simultaneously for all four facility factors and patient age, gender, black race, years with ESRD, 13 summary comorbid conditions, and unit type; analysis was stratified by country, and accounted for facility clustering effects

Figure 1: Adjusted relative risk of death by quartiles of PRS – DOPPS II



Adjusted for age, gender, race, time on dialysis, 13 summary comorbid conditions, and unit type; stratified by country.

Figure 2: Design of the facility-based Delta-Delta analysis method



ΔSMR (SMR2 – SMR1) vs. ΔPRS (PRS2 – PRS1)

Figure 3: Delta-Delta analysis: Decrease in PRS significantly related to decrease in SMR*

PRS

0.2 point decrease

All facilities N=119

p=0.006

SMR

0.19 point decrease

e.g. SMR 1.0 → 0.81

***Restricted to facilities in both DOPPS I and II**

Discussion

- Traditional DOPPS results are observational and so are hypothesis generating
  - Critics of DOPPS cite this limitation loudly and frequently
- Delta – delta analysis is a major validation of the DOPPS approach and brings it closer to proving causality
- Simulates an RCT
- Supports a strong link between achieving targets and hard outcomes

Next Steps for PRS?

Improve the PRS

Improve the PRS

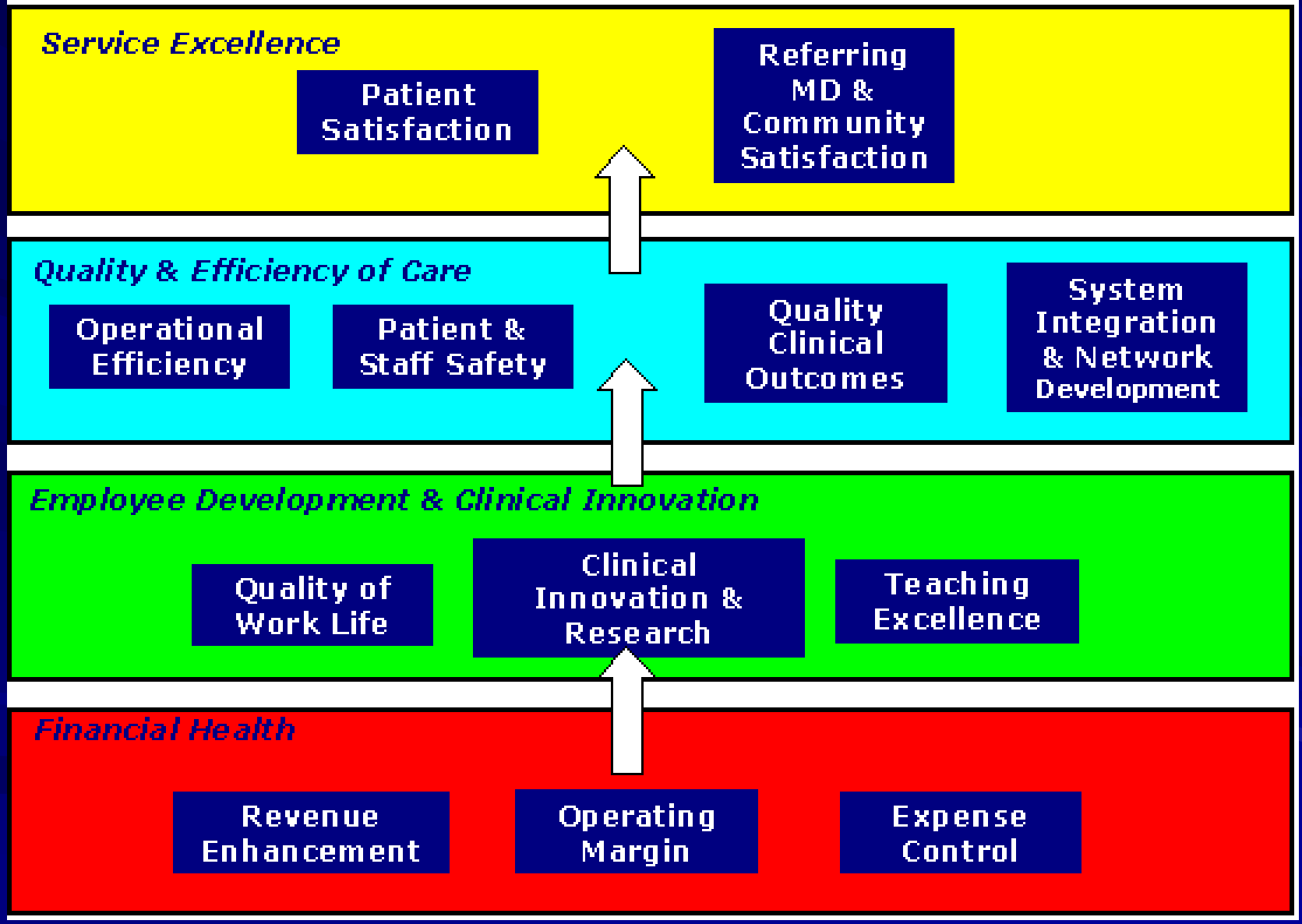
Preliminary ideas

- Substitute HD dose/HD treatment time for dose (Pisoni)
- Substitute ESA resistance index (Hb/ESA dose) for Hb (Jindal)
- Incorporate patient satisfaction
- Incorporate depression +/- Q of L

} Psychosocial aggregate index

- Incorporate staff satisfaction
- Is delta PRS associated with delta QOL? (Moist)

BWH: A hospital's balanced scorecard



DSI

- With Pearl, DSI is ideally positioned to be an industry wide leader in quality of dialysis
- Drs Tannenbaum, Rotstein and Michael are all committed to using the PRS across the chain and in helping to improve it
- ARCH/DOPPS is supporting this new partnership
- The roll out plan for DSI will be coming soon: Stay tuned!

We are 90 years behind Ford, so lets get on with it!

In 1914, the world's first automatic conveyor belt could churn out a car every 93 minutes.

Why waste time learning, when ignorance is instantaneous?