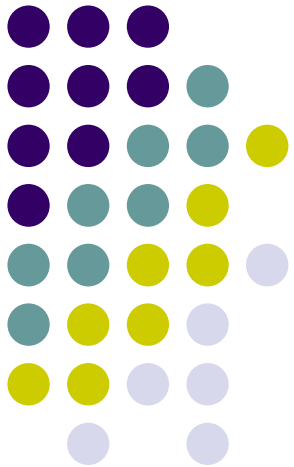
The Case Against Catheters

The Renal Network

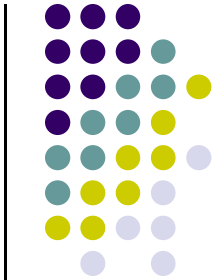
Learning Session

Chicago, IL

February 12, 2009

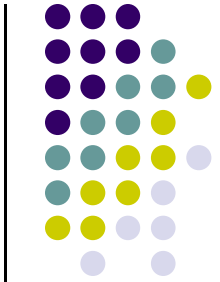


Catheter Problems



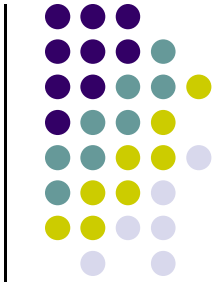
- Dialysis Adequacy
- Subsequent AVF failure
  - Central Vein Stenosis
- Cost per Treatment
- Infection Risk
- Hospitalization
- Mortality
- Ethical

Dialysis Adequacy
Target Kt/V = 1.3



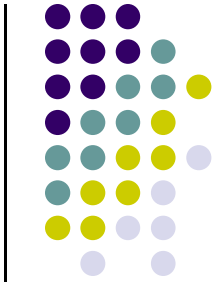
- More alarms (P_v and P_{art}) that interrupt treatment
- Maintain Q_b of ≥ 350
- Low blood flows mitigate advantage of high efficiency dialyzers (K_oA ≥ 800 ml/min)
- K_dUrea = f(Q_b)
- More time (min/kg) to the same Kt/V
- More shortened treatments

Impact of Catheters on Kt/V and HDTd



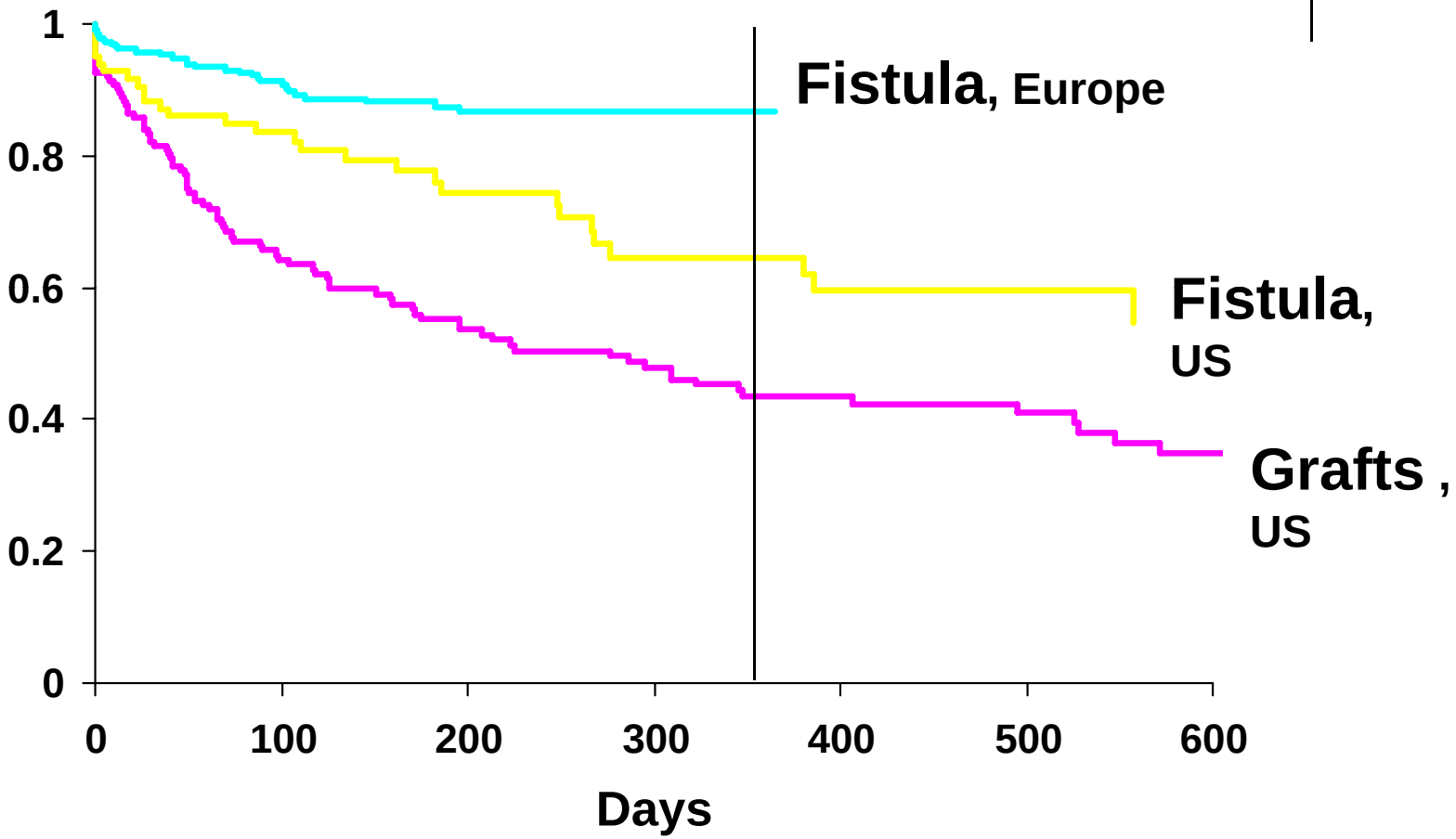
n	Cath	? ≥ 1.3	Kt/V	Min/kg	Short
65	no	no	1.14	2.70	.14
349	no	yes	1.64	2.98	.07
96	yes	no	1.03	2.81	.20
356	yes	yes	1.66	3.14	.09

Effect of Incident Catheter



- AVF have a 65% patency rate in first year after creation if pt started with TCC
- AVG have a 45% patency rate in the first year after creation if pt started with TCC

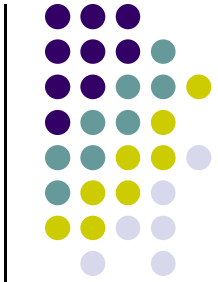
Fistula and Graft Survival in Incident Patients Starting HD with a Permanent VA



Adjusted for differences in age, gender, diabetes, and peripheral vascular disease; *note: in Japan, there were only a small number (n= 88) of incident patients for analysis so confidence interval (C.I.) at one year is much larger than for other countries; in Japan, 1 year AV Fistula survival C.I.=0.60-0.87. DOPPS I

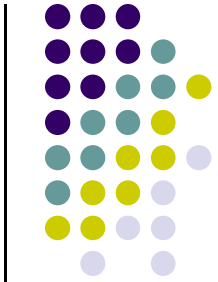
Pisoni et al, Kidney Int, 61:305-316, 2002

Increased cost per treatment



- More EPO use (> u/kg to same Hgb)
- Set up kits (locks, clamps, etc)
- More heparin
  - More heparin during treatment
  - Heparin locks at end of Rx
- Sterile gloves
- Topical antimicrobials, Systemic Antibiotics
- Increased nursing intervention time
- More blood cultures
- More missed treatments
- Shortenend treatments
- High catheter failure rate (50%-90%/year)

Increased Infection Risks



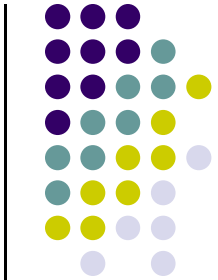
- Bacteremias
  - Osteomyelitis
  - Septic Arthritis
  - Endocarditis
- Outpatient Antibiotic Use
- Hospitalization for sepsis

Bacteremias/100 patient months

	AVF	AVG	CC	NCC
	0.2	0.5	5.0	8.5

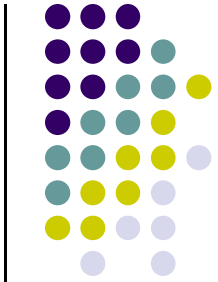
Guidelines for the Prevention of Intravascular Catheter-Related Infections

Events by Access Type



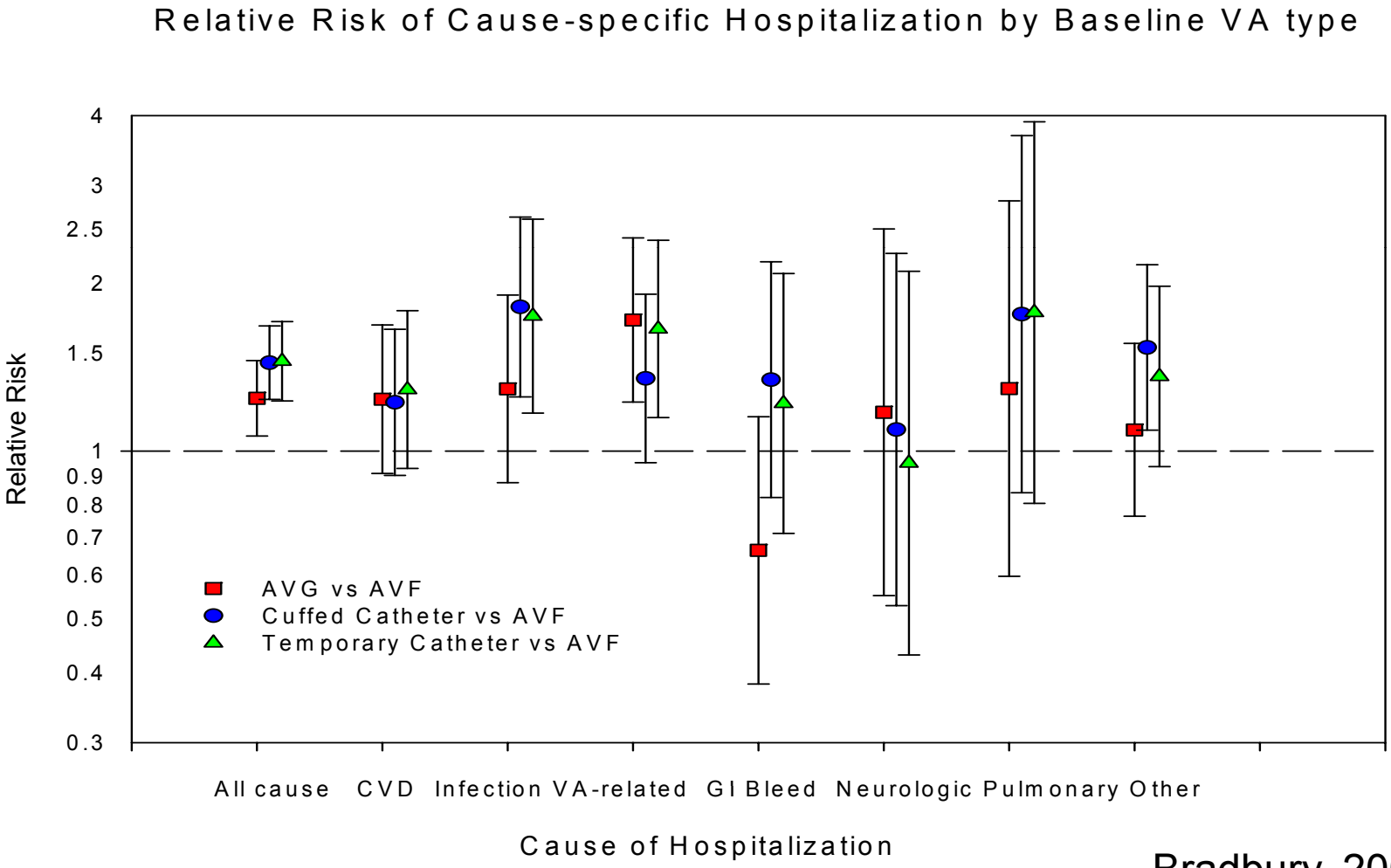
Events per 100 pt-mos	Fistulas	Grafts	C Cath	NC Cath
Admits	9.40	12.90	20.50	32.00
Out Pt **abx**	2.02	2.39	7.87	7.80
Out Pt **Vnco**	1.21	1.72	6.48	7.80
Pos BICltrs	.52	.94	5.80	9.95

Increased Hospitalizations



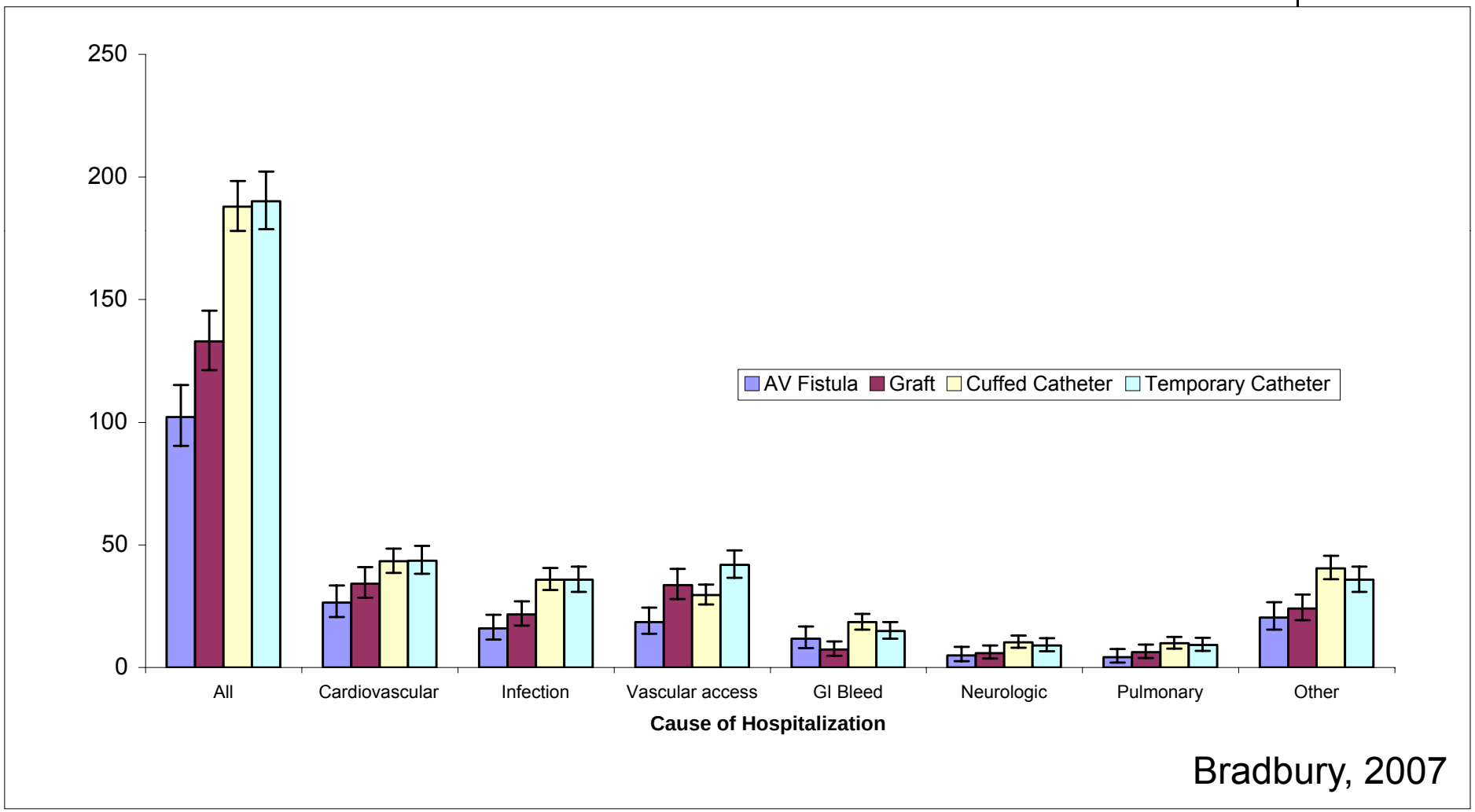
- 30% increase in all cause hospitalization
- 60% increase in hospitalizations for Sepsis

Adj. Risk of Hospitalization Higher for Catheter and Graft Compared to AV Fistula Patients



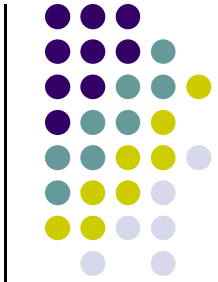
Bradbury, 2007

Hospitalizations: First Six Months on Dialysis



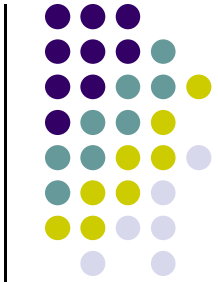
Bradbury, 2007

Increased Mortality



- 30% increase in RR annual mortality
- Catheter use explains most of the difference between US and European gross mortality
- Catheter use explains most of the increased first year mortality
- Increased RR of mortality is
  - Reduced for incident patients when converted
  - Reduced for prevalent patients when converted

Catheter Related Mortality in HD Patients



- Bradbury BD, Fissel RB, Albert JM, et. al. Predictors of Early Mortality in Incident US Hemodialysis Patients in the DOPPS. *Clin J Am Soc Nephrol* 2:89-99, 2007
- Bradbury BD. Role of access in early mortality of incident dialysis patients in the US DOPPS. Presentation. December 4, 2007. Washington, DC. Amgen Anemia Advisory Panel.
- Allon M, Daugirdas J, Depner TA, et.al. Effect of change of vascular access on patient mortality in hemodialysis patients. *Am J Kidney Dis 47:469-477, 2006*

Early Mortality Study

- random sample of 4,802 incident US HD patients participating in DOPPS
- life-table analysis to identify period of elevated risk in 1st year
- cox regression to assess predictors of earlier vs. later mortality
  - Interaction of predictors with time and the association with mortality

Bradbury, 2007

Mortality Rates During 1st Year

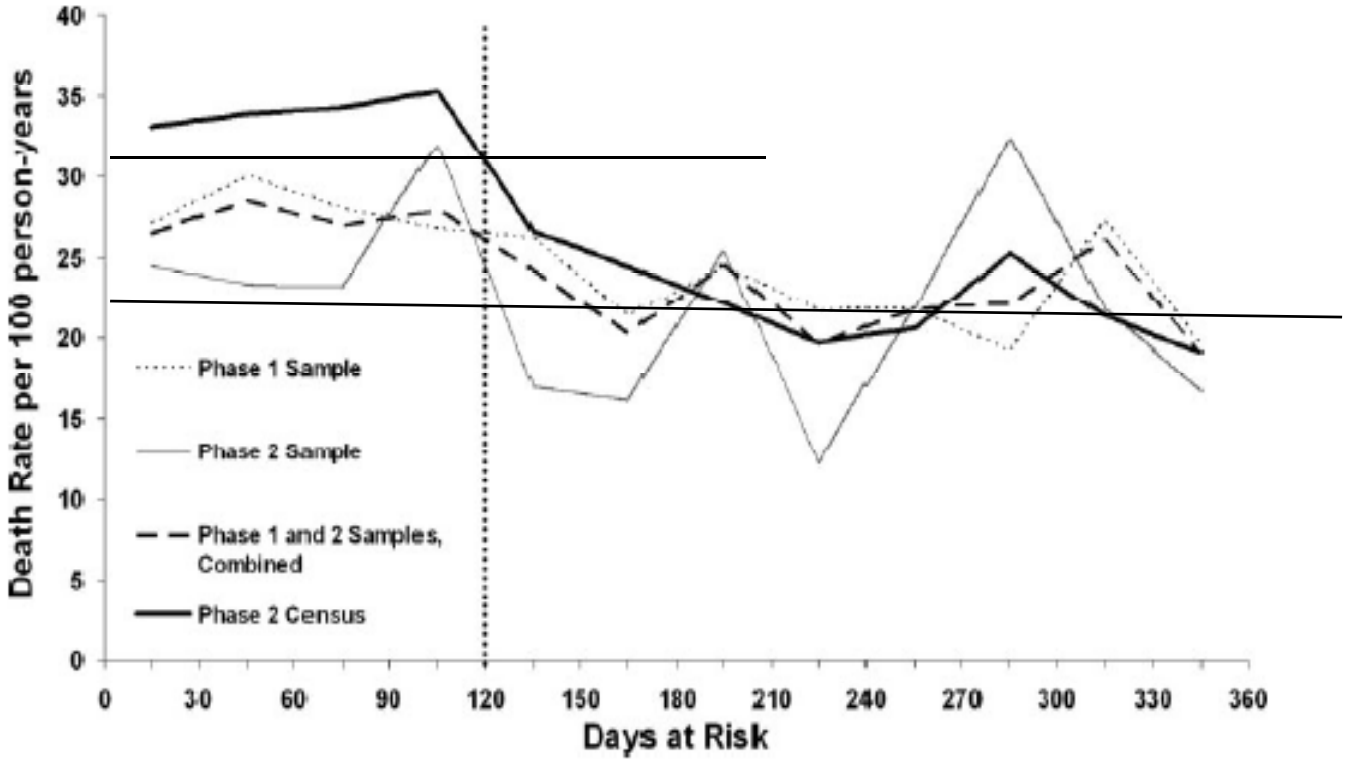


Figure 1. Estimated hazard function for the Dialysis Outcomes and Practice Patterns Study (DOPPS) II Census (n = 4156), DOPPS I sample (n = 3777), DOPPS II sample (n = 1025), and DOPPS I and II samples (n = 4802).

Mortality*	< 120 days	121-365 days	P-value
*per 100 person-years	31.0	23.4	<0.0001

Bradbury, 2007

There is an Excess of Deaths During the First 120 days for Nearly All Causes

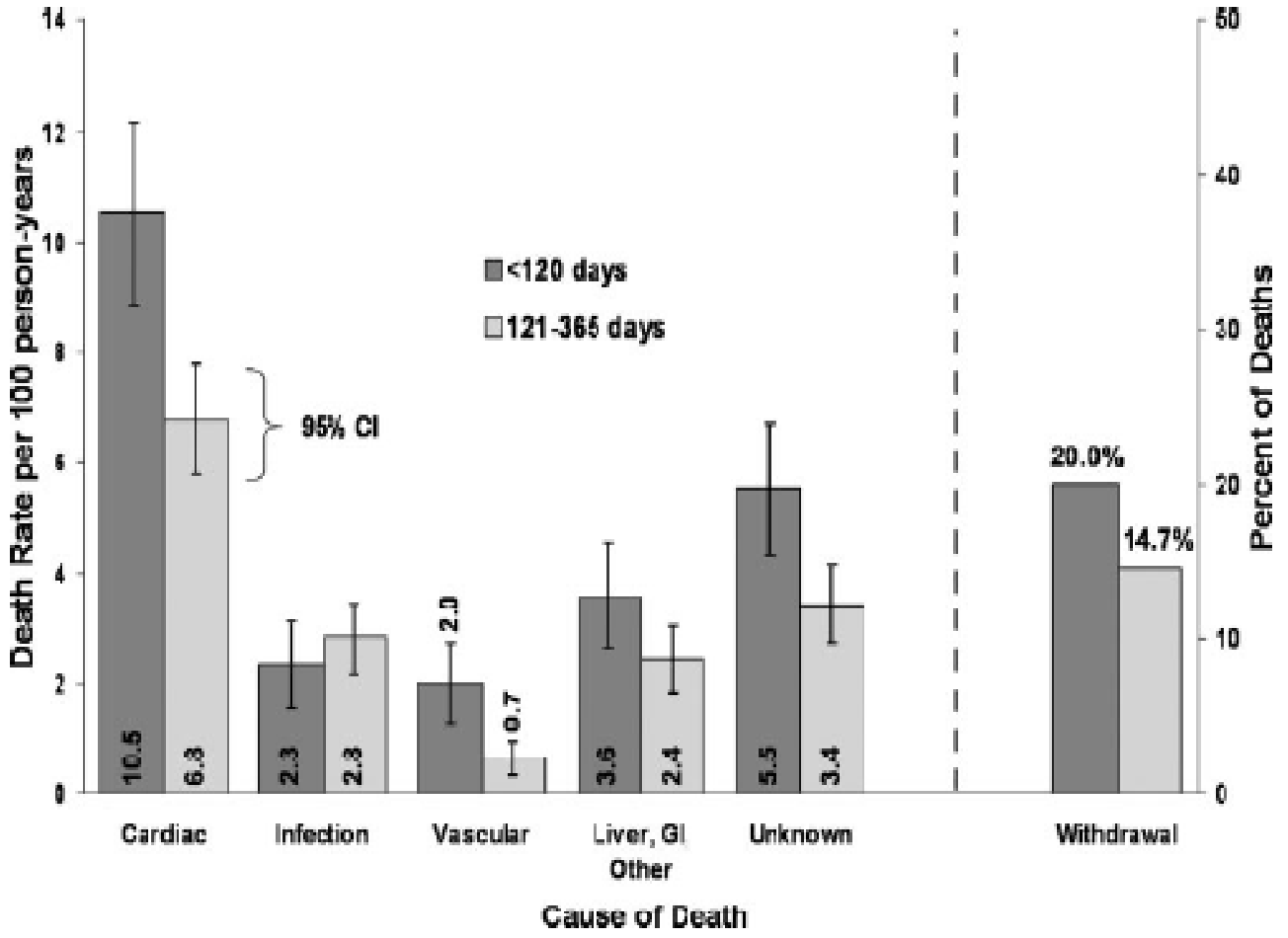


Figure 2. (Left) Cause-specific mortality rates and 95% confidence intervals for the <120- and 121- to 365-d periods. (Right) Percentage of all deaths during the <120 and 121- to 365-d periods that occur subsequent to withdrawal.

Bradbury, 2007

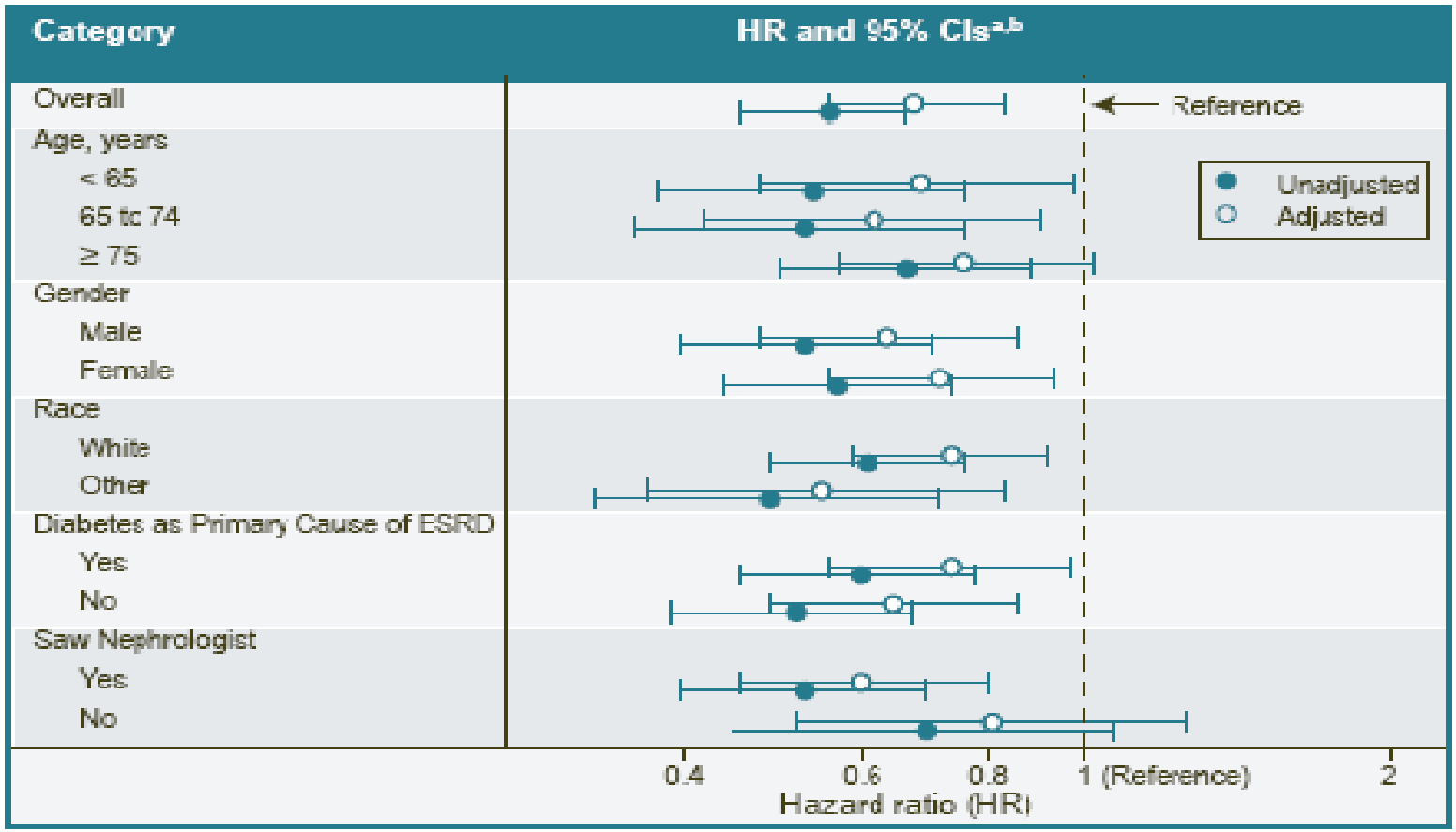
RR death from catheter in year 1

	Death ≤ 120 days			Death at 121-365 days			Overall (≤ 365 days)		
Variable	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Demographics									
Age, per 10 years	1.38	1.24-1.52	<0.0001	1.33	1.20-1.47	<0.0001	1.36	1.26-1.46	<0.0001
Sex (Male *vs* Female)	0.92	0.73-1.15	0.45	1.02	0.84-1.27	0.75	0.96	0.82-1.13	0.75
Race (White *vs* non-white)	1.46	1.12-1.90	0.005	1.39	1.09-1.77	0.008	1.39	1.15-1.67	0.001
BMI (30.0+ vs. 20.0–<25.0)	0.79	0.54-1.17	0.25	1.05	0.78-1.41	0.4	0.95	0.76-1.20	0.5
Vascular access type									
Catheter *vs.* AV Fistula	**1.62**	**1.05-2.51**	**0.02**	**1.42**	**1.02-2.01**	**0.03**	**1.49**	**1.14-1.95**	**0.001**

† Adjusted for all other patient characteristics in the table, as well as etiology of ESRD, albumin-corrected Ca, PTH, Hgb, Ca x P, pre-ESRD ESP use and 11 co-morbidities;

Bradbury, 2007

Conversion to an AV Fistula or Graft Associated with 30% Lower Mortality

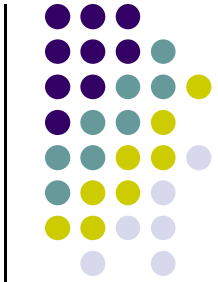


[a]Adjusted for age, sex, race, BMI, primary cause of ESRD, systolic and diastolic blood pressure, previous VA placement, pre-dialysis nephrologist care; albumin, hemoglobin, calcium, phosphorus and white blood cell count levels; and 12 comorbid conditions measured at dialysis initiation.

[b]HR and 95% CI estimates obtained from time-dependent Cox proportional hazards regression models.

Bradbury, 2007

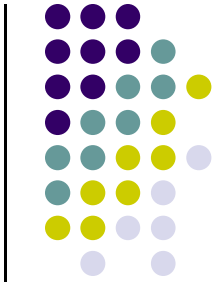
Comparison RR of pts who dialyzed using an AVF both at beginning and end of 1 year interval (HEMO Study)



Conversion	RR	CI
TCC throughout	3.43	2.42 - 4.84
AVF to TCC	2.38	1.76 - 3.23
TCC to AVF	1.37	.81 - 2.32

Allon, 2006

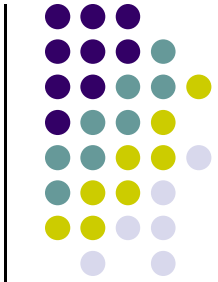
Effect of changing from AVF to TCC



Category	OR	CI
↓ Albumin	1.25	1.09 - 1.45
↓ Weight	1.14	1.06 - 1.22
↓ enPCR	2.22	1.41 - 3.57
↑ Non Acc Hosp	1.19	1.06 - 1.32

Allon, 2006

Effect of changing from TCC to AVF

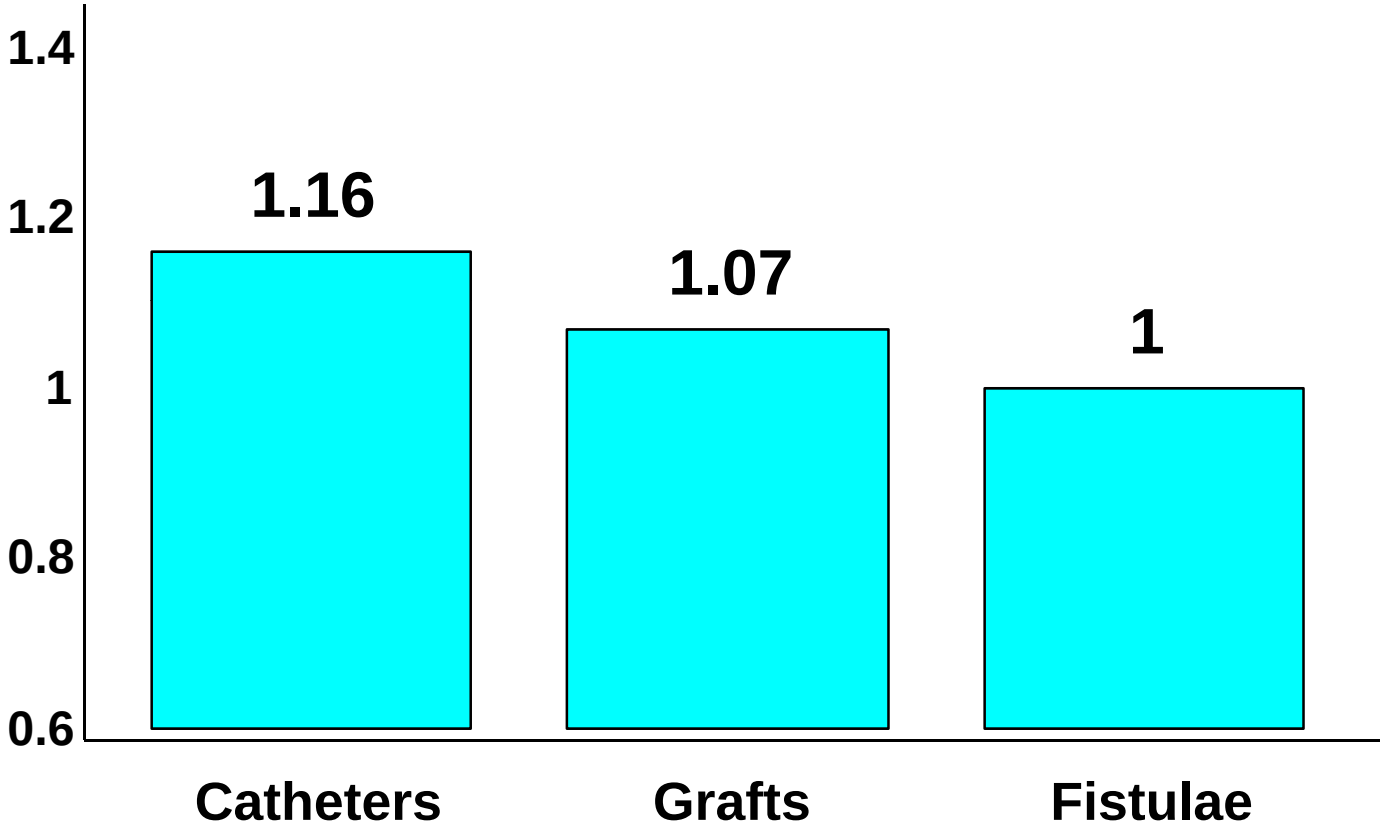


Category	OR	CI
↓ Non Acc Hosp	0.93	0.87 - 0.97

Allon, 2006

Vascular Access: Mortality Risk ~ Facility Based Model

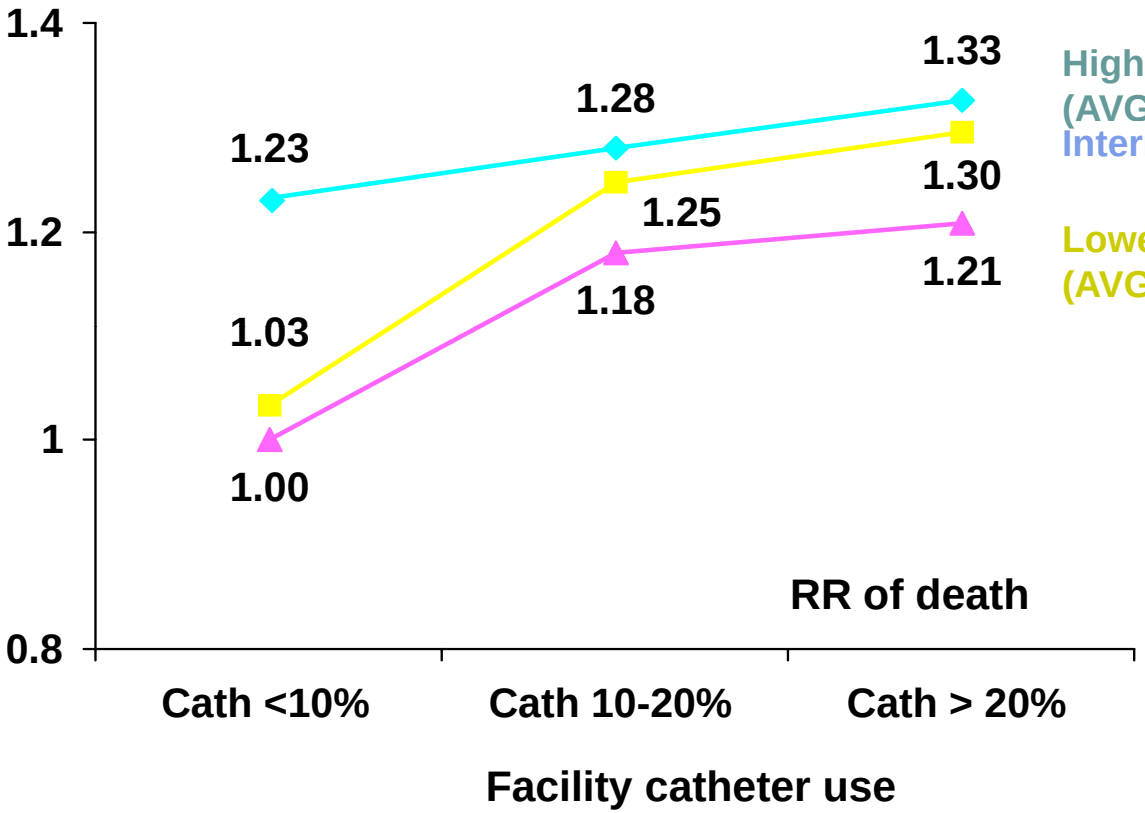
RR of Death among Facility Patients
per 20% more facility use of indicated access type



***DOPPS I+II, 1996-2004; n=25,709; adjusted for age, gender, black race, yrs with ESRD, 14 comorbidity classes, baseline Hgb, Kt/V, serum albumin, calcium, PO_4, accounted for facility clustering effects; stratified by continent [Japan, US, EUR (Fr,Ge,It,Sp,UK]; RR based upon access in use at study entry.**

Pisoni et al, ASN2005

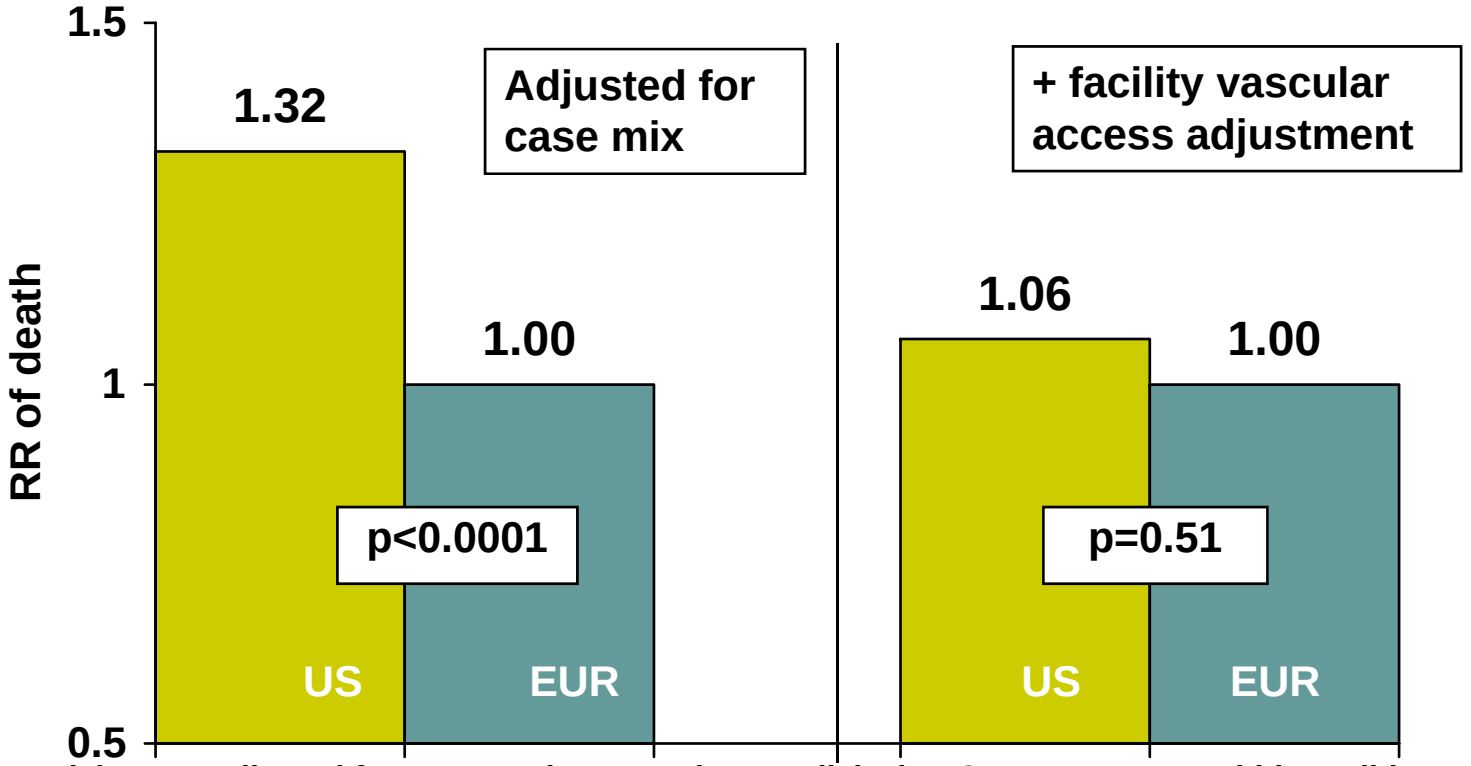
RR mortality by categories of facility catheter use and ratio of AVG:AVF use



Model adjusted for age, gender, race, time on dialysis, 13 summary comorbid conditions, laboratory values, unit type, stratified by region, and accounted for facility clustering effects. DOPPS I + II

Pisoni et al, 2005

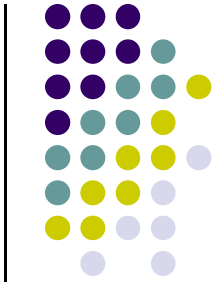
Differences in Facility Vascular Access Explain Much of the Mortality Differences Between the US and Europe in DOPPS



All models were adjusted for age, gender, race, time on dialysis, 13 summary comorbid conditions, laboratory values, and unit type, and accounted for facility clustering effects. DOPPS I + II; n=20,754; EUR=France, Germany, Italy, Spain, and UK.

Pisoni et al, 2005

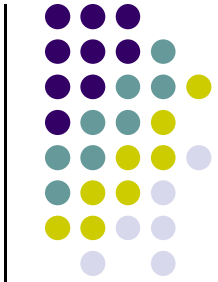
Ethical considerations



"With the knowledge that AVFs are promoted by all authorities as the veritable 'standard of care' for hemodialysis access, we are obligated as physicians who have taken the Hippocratic oath to uphold our vow to 'do no harm' and refuse to place TCCs except as a temporary measure or a last resort."

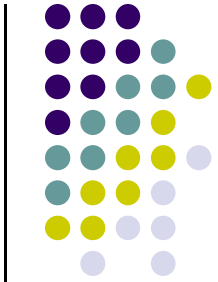
Rehman, CJASN, 2009

Techniques & Tools



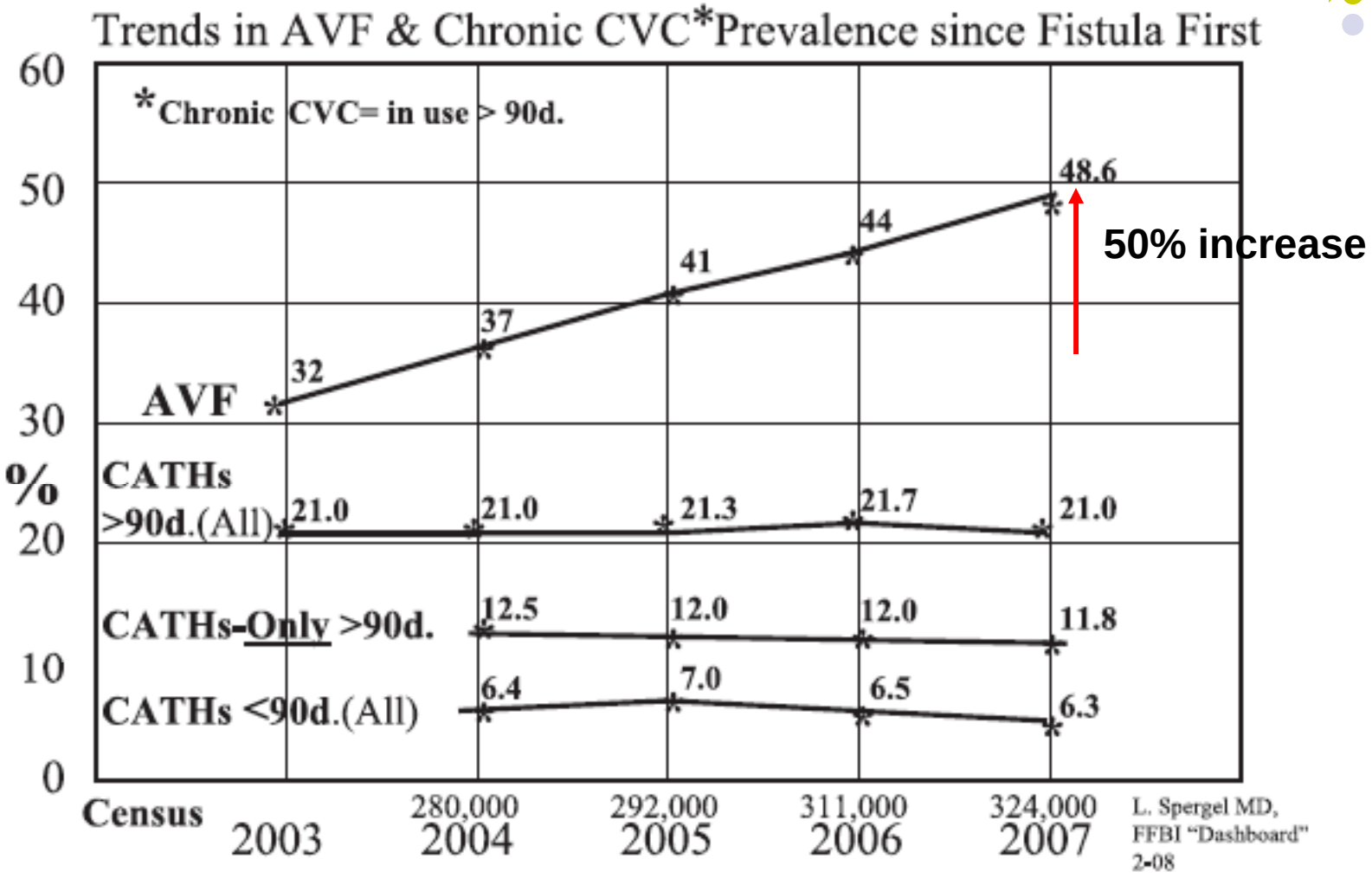
- Fistula First Change Concepts
- What we learned from TRN Catheter Reduction QIP (2001 to 2003)

Fistula First Change Concepts



1. Routine CQI review of vascular access
2. Early referral to nephrologist
3. Early referral to surgeon for “AVF only”
4. Surgeon selection
5. Full range of appropriate surgical approaches
6. Secondary AVFs in AVG patients
7. AVF placement in catheter patients
8. Cannulation training
9. Monitoring and surveillance
10. Continuing education: staff and patients
11. Outcomes feedback

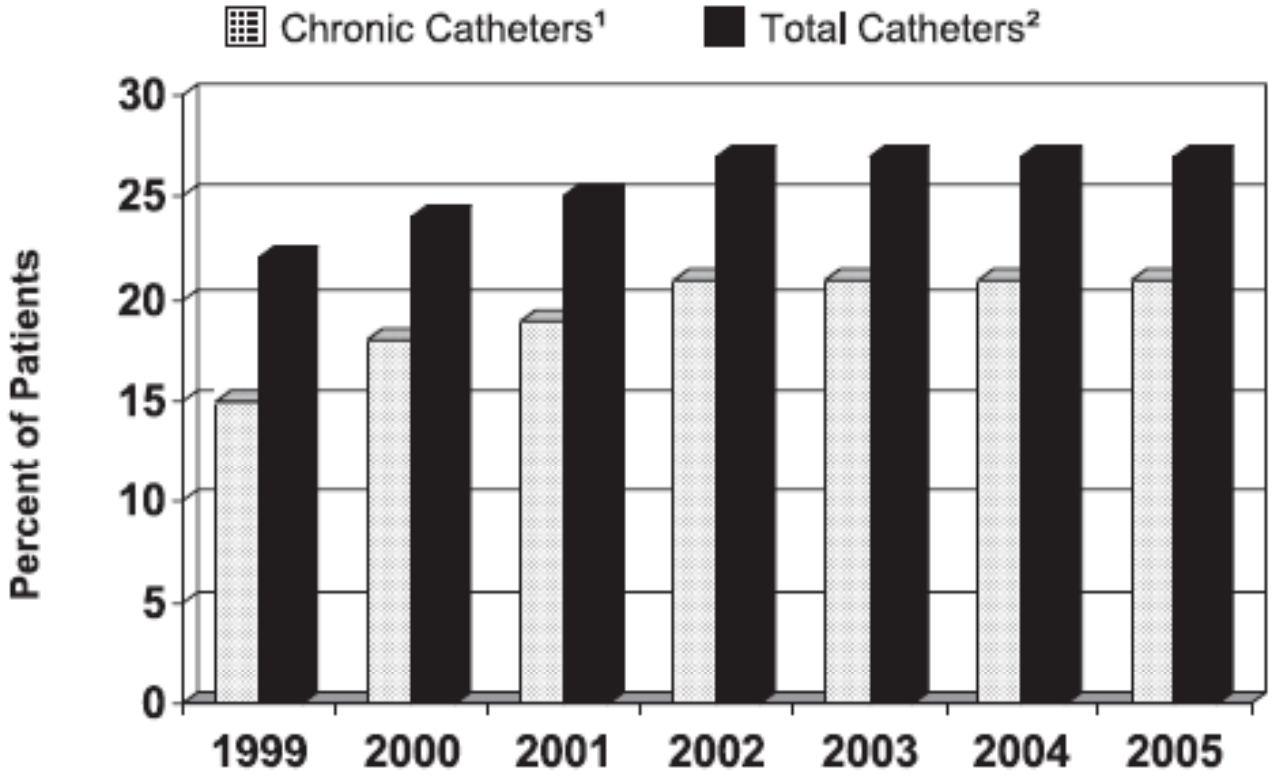
Access Trends since the FFBI



"All" include dual access

Spergel, 2008

Catheters 1999 through 2005

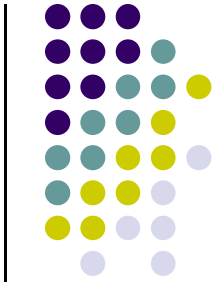


[1] Chronic catheter defined as a catheter in use for 90 days or longer.
[2] Total catheters defined as chronic catheters plus temporary catheters

Source: 2006 Annual Data Report,
ESRD Clinical Performance Measures Project

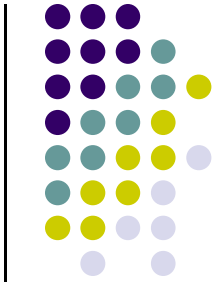
CMS
Centers for Medicare & Medicaid Services

System Requirements for Successful Access Management



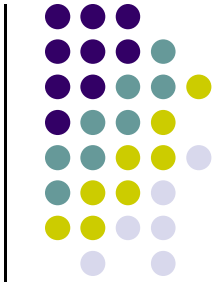
- Pre ESRD modality education and choice
- Early surgical referral
- Preoperative imaging (mapping)Regular monitoring of access maturity and performance
- Early, elective intervention
- Evaluate for secondary AVF creation

Dialysis Providers who reduced catheters and increased fistulas



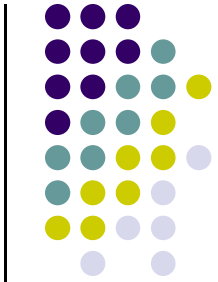
- VAMT and Patient Education
- 100% Referral for new patients
- Overcome barriers by team focused learning and data review
- Early referral, pathways, and protocols
- Patient and staff education
- Transonic Monitoring
- Surgeons accept patients without insurance
- Refer only to surgeons who do AVF preferentially

Successful Strategies I



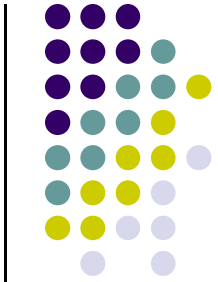
- Primary Care Teams (PCT and RN)
- Consistent PCT assignments (90 days)
- Celebrate and Advertise the small victories (there are no “small” victories)
- Levels of team involvement (formal and casual)
- Continuous, between meeting communication
- Dedicated staff to manage access plans
- Data showed that excuses were just that -- excuses
- Maintain continuity with Nephrologists for patients in NH

Successful Strategies II



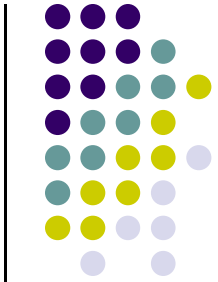
- Focus on the data “we had no idea” -- reject the status quo
- Medical Director meets with “recalcitrant” nephrologist
- Monitoring accesses for maturation and performance
- Selective vascular surgery referral
- Overcome nephrologist’s bias
- Pre-ESRD education
- Staff talk to patients about catheters and access
- Early planning with patient, specific tracking forms

Successful Strategies III



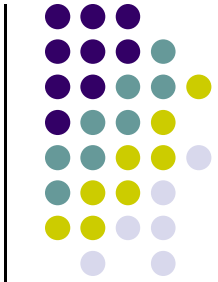
- Communication among caretakers in different venues
- Pre transfer coordination of access planning
- Without protocols, nothing gets done
- Report results to all involved in access care
- Pre-ESRD --> access, transplant, modality of Rx
- PD patients get AVF with Tenckhoff
- It is all about communication
- Monitoring: phys assessment, Qb_{ac},and PrP P_{art}

Manage performance
to create systems where incentives are aligned to desired behaviors



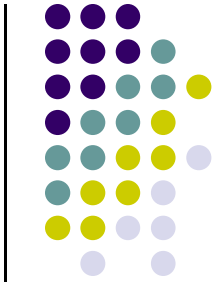
- Correct education deficits
- Hold surgeons and nephrologists accountable
- Feedback of outcome data

Role of Facility Staff



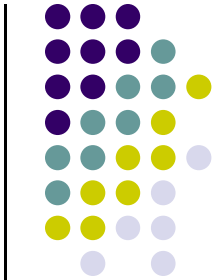
- Medical Director
- Vascular Access Coordinator
- Vascular Access Team
  - Protocols and Care Paths
  - Data Collection
  - Care Plans
  - Monitoring, Surveillance, Physical Assessment
- Collaboration with the renal network

§494.150 Condition: responsibilities of the medical director



The dialysis facility must have a medical director who meets the qualifications of 494.140(a) to be *responsible for the delivery of patient care and outcomes* of the facility. The medical director is *accountable to the governing body for the quality of medical care* provided to the patients. Medical director responsibilities include, but are not limited to the following:

§494.150 Condition: responsibilities of the medical director



… include, but are not limited to the following:

(a) Quality assessment and performance improvement

(b) Staff education, training and *performance*

(c) Policies and procedures. The medical director must –

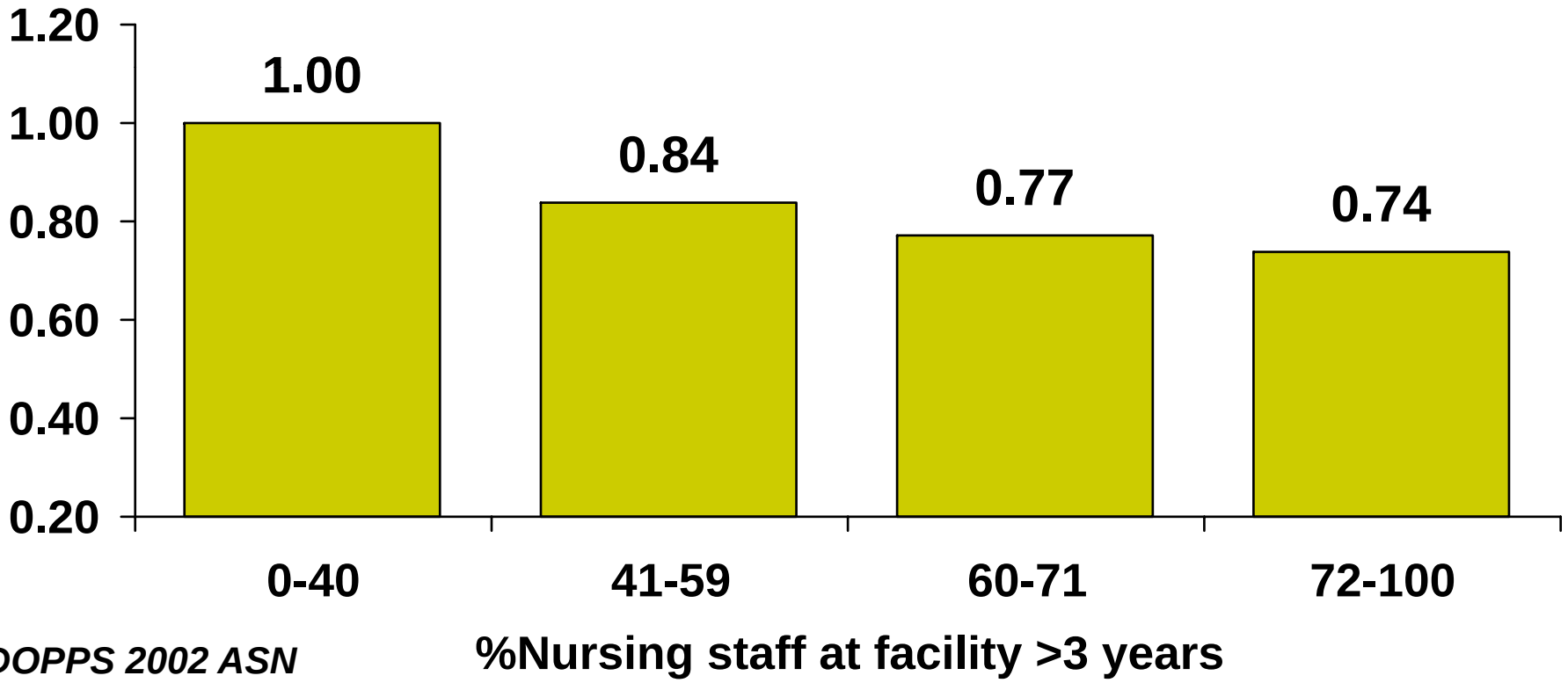
1. Participate in the development, periodic review and approval of a patient care manual for the facility; and

2. Ensure that –

i. All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to *by all individuals* who treat patients in the facility, including *attending physicians and non-physician providers;* and

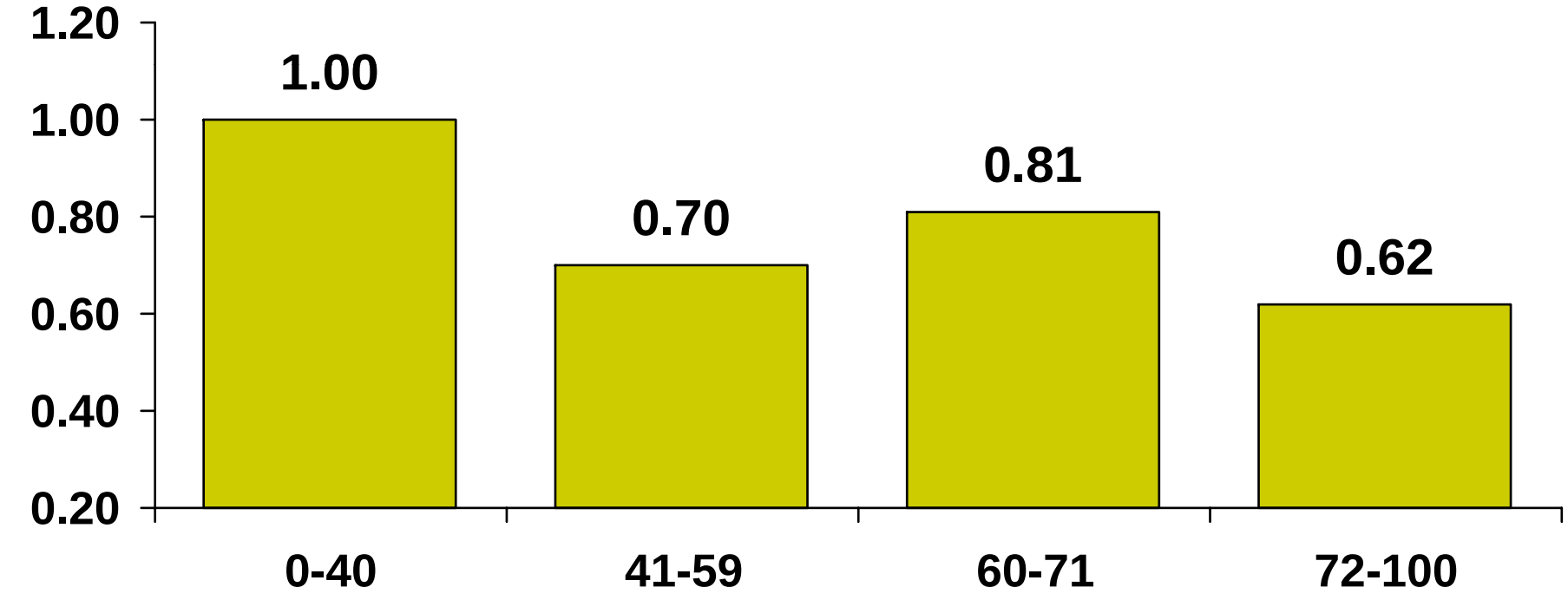
ii. The interdisciplinary team adheres to the discharge and transfer policies specified in 494.180(f)

Association of Graft Failure Risk with %Nursing Staff at Facility >3 Years



DOPPS 2002 ASN

Association of AV Fistula Failure Risk with %Nursing Staff at Facility >3 Years



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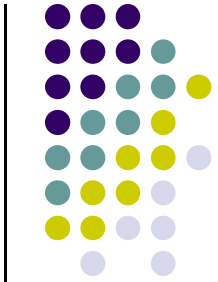
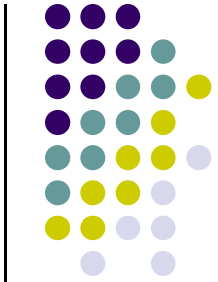
Network and Facility QAPI goals the *same*



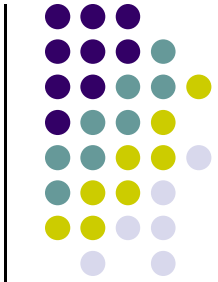
- Improve the quality and safety of dialysis-related services
- Improve independence, quality of life, and rehabilitation of individuals [modality choice]
- Encourage and support collaborative activities to ensure achievement of these goals
- Improve the collection, reliability, timeliness and use of data to measure processes of care and outcomes, maintain patient registry, and support the ESRD network program.

Termination of Medicare Coverage §488.604



- (a) …failure of a supplier of ESRD service to meet one or more conditions for coverage set forth in part 494 will result in the termination of Medicare coverage
- (b) … [can be] based solely on supplier's failure to participate in network activities and pursue network goals as required at §494.180(i) of this chapter

Thoughts on Systems



When placed in the same system, people, however different, tend to produce similar results. -- Peter Senge

Every system is perfectly designed to get exactly the results it gets. -- Donald Berwick

If you do what you always do, you'll get what you've always got. -- W. Edwards Deming

Insanity is doing the same thing over and over and expecting different results -- Albert Einstein