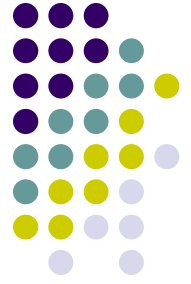


What is expected of the medical director in the new CMS Conditions for Coverage?



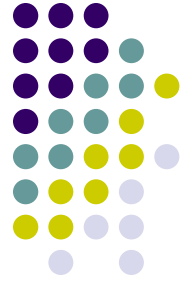
Peter B. DeOreo, MD, FACP
Clinical Professor of Medicine
Chief of Medical Affairs and Quality Assurance
Centers for Dialysis Care
pbd@cdcare.org



“The medical direction of dialysis facilities has been ... sometimes absent, feckless* or uninspired”

lacking purpose
without skill
ineffective, incompetent
lacking the courage to act in any meaningful way;

Gutman, 2007



The responsibility of the Medical Director is to increase the value of the dialysis services

$$\text{Value} = \frac{\text{Quality} * \text{Access}}{\text{Cost}}$$

Part 494 -- CfC for end-stage renal disease facilities



Subpart A – General Provisions

§494.1 Basis and scope

§494.10 Definitions

§494.20 Condition: compliance with Federal, State, and local laws and regulations

Subpart B – Patient Safety

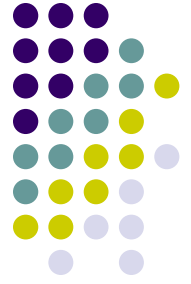
§494.30 Condition: Infection control

§494.60 Condition: Water and dialysate quality

§494.60 Condition: Reuse of hemodialyzers and bloodlines

§494.60 Condition: Physical environment

Part 494 -- CfC for end-stage renal disease facilities



Subpart C -- Patient Care

§494.70 Condition: Patient rights

§494.80 Condition: Patient
Assessment

§494.90 Condition: Patient plan of
care

§494.100 Condition: Care at Home

§494.110 Condition: Quality
assessment and performance
improvement

§494.120 Condition: Special
purpose renal dialysis facilities

§494.130 Condition: Laboratory
services

Subpart D -- Administration

§494.140 Condition: Personnel
qualifications

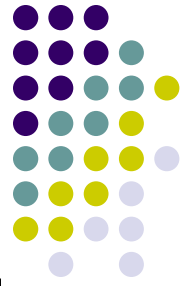
§494.150 Condition:
Responsibilities of the medical
director

§494.160 [Reserved]

§494.170 Condition: Medical
records

§494.180 Condition: Governance

§405.2161 Condition: Director of a renal dialysis facility or renal dialysis center



- Treatment is under the general supervision of a Director who is a physician
- Director is responsible for planning, organizing, conducting and directing the professional ESRD services
- To participate in the selection of a suitable treatment modality, i.e., transplantation or dialysis and dialysis setting, for all patients
- To assure adequate training of nurses and technicians in dialysis techniques
- To assure adequate monitoring of the patient and dialysis process
- To assure the development and availability of a patient care policy and procedures manual and its implementation
- When self-dialysis training is offered, to assure that patient teaching materials are available for use

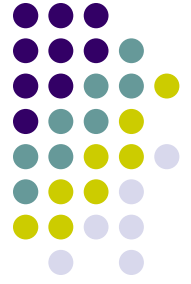


§494.150 Condition: responsibilities of the medical director

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:

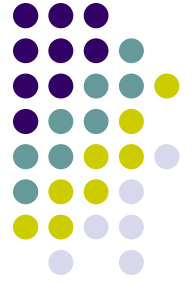
*board certified in medicine with training in nephrology or board certified in nephrology

§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)

Then v. Now



- General Expectations of process
 - Little definition of outcomes
 - No statements of accountability for performance
- Prescriptive expectation of process
 - Definition of expected outcomes
 - Statements of accountability for performance

Categories of Med Dir Responsibilities

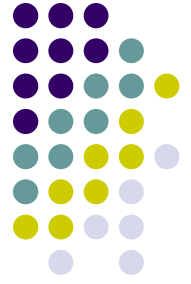


- Governance
- Administration
- Oversight



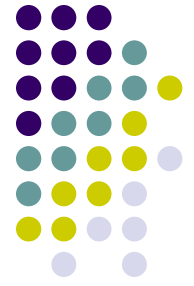
Governance

- Qualifications of the Medical and Associate Staff
- Orientation of the Medical and Associate Staff to the P&P of the facility
- Fully informed of his/her responsibilities as Med Director
- Adequate staff and resources to patient care and Quality Improvement and Performance Improvement



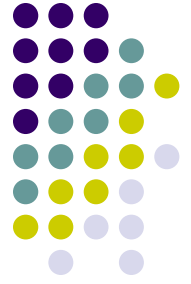
Medical Staff

- Admission
 - Orders and Initial Assessment
- Discharge (involuntary)
 - Continuity of Care
- Infection Control
- Care Planning (assessment and implementation)
- Quality Assurance and Performance Improvement
 - General and Specific Responsibilities
 - Mediation of disputes among the IDT
- Emergency preparedness and continuity of care



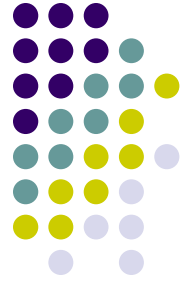
Administration

- Review and revision of P&P
- Adherence to P&P by *all*
 - Patient safety (subpart B)
 - Infection Control, Water/Dialysate, Reuse, Environment
 - Incorporated Standards (AAMI, CDC)
 - Patient care (subpart C)
 - Rights, Assessment, Plan of Care, Home Care, QAPI
 - Interdisciplinary Team (IDT) [QAPI vs. Patient Care]
 - Professionally accepted standards, individualized
 - Unstable Patient monthly care planning
 - Nephrologist monthly visits with patients (quarterly in HD unit)



Oversight/QAPI

- All services in facility
- Critical subsystems
- Written plan that defines: scope, objectives, organization, responsibilities, priorities
- Indicators that monitor the technical and clinical service
- Uses professionally based standards



Oversight/Notification

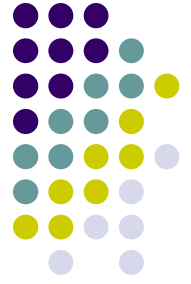
- Critical Subsystems: Water
 - Chloramine break through
 - Component failure threatening safe delivery of dialysis
- Infection Control
 - Break in practice threatening staff or patients
 - Opportunity to improve practice

QAPI/IDT



- Led by the Medical Director
- Monthly meetings, minutes reflecting leadership
- Participation of the Medical Staff
- Data driven, measurable goals, timelines, corrective action
- Benchmarking (USRDS, CPM, K/DOQI, DOPPS, AAMI, Networks, Dialysis Facility Reports, *et. al.*)
- Rapid cycle CQI (monthly PDCA)
- Applies equally to home and in-center dialysis
- Uses data from clinical and technical indicators, surveys
- Regular reports to the governing body

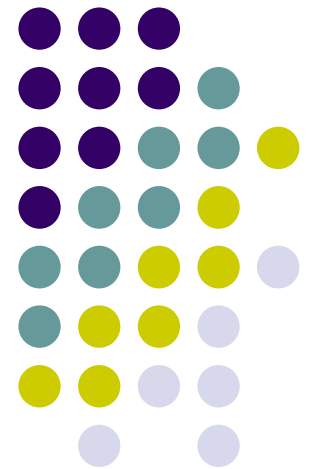
QAPI/Involuntary Discharge



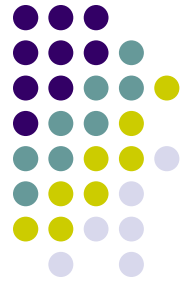
- Disclosed to patient at admission
 - Grievance, appeal, involuntary discharge
- Rarely for non-adherence
- Documented attempts to resolve
- Irreconcilable differences
- 30 day's notice to patient
- Attempts to ensure continuity of care
- Abbreviate process if immediate threat to patients or staff
- Notice to Network, and governing body
- Signatures of both treating nephrologist and medical director

The renal networks

your new best friend



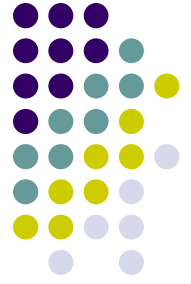
Governance: relationship with ESRD network §494.180(i)



- 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.

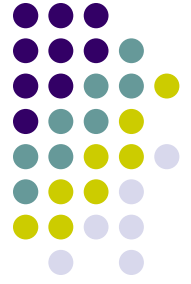
Termination of Medicare Coverage

§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

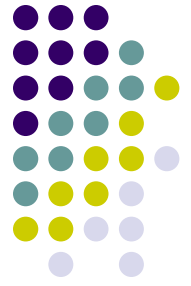
Governance: relationship with ESRD network §494.180(i)



- Receives and acts upon recommendations from the ESRD network
 - Must cooperate with ESRD network designated for its geographic area
 - In fulfilling the terms of the Network's current scope of work
 - Must participate in ESRD network activities and pursue network goals

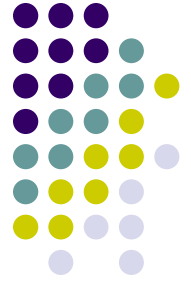
Governance: The CEO

§494.180(a)



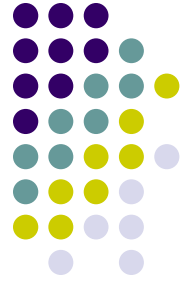
- (3) Relationship with the ESRD networks
 - Collect and analyze data on ESRD patients and their outcomes of care
 - Provide education and oversight to improve the quality of care
 - Support facilities in developing and maintaining an effective QAPI program
 - Respond to complaints and grievances

High leverage strategies for improving outcomes



- Immunization
- Infection control P&P
- Catheter Reduction

Increased Infection Risks



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



Bacteremias/100 patient months



MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports

August 9, 2002 / Vol. 51 / No. RR-10

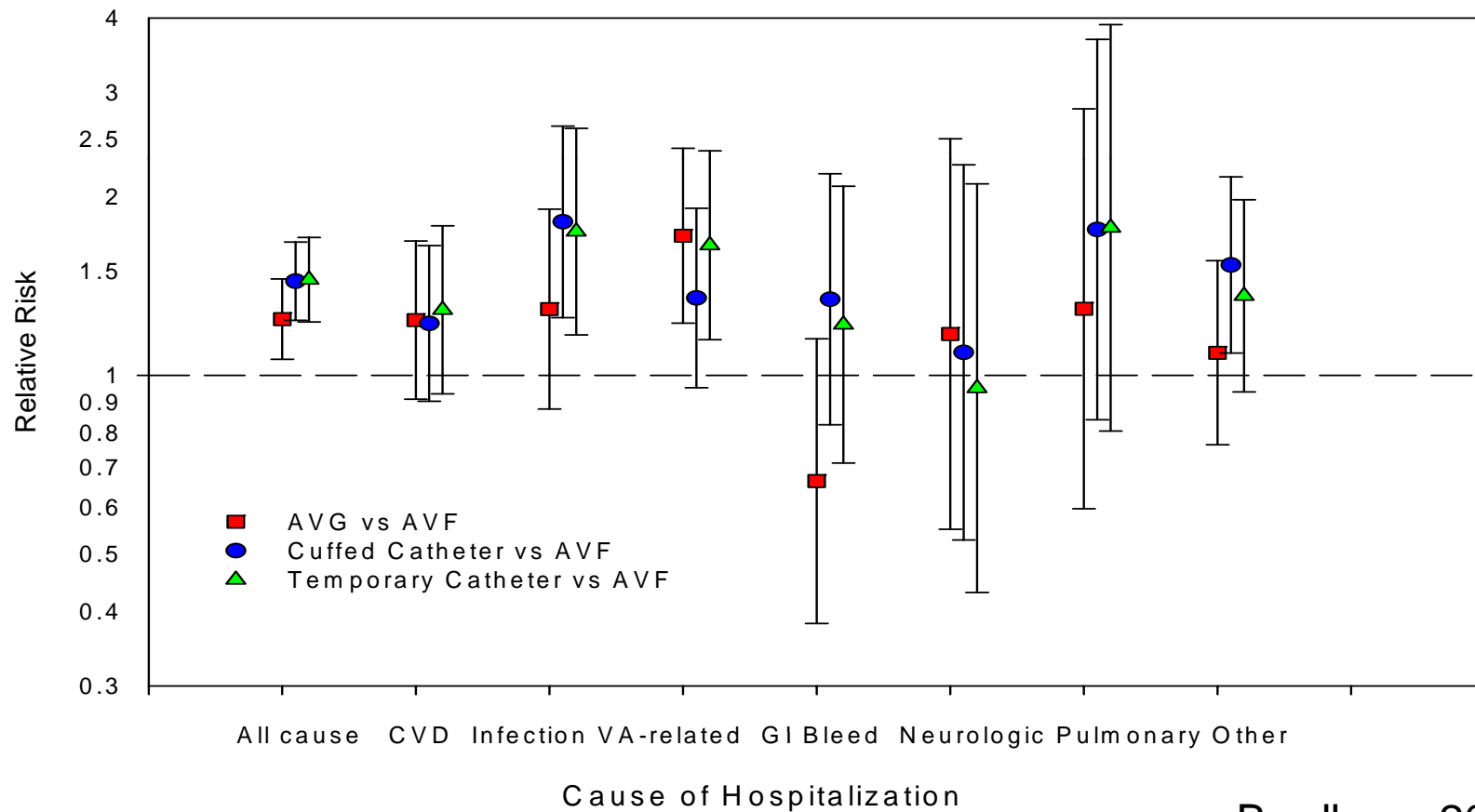
	AVF	AVG	CC	NCC
	0.2	0.5	5.0	8.5

**Guidelines for the Prevention of Intravascular
Catheter-Related Infections**

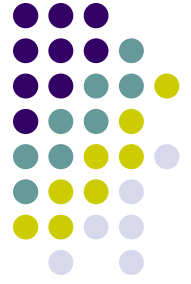
Adj. Risk of Hospitalization Higher for Catheter and Graft Compared to AV Fistula Patients



Relative Risk of Cause-specific Hospitalization by Baseline VA type



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



Mortality Rates During 1st Year

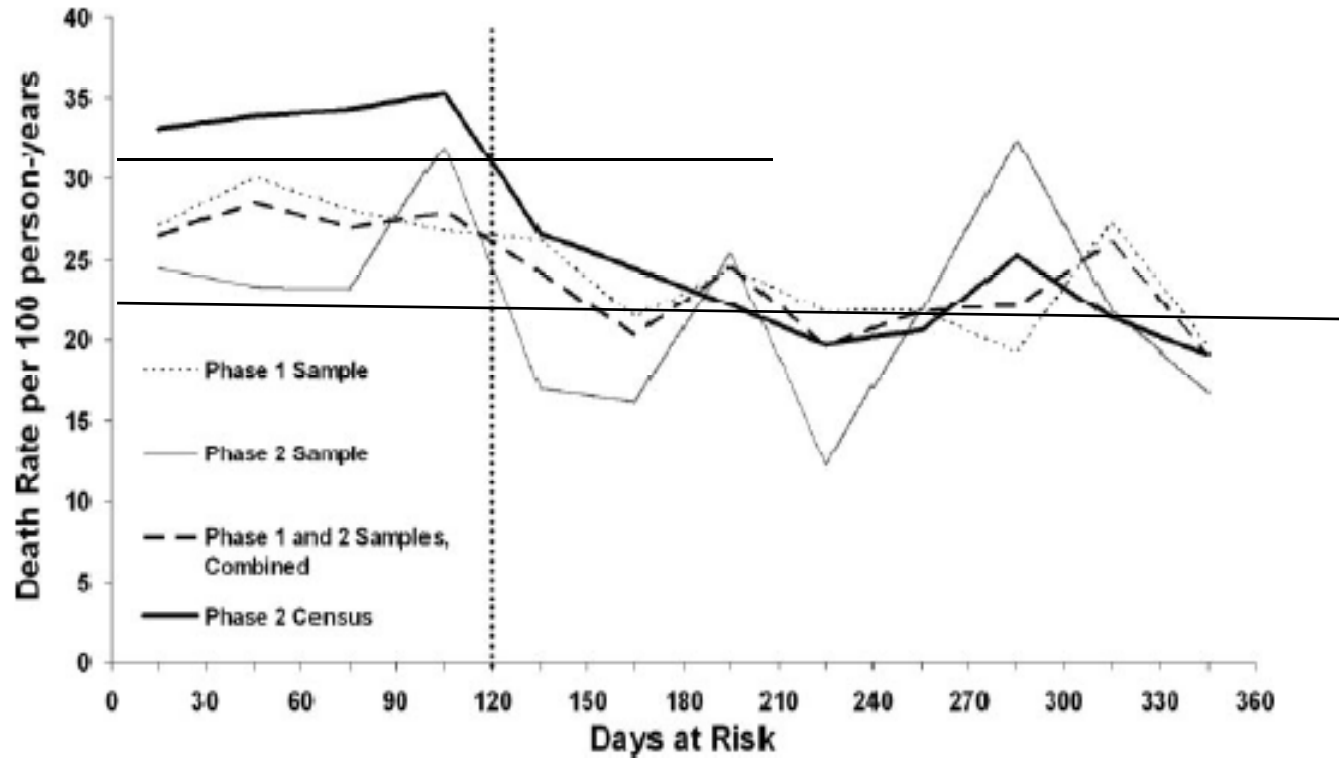
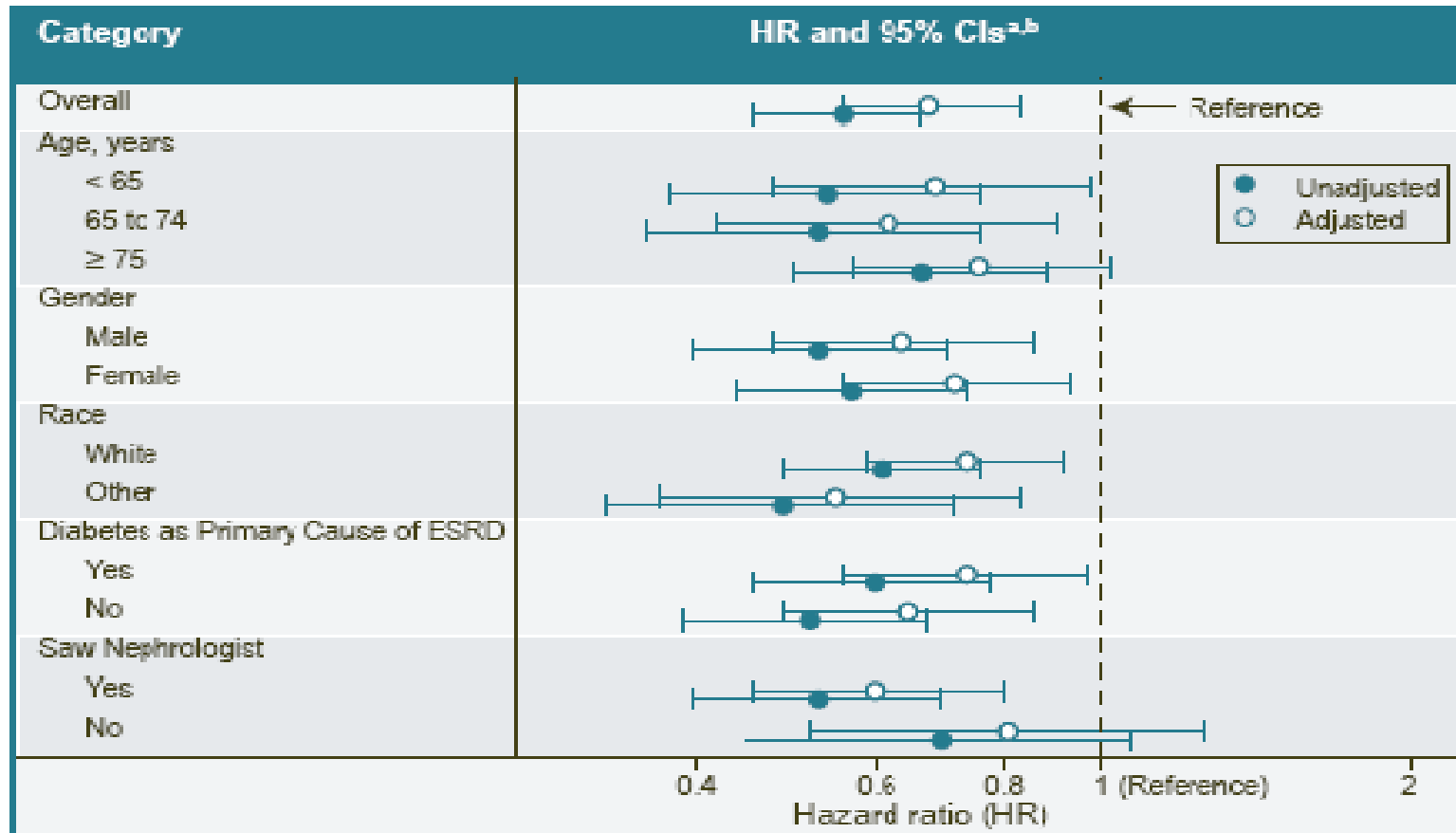


Figure 1. Estimated hazard function for the Dialysis Outcomes and Practice Patterns Study (DOPPS) II Census ($n = 4156$), DOPPS I sample ($n = 3777$), DOPPS II sample ($n = 1025$), and DOPPS I and II samples ($n = 4802$).

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

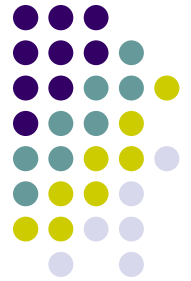
Conversion to an AV Fistula or Graft Associated with 30% Lower Mortality



^aAdjusted 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.

^bHR and 95% CI estimates obtained from time-dependent Cox proportional hazards regression models.

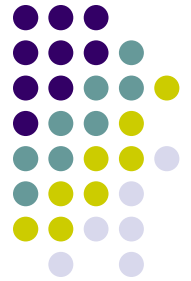
Comparison RR of pts who dialyzed using an AVF both at beginning and end of 1 year interval (HEMO Study)



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

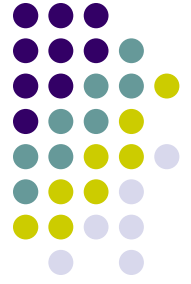
Effect of changing from AVF to TCC



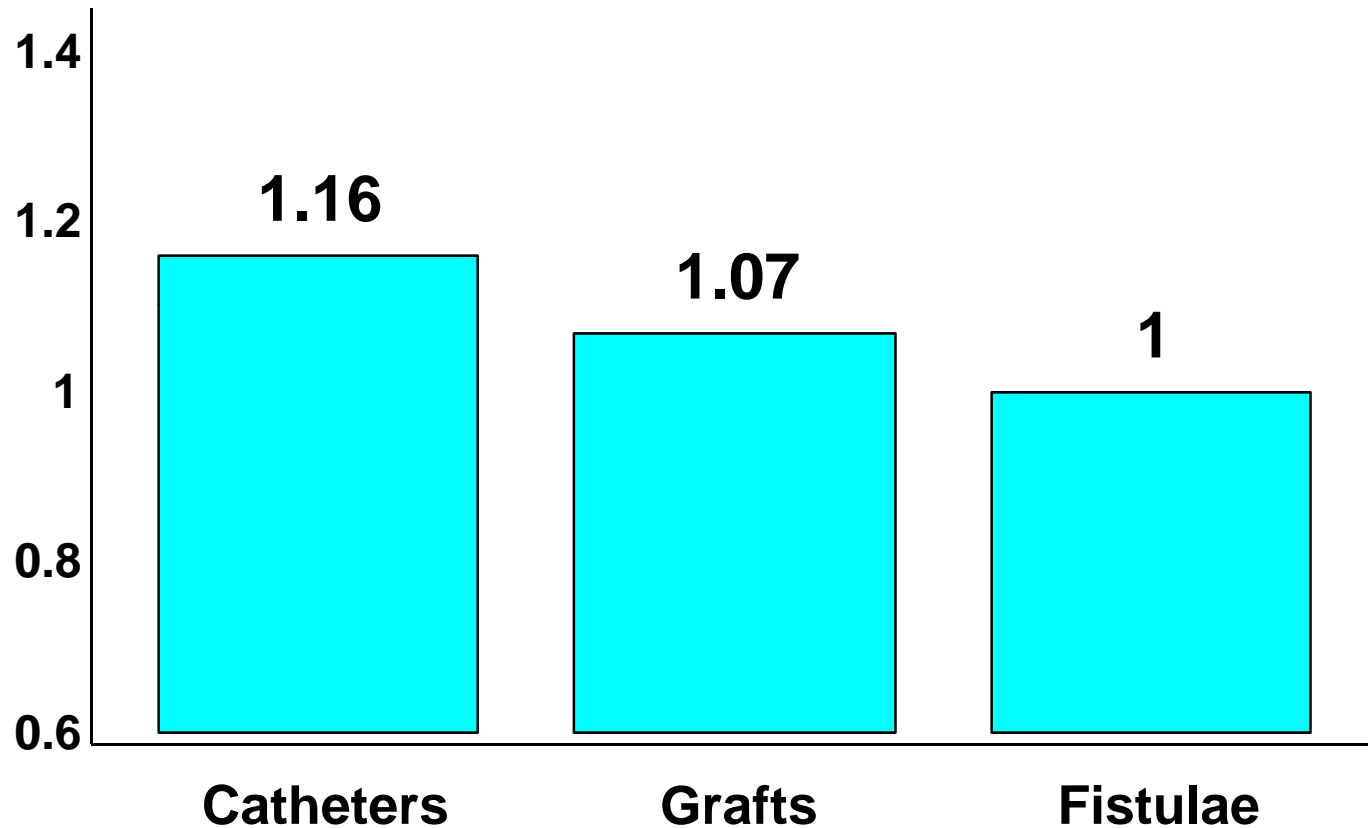
Category	OR	CI
↓ Albumin	1.25	1.09 - 1.45
↓ Weight	1.14	1.06 - 1.22
↓ enPCR	2.22	1.41 - 3.57
↑ Non Acc Hosp	1.19	1.06 - 1.32

Allon, 2006

Vascular Access: Mortality Risk ~ Facility Based Model



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

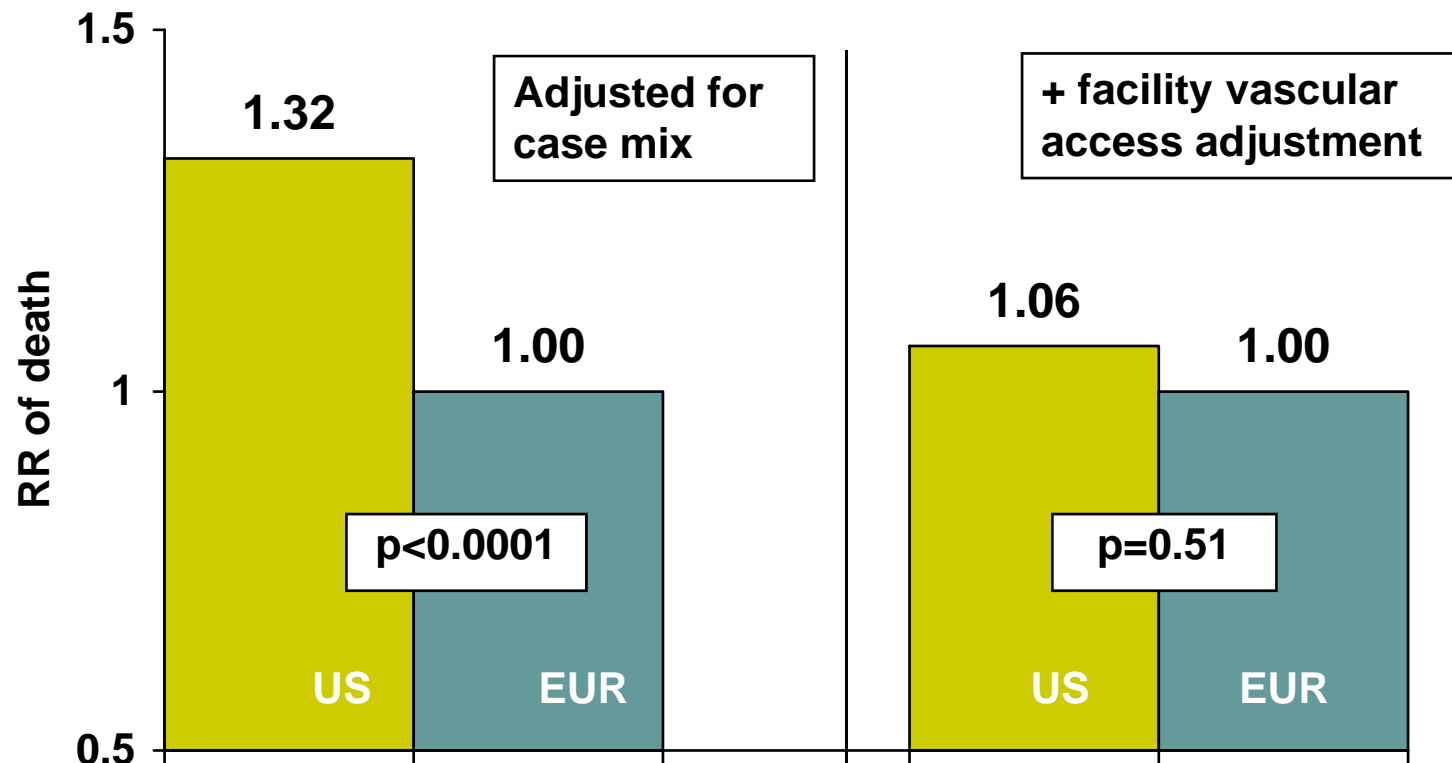


*DOPPS I+II, 1996-2004; n=25,709; adjusted for age, gender, black race, yrs with ESRD, 14 comorbidity classes, baseline Hgb, Kt/V, serum albumin, calcium, PO₄, accounted for facility clustering effects; stratified by continent [Japan, US, EUR (Fr,Ge,It,Sp,UK)]; RR based upon access in use at study entry.

Pisoni et al, ASN2005

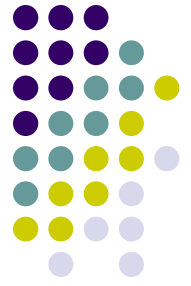


Differences in Facility Vascular Access Explain Much of the Mortality Differences Between the US and Europe in DOPPS

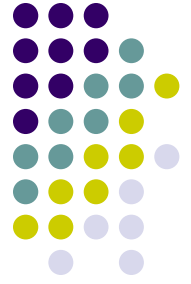


All models were adjusted for age, gender, race, time on dialysis, 13 summary comorbid conditions, laboratory values, and unit type, and accounted for facility clustering effects. DOPPS I + II; n=20,754; EUR=France, Germany, Italy, Spain, and UK.

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



Successful Facilities

- Physician leadership
- Communication between physicians
- CKD stage 4 AVF creation
- Pre-referral venous mapping
- Selective surgeon referral
- Interdisciplinary Teams and CQI process
 - Written plans of care
 - Accountability of team members
 - Data feedback, review and communication
 - Goals and time frames

Don't be feckless

