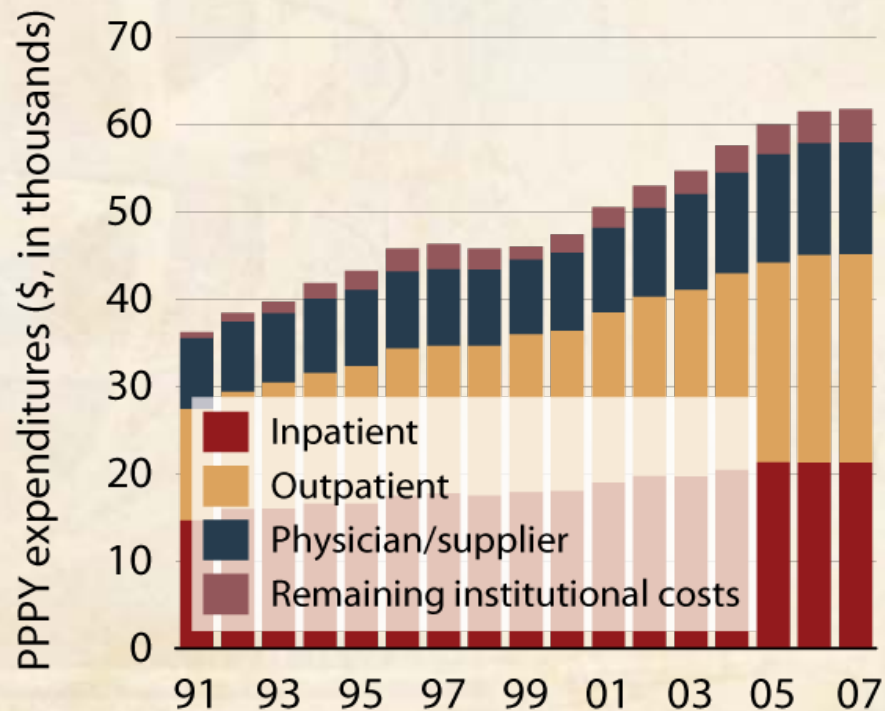


Fistula First, Catheters Last: If We Have to Use Them Let's Take Care of Them

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Per person per year total Medicare ESRD expenditures

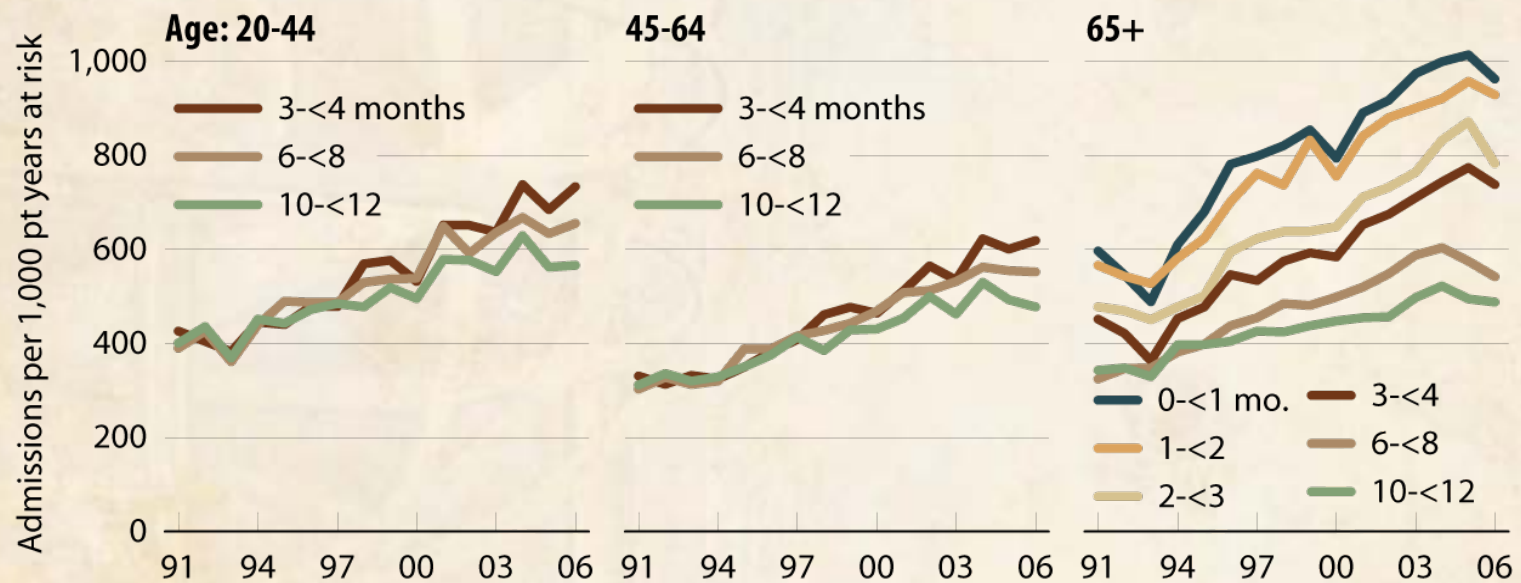
Figure p.23 (Volume 2)



Period prevalent ESRD patients with Medicare as primary payor & not enrolled in Medicare Advantage.

Adjusted admissions for infection in the first year of hemodialysis, by month & age

Figure 1.8 (Volume 2)



We believe that we can do something about this.

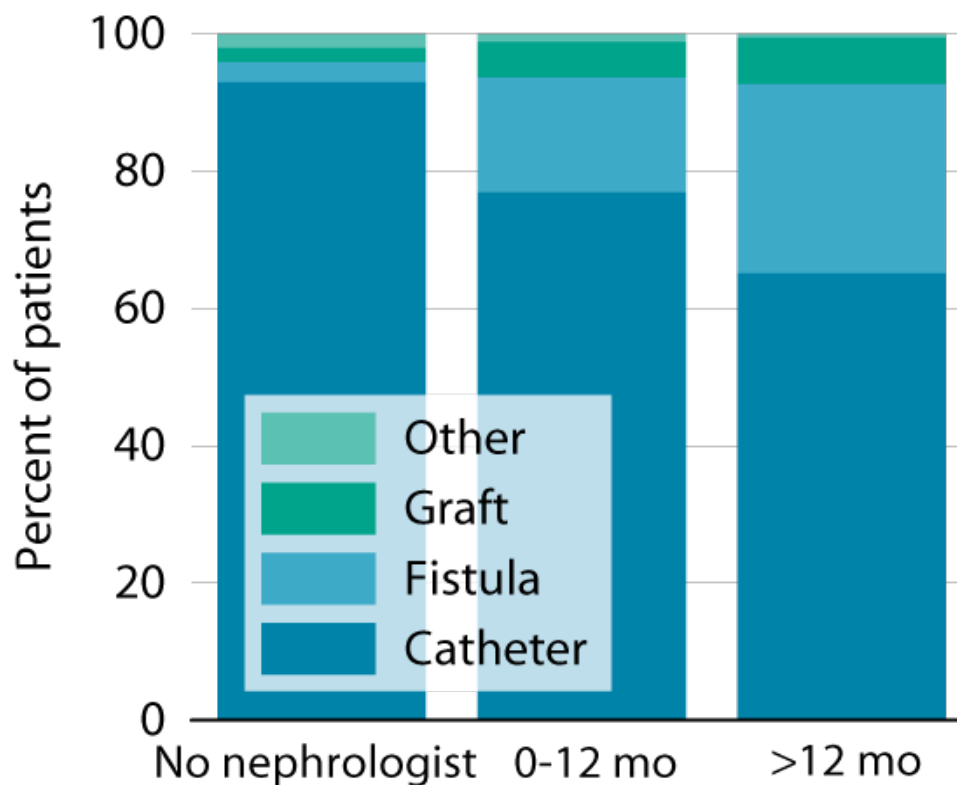
Incident hemodialysis patients age 20 and older; followed from the day of onset of ESRD; adjusted for gender, race, & primary diagnosis. Incident hemodialysis patients alive at day 90 after initiation, 2005, used as reference.

Fistula First and KDOQI

- 2000 KDOQI set a standard of 50% of new pts starting dialysis have a functioning AVF
- Reiterated in 2006, asking for 65% of prevalent pts have an AVF and less than 10% have catheters
- In 2006 82% of patients starting dialysis still had catheters

First access at initiation, by nephrologist care, 2006

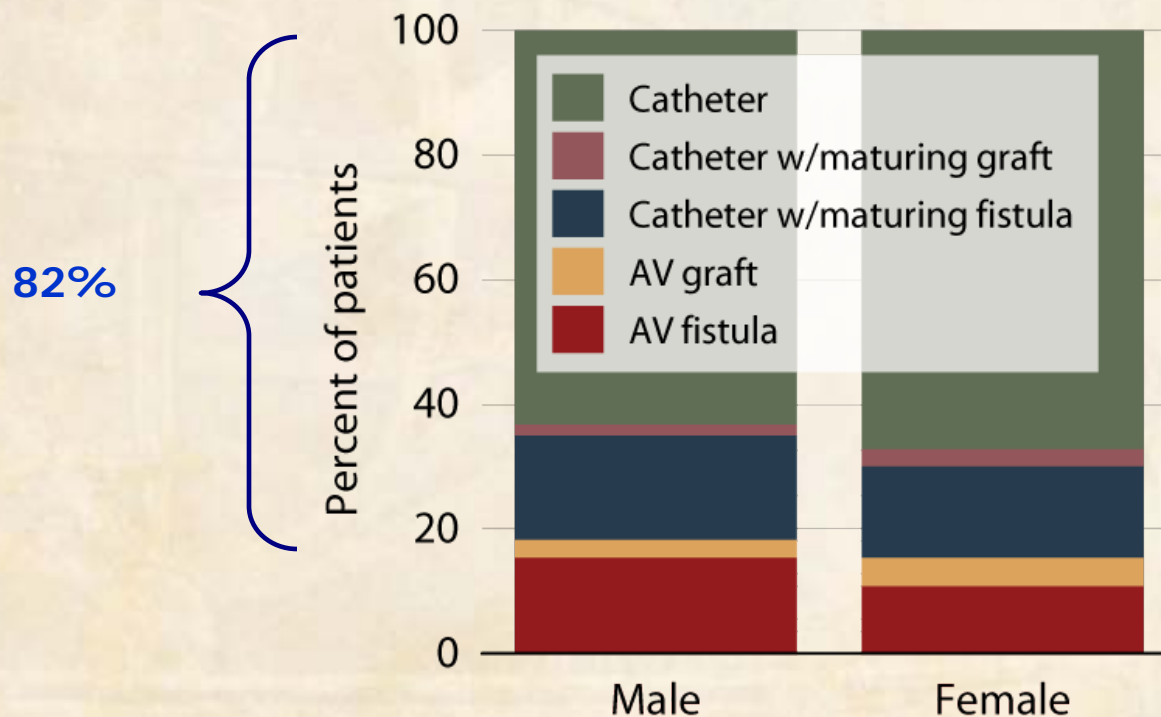
Figure 3.4 (Volume 2)



incident hemodialysis patients, 2006, with new (revised edition) Medical Evidence forms.

Vascular access use at initiation, by gender, 2007

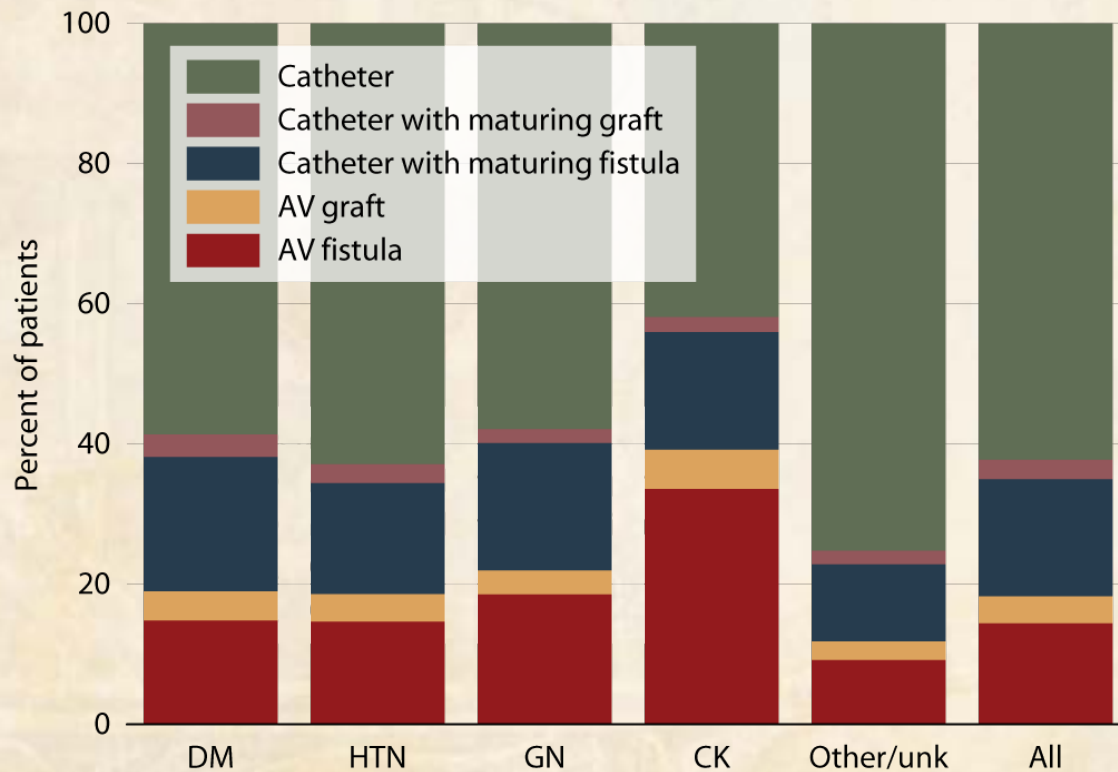
Figure p.10 (Volume 2)



Incident hemodialysis patients, 2007, with new (revised edition) Medical Evidence forms.

Access use at first outpatient dialysis, by primary diagnosis, 2007

Figure 3.1 (Volume 2)



Incident hemodialysis patients, 2007.

So What Happened?

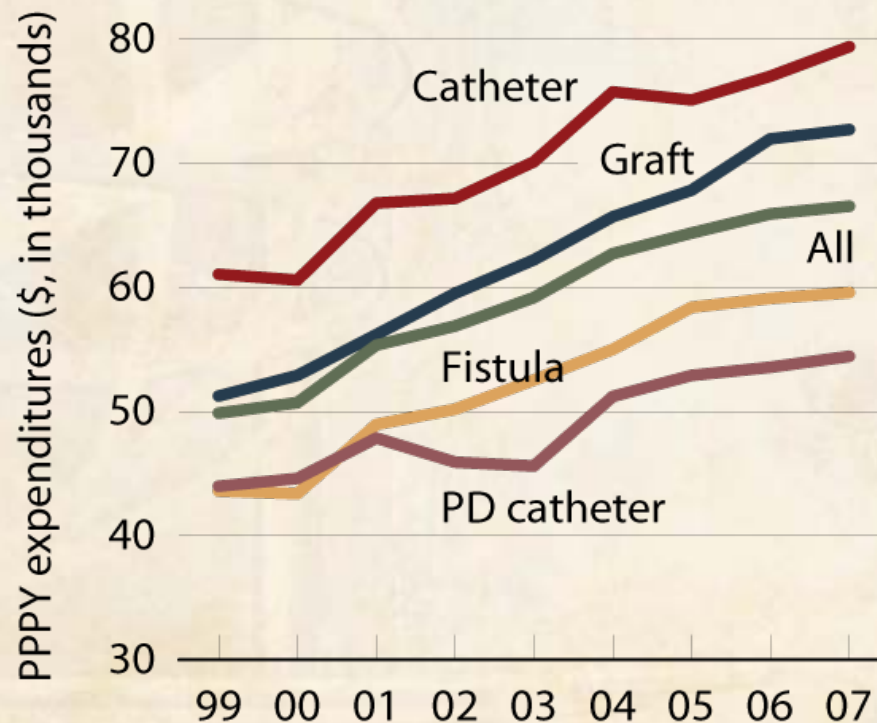
- In 2007, Drs Lazarus, Himmelfarb and Hakim reported, the success of Fistula First has been accompanied by an unplanned increase in HD catheters
- Proposed initiative for a dual goal of Fistula First and Catheter Last

So...

- Mortality remains high, greater than 20% per year
- Hospitalizations are high and unchanged in over 10 years, mostly due to cardiovascular issues and infection, the latter largely due to catheters
- What about costs?

Per person per year total expenditures, by access type

Figure 11.17 (Volume 2)



Dialysis patients from the 1999–2007 ESRD CPM data with Medicare as primary payor & vascular access data. Intent-to-treat model. Vascular access type in use in December prior to cost years 1999–2007.

Catheter Complications and Infection

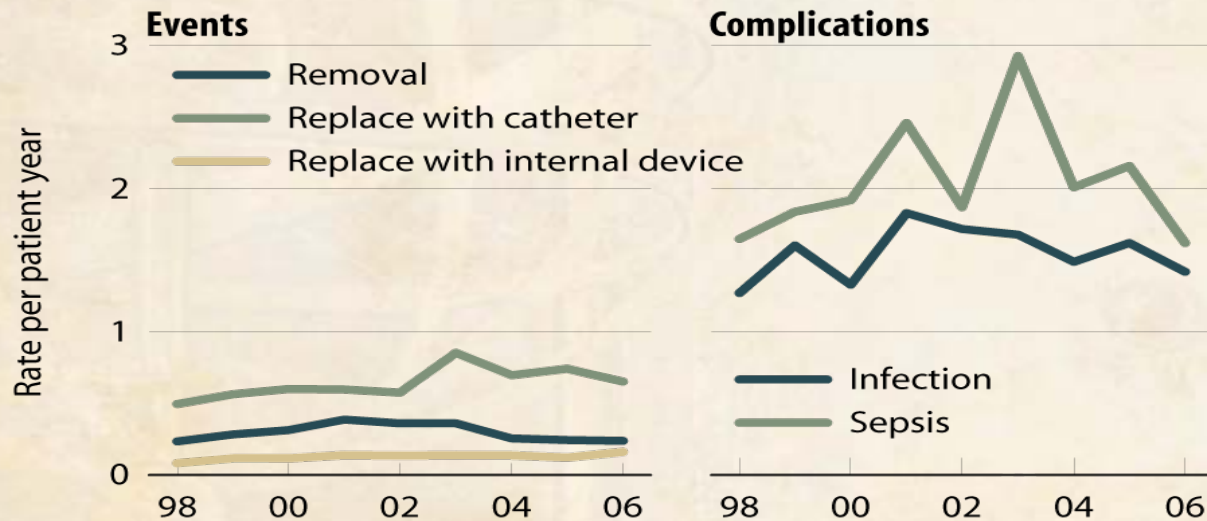
- Complications related to prolonged catheter use include increased mortality, morbidity, and cost
- Infectious hospitalizations approached CVD hospitalizations for the first time in 2005

Catheter Events and Hospitalizations

Catheter events & complications

Figure 5.20 (Volume 2)

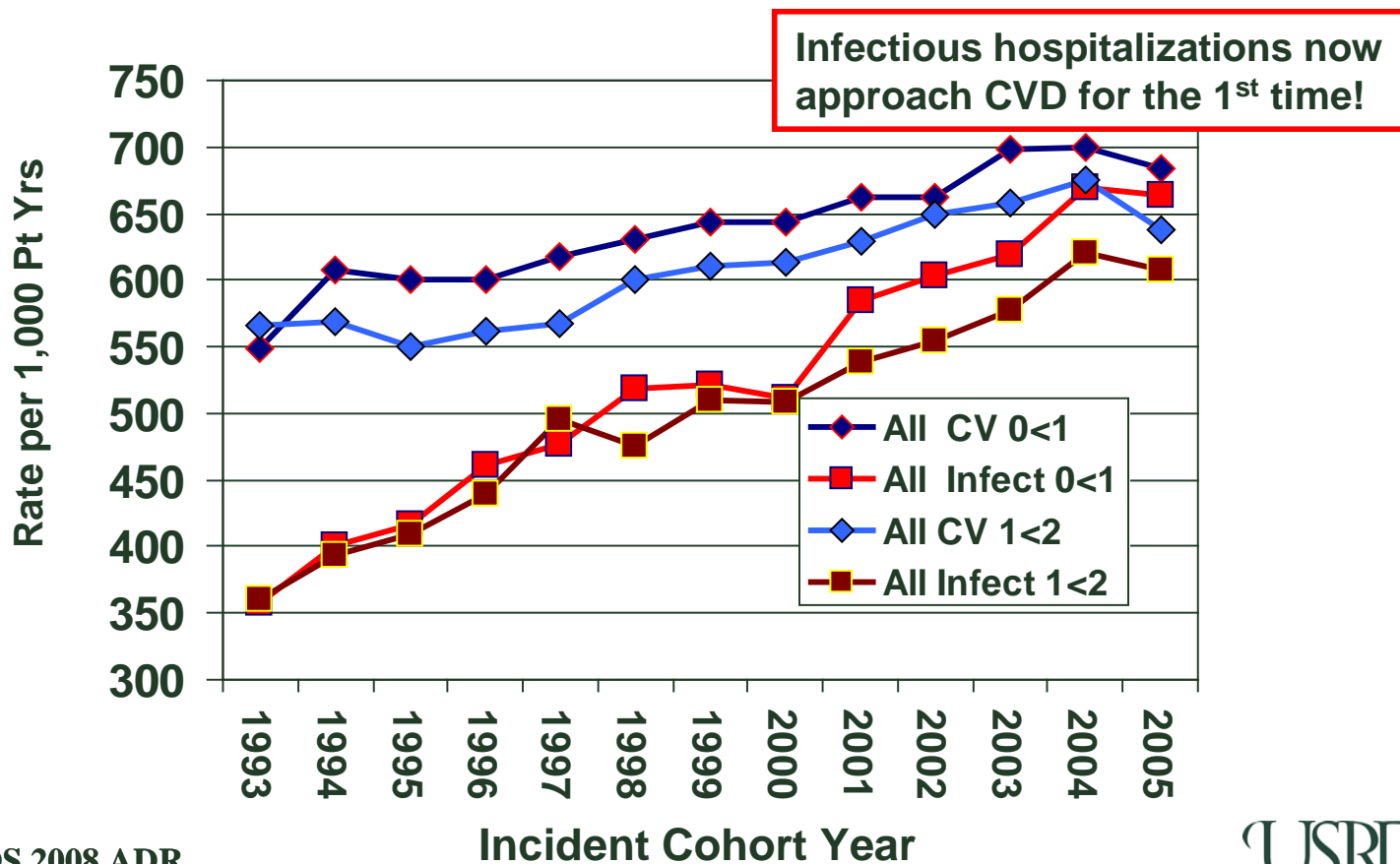
Fistula events and complication are .2 to .4 as prevalent



Prevalent hemodialysis patients age 20 & older, ESRD CPM data; only includes patients who are also in the USRDS database. Year represents the prevalent year & the year the CPM data were collected. Access is that listed as "current" on the CPM data collection form.

Trends in CVD and Infectious Hospitalization rates in the first month

Adjusted for age, gender, race and cause of ESRD

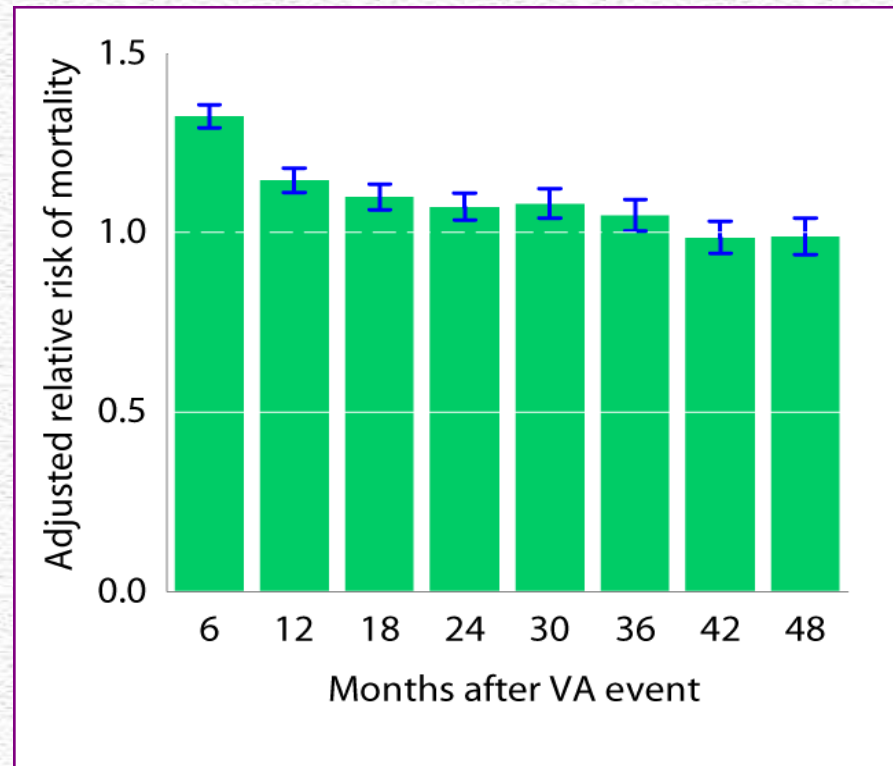


Infection Trends

- Infection hospitalizations substantially increasing over past 10 years, largely due to catheters
- Infection hospitalizations increasing at a rate greater than cardiovascular hospitalizations
- Much higher costs in patients with catheters
- There is even likely a linkage between one access infection and associated ongoing risk of death
- Higher mortality in catheter patients and facilities

Adjusted relative risk of mortality after VA event: dialysis

Figure 6.30

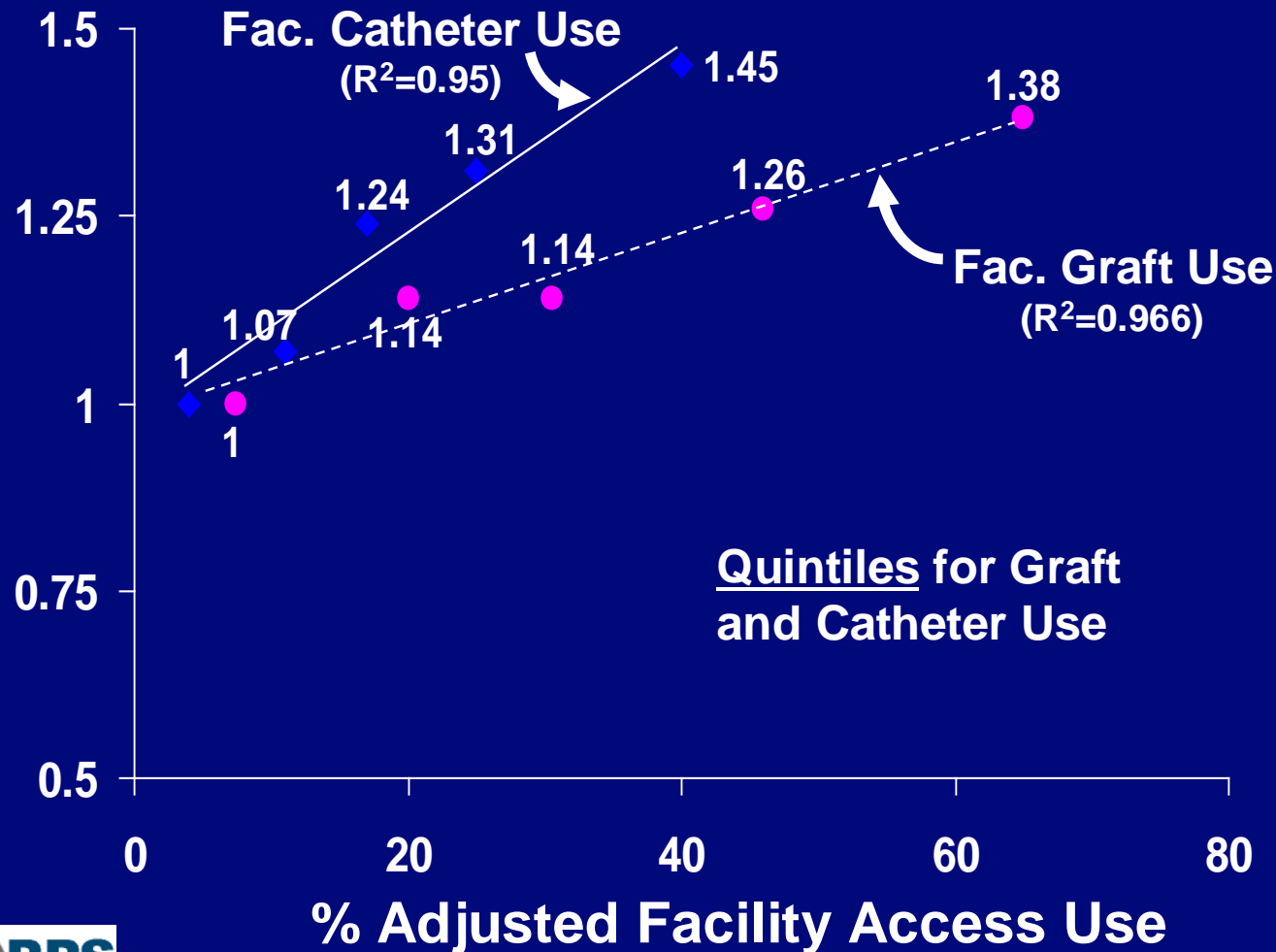


Incident dialysis patients with 90-day rule, Medicare as primary payor, & Part A & B claims, 1992–2000 combined; adjusted for age, gender, race, & primary diagnosis. Reference cohort: patients without corresponding diseases in the first year after ESRD initiation + 90 days.

Foley RN, Guo H, Snyder JJ, Gilbertson DT, Collins AJ:
Septicemia in the United States Dialysis Population, 1991 to 1999.
Journal of the American Society of Nephrology 15 (4): 1038-1045, 2004

Mortality Risk in Facilities that have Greater Use of Catheters or AV Grafts versus low use

RR of death



Changes Needed to Occur to Reverse These Trends

- In 2009, CMS increased the reimbursement rate for AVF placement to surgeons by 30%
- As of 11/09, 54.4% of patients nationwide had functioning AVF's

Boston Meeting Recommendations #1: Infection and Access

- Acknowledge: The catheter problem is *iatrogenic*
- Hospitals, health plans, nephrologists, providers and vascular surgeons (current 50% primary failure rate) need to be accountable for the reducing catheter placement; Implement the Hakim – Himmelfarb recommendations.
- CMS might consider changing the emphasis on traditional CPMs and surveys to assure maximum reduction in catheters and improving catheter care - moving catheters, as a CPM to the very highest level of scrutiny and surveys
- Vaccination, as a CPM, needs to be an important aspect of facility practice and accountability

So Why Do We Still Have Catheters?

- Elderly patients are increasing worldwide
- The myth that the use of AVF's in this population is still perceived because:
 - Age related, advanced atherosclerosis may increase failure rates in this population
 - Increased infections in this population due to poorer health and increased co-morbid conditions

Current Evidence Suggests:

- Old age should not comprise a drawback in selecting the appropriate vascular access modality.
- Vascular access options in elderly ESRD patients should not be any different than younger individuals
- ESRD rates are rising the most quickly among those 65 and older

Risks of Tunneled-Cuffed Catheters (TCC)

- Threefold increased mortality compared with AVF's
- Sepsis related death is 100 times greater in the dialysis population with infection related death and all cause mortality being the highest with TCC's
- 22% of pts with TCC's develop osteomyelitis, septic arthritis, and endocarditis and progress to death

Cost of Tunneled-Cuffed Catheters

- Placement of TCC - \$13,000
- Treating of one TCC-related episode of bacteremia is as high as \$45,000

Additional Consequences

- Poor Quality of Life
- Reduced dialysis adequacy (25.2% of pts had a KT/V of < 1.2)
- Central venous stenosis
- Primary cuffed catheter failure rate of 52% to 91% per year.

Patient Choice a Contributing Factor?

- 77% of AVF users would recommend to a friend, while 62% of pts with TCC would
- 11% of AVF users wanted to switch to another access while 32% of TCC users did
- 97% of TCC users considered their access to be easier to use than pts with a AVF (86%)

Measures to Increase Fistula Prevalence

- Pre-ESRD care by a nephrologist
- Pre-ESRD access surgery
- Adequate fistula maturation
- Successful fistula cannulation

Treatment of Catheter Thrombosis or Malfunction

- *Immediate* Disfunction is usually related to placement
- Later problems, caused by intraluminal or extraluminal thrombosis
- Sub-optimal dialysis flow with high negative arterial pressures
- Recognized by the inability to aspirate blood in extreme cases

Low Blood Flows

- Changing the patients position
- Switching the arterial and venous lines, Charge RN must be notified
- Forceful aspiration and flushing with a small syringe by an RN
- Instillation of a thrombolytic agent into the catheter lumen for 30-60 minutes

Persistent Catheter Malfunction

- Requires exchange of catheter over a guidewire
- Prior to exchange the catheter should be imaged to evaluate for the presence of a fibrin sheath

Prophylaxis of Thrombosis

- Use of heparin in the catheter ports at the end of each dialysis session
- Concentration of heparin varies from 1000U/ml to 5000U/ml
- Caution should be exercised when using the higher concentration as leakage is possible

Use of Heparin vs Citrate

- Small prospective study of one lumen instilled with 5000u/ml heparin and 30% citrate showed no difference in frequency of thrombosis between the 2 lumens.
- Large retrospective study found no difference between heparin and citrate locks in terms of frequency of thrombolytic installation or catheter exchange
- Randomized study comparing citrate and heparin observed similar frequencies of of treatment but a 3 fold risk for bleeding complications

Vascular Stenosis and Thrombosis

- Catheters can produce stenosis or thrombosis of the central vein
- More common with subclavian catheters
- Can occur in internal jugulars with prolonged use
- Central vein stenosis may become evident after creation of an ipsilateral vascular access. May require ligation of access to alleviate edema

Bacteremia

- One study of 108 pts with TCC's showed the first episode of bacteremia in 35% of patients within 3 months and 48% after 6 months
- Frequency of catheter related bacteremia has ranged from 2.0 to 5.5 episodes per 1000 catheter days
- Serious complication occurs in 5-10% of pts and is 3.5 –fold likely when the infection is Staph aureus

Prophylaxis of Bacteremia

- Use of aseptic technique, including washing of hands, wearing clean gloves, and minimizing the duration of air exposure of catheter lumens
- Soaking of catheter hubs with 2% chlorhexidine or povidone-iodine before connection and disconnection
- Use of masks when catheter lumen is exposed

Use of Connection Devices

- Port connection devices can be used to reduce the number of times the catheter lumen is exposed to air, thus in effect reducing the chance of contamination.
- Some centers have reported problems with connectivity and have expressed concern over what is perceived as increased clotting
- Anecdotal studies have show a decrease in infection

Routine Catheter Care

- Cleaning of catheter access site with chlorhexidine, dilute sodium hypochlorite or povidine iodine with soaked gauze pads or swabs on dialysis days
- Move cleaning swab/pad from the center of the excess site with a circular motion
- Allow the solution to dry thoroughly before the dressing is applied

Routine Catheter Care

- Exit site can be covered with gauze or a transparent dressing.
- Transparent dressings are preferred in most settings as they secure the device, permit continuous visual inspection, permits patients to bathe or shower, and requires less frequent dressing changes.

Antimicrobial Locks

- Standard Antibiotics
- Antimicrobial Agents such as taurolidine and 3% citrate
- 5 randomized trials documented substantial efficacy of antibiotic locks (gentamycin, minocycline or cefotaxime) in prophylaxis against catheter related bacteremia
- 3 studies documented reductions with taurolidine or 30% citrate lock

Alternative to Lock Solutions

- Application of a topical antibiotic ointment at the exit site
- Sterilizes the skin flora from which the biofilm derives infection
- 2 studies, one using mupirocin and one using polysporin, demonstrated a marked reduction in the frequency of infection
- Long term use of ABX may produce highly resistant infections

In Conclusion

- Fistula's are the access of choice due to :
 - Decrease in infection
 - Decrease on other complications
- Fistula's can be utilized on all ages, regardless of co-morbid conditions
- Catheters should only be used as a bridge between transplantation or the maturation of a permanent internal access