Budapest Nephrology School

August 30, 2010

The vexing problem of suboptimal initiation of dialysis:

Can we do better?

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Disclosures 2007 – 2010

- Speaker Fees: Amgen, Ortho Biotech, Genzyme, Shire, Roche, Baxter, Bayer, RAI
- Advisory Boards: Amgen, Ortho Biotech, Genzyme, Shire, Roche, Baxter, Astra Zeneca
- Research Grants: Ortho Biotech (principle investigator, multicentre studies), Amgen (site investigator)
- None of these are relevant for my talk today

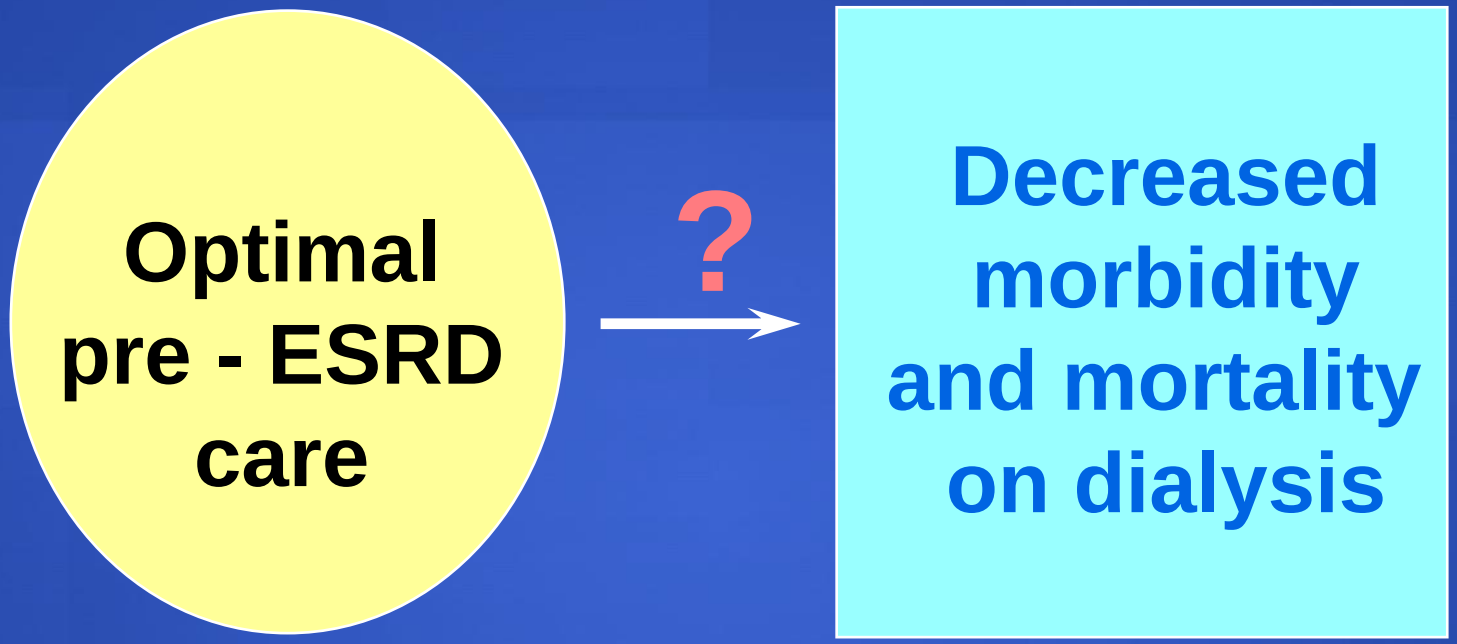
Road map

- A framework for analysis
- Care in the Community
  - Non referral and late referral
- Care after referral
  - Solo nephrology care
  - Multidisciplinary team based care
- Initiation of Dialysis
  - Suboptimal starts
- STARRT study data
- Optimizing Care
  - Challenges and opportunities

What percentage of North American patients experience a suboptimal initiation of dialysis?

1) 0 – 19%
2) 20 – 39%
3) 40 – 59%
4) 60 – 79%
5) > 80%

Mirror, mirror on the wall



Clearly, there is an association between mortality on dialysis and suboptimal pre-ESRD care. It seems plausible that better pre-ESRD care will lead to better outcomes.

Suboptimal starts
Late Referrals/Unplanned starts

- Consequences
  - Anemia
  - Metabolic acidosis
  - Hyperphosphatemia
  - Hypoalbuminemia
  - Hypertension, volume overload
  - Low prevalence of AV Fistula as initial dialysis access
  - Low rate of initiation of home dialysis
  - Delayed referral to transplant
  - Increased hospitalization rate
  - Higher cost of dialysis initiation
  - Increased 1 yr mortality

Kessler et al 2003; Metcalfe et al 2000; Lorenzo et al 2004

A Framework

Care in the community

A) Primary care
B) No care

Non Referral

Early
Late

Nephrology Care

A) Nephro-logist alone
B) Multi-disciplinary predialysis team

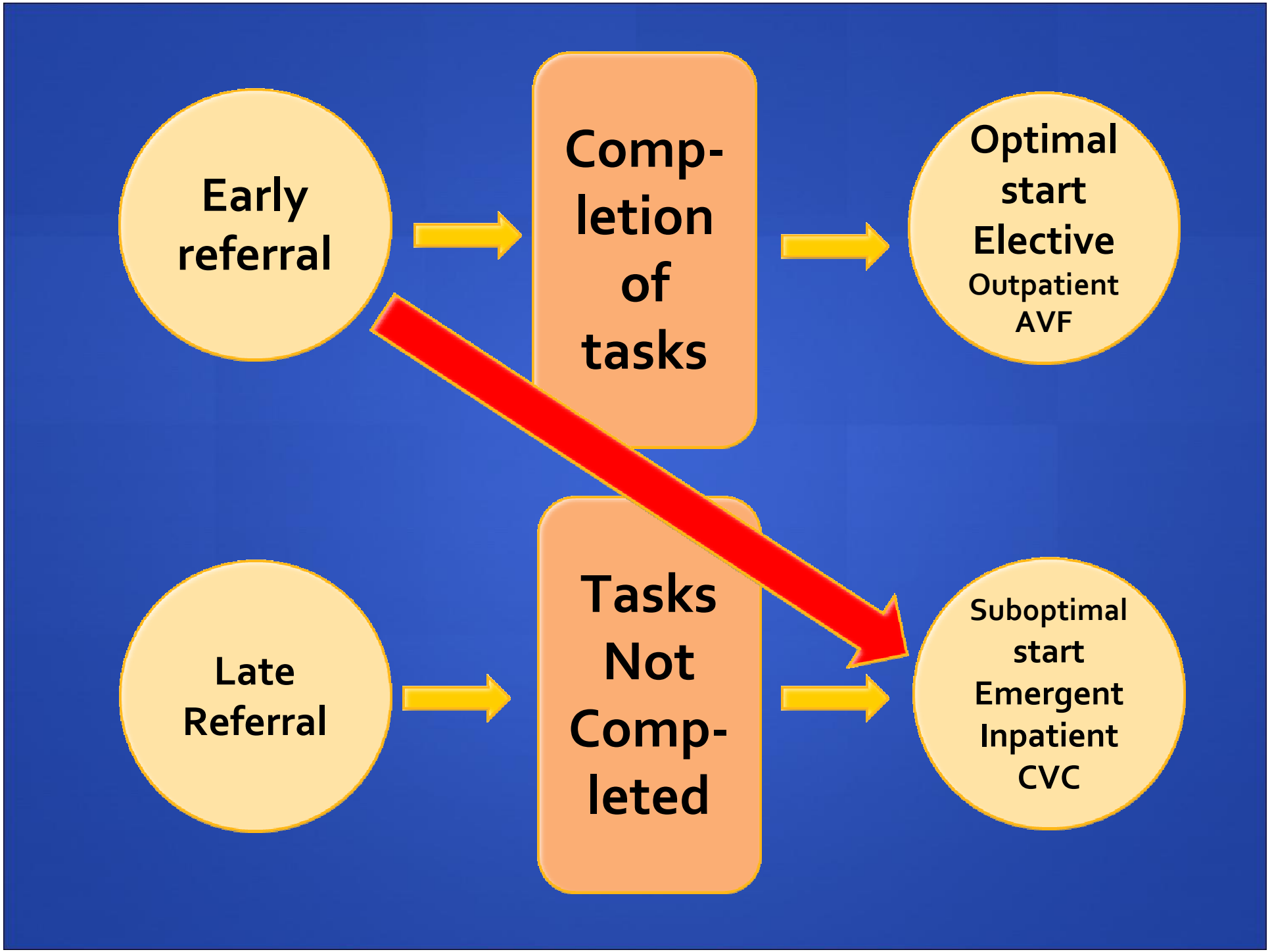
ESRD Care

A) Conservative
B) Dialysis
C) Transplant

Focus on Year 1

Referral

Preparation


Early referral
Comp-letion of tasks
Optimal start Elective Outpatient AVF
Late Referral
Tasks Not Comp-leted
Suboptimal start Emergent Inpatient CVC

Suboptimal starts

Cardio/renal protection

Preparation for ESRD

1) Patient education
2) Modality choice
   - include no dialysis & trial of dialysis options
3) Transplant consideration
   - Is preemptive possible?
4) Dialysis access creation
5) Smooth entry into ESRD program

All this takes time, especially vascular access

Pre-ESRD Care in Canada

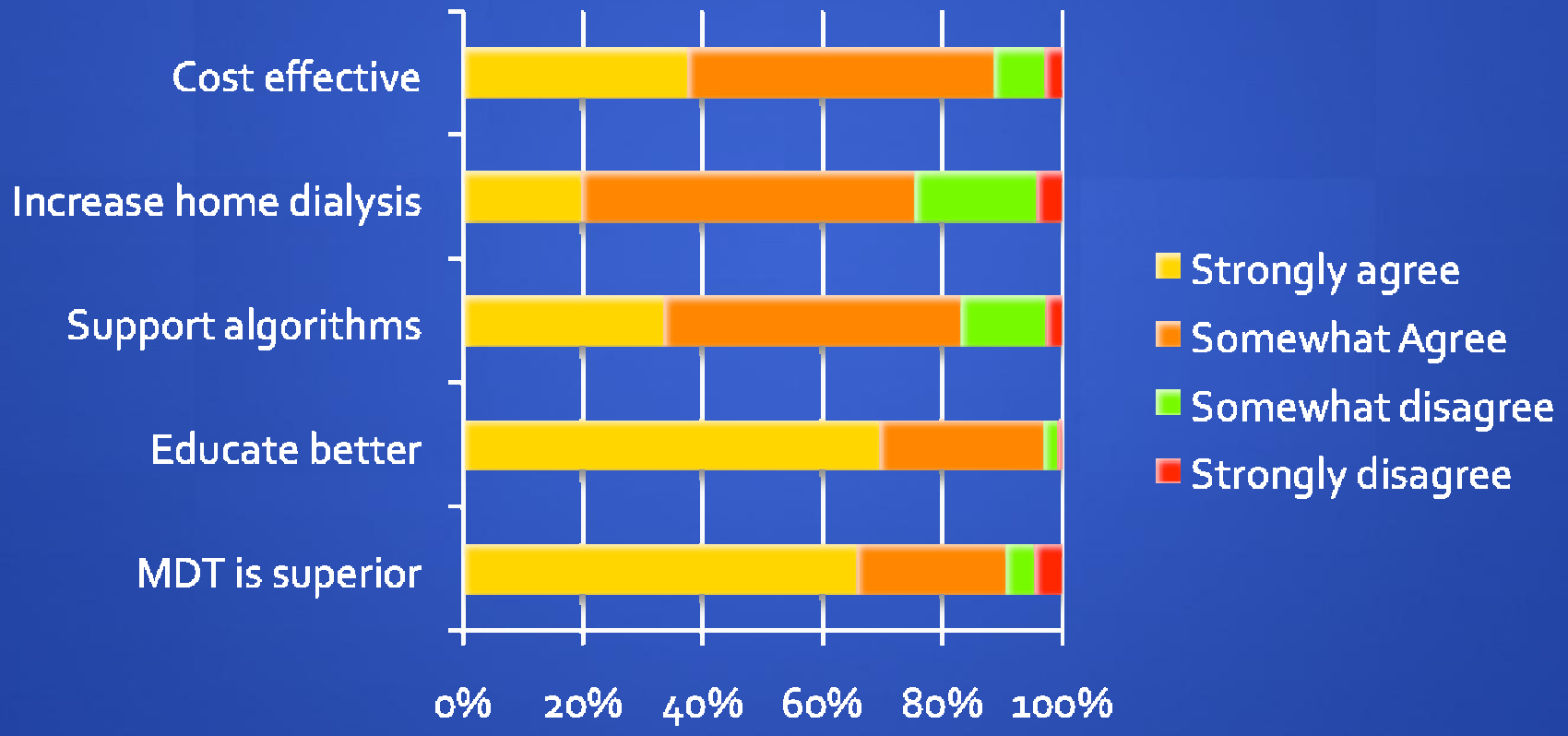
- Centralized health care system, integration of stages 3,4,5 and 5D care
- Extensive use of multidisciplinary team based care
  - Nurse clinician/educator
  - Social worker
  - Dietician
  - Pharmacist
- Canadians have shown the world that management of patients by nephrologists with a multidisciplinary predialysis team is superior to care provided by a nephrologist alone

Ontario: Current Funding Formula

November, 1998

	Life Support 1986	JPPC 1997	MOH 1998
Overhead	17%	17%	11.4%
Level 1 HD	34,510	31,540	21,311
Level 2 HD	40,377	39,963	31,122
CAPD	27,256	28,068	26,725
CCPD		32,321	30,774
Pre-ESRD Clinic		252.95	240.85

Attitudes of Canadian nephrologists towards multidisciplinary predialysis care



Mendelssohn DC et al. AJKD 47: 277-284; 2006

Chapter One

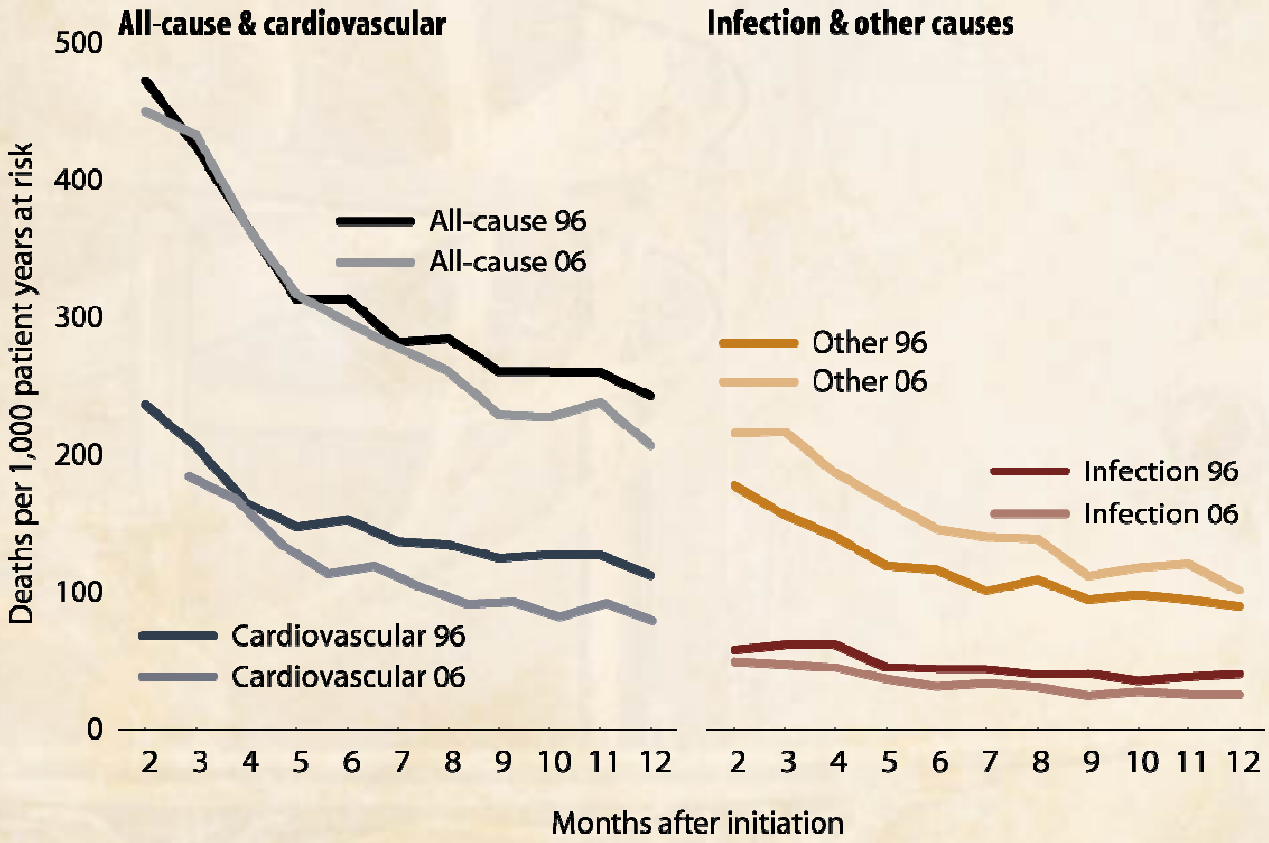
Emerging Issues: First-year mortality

USRDS 2009
Annual Data Report

USRDS

All-cause & cause-specific mortality in the first year of hemodialysis

Figure 1.1 (Volume 2)

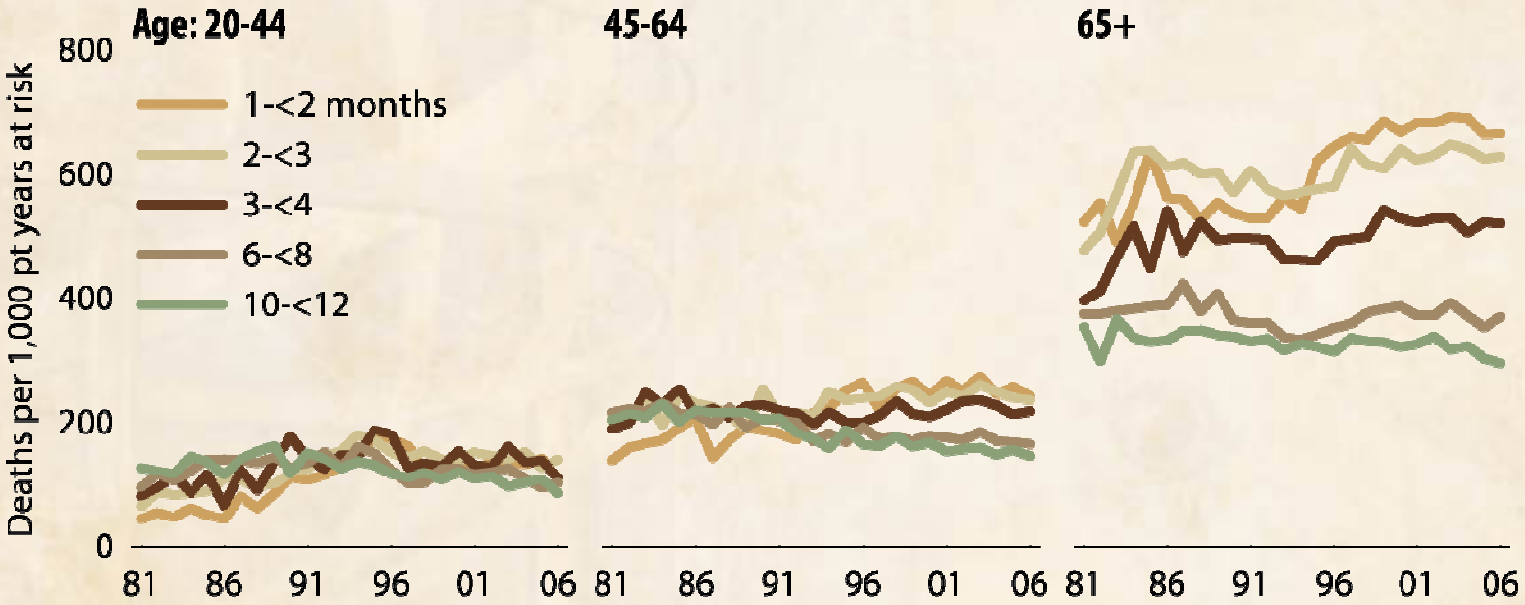


Incident hemodialysis patients; followed from the day of onset of ESRD; adjusted for age, gender, race, and primary diagnosis. Incident hemodialysis patients, 2005, used as reference.

USRDS

Adjusted all-cause mortality in the first year of hemodialysis, by month & age

Figure 1.2 (Volume 2)



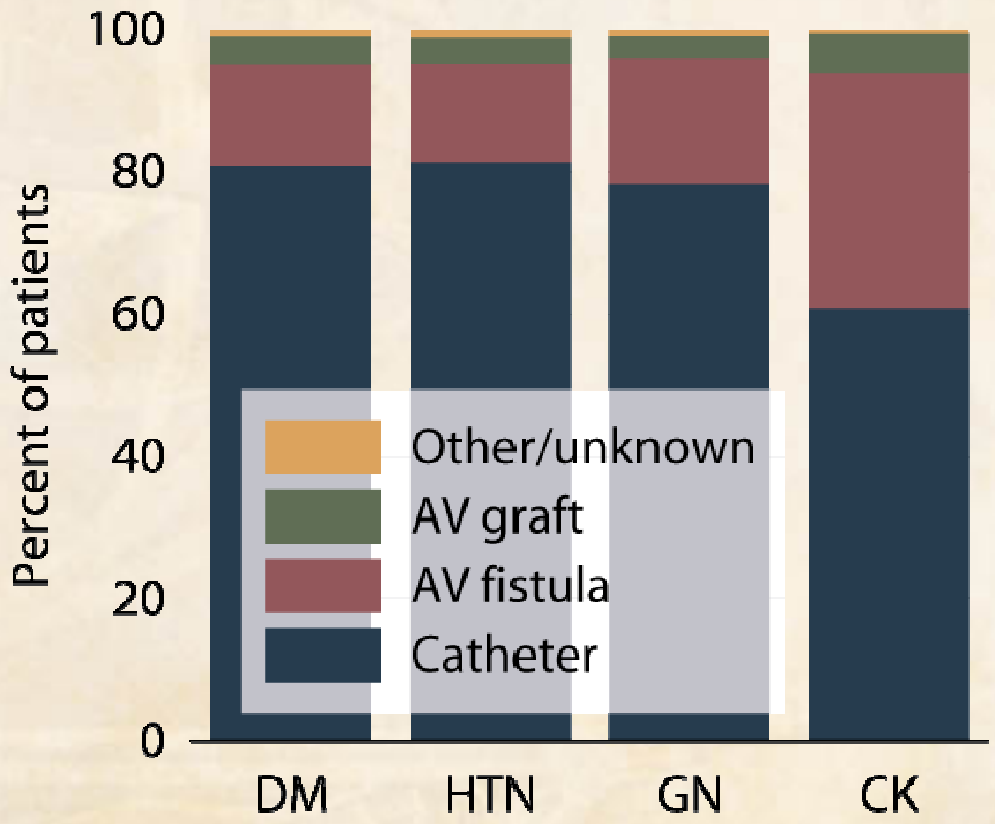
Incident hemodialysis patients age 20 and older; followed from the day of onset of ESRD; adjusted for gender, race, & primary diagnosis. Incident hemodialysis patients, 2005, used as reference.

USRDS 2009 ADR

USRDS

First access at initiation in patients with 12+ months of nephrologist care, by primary diagnosis, 2007

Figure 3.4 (Volume 2)

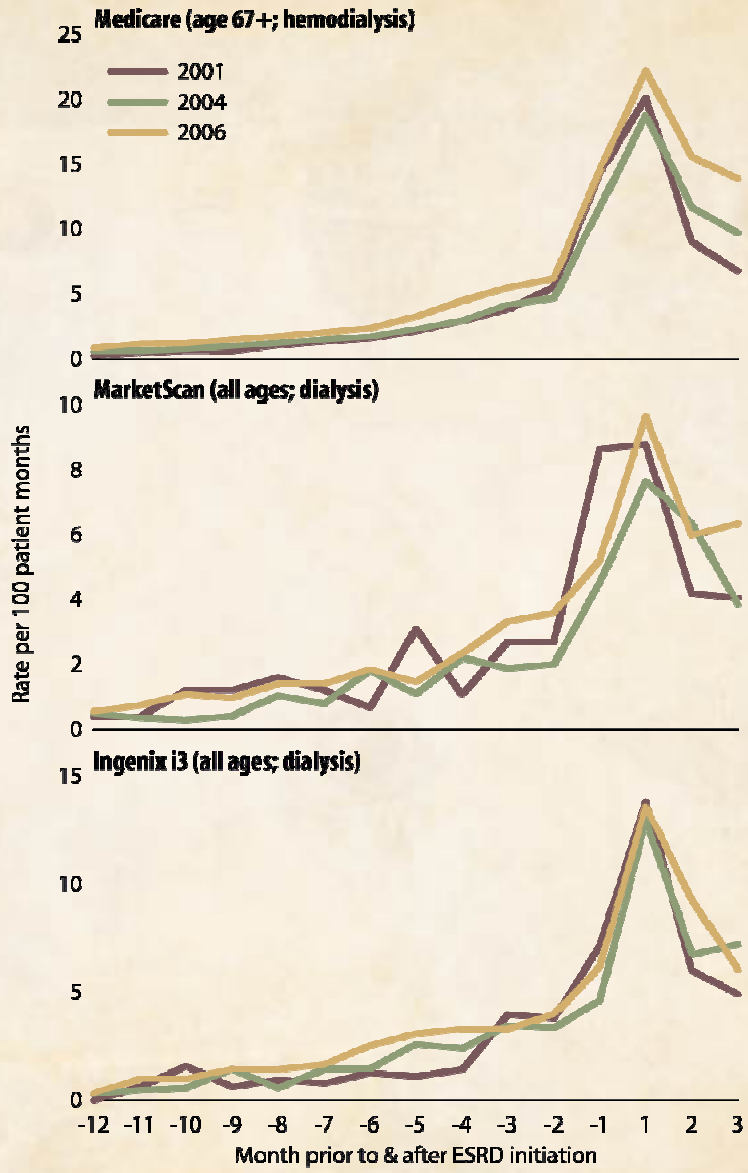


Incident hemodialysis patients, 2007.

USRDS

Rates of arteriovenous (AV) fistula placements during the transition to ESRD, by year & dataset

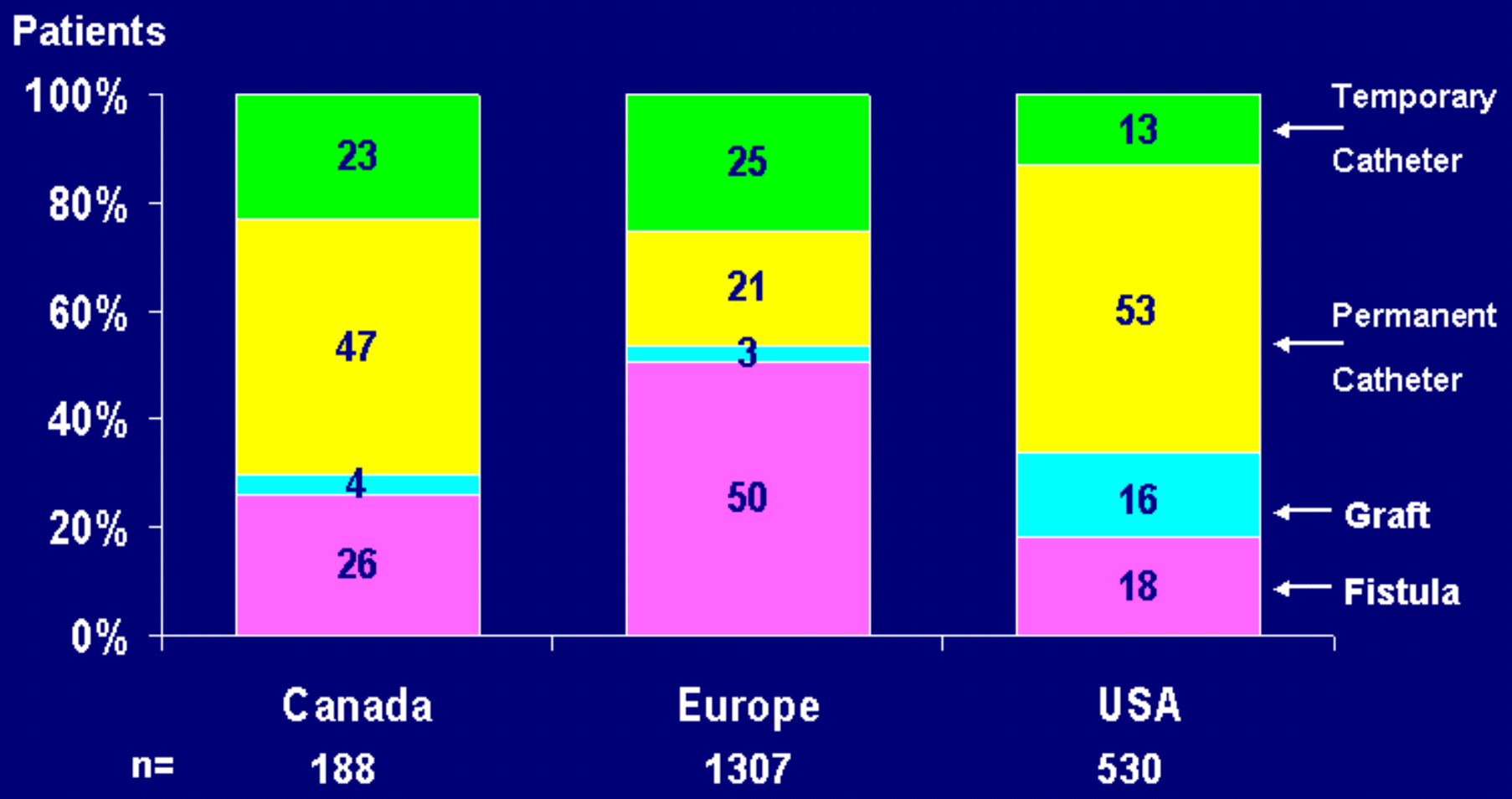
Figure 7.25 (Volume 1)



Incident dialysis patients eligible for two years prior to ESRD. Medicare patients include those age 67 and older at initiation, and only those known to initiate on hemodialysis. Type of dialysis is not identifiable in the MarketScan or Ingenix i3 datasets, so data included dialysis patients.

USRDS

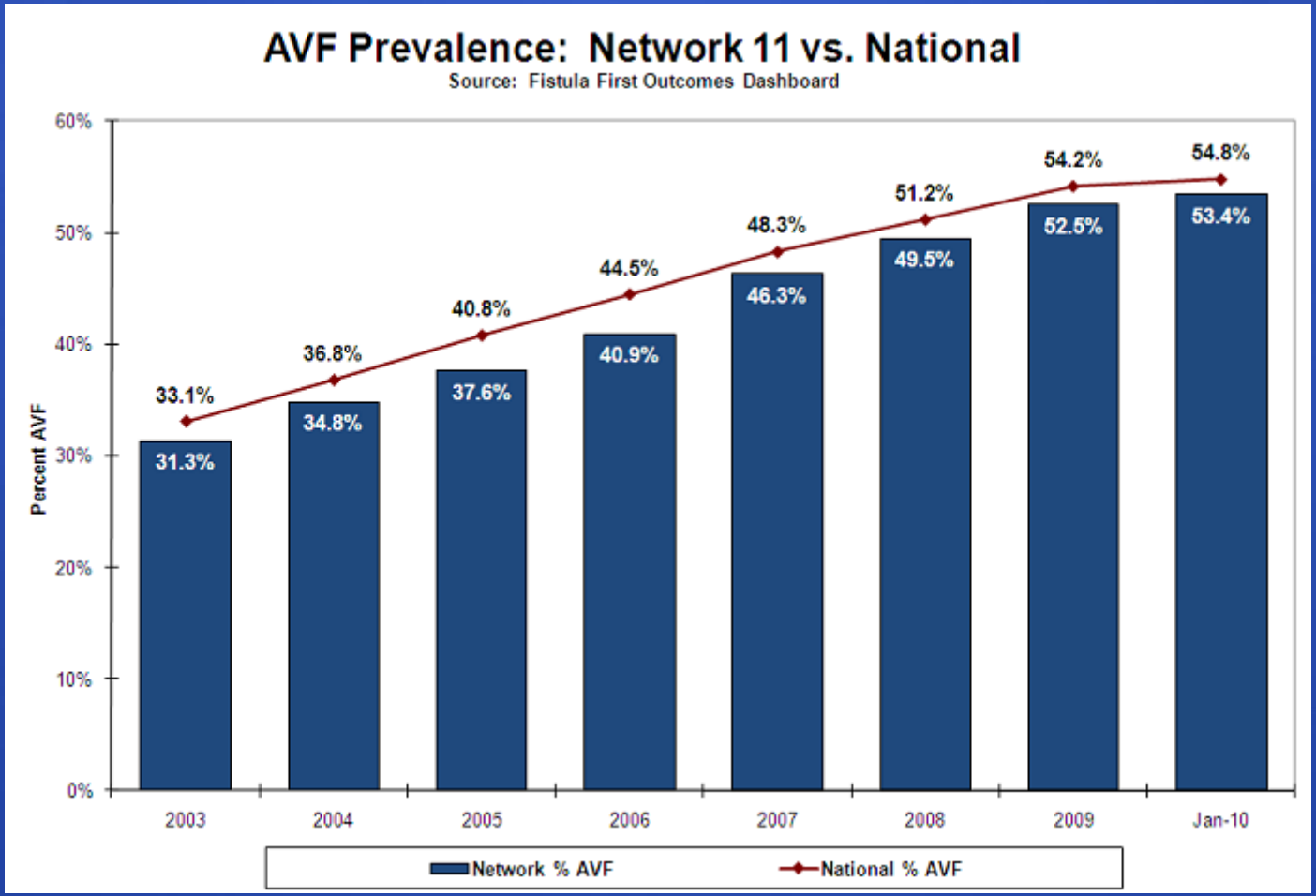
Vascular Access Use, Among Incident HD Patients: Canada, Europe, and USA



Incident patients entering DOPPS within 5 days of first-ever chronic dialysis; n= # of patients

Mendelsohn DC et al. Nephrology Dialysis and Transplant 21(3):721-728, 2006

Fistula First Initiative



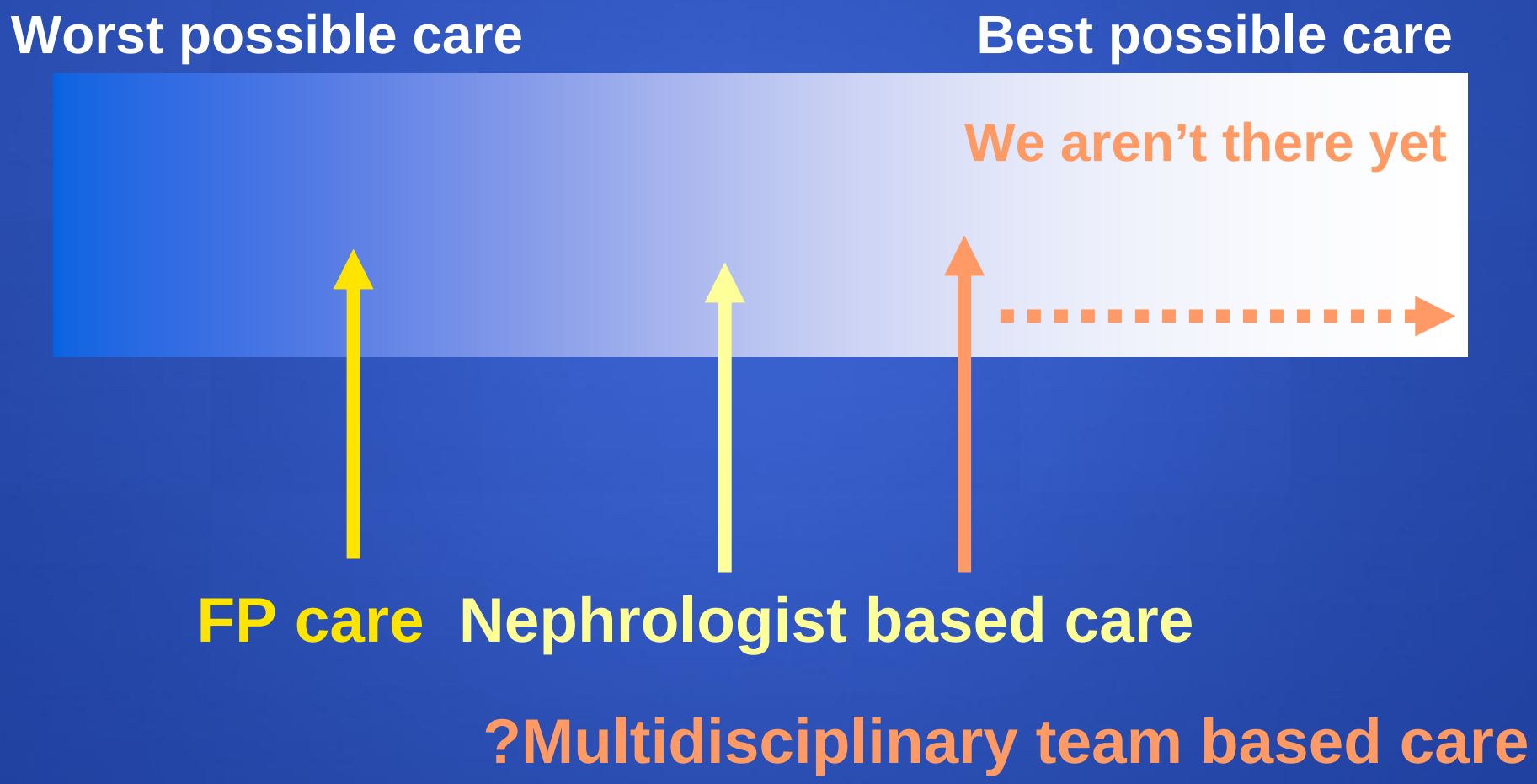
Timing of Pre-ESRD Care and Catheter Use

Timing of When Patient 1st Seen by Nephrologist Before ESRD onset	% Catheter use at ESRD start (US)	% Catheter use at ESRD start (Fr, Ger, It)
Not seen or seen < 1 mo prior to ESRD	88 (n=52)	62 (n=42)
1 – 4 mo prior to ESRD	82 (n=28)	50 (n=22)
4 mo – 1 yr prior to ESRD	64 (n=28)	23 (n=46)
1 – 2 yrs prior to ESRD	72 (n=46)	26 (n=62)
>2 yrs prior to ESRD	63 (n=91)	19 (n=157)

DOPPS

Rayner & Pisoni, Seminars in Dial 2010

Optimizing CKD Care



Can we find the right road?

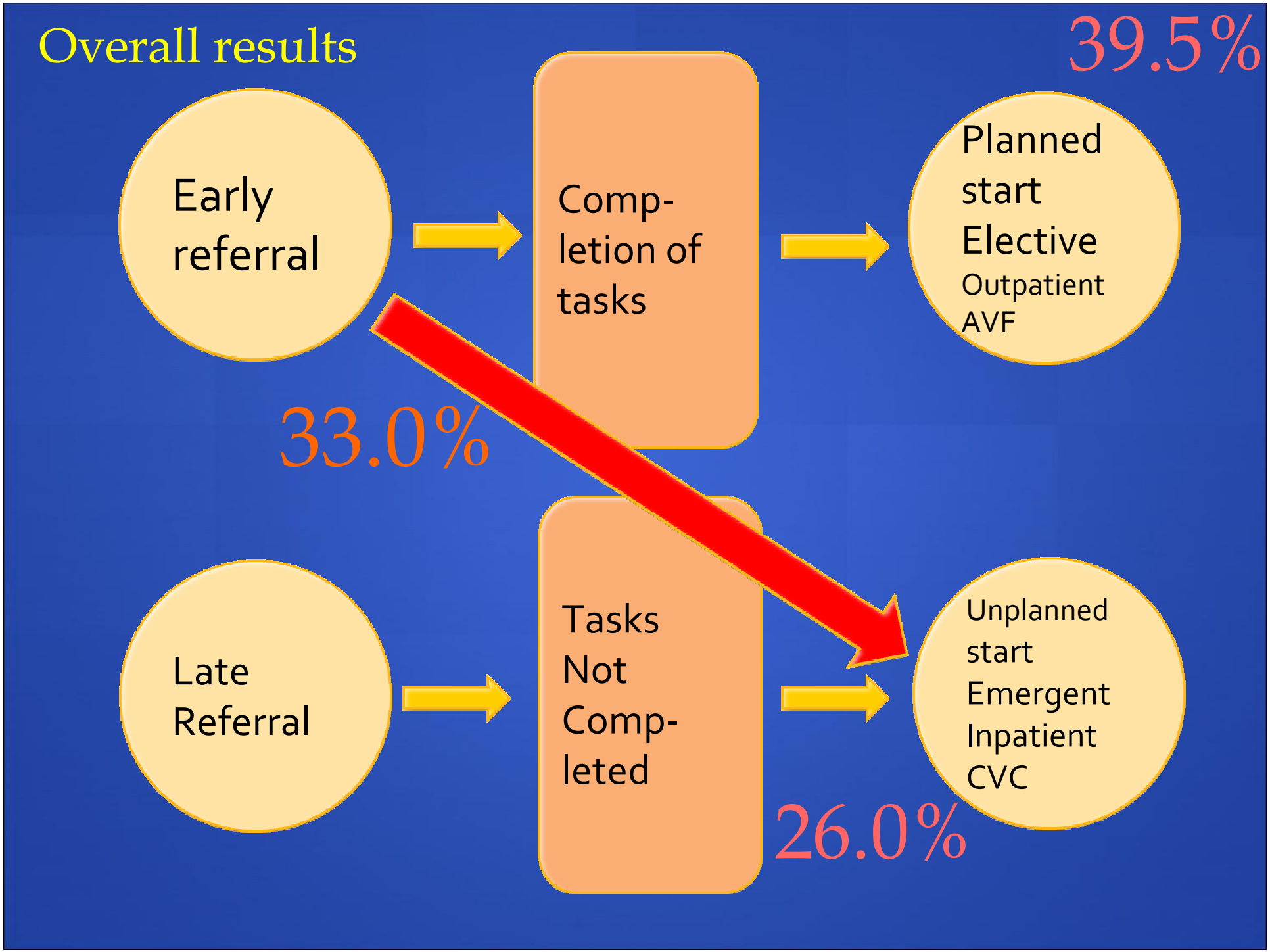
Definitions

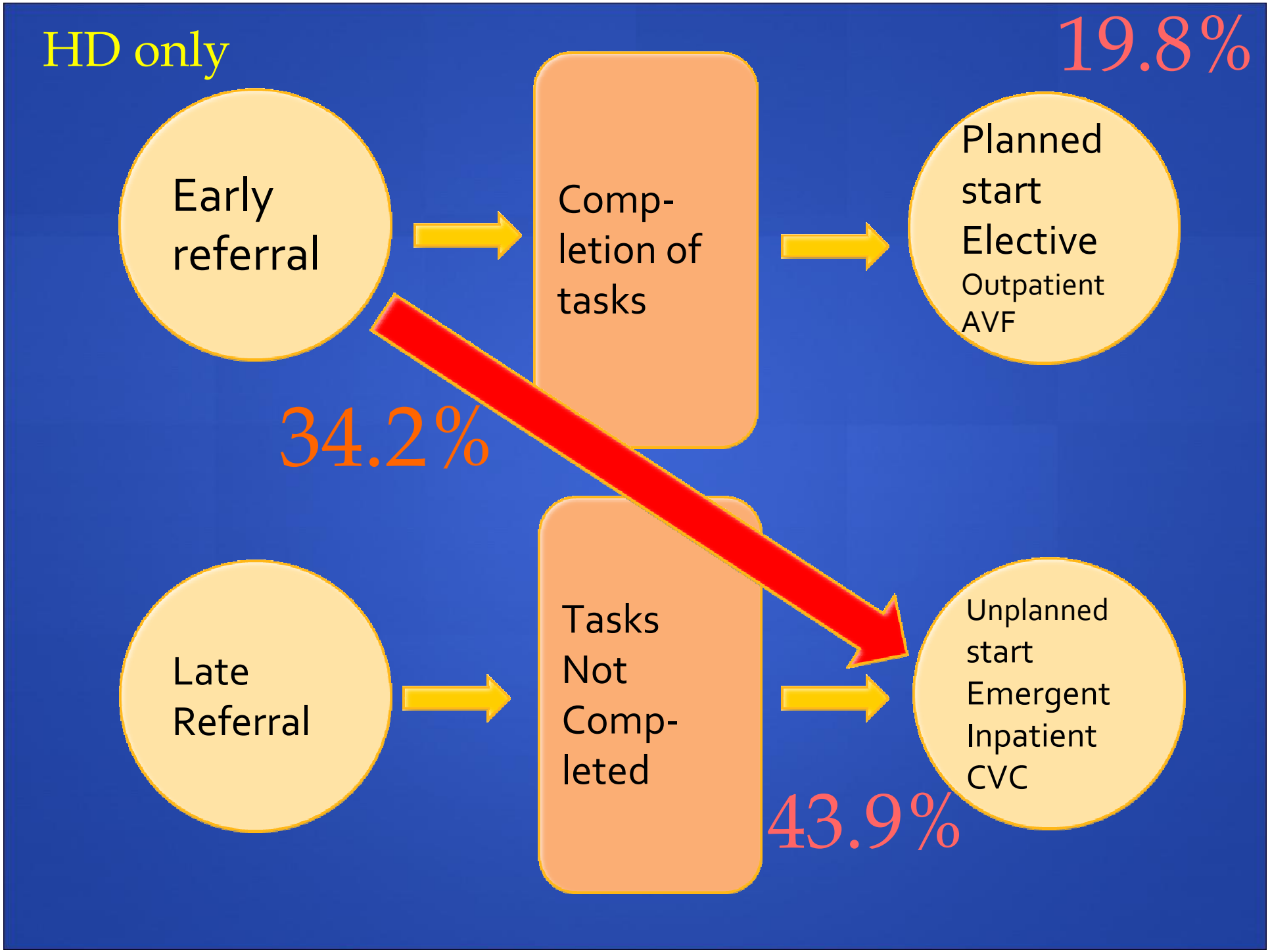
- Optimal start
  - ~~Planned~~
  - (Pre-emptive transplant)
  - Elective
  - Outpatient
  - Early referral
  - Chronic modality of choice
  - Permanent access
    - AVF/AVG
    - PD catheter
- Suboptimal start
  - ~~Unplanned~~
  - Urgent
  - Inpatient
  - Late referral
  - Acute modality
    - Usually HD
  - Temporary access
    - CVC

STARRT: Study to assess renal replacement therapy

- A Canadian multicentre retrospective chart review
- Include all patients who started chronic dialysis or who had a pre-emptive live donor transpant from
- July 1, 2006 to December 31, 2006
-Follow prospectively for 6 months
-N = 339, 10 facilities
- Primary outcomes:
    a) hospital versus non hospital start
    b) duration of pre-ESRD care
    c) access at dialysis initiation
-Data that follows is preliminary and confidential!
    -5 posters presented at ASN 2009

Ortho Biotech sponsored study, ongoing


Overall results
39.5%
Early referral
Comp-letion of tasks
Planned start Elective Outpatient AVF
33.0%
Late Referral
Tasks Not Comp-leted
Unplanned start Emergent Inpatient CVC
26.0%


HD only
19.8%
Early referral
Comp-letion of tasks
Planned start Elective Outpatient AVF
34.2%
Late Referral
Tasks Not Comp-leted
Unplanned start Emergent Inpatient CVC
43.9%

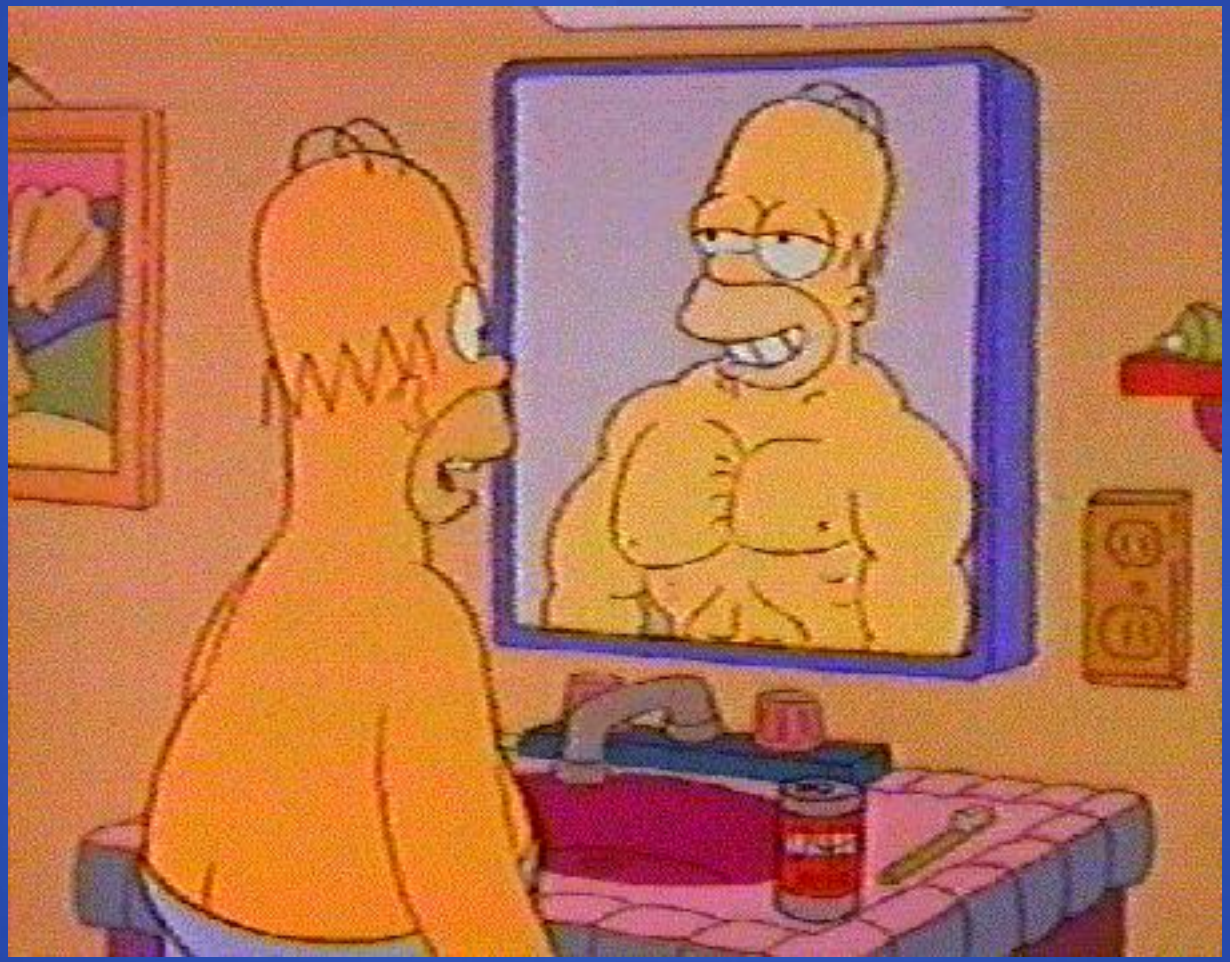
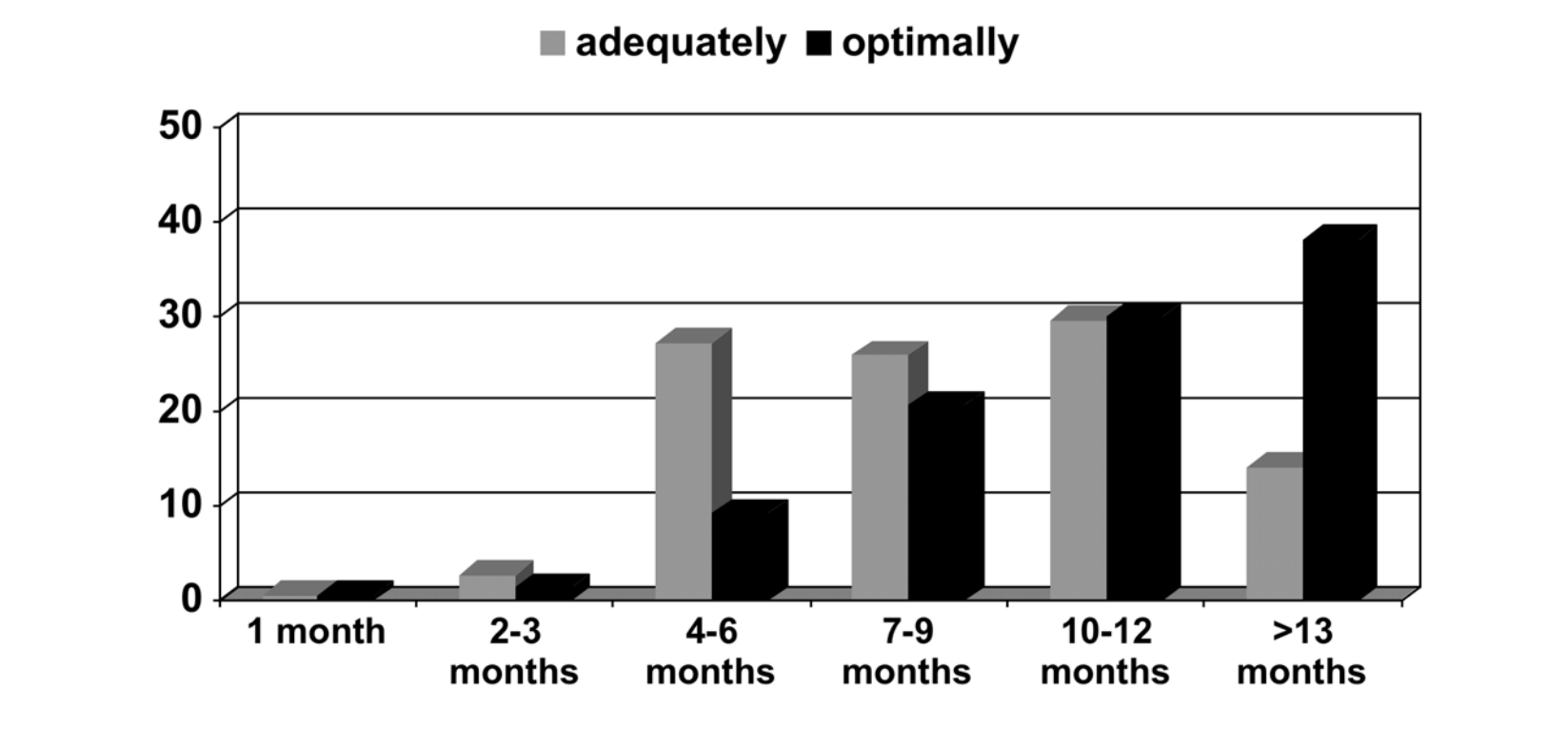
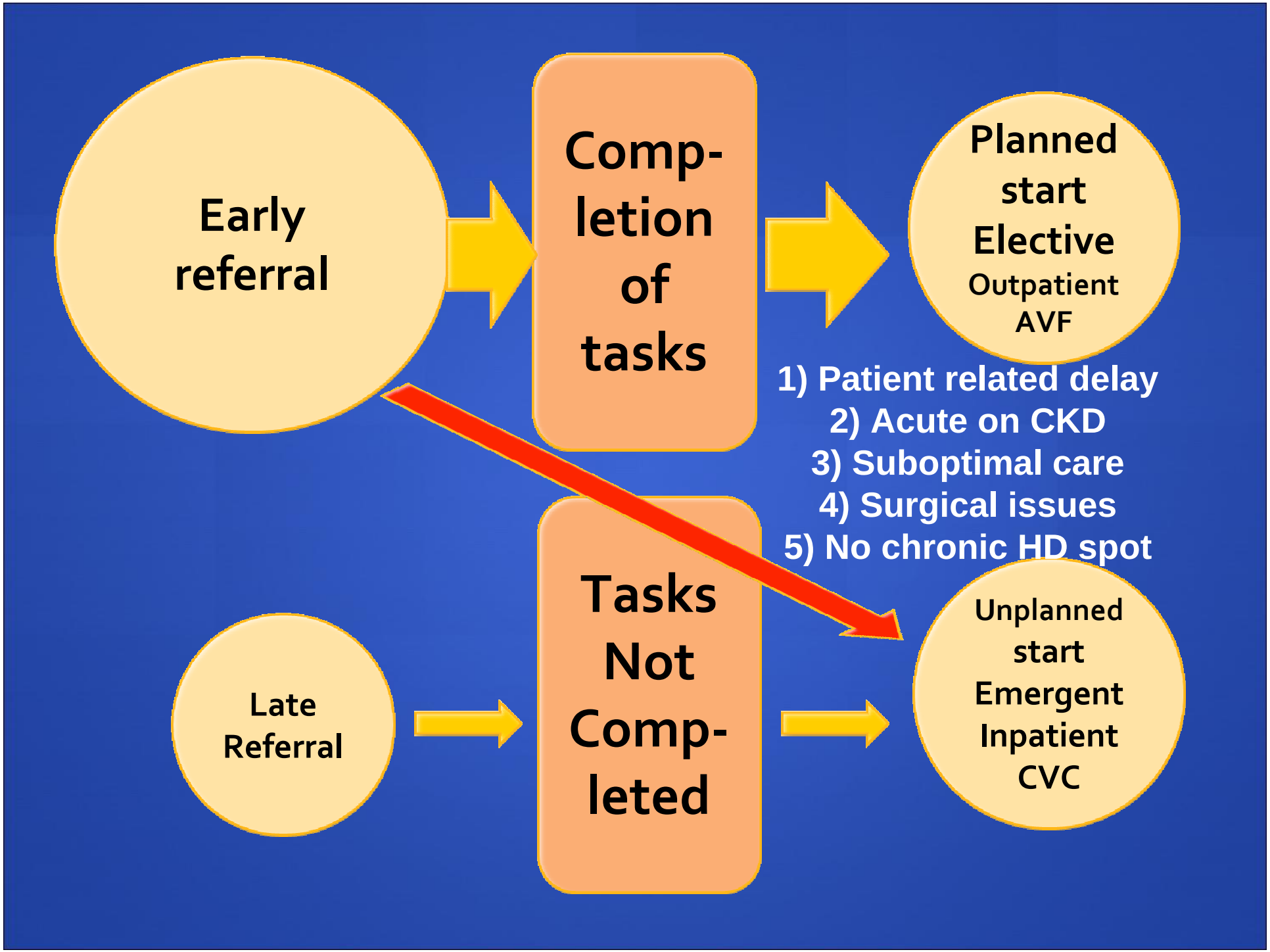


Figure 5: The literature is unclear about what the cut off time between an early referral and a late referral should be. If the cut-off is defined as the minimum amount of time required to adequately (or optimally) prepare a patient for an elective start on either modality, then in my opinion the cut-off should be:



AJKD 47: 277-284; 2006


Early referral
Comp-letion of tasks
Planned start Elective Outpatient AVF
1) Patient related delay
2) Acute on CKD
3) Suboptimal care
4) Surgical issues
5) No chronic HD spot
Late Referral
Tasks Not Comp-leted
Unplanned start Emergent Inpatient CVC

Timing of tasks

- At eGFR < 30 – renal education
- At eGFR 20 – 30 – modality decision
- At eGFR 20 – vascular studies and refer to vascular surgeon for those destined for HD
- Adjust the above based on rate of decline of eGFR

Problems and Solutions

- Improve community based care
  - Referral guidelines
  - CKD Management guidelines
- Improve nephrology care
  - Targets for CKD clinics, CQI based on them
  - Advocate for resources
    - Multidisciplinary team based care
    - Chronic dialysis resources
  - Reduce patient related delays
- Improve the initiation of dialysis, especially during the first 90 days
  - Overcome problems related to late referral and/or unplanned starts
    - Right Start Program

Early referral

Excessive referral

Non-referral

Late referral

Inappropriate referral

Timely referral

CANADIAN SOCIETY OF NEPHROLOGY
SOCIÉTÉ CANADIENNE DE NÉPHROLOGIE

CSN Position Paper on Care and Referral of Adult Patients with Reduced Kidney Function

October 2006

www.csnscn.ca

Pragmatic Balance

- Identify and refer earlier patients with serious and progressive CKD
- Identify and manage without referral, patients with stable and non-progressive CKD

Referral is recommended when:

1) Acute renal failure
2) Stage 4 (eGFR 16 – 30) and stage 5 imminent ESRD (eGFR < 15)
3) progressive decline of eGFR
4) Persistent proteinuria > 100 mg/mmol

   NB: 100 mg/mmol = 890 mg/24 hr

5) inability to achieve treatment targets

REVIEW CMAJ

CLINICAL GUIDELINES

Guidelines for the management of chronic kidney disease

Adeera Levin MD, Brenda Hemmelgarn MD PhD, Bruce Culleton MD MSc, Sheldon Tobe MD, Philip McFarlane MD PhD, Marcel Ruzicka MD PhD, Kevin Burns MD, Braden Manns MD MSc, Colin White MD, Francoise Madore MD MSc, Louise Moist MD MSc, Scott Klarenbach MD MSc, Brendan Barrett MD MSc, Robert Foley MD MSc, Kailash Jindal MD, Peter Senior MBBS PhD, Neesh Pannu MD MSc, Sabin Shurraw MD, Ayub Akbari MD, Adam Cohn MD, Martina Reslerova MD PhD, Vinay Deved MD, David Mendelssohn MD, Gihad Nesrallah MD, Joanne Kappel MD, Marcello Tonelli MD SM, for the Canadian Society of Nephrology

What do we know about initiation of HD? Can we overcome a suboptimal start?

- Mortality rates within the first 90 days of initiation of hemodialysis are relatively much higher than after that.
- Many factors seem to interact to cause this effect:
  - Patient instability
  - late referral
  - inadequate preparation for HD
  - fragmented and ineffective care provided by medical programs
  - Imbalance of pt at initiation – rapid decline of RRF
  - Vascular access

The RightStart® Program: Reduction of Mortality in Incident ESRD Patients with Early intervention

RL Wingard[1], L Pupim[2], TA Ikizler[2], JE Thomas[1], R Hakim[1]

[1]Renal Care Group, Inc., Nashville, Tennessee; [2]Vanderbilt University Medical Center, Nashville, Tennessee

Wingard et al (2007) CJASN:2, 1170-75

CJASN ePress. Published on October 17, 2007 as doi: 10.2215/CJN.04261206

Early Intervention Improves Mortality and Hospitalization Rates in Incident Hemodialysis Patients: RightStart Program

Rebecca L. Wingard,* Lara B. Pupim,†‡ Mahesh Krishnan,‡ Ayumi Shintani,† T. Alp Ikizler,† and Raymond M. Hakim*

**Fresenius Medical Care–North America, Inc., and †Division of Nephrology, Vanderbilt University Medical Center, Nashville, Tennessee; and ‡Amgen, Inc., Thousand Oaks, California*

Background and objectives: Annualized mortality rates of chronic hemodialysis (CHD) patients in their first 90 d of treatment range from 24 to 50%. Limited studies also show high hospitalization rates. It was hypothesized that a structured quality improvement program (RightStart), focused on medical needs and patient education and support, would improve outcomes for incident CHD patients.

Design, setting, participants, & measurements: A total of 918 CHD incident patients were prospectively enrolled in a multicenter RightStart Program, and compared with a time-concurrent group of 1020 control patients from non-RightStart clinics. RightStart patients received 3 mo of intervention in management of anemia, dosage of dialysis, nutrition, and dialysis access and a comprehensive educational program. Outcomes were tracked for up to 12 mo.

Results: At 3 mo, RightStart patients had higher albumin and hematocrit values. Dose of dialysis and permanent access placement were not statistically significantly different from control subjects. Compared with baseline, Mental Composite Score for RightStart patients improved significantly. Mean hospitalization days per patient year were reduced with RightStart *versus* control subjects. Mortality rates at 3, 6, and 12 mo were 20, 18, and 17 for RightStart patients *versus* 39, 33, and 30 deaths per 100 patient-years for control subjects, respectively.

Conclusions: A structured program of prompt medical and educational strategies in incident CHD patients results in improved morbidity and mortality that last up to 1 yr.

Clin J Am Soc Nephrol 2: 1170–1175, 2007. doi: 10.2215/CJN.04261206

The mortality rate of treated patients with ESRD was 23 deaths per 100 patient-years at risk in 2003, as reported by the US Renal Data System (USRDS) (1). This high mortality rate, as compared with other countries (2), persists despite recent advances in our understanding of the uremic state and improvements in the science and technology of renal replacement therapy. In addition, in 2003, patients with ESRD spent an average of 14 d/yr in the hospital, which comprises more than one third (38%; $6 billion dollars) of the $16 billion dollars spent annually to care for patients with ESRD (1).

Although patients with ESRD qualify for Medicare benefits, regardless of age, those who are younger than 65 yr must undergo 90 d of therapy before qualifying for these benefits. To present uniform outcomes data, the USRDS analyzes all data for all patients after 90 d of therapy, regardless of age at initiation of therapy; therefore, the high mortality rate noted may represent an underestimation of the mortality risk for all incident patients, because it does not include mortality data of the first 90 d of dialysis therapy.

A limited number of studies have examined the outcomes of patients in the first 90 d. The earliest data reported were by Held *et al.* in 1990 (3), citing a 12% mortality rate in the initial 90 d of dialysis treatment. This represents an annualized rate of 48 deaths/100 patient-years in patients who start dialysis. These data are confirmed by Khan *et al.* (4), who reported a similar annualized rate of 50 deaths/100 patient-years. Soucie and McClellan (5), using voluntary facility reports, measured a mortality rate of 24 deaths/100 patient-years at risk. Finally, mortality data from Renal Care Group (unpublished data) as tracked for all patients from 1996 until 2006, ranged from 40 to 45 deaths/100 patient-years of annualized mortality (N > 10,000 incident patients). No study has systematically examined this issue, especially in terms of interventions to improve this unacceptably high death rate.

The goal of this particular quality improvement program was to implement an intervention strategy focused on improving the clinical outcomes during the initial 90 d of maintenance hemodialysis. We hypothesized that application of a broad and systematic program in the first 90 d may improve the mortality and morbidity rates of this incident CHD population. Specifically, we developed a program that comprises intensive patient education, encouragement, and support coupled with an intervention strategy to implement in a timely manner "best practices" and National Kidney Foundation Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines, which have

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RightStart® Goals

Defined goals for each healthcare team member

General Goals

Ongoing individualized Patient Education & Self-Care, Medication Reviews, care plans, recommendation for a liberal diet

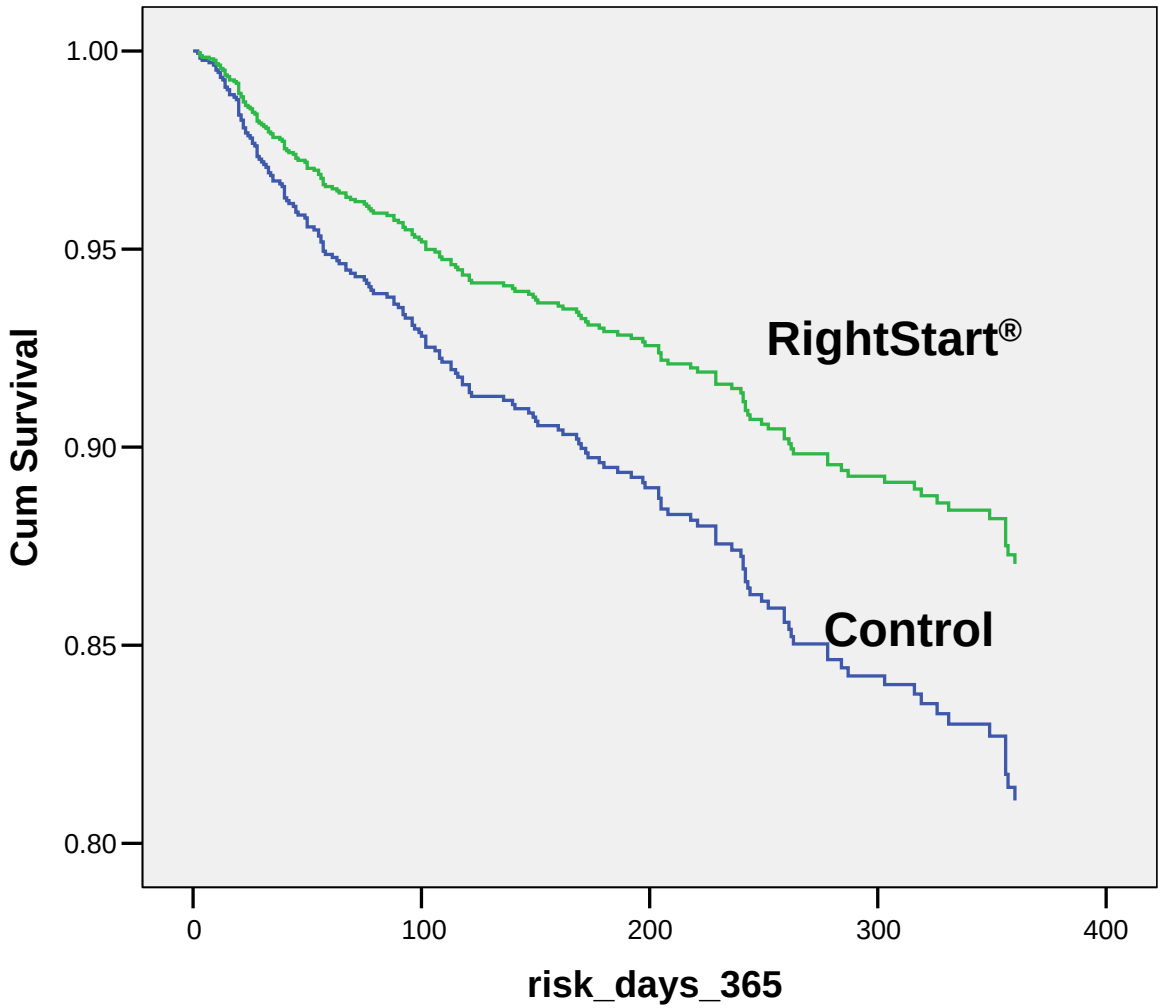
Protocol-driven outcomes

Specific Goals

Week 2:	URR >=70%
Weeks 3-4:	Target EDW Hct >=30%, T. Sat >=20% Transplant referral & permanent access planning
Weeks 5-6:	Stable BP
Weeks 7-8:	Hct >=33% PO4 3.5-5.5 mg/dL Use Permanent Access
Weeks 9-10:	Review Goal Achievement
Weeks 11-12:	HgbA1C <=7% Albumin >=3.7 g/dL PTH 150-300 (BiPTH 75-150)

Renal Care Group

Survival Curve, 1st 365 Days
Adjusted Cox-proportional hazards regression model



Adjusted by age, race, gender, diabetes

P<0.001 by Cox Log-rank, Breslow, and Tarone-Ware tests at 90, 180, and 365 day exposure levels.

Renal Care Group

A Prospective Randomized study of Case Managed Initiation of HD

- An Ortho sponsored, investigator driven RCT
- Nurse case manager deliver focused intervention and education
- Control group receives similar philosophy of care, guidelines and targets but applied routinely by clinical staff without a specific case manager
- Randomization by facility, N = 30
- Protocol and budgets under development

PEAK Performance Excellence and Accountability in Kidney Care

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Nephrology Nursing Certification Commission
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NxStage Medical
Renal Advantage Inc.
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Satellite Healthcare
U.S. Renal Care
Watson Pharma, Inc.

Conclusions

1) Late referral, unplanned starts, and initiation of HD with a CVC are linked problems, the term I prefer is suboptimal start
2) The problem of first year mortality is now in the forefront
3) Suboptimal starts are equally associated with high death rates whether patients were referred early or late. The benefit of an early referral is completely lost if the patient proceeds to have a suboptimal start.
4) Efforts are needed both before and after dialysis starts, and are likely to have impact

- eGFR care pathways/thersholds for VA creation are required
- The problem of patient related delay requires urgent attention
- The Right Start program may be adaptable to your environment