The vexing problem of suboptimal initiation of dialysis: Can we do better?

David C Mendelssohn
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
Optimal pre-ESRD care

Decreased morbidity and mortality on dialysis

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

Referral

Non Referral

Early Late

Nephrology Care

A) Nephrologist alone
B) Multi-disciplinary predialysis team

Preparation

ESRD Care

A) Conservative
B) Dialysis
C) Transplant

Focus on Year 1
Early referral

Optimal start
Elective
Outpatient
AVF

Comp.letion of tasks

Tasks Not Com-leted

Suboptimal start
Emergent
Inpatient
CVC

Late Referral
Suboptimal starts
Prepare For ESRD

Cardio/renal protection

Diagnosis
Reversible factors

Treat CV risk factors, associated conditions and slow rate of progression towards ESRD

Time
## 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**

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Overhead</td>
<td>17%</td>
<td>17%</td>
<td>11.4%</td>
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<tr>
<td>Level 1 HD</td>
<td>34,510</td>
<td>31,540</td>
<td>21,311</td>
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<tr>
<td>Level 2 HD</td>
<td>40,377</td>
<td>39,963</td>
<td>31,122</td>
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<tr>
<td>CAPD</td>
<td>27,256</td>
<td>28,068</td>
<td>26,725</td>
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<tr>
<td>CCPD</td>
<td>32,321</td>
<td>30,774</td>
<td></td>
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<tr>
<td>Pre-ESRD Clinic</td>
<td>252.95</td>
<td>240.85</td>
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</table>
Attitudes of Canadian nephrologists towards multidisciplinary predialysis care

Mendelssohn DC et al. AJKD 47: 277-284; 2006
Chapter One
Emerging Issues: First-year mortality
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.
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.
First access at initiation in patients with 12+ months of nephrologist care, by primary diagnosis, 2007

Figure 3.4 (Volume 2)
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.
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

Fistula First Initiative

AVF Prevalence: Network 11 vs. National
Source: Fistula First Outcomes Dashboard

- 2003: 33.1%
- 2004: 36.8%
- 2005: 40.8%
- 2006: 44.5%
- 2007: 48.3%
- 2008: 51.2%
- 2009: 54.2%
- Jan-10: 54.8%

- Network % AVF
- National % AVF
### Timing of Pre-ESRD Care and Catheter Use

<table>
<thead>
<tr>
<th>Timing of When Patient 1st Seen by Nephrologist Before ESRD onset</th>
<th>% Catheter use at ESRD start (US)</th>
<th>% Catheter use at ESRD start (Fr, Ger, It)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not seen or seen &lt; 1 mo prior to ESRD</td>
<td>88 (n=52)</td>
<td>62 (n=42)</td>
</tr>
<tr>
<td>1 – 4 mo prior to ESRD</td>
<td>82 (n=28)</td>
<td>50 (n=22)</td>
</tr>
<tr>
<td>4 mo – 1 yr prior to ESRD</td>
<td>64 (n=28)</td>
<td>23 (n=46)</td>
</tr>
<tr>
<td>1 – 2 yrs prior to ESRD</td>
<td>72 (n=46)</td>
<td>26 (n=62)</td>
</tr>
<tr>
<td>&gt;2 yrs prior to ESRD</td>
<td>63 (n=91)</td>
<td>19 (n=157)</td>
</tr>
</tbody>
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Rayner & Pisoni, Seminars in Dial 2010
Optimizing CKD Care

Worst possible care

FP care

Nephrologist based care

Best possible care

We aren’t there yet

?Multidisciplinary team based 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 transplant 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

Early referral

Complication of tasks

Planned start Elective Outpatient AVF

Tasks Not Completed

Unplanned start Emergent Inpatient CVC

39.5%

33.0%

26.0%
Early referral

Comp-learning of tasks

Tasks Not Completed

Late Referral

19.8%

HD only

34.2%

Planned start Elective Outpatient AVF

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

Tasks Not Completed

Unplanned start
Emergent
Inpatient
CVC

Late Referral
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
Non-referral

Late referral

Excessive referral

Inappropriate referral

Early referral

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

October 2006
www.csnschn.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
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 Mendelsohn 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
Early Intervention Improves Mortality and Hospitalization Rates in Incident Hemodialysis Patients: RightStart Program

Rebecca L. Wingard,† Ε Liza B. Pupim,†‡ Mahesh Krishnan,§ Ayumi Shintani,∥ T. Ali Ikizler,∥ and Raymond M. Hakim¶

†Renal Care Group-North America, Inc., and ‡Division of Nephrology, Vanderbilt University Medical Center, Nashville, Tennessee and ¶Avery, 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 38%. Prior studies showed 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 698 CHD incident patients were prospectively enrolled in a multicenter RightStart Program, and compared with a time-matched group of 1033 control patients from non-rightstart clinics. RightStart patients received 3 mos of intervention in management of anemia, design of dialysis, nutrition, and dialysis access and a comprehensive educational program. Outcomes were tracked for up to 12 mos.

Results: At 1 mo, RightStart patients had higher albumin and hematocrit values. Mean dialysis and permanent access placement were not 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 mos were 26, 18, and 17% for RightStart patients versus 39, 32, and 31% per patient-year for control subjects, respectively.

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

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

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

RL Wingard1, L Pupim2, TA Ikizler2, JE Thomas1, R Hakim1

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

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

Abbott Laboratories
Affymetrix
AMAG Pharmaceuticals
American Kidney Fund
American Nephrology Nurses’ Association
American Renal Associates, Inc.
American Society of Diagnostic and Interventional Nephrology
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
California Dialysis Council
Centers for Dialysis Care
DaVita, Inc.
Dialysis Patient Citizens
DSI, Inc.

Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Genzyme
Kidney Care Council
National Association of Nephrology Technicians and Technologists
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
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/thresholds for VA creation are required
- The problem of patient related delay requires urgent attention
- The Right Start program may be adaptable to your environment