Dialysis Initiation: Getting the Patient Off on the Right Foot and Maintaining It
Goals for the First 30 Days

Joseph A. Kuhn, MD, FACP
May 24, 2012
Columbus, Ohio

Goal Setting for the First 30 Days

WHY ???
Dialysis Initiation: Getting the Patient Off on the Right Foot and Maintaining It

Goals for the first 30 days:
1. Reduce high mortality, morbidity, and hospitalization rate on dialysis initiation!
2. Reduced the high cost at the initiation of renal replacement therapy

Discuss:
1. Value of a CKD program in your area
2. Role of TOPs (Treatment Options Program - FMC)
3. Role of Right Start - FMC
4. Dialysis Adequacy
5. Catheter Reduction
A Special Group: New Patients Have Special Needs

New HD Pts Arrive:
• Anemic
• Malnourished
• Underdialyzed (uremic)
• With catheter
• High inflammatory state (catheter)
• Inactive
• Jobs threatened
• Overwhelmed
• More likely to be hospitalized
• More likely to die
• DEPRESSED

Background: Why do we need CKD Programs, TOPs, and Right Start???

• ESRD patients <65 years old do not receive Medicare coverage until 91 days of ESRD therapy. In order to make results comparable across age groups, USRDS has been reporting mortality rates for all patients after 90 days of ESRD therapy.

• Several studies of incident dialysis have highlighted multiple co-morbidities and risk factors that are present in the majority of patients starting dialysis therapies. Nevertheless, few studies have focused on the mortality of dialysis patients during these initial 90 days, or on processes to reduce it.

Published Data for Initial 90 Day Mortality

• 1990 USRDS (Held et al): reported a 12% mortality rate in the initial 90 days (48 deaths/100 pt years at risk) in patients starting dialysis.
• Khan et al (AJKD 1995): reported a 12.6% mortality rate during the initial 90 days (50 deaths per 100 pt years at risk).
• Soucie and McClellan (JASN 1996): reported avg mortality rate of 24 deaths per 100 pt yrs at risk, based on data supplied by facility staff.
• FMS had reported internally a 10% mortality during that initial 90 day period of time, or an annualized 40 deaths per 100 pt years at risk; this compares to less than 16 deaths per 100 pt years at risk for prevalent patients.
CKD Care

Almost 59% of incident patients said they received care from nephrologists before the onset of ESRD.

- Among the HD incident patients who had received pre-ESRD care from nephrologists, 20% of them have fistulae as their first access vs. 12.9% overall.

- Barriers:
  - Patient reluctance to have permanent access
  - Lack of timely surgical follow-up
  - Use of catheters to “trial” dialysis
  - Patients are “older and sicker”

Pre-ESRD nephrologist care, by primary diagnosis, 2009

<table>
<thead>
<tr>
<th>Condition</th>
<th>Neph care, &gt;12 months</th>
<th>Neph care, 0-12 months</th>
<th>No nephrologist care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>0%</td>
<td>20%</td>
<td>80%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>80%</td>
<td>20%</td>
<td>0%</td>
</tr>
<tr>
<td>GN</td>
<td>60%</td>
<td>40%</td>
<td>0%</td>
</tr>
<tr>
<td>Cystic kidney</td>
<td>40%</td>
<td>60%</td>
<td>0%</td>
</tr>
</tbody>
</table>

In the US many CKD patients followed by a nephrologist still start dialysis with a temporary catheter.
Access use at first outpatient hemodialysis, by pre-ESRD nephrology care, 2009

Figure 1.19 (Volume 2)

Incident hemodialysis patients, 2009.
Dialysis Initiation: Getting the Patient Off on the Right Foot and Maintaining It

How can CKD Programs and TOPs (Treatment Options Program FMC) decrease Early Mortality and Morbidity?
What should be components of your CKD program and why?

- If we wait until ESRD to prepare a patient for dialysis we get:
  - Hemodialysis with a catheter
  - No preemptive transplant
  - No permanent access
  - No home dialysis

When a patient starts hemodialysis with a catheter, chances are that they will continue hemodialysis only
Dialysis Initiation: Getting the Patient Off on the Right Foot and Maintaining It

- We must change:
  - Late referral to Nephrology
  - Inability of Nephrology Community to coordinate care to move patient to ESRD care (CKD Program)
    - Slow progression
    - Treat comorbid conditions
    - ESRD education
    - Dietary and Social Services
    - Timely Access

---

30-20-10 Program

At GFR of 30/ml/min:

- Renal function is 30% of "normal" (i.e. progressive), particularly if proteinuria and/or hypertension
- NIH recommends referral to renal care for Chronic Renal Insufficiency, documented by:
  - Creatinine clearance of <50 ml/min (GFR <60 ml/min)
  - Diabetes with Proteinuria
  - PCKD
  - Patients who need dialysis for "acute renal failure"
- Most labs will provide calculation of GFR based on patient's creatinine (recommendation of American Clinical Lab Association)
- Timely referral to renal care leads to improved patient outcomes.

---

The 30-20-10 Plan

<table>
<thead>
<tr>
<th>CrCl of 30-50 ml/min</th>
<th>CrCl of 20 ml/min</th>
<th>CrCl of 10 ml/min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refer to Nephrologist</td>
<td>Assess Residual Renal Function</td>
<td>Evaluate Nutritional Status</td>
</tr>
<tr>
<td>Diabetes Management (BP, Glucose control, etc.)</td>
<td>Uremic symptoms — PCC Feedback</td>
<td>Refer to TOPS Education Coordinator, Dietitian, Social Worker, Financial Counselor</td>
</tr>
<tr>
<td>Encourage to save arm veins</td>
<td>Begin Evaluating Potential Donor for Transplantation</td>
<td>Determine modality choices with patient</td>
</tr>
<tr>
<td>Vascular mapping</td>
<td>Placement of permanent access (strong preference for AV fistula or tunneled PD catheters)</td>
<td>Disease Management Cardiac/vascular evaluation, VHR</td>
</tr>
<tr>
<td>REFER TO TOPS AGAIN</td>
<td>Refer to patient, mentor and patient-family support group</td>
<td>Consider definitive therapy (dialysis, TX)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Co-Morbidity Management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Continue educational support (Dietary, Social Service, Financial)</td>
</tr>
</tbody>
</table>
### NKF Pre-Dialysis Goals and Risk of Death

<table>
<thead>
<tr>
<th>Goals</th>
<th>Relative risk of death</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td>3</td>
<td>0.9</td>
</tr>
</tbody>
</table>

#### Three NKF pre-dialysis goals - Key Drivers:

1. Creation of a permanent access
2. Treatment of anemia to recommended targets
3. Maintenance of adequate nutrition
Pre-Dialysis Goals and Risk of Death

So far we know these are important:
Timely referral
Access
Anemia Rx
Nutrition

USRDS Data and Risk of Death

- 82% of US patients start dialysis with a temporary catheter
- From 1993 to 2005 in the first 3 months of dialysis, hospitalizations for cardiovascular disease increased 20-30%
- Hospitalizations for infection increased by 200%
- Mortality in months 1 through 5 on dialysis were higher in 2005 than in 1998
- First year dialysis patient mortality rates are unchanged from 1996

USRDS Data and Risk of Death - Conclusion

1. Reducing high catheter rates is key to reducing early hospitalization and mortality
2. CKD Education and Timely Referral are key strategies to reduce high catheter rates
**Dialysis Outcomes and Practice Patterns Study (DOPPS) Data Shows:**

- A substantial proportion of the first-year mortality can be reduced by addressing modifiable factors including temporary catheter use, preservation of residual renal function, pre-dialysis nephrology care, BP control, and adequate nutrition.
- Highest priority targets should include decreasing catheter use and treating malnutrition.
- Phosphorus control, preserving kidney function, and avoiding excessively low BP levels are also important.

**Pre-dialysis nephrology care helps!**

---

**Nephrology Practice: Realities of CKD Care**

- Nephrology Practices Provide CKD care to many patients, only a small number of whom will progress to ESRD.
- There is no consistent, accepted CKD clinic program across independent nephrology practices.
- Nephrology clinics lack data about Timely Referral for their patient population.
- Management of CKD co-morbidities and complications, permanent access and modality education may be difficult to deploy across the CKD clinic population without special personnel and technology resources.
- Real-time assessment of outcomes at CKD stages 4 and 5 for a specific clinic patient population may be difficult to obtain without special personnel and technology resources not currently available to the average CKD clinic.

---

**Dialysis Providers CKD Initiative Realities**

- Have a variety of disconnected, but ongoing efforts to improve vascular access preparation.
- Have developed educational materials and personnel resources to support preparation for RRT, reduce the use of temporary catheters and to assess patient status at the initiation of RRT, but these resources are not consistently and fully available to all nephrology clinics.
- Have traditionally had limited access to support individual clinic efforts to improve late stage CKD care and to, therefore, improve the health of patients who must start RRT.
- Have technology resources to assist in the collection of baseline data, the development of technology tools for patient care, and to collect outcomes data to help identify best practices associated with best outcomes.
Theory: Consistent CKD Education and Case Management is Key to Improved Patient Outcomes and Growth

- Effort to Improve Practice ESRD Growth Through Upstream Patient Education and Primary Care Community Awareness
- Increase the Number of Patients that Survive late Stage CKD to Dialysis
- Reduce Incident Catheter Rates
- Improve Long Term Patient Retention

Patient Retention Key to Growth

- Goal is to improve Patient Retention

Dialysis Initiation: Getting the Patient Off on the Right Foot and Maintaining It

Value of Comprehensive CKD Program
- If no CKD care: HD with catheter
  - No: Access
    - Home Dialysis
    - Pre-emptive Transplant
- Result: More likely to stay with HD, catheter, and to risk hospitalization and early death
Nephrology Associates, PA of Delaware

Nephrology Associates, PA

Nephrology Associates CKD Program
Established 7 years ago after 2 years of study and preparation
-NOT just an anemia management program
-10 offices, 25 Nephrologists, 12 NP’s, > 125 employees
Nephrology Associates CKD Program

Model:
- Physician and NP’s
- First, I spoke at dinner programs throughout DE to referral physicians about CKD
- Wrote Algorithms for NP’s
- Trained NP’s in office care (office care, E+M documentation, billing)
- ESA/Fe protocols for Office nurses
- Compiled teaching materials
- Had CKD program brochure printed
- Templates made for EHR

Nephrology Associates CKD Program

Access: Surgeons and Nephrology Interventional Physicians
Transplant Referral: pre-emptive transplant
Modality Discussion: NP’s and TOPS
Dietitian: In house + private practice
Social Worker (FMC/TOPS)

Nephrology Associates CKD Program

Elements
1. Slow Progression/ Treat underlying disease
2. Hypertension
3. Anemia
4. Acidosis
5. Ca/ PO4/ I-PTH/ Vit. D
6. Nutrition
7. Lipids
8. Diabetes Management
9. Smoking Cessation
10. Modality Training (30/20/10)
11. Vaccination: Hep B, Annual influenza, Pneumovax

Importance of CQI and a robust data base and easily searched EHR
CQI projects: Anemia and Iron Management
  Transplant Referral
  Access Placement
  Vaccination
  Tops Referral/ Modality Training

CKD Program is: Right for patients
A loss leader - not a money maker at first glance but:
  Increases practice referrals
  Captures patients for hospital care and ESRD
  Decreases Hospitalization and Early Mortality (Increases Dialysis Population)
  ESAs/ IV Fe: Modest $ makers
Nephrology Assoc. Follows a Large Diverse Population of Patients

- Total Practice Patient and ESRD Patient Growth Appears to be Slowing – 93% Overall ESRD Patient Market Share
- 40%+ New Practice Patients Each Year – 47% Patients Enter Practice Through Office
- Consistent CKD Patient Management Process is Key to Continued Growth and Success

Nephrology Associates, PA

- Increased Effort to Establish CKD Protocol
- 60% of New ESRD Starts have Been Referred Timely to Practice
- Timely Referral Leads to Better Patient Retention
- Maximizing 4+ Monthly ESRD Visits

Dominant Four County ESRD Patient Market Share

- Dominant Market Share Facilitates Consistent CKD Referral Patterns
- 93% Combined Market Share in Four County Area
Increased Effort to Establish CKD Protocol

- 14% Increase in Patients Utilizing the Outpatient Clinics
- Dedicated Physician Resource for CKD Program Development

Nephrology Associates - Stage 4

Stage 4 – New Castle & Cecil County
Maximizing 4+ Monthly ESRD Visits

- In a Stable ESRD patient on dialysis > 1 year, one can argue the value of weekly physician/extender visits, BUT
- Personal Opinion: In the first 30 days you can’t see the patient too much!!
- Personal Opinion: Since in all units, there are always new patients, weekly visits should be the standard

Knowledge of ESRD Therapies and Frequency of Nephrology Visits per # of Visits in Preceding Year

- n=676 per self-administered questionnaire
- Pts from CRIOS study


Maximizing 4+ Monthly ESRD Visits

- Dedicated Physician Extender Resource
- Ensure Maximum MCP Visits and Outcomes
- 8% Home Ratio
Maximizing the Impact of the CKD Clinic

1. The scope of CKD at Nephrology Associates
2. Practice Believes that CKD patients will benefit from special management
3. Key management components to improve Outcomes – Education and Management of CKD Population
4. FMC Partnership : Coordinator Position

Timely Practice Patient Referral
Impacts Key FMC Metrics

- Practice Patient Referral Dynamics Has Direct Impact on Key FMC Metrics
- Goal is to Move Practices to Upper Right by Working Upstream to Change Practice Patient Dynamics
- Modifiable Practice Patterns

Consistent Application of Pre-ESRD Care to 1,700 Annual New Starts Key to Continued Success

- 2,117 New Dialysis Starts – Average ~42 Per Month Including Transients
- 46% of New Starts Over the Age of 65
- 74% of New Starts have Been Followed in the Office Prior to ESRD
- Goal is to Apply Consistent CKD Care Strategies to Drive Growth in ESRD Population
Nephrology Associates Patient Retention Tops Among Group
Strategies Practices

• Opportunity to Improve Patient Retention Exists with Support from FMC Group Strategies Initiative

Nephrology Associates CKD Program

• Improve patient outcomes at CKD stages 4 and 5
• Reduce patient morbidity and mortality at 120 days and 1 year on dialysis
• Reduce the use of temporary catheters in dialysis
• Increase the number of patients using home therapies
• Reduce hospitalizations for late stage CKD patients and for patients during the first year of RRT
• Improve the Quality of Life for patients with late stage CKD patients and for patients during the first year of RRT
• Set an expected standard for Vascular Access, Nutrition, and Modality Education for the majority of patients at the start of RRT

Dialysis Initiation: Getting the Patient Off on the Right Foot and Maintaining It

Fresenius Treatment Options Program
Treatment Option Program

- Initiated to educate patients with Stage 3 or 4 CKD prior to ESRD
- Consists of a two-hour education program provided at least every month in each FMC “area”
- Patients are referred by their nephrologists or PCPs
- Non-biased presentation of available treatment modalities
  - Home Therapy
  - Transplant
  - No therapy
- Patients are encouraged to attend with family members

Fresenius Treatment Options Program

Currently in DE done in Home Dialysis Programs
- Will travel
- Will see patients quickly and one on one
- Comprehensive
- Reports back to physicians
- Will do follow up

Treatment Options Program

NOT just a home dialysis discussion
- Will help you get a patient to accept ESRD, dialysis, and access
- Will discuss palliative care / hospice
- Will help with transplant referral
- Will get social service help and Commercial Insurance help
Treatment Options
September 2006 thru May 2011
• Approximately 55,500 per-ESRD educations performed
• 170,245 patients admitted total FMS
  – 17,274 of this group received TOPS education (10.1%)
  – 152,971 starts did not have TOPS education (89.8%)
• 5,155 patients without TOPS started on HT = 3.3%
• 3,766 patients with TOPS started on HT = 21.8%

Treatment Options
Program January thru May 2011
• 7,570 pre-ESRD educations performed
• 14,812 patients admitted total FMS
  – 2,402 of this group received TOPS education (16%)
  – 12,410 starts did not have TOPS education (84%)
• 302 patients without TOPS started on HT = 2%
• 408 patients with TOPS started on HT = 17%

HD Catheter Starts 2011

\[ \text{% Total TOPS HD cath starts YTD (1,127 of 2,402)} \]
\[ \text{% Total non-TOPS HD cath starts YTD (9,827 of 12,410)} \]
**Fistula/Graft Starts 2011**

- % Total TOPS fist/graft starts YTD (820 of 2,402)
- % Total non-TOPS fist/graft starts YTD (2,037 of 12,410)

**Home Therapy Starts 2011**

- % Total TOPS HT starts YTD (408 of 2,402)
- % Total non-TOPS HT starts YTD (302 of 12,410)

**Treatment Options Program**

- Participation in TOPS leads to:
  - Increased knowledge about Home Therapies and rate of home therapy selection
  - Decrease use of hemodialysis catheters
  - Greater use of AVF at start of dialysis
  - Improved survival rate at 90 days after initiation of dialysis
FMC RightStart Program
What to do when the patient arrives

Programs to Improve ESRD Patient Outcomes

Raymond M. Hakim, M.D., Ph.D.
July 2011

RightStart
(Program to improve outcomes in incident ESRD Patients)

Once your patient has gotten to the dialysis unit - additional education and follow up over first 4 months

- Two forms:
  1. Field based: each patient receives a case manager (nurse or dietitian)
  2. Telephonic: case manager, usually a nurse – less expensive, less successful at making contact
RightStart

Widely accepted in North BU and former RCG units- 2011
-300 field based units: face to face visit q 2 weeks
-800 telephonic units: Telephone call q 2 weeks

CMS Patient Education Record Topics
- Welcome to Dialysis
- Dialysis Management: Treatments & Meds
- Rehabilitation & Quality of Life
- Infection Prevention, Safety, Personal Care
- Nutrition Management
- Medical Emergencies & Natural Disasters
- Treatment Options

Additional RightStart Topics
- RightStart Welcome brochure
- Traffic lights
- Healthy Heart
- Anemia
- Strong Bones reinforcement
- Nutrition/Fluid management reinforcement
- Diabetes
  - What is diabetes?
  - Blood sugar control
  - Diabetes medicines
  - Hypoglycemia
  - Hyperglycemia
  - Sick day guidelines
  - Eye care
  - Mouth care
  - Keeping active

Combine RightStart and Diabetes Programs
Primary Areas of Patient Care

<table>
<thead>
<tr>
<th>RSCM (follow pts 1x4 months)</th>
<th>All Patients Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Education/Medical Options</td>
<td>Nursing home pts</td>
</tr>
<tr>
<td>Vascular Access</td>
<td>Non-English speaking pts</td>
</tr>
<tr>
<td>Medication Reviews</td>
<td>Spouse/significant other</td>
</tr>
<tr>
<td>Nutrition</td>
<td>for confirmed pts</td>
</tr>
<tr>
<td>Rehab/PW referrals</td>
<td></td>
</tr>
<tr>
<td>Foot Exam/Therapy</td>
<td></td>
</tr>
<tr>
<td>Glucose control - home records</td>
<td></td>
</tr>
<tr>
<td>Prevention (eye exam)</td>
<td></td>
</tr>
<tr>
<td>Case Follow up and input</td>
<td></td>
</tr>
<tr>
<td>Self Care</td>
<td></td>
</tr>
<tr>
<td>Electronic Documentation/Outcomes</td>
<td></td>
</tr>
</tbody>
</table>
What Do Patients Say They Want?
(I CARE)

Information
Compassion
Attitude
Responsiveness
Expertise

Outcomes for 1st 90 Day Patients vs. 91+ Days

- Hospital Days/Pt Year at Risk
- Mortality

Co-Morbidities and Risk Factors Associated with Early Mortality

- Co-Morbidity
  - Age
  - Nutritional Status
  - Diabetes
  - Cardiovascular Disease
  - LVH
  - Depression

- Risk Factors
  - Unplanned start (w/o permanent access)
  - Short (<4 months) prior nephrological care
  - Low residual renal output

- Reversible Risk Factors
  - Anemia (Hgb <10)
  - Low albumin <3.5 g/dl
  - High Phosphorus
  - High catheter rate
  - Depression

- 57% had albumin concentration below lower limit of normal
- 80% of patients with Hct < 28% were not receiving EPO
- 50% had no visit with dietitian (21% had one visit)
- Only 25% had a permanent access 30 days before starting dialysis
- 33% used temporary access (catheters) 60 days after initiation

Laboratory Outcomes Following Initiation of Dialysis (N = 7,658)

<table>
<thead>
<tr>
<th>6 Months</th>
<th>6-12 mo</th>
<th>12-24 mo</th>
<th>24 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>% with URR &gt; 65%</td>
<td>43</td>
<td>68</td>
<td>76</td>
</tr>
<tr>
<td>Median Dialysis Time (min)</td>
<td>210</td>
<td>210</td>
<td>210</td>
</tr>
<tr>
<td>% patients with HCT &gt; 33%</td>
<td>41</td>
<td>58</td>
<td>60</td>
</tr>
<tr>
<td>% of patients with Albumin &gt; 3.5</td>
<td>63</td>
<td>81</td>
<td>86</td>
</tr>
</tbody>
</table>

Rocco: AJKD, 2001
Transition from CKD to ESRD
Psychological Impact

How do patients cope with “Their kidneys dying”?

Stages of Grief
1. Denial
   • I don’t know why I am here.
   • It’s just until my kidneys get better.

2. Anger
   • I don’t need this in my life.
   • My doctor did not tell me about this.

3. Bargaining
   • Can I dialyze once a week, but longer?
   • Can I keep my catheter? I hate to get stuck.

4. Depression
   • My kidneys are dead.
   • I do not use the bathroom as much.

5. Acceptance
   • Can I eat better?
   • Can I work at home?

Patient Perception Is Their Reality
### RightStart® Grid

- **Week:** 1/2 3/4 5/6 7/8 9/10 11/12
- **Goals**
  - M.D.
  - Nursing
  - S.W.
  - R.D.

### RightStart® Goals

**Defined goals for each healthcare team member**

**General Goals**

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

**Specific Goals**

- **Week 2:** Sp Kt/V ≥ 1.4
- **Weeks 3-4:** Target EDW
  - Hgb >10, T. Sat >=20%
  - Transplant referral & permanent access planning
- **Weeks 5-6:** Stable BP
- **Weeks 7-8:** PO4 1.5-3.1 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)

### Where Should We Focus Our Care?

Contribution of “Actionable” items to Mortality

Lacson et al, AJKD, 53(1), 79-90, 2009
Teaching (Eat, Eat, Eat!)

- Megestrol Alb ≤ 3.2
- Renal Dietitians
- RightStart
- Star Plan

 Supplements on HD Alb < 3.7

- Binders Phos > 5.5
- Paricalcitol PTH > 300

Relative Risk of Mortality: Albumin

Incident FMS Patients, 1/1/07-9/30/07, n=16,178

Phosphorus vs. Albumin (Q3 07)

N= 95,606 Patients at FMS Legacy Facilities

A higher albumin does not correlate with higher phosphorus
“Patient Messages” to Improve Nutrition

1. “One of the advantages of starting dialysis, is that you can eat more and better”. Eat well, and we’ll dialyze well.
2. “You lose some protein during dialysis, so replenishing the protein in your body is important”.
3. Do not skip meals, if you cannot eat a meal, be sure to have a protein drink or other protein supplement.
4. Eat before coming to treatment, preferably 30 minutes before if possible. Then eat some protein right after treatment, bring a lunch with you to eat after treatment to restore protein and energy levels.

• Be sure to eat at least 2-3 servings of protein foods everyday (eggs, chicken, lean beef, fish, supplements) and always eat protein food first in the meal.

—97% of patients with albumin 4.0 g/dl or higher eat within 30 minutes before and 30 minutes after dialysis.
Enrollment Process

- **RightStart®, N=923**
  - Prospective enrollment of all new patients within one to three weeks of dialysis initiation
  - Exclusions:
    - Seasonal or transient patients
    - Nursing home residents
    - Patients with cognitive dysfunction that precludes ability to learn

- **Time-Concurrent Control Group, N=1,047**
  - Retrospective data retrieval of all new patients in non-RightStart® clinics in same geographic area for one year concurrent with the RightStart® program

---

Demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>RightStart®</th>
<th>Control Group</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>61.8 ± 16.0</td>
<td>62.0 ± 17.2</td>
<td>NS¹</td>
</tr>
<tr>
<td>Male/Female</td>
<td>45.8%/54.2%</td>
<td>46.6%/53.4%</td>
<td>NS¹</td>
</tr>
<tr>
<td>Diabetes (I &amp; II)</td>
<td>53.8%</td>
<td>53.8%</td>
<td>NS¹</td>
</tr>
<tr>
<td>Caucasian</td>
<td>57.2%</td>
<td>47.8%</td>
<td>P&lt;0.05²</td>
</tr>
<tr>
<td>AA/Hispanic</td>
<td>36.5%</td>
<td>36.2%</td>
<td>NS²</td>
</tr>
<tr>
<td>Other</td>
<td>6.3%</td>
<td>16%</td>
<td>NS²</td>
</tr>
</tbody>
</table>

¹ = Student’s t-test
² = Chi-square

---

Adequacy and Vascular Access Outcomes

- Percent of Patients with Sp Kt/V ≥ 1.4
- Percent Reduction of Catheters
Laboratory Parameters

Percent of Patients with Hgb ≥ 11

Percent of Patients with Albumin ≥ 3.5 g/dL

Month 0 1 2 3 4 5 6 7 8 9 10

% Patients Meeting Target

Patient Education Tool for Catheter Pts

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.
Mortality Hazard Ratios

<table>
<thead>
<tr>
<th>Mortality Period</th>
<th>Unadjusted Hazard Ratio (95% CI)</th>
<th>Adjusted Hazard Ratio (95% CI)</th>
<th>P Value (Adj. Hazard Ratio)</th>
<th>RightStart (deaths per 100 pt yrs)</th>
<th>Control (deaths per 100 pt yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>90-days</td>
<td>0.52 (0.35-0.76)</td>
<td>0.60 (0.37-0.97)</td>
<td>0.037</td>
<td>0.20</td>
<td>0.39</td>
</tr>
<tr>
<td>180-days</td>
<td>0.55 (0.40-0.75)</td>
<td>0.60 (0.40-0.91)</td>
<td>0.015</td>
<td>0.18</td>
<td>0.33</td>
</tr>
<tr>
<td>365-days</td>
<td>0.60 (0.46-0.79)</td>
<td>0.66 (0.46-0.95)</td>
<td>0.026</td>
<td>0.17</td>
<td>0.30</td>
</tr>
</tbody>
</table>

1 = Control used as reference group
2 = Adjusted for age, gender, race, diabetes

Reduce Cycle Time:
Example: Efficiency of Epogen Management

- Time (Days) from Date of 1st Outpatient Dialysis to Date of 1st Epogen Order

- Components Measured
  - Days to 1st Lab Draw
  - Days to 1st EPO Order
**Days to First Lab Draw for Incident Patients**

![Bar chart showing Days to First Lab Draw for Incident Patients](chart1)

- *p<0.0001

**Days to First EPO Order for Incident Patients**

![Bar chart showing Days to First EPO Order for Incident Patients](chart2)

- *p<0.0001

**Percent of Pts with Hgb 11-12 g/dL at 120 Days**

![Bar chart showing Percent of Pts with Hgb 11-12 g/dL at 120 Days](chart3)

- *p=0.02

**Percent of Pts with Albumin >=3.5 g/dL at 120 Days**

![Bar chart showing Percent of Pts with Albumin >=3.5 g/dL at 120 Days](chart4)

**Percent of Pts with Phosphorus 3.5-5.5 mg/dL at 120 Days**

![Bar chart showing Percent of Pts with Phosphorus 3.5-5.5 mg/dL at 120 Days](chart5)

**Percent of Pts with spKt/V >=1.4 at 120 Days**

![Bar chart showing Percent of Pts with spKt/V >=1.4 at 120 Days](chart6)

- *p<0.001

**Percent of Pts with eKt/V >=1.2 for FMS pt group**

![Bar chart showing Percent of Pts with eKt/V >=1.2 for FMS pt group](chart7)
Percent of Pts with AV-Fistula at 120 Days

- Control: 25.2%
- RightStart: 34.4%

**p<0.0001

Average Number of Foot Checks Done During First 120 Days (diabetic pts only)

- Control: 0.6
- RightStart: 1.9

**p<0.0001

One Year Survival of RightStart Pts vs. Case-Control matching, All Pts n=approx 8,000

Hazard Ratios

- At 120 days: 0.66
- At 1 year: 0.78

P<0.0001
Data

<table>
<thead>
<tr>
<th>Patients</th>
<th>Treatments per Patient</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cohort Total</td>
<td>Day 1-120</td>
<td>Day 1-180</td>
</tr>
<tr>
<td>Possible</td>
<td>51.3</td>
<td>78</td>
<td></td>
</tr>
<tr>
<td>Right Start</td>
<td>1,144</td>
<td>41.80</td>
<td>60.80</td>
</tr>
<tr>
<td>Non-RS</td>
<td>6,838</td>
<td>35.98</td>
<td>51.30</td>
</tr>
<tr>
<td>Delta</td>
<td>5.82</td>
<td>9.50</td>
<td></td>
</tr>
</tbody>
</table>

Incident patients 1/1/10 to 6/30/10

Summary

1. Patients initiating dialysis present with several co-morbidities and risk factors, and knowledge deficits that are associated with a high initial 90-day mortality rate, (generally not reflected in published data).

2. Several of these risk factors can be attenuated or reversed more rapidly with an intensive team effort during the initial 90 days of therapy.

3. The RightStart® program, consisting of focused attention on reversible risk factors and patient education, resulted in a significant reduction in mortality and hospitalization during those initial 90 days, which extended up to 1 year following initiation of dialysis.

Top 10 Lessons Learned from RightStart for Incident Dialysis Patients

1. Reduce cycle time
   a) Lab panel on 1st treatment
   b) Lab follow-up by MD and RN next (2nd) treatment
3. Delay heavy (intensive) teaching until 2-3 weeks after start
4. Team-driven “curriculum”
5. Emphasize good nutrition—“Eat well and we'll dialyze you well”
6. Provide oral nutritional supplements early on
7. Get rid of catheters ASAP
8. Include family members or next of kin in education
9. Focus on pt as most important team member
10. Assure TOPS program participation before starting dialysis
Dialysis Adequacy

• There is no more important time to establish dialysis adequacy than the first 30 days
  – Catheter, poorly functioning access, denial, stretching the boundaries, hospitalization, poor control of BP, volume
• Urea kinetics is not the only measure of adequacy: TIME

Dialysis Adequacy

• Before we rush to cut time based on Kt/V remember this takes into account UREA removal not Na, K, HzO, PO4
  – Volume requires time
  – PO4 requires time
  – K requires time to do safely

Dialysis Adequacy

• No downside to spKt/V > 1.4 other than time
• Tremendous potential upside
• We have been wrong before in shortening dialysis (1980’s)
• Role of time (t)
Dialysis Adequacy

DOPPS
- RR of Death 0.81 > 4 Hrs vs < 4 Hrs
- Each additional 30 min: decrease risk of death 7%

Australia/ New Zealand
- Survival worse < 3.5 hours and better 4.5-4.9 hours
- FMS Data
  - Each 15 min. decrease from 4 hours: 12% increase risk of death

Dialysis Adequacy

  http://www.nejm.org/doi/pdf/10.1056/NEJMoa1001593 demonstrates that more frequent dialysis leads to improve blood pressure control, decreased left ventricular mass, and better phosphorus control.

Dialysis Adequacy

  http://cjASN.asnjournals.org/content/early/2010/12/09/CJN.08450910.full.pdf+html suggests that increasing time (t) on dialysis (t) to control blood pressure or more frequent dialysis will lead to decrease left ventricular hypertrophy and fibrosis by control of extracellular fluid volume.
Ultrafiltration Rate
- HEMO Study: UF Rates > 10 ml/Kg/hr associated with increased risk of death
  • Other studies >13 ml/kg/hr

Dialysis Adequacy
- Longer dialysis will lead to more gentle ultrafiltration and better control of blood pressure and extracellular fluid volume. This will allow reduction in antihypertensive agents which seem to contribute to better control blood pressure at the expense of higher levels of extracellular fluid volume. This current approach (antihypertensive agents rather than longer or more frequent dialysis to control blood pressure) has not been successful in controlling left ventricular hypertrophy and fibrosis.

Dialysis Adequacy
- Is t the answer?
Dialysis Adequacy

Hemodialysis Time (td):
- ≤ 100 Kg.: 4 Hrs.
- 100-115 Kg.: 4.25 Hrs.
- ≥ 115 Kg.: 4.5 Hrs.

When a hemodialysis catheter is in place, increase dialysis time by 0.5 Hrs. Dialysis time will be decreased by 0.5 hours when the hemodialysis catheter is removed.

Maximum ultrafiltration rate will be 12 ml/Kg/Hr. based on estimated dry weight. Maximum fluid removal may be rounded up to the nearest 0.2 Kg (200 ml) over the length of the dialysis. Dialysis time is to be extended when interdialytic weight gain exceeds this maximum. Time is to be based on 12 ml/Kg/Hr. maximum.

Dialysis Adequacy

If eKt/V < 1.15, dialysis time will be extended by 0.5 Hrs if the patient dialyzed their prescribed time for eKt/V determination.

If eKt/V is 1.15 to 1.19, dialysis time will be extended 0.25 Hrs if the patient dialyzed their prescribed time for eKt/V determination.

If the patient has intradialytic hypotension or severe cramping at the prescribed time, contact the physician or physician extender for added treatment time.

Dialysis Adequacy

Fresenius Medical Services Penndel Region

Hemodialysis Treatment Time

Hemodialysis treatments at this Fresenius unit are at a minimum of four hours. It is well documented that missing or shortening dialysis treatments is detrimental to your health and is highly discouraged by our medical and nursing staff.

Dialysis treatment times will be extended if fluid weight gains are in excess of a predetermined amount based on your dry body weight.

Dialysis treatment times are also extended if you dialyzed through a dialysis catheter rather than a fistula or graft.

Dialysis treatment times may need to be extended because of inadequate clearance of dialysis toxins based on a measurement known as Kt/V. Finally, if significant decrease in your blood pressure or severe cramping occur at your prescribed time, your treatment will be extended for your safety and comfort. Slower fluid removal with longer treatment time will almost always alleviate these symptoms.

We hope that you understand that this policy is based on our concern for your health and dialysis safety.

Medical director: ___________________
Patient Signature: ___________________
Goals First 30 Days

• For the immediate future, catheters will not go away
• Unless you have a catheter reduction plan in your unit, the patient with a catheter at the start of dialysis will still be using it in 6-12 months !!!!

Goals First 30 Days

• Catheter Reduction Program
  – Have a Program in Place, not “Business as Usual”
  – Select and Utilize Vascular Access Managers and Expert Cannulators
  – Review at CQI for trends

Why the Concern With Catheters?

Compared to AVF/Gs, CVC patients have:

• Two to three times increased risk of death
• Five to ten times increased risk of septicemia
• Hospitalized eighteen days per year, compared to nine days
• Reduced Kt/V, HGB and albumin values
• Higher ESA, antibiotic and thrombolytic use
• Higher expenses to facility and the healthcare system
Catheter Reduction Program

1. Surgical consultation day of admission
   - Takes time to get appt. and then to schedule surgery: must be considered urgent

2. Permanent access placed within 2-3 weeks of admission
   - Vein mapping by time of surgical visit

3. Utilization of AVF without CVC in 90 days from placement (Graft 45 days)
   - AVF assessed by 4 weeks for maturation and plan made if not progressing (50%)

Vascular Access Team Roles and Responsibilities

• Medical Director:
  • Directs Team with implementation of CRP Checklist and responsibilities
  • Leads staff meeting to review risks of CVCs, Best Practice Checklist, Access Plan, Expert Cannulator, and Vascular Access Manager roles, responsibilities and expectations of team.
  • Ensures processes are in place to make certain all patients are educated regarding importance of permanent access placement.
  • Oversees and monitors processes to ensure all CVC patients have access plans in place.
  • Reviews and addresses barriers that may be preventing permanent access placement.
  • Leads QAI team in the analysis of idiosyncratic, unexplained, and uncontrolled patient data.
  • Educates other clinical disciplines regarding risks of AVF closely monitored.
  • Coordinates with Medical Director to assure appropriate CRP processes are in place and working.
  • Oversees Vascular Access Managers and Expert Cannulators activities.
  • Oversees tracking and reporting to QAI committee on status and progress of CVI Reduction program.

• Physician Assistant:
  • Directs Team with implementation of CRP Checklist and responsibilities
  • Leads staff meeting to review risks of CVCs, Best Practice Checklist, Access Plan, Expert Cannulator, and Vascular Access Manager roles, responsibilities and expectations of team.
  • Ensures processes are in place to make certain all patients are educated regarding importance of permanent access placement.
  • Oversees and monitors processes to ensure all CVC patients have access plans in place.
  • Reviews and addresses barriers that may be preventing permanent access placement.
  • Leads QAI team in the analysis of idiosyncratic, unexplained, and uncontrolled patient data.
  • Educates other clinical disciplines regarding risks of AVF closely monitored.
  • Coordinates with Medical Director to assure appropriate CRP processes are in place and working.
  • Oversees Vascular Access Managers and Expert Cannulators activities.
  • Oversees tracking and reporting to QAI committee on status and progress of CVI Reduction program.

• Clinic Manager:
  • Oversees CRP checklist and resource implementation.
  • Partners with Medical Director to ensure appropriate CRP processes are in place and working.
  • Oversees Vascular Access Managers and Expert Cannulators activities.
  • Oversees tracking and reporting to QAI committee on status and progress of CVI Reduction program.

• Vascular Access Manager (VAM):
  • Designated by QAI Committee
  • Implements VAM Roles and Responsibilities
  • Educates patients, implements Catheter Access Plan, and completes Catheter Access Plan and procedures.
  • Refers to UAB Roles and Responsibilities for additional details.

• Expert Cannulator:
  • Designated by QAI committee
  • Nurse or PCT designated as Expert Cannulator to assess and cannulate all new AVF/G.
  • Refer to Expert Cannulator Program Guidelines for additional details.

• Registered Nurse:
  • Discusses VA Plan during first meeting with patient and ongoing
  • Implements applicable CRP checklist elements
  • Assists team to identify barriers that may be preventing permanent access placement
  •如果指定，实施VAM职责

• Patient Care Technician:
  • Implements applicable CRP checklist elements
  • Discusses VA Plan during first meeting with patient and ongoing with patients
  • Assists team to identify barriers that may be preventing permanent access placement
  • Implement VAM Expert Cannulator functions under RN supervision

• Dietitian:
  • Implementation of applicable CRP checklist elements.
  • Discusses VA Plan during first meeting with patient and ongoing with patients
  • Assists team to identify barriers that may be preventing permanent access placement
  • Educates patients, implements Catheter Access Plan, and completes Catheter Access Plan and procedures.

• Social Worker:
  • Implements applicable CRP checklist elements.
  • Discusses VA Plan during first meeting with patient and ongoing with patients
  • Assists team to identify barriers that may be preventing permanent access placement
  • Discusses risks of CVCs including relationship of poor outcomes to CVCs.
  • Assists team to identify barriers that may be preventing permanent access placement
  • Discusses risks of CVCs and helps address specific barriers to permanent access
  • Assist with insurance or transportation issues
Dialysis Initiation: Getting the Patient Off on the Right Foot and Maintaining It

Discuss:
1. Value of a CKD program in your area
2. Role of TOPs
3. Role of Right Start
4. Adequacy Program
5. Catheter Reduction Program

THE END