Risk Stratification in Renal Care

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Vice President, Operations
Fresenius Disease Management Optimal Renal Care
Chronic Kidney Disease

- **Chronic Kidney Disease** is a rapidly growing problem

- What is needed to address this problem?
  - Identification
  - Stratification
  - Management
    - Physician management
    - Disease management (encompassing the spectrum from population management to intensive case management).

Can **Chronic Kidney Disease** be considered health care’s latest epidemic?
Incidence of CKD - ESRD
per million population, 1990, by HSA, unadjusted

USRDS, 2000
Kidney Failure = ESRD
Can be considered an *epidemic*
Incident Rates by Primary Diagnosis
(per million population, unadjusted)
Kidney Failure Compared to Cancer Deaths in the U.S. in 2000*

(in Thousands)

<table>
<thead>
<tr>
<th></th>
<th>Lung Cancer</th>
<th>Kidney Failure</th>
<th>Colon Cancer</th>
<th>Breast Cancer</th>
<th>Prostate Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Deaths</strong></td>
<td>157</td>
<td>99</td>
<td>57</td>
<td>42</td>
<td>32</td>
</tr>
</tbody>
</table>

*SEER, 2003
Chronic Kidney Disease (CKD)

**Defined as:**

- Renal dysfunction that persists for more than 3 months.
- Stratified (Stage 1-5) from minimal damage to End-Stage Renal Disease (ESRD)
  - CKD (no renal replacement therapy)
  - Dialysis: Hemodialysis & Peritoneal Dialysis
  - Functioning Kidney Transplant
- Multiple organ effects – most die of CVD before reaching ESRD
# Stages of Chronic Kidney Disease

**National Kidney Foundation KDOQI**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
<th>GFR (ml/min/1.73 m²)</th>
<th>Action†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kidney Damage with Normal or ↑ GFR</td>
<td>&gt;90 (CKD Risk Factors)</td>
<td>Screening, CKD Risk Reduction</td>
</tr>
<tr>
<td>2</td>
<td>Kidney Damage with Mild ↓ GFR</td>
<td>60-89</td>
<td>Estimating Progression</td>
</tr>
<tr>
<td>3</td>
<td>Moderate ↓ GFR</td>
<td>30-59</td>
<td>Evaluating and Treating Complications</td>
</tr>
<tr>
<td>4</td>
<td>Severe ↓ GFR</td>
<td>15-29</td>
<td>Preparation for Kidney Replacement Therapy</td>
</tr>
<tr>
<td>5</td>
<td>Kidney Failure</td>
<td>&lt;15 or Dialysis</td>
<td>Replacement, if Uremia Present</td>
</tr>
</tbody>
</table>

† Includes actions from preceding stages.
# How many patients in the U.S. are affected by CKD?

## Percent of Tested Patients and Estimated U.S. Individuals with CKD

<table>
<thead>
<tr>
<th>Data source</th>
<th>GFR 30-59</th>
<th>GFR 15-29</th>
<th>GFR &lt; 15 (no RRT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHANES (K/DOQI Analysis)¹</td>
<td>4.3%</td>
<td>0.2%</td>
<td>K/DOQI Stage 5</td>
</tr>
<tr>
<td></td>
<td>7,600,000</td>
<td>400,000</td>
<td></td>
</tr>
<tr>
<td>KP SO CA²</td>
<td>4.75%</td>
<td>0.27%</td>
<td>0.04%</td>
</tr>
<tr>
<td>Southwestern U.S. Health Plan³</td>
<td>4,200,000 in U.S. with CKD (conservative definition)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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What Can Be Done About It?

• Managing End-Stage Kidney Disease (ESRD) on RRT
  – Disease Management interventions based upon risk stratification
    • ESRD Managed Care Demonstration Project (Medicare)
    • Optimal Renal Care; Renaissance Renal Management Services

• Managing Earlier Stages of Chronic Kidney Disease (CKD)
  – Identification & Stratification: K/DOQI Staging Guidelines
  – Stage-specific Approach to Management
    • Population Management in early Stages
    • Case / Care Management pre-dialysis / pre-kidney transplant
  – CKD Disease Management Programs that manage co-morbid conditions (CVD; diabetes; hypertension)
    • Prepare for dialysis and/or transplant when needed

• Evidence of Improved Outcomes from Key Interventions
Risk Stratification and Prediction of Hospitalization and Mortality

Overview of Optimal Renal Care Risk Stratification Process
Risk Stratification Tool

Optimal Renal Care Risk Stratification:

- Predicts hospitalization; mortality
- Partially built upon the Index of Coexisting Disease (ICED) Risk Stratification
- 6 Additional components:
  - Utilization (Time since last acute care episode)
  - Psychosocial variables such as social support structure (lives alone; no support system)
  - Adherence with medical regimen
  - Specific Clinical indicators
  - Co-morbid conditions
  - Age
Risk Stratification Tool

• Has identified *Predictive Components* of co-morbid conditions for the kidney patient
• Has defined *Time Dependence* of stratification and re-stratification
  – Assigns types and frequency of interventions based on risk stratification score
  – Predicts hospitalization and mortality over time
• Demonstrates changes of *Risk Stratification* over time
  – Reports outcomes of initial and ongoing risk stratification outcomes
  – Manage components that predict change
ORC Stratification Results

**Levels**
- Low Risk
- Medium
- High

**Frequency of re-stratification**
- Quarterly (every 90 days)
- More frequently based upon:
  - Member specific care plan
  - Hospital utilization; SNF utilization
  - Specific care coordination activities
  - Clinical judgment
Global Assessment Drives Risk Scoring

Dialysis Prescription (HD orders, anemia, Bone D, etc)

Unified Care Plan
Risk Stratification

Co-morbidity Management
Primary and Secondary Prevention

Disease Management Processes and Interventions

Patient Education

Rapid Cycle Initiatives / Modules
Validation of the Risk Stratification Process
Tulane University Validation
Goals

• Validate ORC Additive ICED-Based Risk Stratification
  – Hospitalization, Mortality
• Identify Predictive Components
• Determine Time Dependence of Stratification
  – Hospitalization, Mortality
• Changes of Risk Stratification over Time
  – Outcomes of patients who changed risk stratification
  – Components that predict change
Study Design

• Retrospective analysis
  – 965 patients in 8 health plans who had an initial risk stratification
• Data collected prospectively
• Endpoints
  – Time to first hospitalization
  – Hospitalizations over time
  – Mortality
# Patient Demographics

## Study Population

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td><strong>965</strong></td>
</tr>
</tbody>
</table>

## Age

- Male: 57.70%
- Female: 42.30%

## Time on dialysis

- Male: 57.70%
- Female: 42.30%

## % Diabetic

- 52%

### Example Change in Risk Stratification

<table>
<thead>
<tr>
<th>First and Second Risk Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stayed Same</td>
<td>48.0%</td>
</tr>
<tr>
<td>Changed</td>
<td>52.0%</td>
</tr>
<tr>
<td>Decreasing</td>
<td>47.3%</td>
</tr>
<tr>
<td>Increasing</td>
<td>4.7%</td>
</tr>
<tr>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Stay Low</td>
<td>9.1%</td>
</tr>
<tr>
<td>Become Medium</td>
<td>2.2%</td>
</tr>
<tr>
<td>Become High</td>
<td>0.0%</td>
</tr>
<tr>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Stay Medium</td>
<td>30.6%</td>
</tr>
<tr>
<td>Become Low</td>
<td>16.1%</td>
</tr>
<tr>
<td>Become High</td>
<td>2.5%</td>
</tr>
<tr>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Stay High</td>
<td>8.3%</td>
</tr>
<tr>
<td>Become Low</td>
<td>6.0%</td>
</tr>
<tr>
<td>Become Medium</td>
<td>25.2%</td>
</tr>
</tbody>
</table>
Risk Stratification and 365 Day Patient Survival

- Stratification predicts mortality
- Low mortality for a dialysis population

*P* < .01
Risk Stratification and 365 Day Hospitalization

- Stratification predicts hospitalization risk

N = 965

P < .0001
Patients who increased from low to medium risk had a trend toward earlier hospitalization.
Patients who increased from a medium to high risk had poorer outcomes from the onset.
High risk patients who decreased risk level at 90 days had longer time to hospitalization.

Survival Distribution Function

Became Low
Became Medium
Stayed High

P < .01
## Sample Risk Stratification Co-Morbid Conditions Outcomes

<table>
<thead>
<tr>
<th>Co-Morbid Condition</th>
<th>Members With</th>
<th>Percent With</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>259</td>
<td>86.3%</td>
</tr>
<tr>
<td>Diabetic Insulin Dependent</td>
<td>125</td>
<td>41.7%</td>
</tr>
<tr>
<td>Diabetic Diet Controlled</td>
<td>51</td>
<td>17.0%</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>102</td>
<td>34.0%</td>
</tr>
<tr>
<td>Ischemic Heart Disease</td>
<td>100</td>
<td>33.3%</td>
</tr>
<tr>
<td>Ophthalmologic Conditions</td>
<td>85</td>
<td>28.3%</td>
</tr>
<tr>
<td>Musculoskeletal Connective Tissue Disease</td>
<td>77</td>
<td>25.7%</td>
</tr>
<tr>
<td>Peripheral Vascular Disease</td>
<td>74</td>
<td>24.7%</td>
</tr>
<tr>
<td>Nonvascular Nervous System Disease</td>
<td>73</td>
<td>24.3%</td>
</tr>
<tr>
<td>Anticoagulation Conditions</td>
<td>66</td>
<td>22.0%</td>
</tr>
<tr>
<td>Gastrointestinal Disease</td>
<td>62</td>
<td>20.7%</td>
</tr>
<tr>
<td>Cardiac Arrhythmias</td>
<td>60</td>
<td>20.0%</td>
</tr>
<tr>
<td>Other Heart Disease</td>
<td>55</td>
<td>18.3%</td>
</tr>
<tr>
<td>Cerebral Vascular Disease</td>
<td>48</td>
<td>16.3%</td>
</tr>
<tr>
<td>Malignancy</td>
<td>38</td>
<td>12.7%</td>
</tr>
<tr>
<td>Respiratory Disease</td>
<td>37</td>
<td>12.3%</td>
</tr>
<tr>
<td>Hepatobiliary Disease</td>
<td>26</td>
<td>8.7%</td>
</tr>
<tr>
<td>Hematologic Conditions</td>
<td>22</td>
<td>7.3%</td>
</tr>
<tr>
<td>Urinary Tract Disease</td>
<td>18</td>
<td>6.0%</td>
</tr>
<tr>
<td>HIV AIDS</td>
<td>6</td>
<td>2.0%</td>
</tr>
</tbody>
</table>
Expanding the risk stratification and intervention link

Chronic Kidney Disease

Pre-renal replacement therapy
Costs of Kidney Failure Are High (in $billions for 2000)

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney Failure Care</td>
<td>19.3</td>
</tr>
<tr>
<td>Kidney Failure Accounts for 6% of Medicare Payments while the percent of Medicare patients on dialysis is less than 1%</td>
<td></td>
</tr>
<tr>
<td>Lost Income for Patients Is $2-4 Billion/Yr</td>
<td></td>
</tr>
<tr>
<td>Total NIH Budget</td>
<td>17.8</td>
</tr>
</tbody>
</table>
Early Treatment Makes a Difference

![Graph showing the impact of different treatments on GFR over time](graph.jpg)

- **No Treatment**
- **Current Treatment**
- **Early Treatment**

**Kidney Failure**
Only 10% of Medicare beneficiaries with diabetes receive annual urine albumin tests

Patients are referred late to a nephrologist, especially African American men

Less than 1/3 of people with identified CKD get an ACE Inhibitor

McClellan, et al., 2000
Kinchen, 2002
McClellan et al., 1997
Parallels Between Hypertension in 1972 and Kidney Disease in 2004 (NKDEP)

- Recent documentation of effective therapy
- Treatment of a silent disease to reduce risk for a disastrous outcome
- Simple screening
- Advantages for patients, physicians, industry
Stages in Progression of CKD and Therapeutic Strategies

- Normal
  - Screening for CKD risk factors
- Increased risk
  - CKD risk reduction
  - Screening for CKD
- Damage
  - Diagnosis & treatment
  - Treat comorbid conditions
  - Slow progression
- ↓ GFR
  - Estimate progression
  - Treat complications
  - Prepare for replacement
- Kidney failure
  - Replacement by dialysis & transplant
- Complications
- CKD death
Background

- Chronic kidney disease (CKD) is a worldwide public health problem
- There is a rising incidence and prevalence of kidney failure, with poor outcomes and high cost
- There is an even higher prevalence of earlier stages of CKD
Background (cont’d)

- Adverse outcomes of CKD can often be prevented or delayed
- Earlier stages of CKD can be detected through laboratory testing
- Treatment of earlier stages of CKD is effective in slowing the progression toward kidney failure and correcting complications associated with progressive loss of kidney function
- Treatment of cardiovascular disease risk factors should be effective in reducing cardiovascular disease events, both before and after the onset of kidney failure
Background (cont'd)

- CKD is under-diagnosed and under-treated, resulting in lost opportunities for prevention
- One reason is the lack of agreement on a definition and classification of stages in the progression of CKD
“Normal” GFR vs. Age

- Inulin (Davies and Shock 1950)
- NHANES III Estimated GFR (median, 5th, 95th %iles)
<table>
<thead>
<tr>
<th>Early Detection of CKD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions that delay progression</td>
</tr>
<tr>
<td>Prevention of uremic complications</td>
</tr>
<tr>
<td>Modification of comorbidity</td>
</tr>
<tr>
<td>Preparation for RRT</td>
</tr>
<tr>
<td>ACE inhibitors</td>
</tr>
<tr>
<td>Malnutrition</td>
</tr>
<tr>
<td>Cardiac disease</td>
</tr>
<tr>
<td>Education</td>
</tr>
<tr>
<td>BP control</td>
</tr>
<tr>
<td>Anemia</td>
</tr>
<tr>
<td>Vascular disease</td>
</tr>
<tr>
<td>Informed choice of RRT</td>
</tr>
<tr>
<td>Blood sugar control</td>
</tr>
<tr>
<td>Osteodystrophy</td>
</tr>
<tr>
<td>Neuropathy (in diabetics)</td>
</tr>
<tr>
<td>Timely access placement</td>
</tr>
<tr>
<td>Protein restriction?</td>
</tr>
<tr>
<td>Acidosis</td>
</tr>
<tr>
<td>Retinopathy (in diabetics)</td>
</tr>
<tr>
<td>Timely initiation of dialysis</td>
</tr>
</tbody>
</table>

Proven & Accepted Interventions

Delay CKD progression and/or slow progression of CVD

- Improved glycemic control in diabetics
- BP control
- ACEI/ARB in DM and in non-DM with proteinuria
- Anemia management (New evidence)
- Protein Restriction (with Dietitian guidance)
- Timely nephrologist referral
- Multidisciplinary team management
- CV risk reduction (usual measures)
<table>
<thead>
<tr>
<th>Test or screening procedure</th>
<th>Result</th>
<th>Date</th>
<th>Time Frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine level or GFR</td>
<td></td>
<td></td>
<td>3 months</td>
</tr>
<tr>
<td>PTH level</td>
<td></td>
<td></td>
<td>6 months</td>
</tr>
<tr>
<td>Calcium level</td>
<td></td>
<td></td>
<td>3 months</td>
</tr>
<tr>
<td>Phosphorus level</td>
<td></td>
<td></td>
<td>3 months</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td></td>
<td></td>
<td>1 month if on EPO</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 months if not on EPO</td>
</tr>
<tr>
<td>Serum Albumin</td>
<td></td>
<td></td>
<td>3 months</td>
</tr>
<tr>
<td>Fasting Lipid Profile</td>
<td></td>
<td></td>
<td>12 months</td>
</tr>
<tr>
<td>HgbA1C for Diabetics only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B Vaccination Series</td>
<td></td>
<td></td>
<td>Once</td>
</tr>
<tr>
<td>Hepatitis B Surface Antibody</td>
<td></td>
<td></td>
<td>1 month after complete Hep B vaccine series</td>
</tr>
<tr>
<td>Pneumococcal Vaccination (Pneumovax)</td>
<td></td>
<td></td>
<td>Once when less than 65</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Once over age 65 if 5 or more years since last vaccination</td>
</tr>
<tr>
<td>Influenza Vaccination</td>
<td></td>
<td></td>
<td>Each Fall</td>
</tr>
<tr>
<td>Preventative Health Visit to PCP</td>
<td></td>
<td></td>
<td>1 year</td>
</tr>
</tbody>
</table>
# CKD Program: Patient Tracking

## Interview Data Collection

<table>
<thead>
<tr>
<th>Information item from patient</th>
<th>Answer</th>
<th>Criteria</th>
<th>Discipline for follow up if needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last visit to Nephrologist</td>
<td></td>
<td>3 months</td>
<td>Nephrologist’s Office</td>
</tr>
<tr>
<td>Last visit to PCP</td>
<td></td>
<td>12 months</td>
<td>PCP’s Office</td>
</tr>
<tr>
<td>Modality Selection Made or changed</td>
<td>Committed to a dialysis modality</td>
<td>ORC Social Worker and/or Nephrologist, PD nurse</td>
<td></td>
</tr>
<tr>
<td>How is Blood Pressure?</td>
<td></td>
<td>Usually &lt; 140/90, if not:</td>
<td>Nephrologist ORC Pharmacist ORC Social Worker ORC Dietitian</td>
</tr>
<tr>
<td>• Alert nephrologist and have patient call nephrologist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Taking meds, if not why? (Pharm or SW)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Restricting salt?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home BP Monitoring? If no, are you interested in doing Home BP monitoring?</td>
<td>No</td>
<td></td>
<td>Give information about HIP Class.</td>
</tr>
<tr>
<td>If takes EPO, getting follow up at ORC-HIP Program?</td>
<td>All Stage 4 CKD patients should be managed at HIP Home EPO program</td>
<td>ORC Pharmacist</td>
<td></td>
</tr>
<tr>
<td>Are you eating well? Is weight dropping? Do you have dietary questions</td>
<td>No problems</td>
<td>ORC Dietitian</td>
<td></td>
</tr>
<tr>
<td>How are you dealing with CKD? How is your family reacting? Do you have enough help at home? Are you feeling more sad or anxious? Are you sleeping well? Are you still working or going to school?</td>
<td>Doing OK</td>
<td>ORC Social Worker</td>
<td></td>
</tr>
<tr>
<td>Are you smoking? If yes, are you thinking about quitting?</td>
<td>No</td>
<td></td>
<td>Give information about HIP smoking cessation program</td>
</tr>
<tr>
<td>Are you on cholesterol lowering medication? If so, are you following the program?</td>
<td>No</td>
<td>ORC Pharmacist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>ORC Social Worker ORC Dietitian</td>
<td></td>
</tr>
<tr>
<td>If you are diabetic, are you followed by the HIP diabetes program?</td>
<td>No</td>
<td>Refer to HIP diabetes case manager</td>
<td></td>
</tr>
<tr>
<td>Review Test/procedure table with patient</td>
<td>Patient has met all criteria</td>
<td>If not, suggest follow up as appropriate, notify physicians and other disciplines.</td>
<td></td>
</tr>
</tbody>
</table>
Managing Stage 4-5 (Pre-Dialysis) Patients - Case for a Case Manager

Stage 4-5 CKD identified by PCP (GFR < 30)

- Confirm GFR < 30 for 3 months?
  - Yes: Begin CKD Tracking Module (Case Manager)
  - No: CM completes evaluation, determines educational needs for modality selection.

- Patient receives appropriate Modality Education?
  - Yes: Patient Selects a Dialysis Modality?
  - No: Exit this Module, but continue CKD Tracking in PCM

Patient Selects a Dialysis Modality:

Hemodialysis

- CM contacts member q2weeks, may refer to nephrologist or dialysis patient or visit dialysis facility.

- Patient Selects Hemodialysis?
  - Yes: Yes
  - No: No

- Patient Referred to and seen by Vascular Surgeon?
  - Yes: Patient has Vascular Access Surgery?
  - No: No

- CM Supplies Post-Surgery Education and monitors Access - may refer back to Surgeon if access insufficient.

Peritoneal Dialysis

- CM requests vascular surgery referral from Nephrologist (may coordinate appointment)

- Patient Referred to and seen by Vascular Surgeon?
  - Yes: Patient has Vascular Access Surgery?
  - No: No

- CM Supplies Post-Surgery Education and monitors Access - may refer back to Surgeon if access insufficient.

- Patient Referred to and seen by PD Nurse?
  - Yes: Patient accepted for PD program?
  - No: No

- Patient followed periodically by PD RN and Nephrologist

- Continue Kidney Transplant and CKD Tracking Modules

- Begin Kidney Transplant Module

- Patient Referred to and seen by PD Nurse?
  - Yes: Yes
  - No: No

- Patient accepted for PD program?
  - Yes: Yes
  - No: No

- Patient followed periodically by PD RN and Nephrologist

- Continue Kidney Transplant and CKD Tracking Modules

- Begin Kidney Transplant Module

- Patient Referred to and seen by PD Nurse?
  - Yes: Yes
  - No: No

- Patient accepted for PD program?
  - Yes: Yes
  - No: No

- Patient followed periodically by PD RN and Nephrologist

- Continue Kidney Transplant and CKD Tracking Modules

- Begin Kidney Transplant Module

- Patient Referred to and seen by PD Nurse?
  - Yes: Yes
  - No: No

- Patient accepted for PD program?
  - Yes: Yes
  - No: No

- Patient followed periodically by PD RN and Nephrologist

- Continue Kidney Transplant and CKD Tracking Modules

- Begin Kidney Transplant Module

- Patient Referred to and seen by PD Nurse?
  - Yes: Yes
  - No: No

- Patient accepted for PD program?
  - Yes: Yes
  - No: No

- Patient followed periodically by PD RN and Nephrologist

- Continue Kidney Transplant and CKD Tracking Modules

- Begin Kidney Transplant Module
Conclusion
Risk Stratification and Renal Care

- **ESRD Managed Care Demonstration Project (Medicare)**
  - Disease Management can be Cost-effective in ESRD
    - Interventions based on risk stratification acuity level
- **ESRD Quality Improvement is Critical to Long-term Success**
  - Speeds improved outcomes such as:
    - Vascular access outcomes; Reduction of extremes of blood pressure; reduction of fluid volume overload/heart failure; glycemic control
- **The US Renal Disease Care Management Marketplace**
  - Optimal Renal Care Approach to ESRD
- **Earlier Stages of CKD**
  - Sizable problem – Costly, semi-preventable, not well managed
  - Staging Care and applying proven interventions
  - Managing co-morbid conditions (CVD)