Clinical Performance Goals
2012-2013
Clinical Performance Goals
2012-2013

Table of Contents

Table of Contents ........................................................................................................1
Health Care Quality Improvement Program .............................................................. 2
ESRD Quality Incentive Program (QIP) .................................................................. 5
Clinical Performance Measures ................................................................................ 7
Chapter 1: Hemodialysis CPM Indicators ................................................................. 8
  Adequacy of Dialysis .............................................................................................. 9
  Anemia Management ............................................................................................. 12
  Nutritional Status ................................................................................................ 17
  Bone and Mineral Metabolism ........................................................................... 18
  Vascular Access ................................................................................................... 20
Chapter 2: Peritoneal Dialysis CPM Indicators ......................................................... 22
  Adequacy of Dialysis ............................................................................................ 23
  Anemia Management ............................................................................................ 24
  Nutritional Status ................................................................................................ 29
  Bone and Mineral Metabolism ........................................................................... 30
Chapter 3: Other QAPI Initiatives ........................................................................... 32
  Medical Injuries and Medical Errors Identification .......................................... 33
  Hemodialyzer Reuse Program ........................................................................... 35
  Patient Satisfaction and Grievances ................................................................... 36
  Health Outcomes: Physical and Mental Functioning and Patient Survival .......... 37
  Infection Control ................................................................................................ 38
  5-Diamond Patient Safety Program .................................................................... 40
  Additional Information ......................................................................................... 42
The Centers for Medicare & Medicaid Services (CMS), which oversees the Medicare program, contracts with 18 ESRD Network Organizations throughout the United States. The ESRD Networks perform oversight activities to assure appropriateness of services and protection for ESRD patients. This approach has been named the ESRD Health Care Quality Improvement Program (HCQIP).

The ESRD HCQIP is based on the assumption that most health care providers need and welcome both information, and where necessary, help in applying the tools and techniques of quality management.

The Network has established performance goals based on past performance, CMS thresholds and the NKF-K/DOQI Clinical Practice Guidelines. With the new Conditions for Coverage, the expectation is that facilities develop an internal Quality Assessment and Performance (QAPI) plan to promote continuous improvement.
Excerpt from the Conditions for Coverage

§494.110 The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement (QAPI) program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility’s organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

The Measures Assessment Tool (MAT) is a reference for community-accepted standards and values for listed elements of QAPI required in the Conditions for Coverage. Facilities are expected to use the community-accepted standards and values associated with clinical outcomes as referenced on the MAT. Facilities are also expected to use the “fourth-quarter Lab Data”, CROWNWeb (when it becomes available), and Dialysis Facility Reports to determine comparison or “average” values associated with clinical outcomes.
You can access the latest MAT by going to the Network websites:

- [www.therenalnetwork.org](http://www.therenalnetwork.org) – click the “Conditions for Coverage” link
- [www.esrdnetwork4.org](http://www.esrdnetwork4.org) -- click the “Conditions (CfC)” link

This *Clinical Performance Goals* document provides measures (based on the MAT requirements) to assess facility-level patient care processes and outcomes, and to identify opportunities for improvement.

The goal of the Network is to combine efforts with renal facilities to improve performance in the delivery of quality patient care.
ESRD Quality Incentive Program (QIP)

The End Stage Renal Disease (ESRD) Quality Initiative promotes ongoing CMS strategies to improve the quality of care provided to ESRD patients. This initiative supports quality improvement efforts among providers and makes available quality information that will enable patients to participate in making health care decisions. Quality measures for dialysis facilities are available to consumers on Dialysis Facility Compare on the Medicare.gov website.

CMS developed the ESRD QIP to be the nation's first pay-for-performance (also known as "value-based purchasing") quality incentive program as mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) section 153(c). This first-of-its-kind program provides the ESRD community with the opportunity to enhance the overall quality of care that ESRD patients receive as they battle this devastating disease.

The ESRD QIP Quality Measures change from year to year and may include outcomes as well as process indicators.

For more information on the measures, visit:
https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDQualityImproveInit/index.html
Format of this Booklet

Hemodialysis and Peritoneal Dialysis clinical indicator goals differ slightly. This booklet groups the major domains of care by modality.

Look for the Blue or Green flag in the upper right corner of the page, which are used to differentiate between the modalities.

Chapter 1 deals with Hemodialysis clinical indicators and has a blue flag.

Chapter 2 deals with Peritoneal Dialysis clinical indicators and has a green flag.

Chapter 3 includes additional QAPI topics that are mentioned by the Conditions for Coverage.

*All data represented in the tables and graphs come from the “fourth-quarter Lab Data” 2011 aggregate, unless otherwise specified. These results are inclusive of all insurance types (i.e. Medicare beneficiaries and non-Medicare individuals) and are not limited by prescription, e.g. Anemia results are for all patients not just those receiving ESA.*
Clinical Performance Measures

The ESRD Clinical Performance Measures (CPM) Project is a national effort led by CMS and the 18 ESRD Networks.

For 18 years, clinical information was collected and reported with unit, state, Network and national comparisons. As the ESRD program transitions to an all electronic collection method, the data used to drive this effort was in the form of the “fourth-quarter Lab Data” project (aggregated for the time period of October-November-December) and “Vascular Access” projects (aggregated monthly).

Facilities are asked to report clinical information designed to reflect values for the five major domains of care: Adequacy of Dialysis, Anemia Management, Nutritional Status, Bone and Mineral Metabolism and Vascular Access.
Topics included in this section:

Adequacy of Dialysis including Kt/V and URR

Anemia Management

Nutritional Status

Bone & Mineral Metabolism

Vascular Access
Numerous outcome studies have demonstrated a correlation between the delivered dose of hemodialysis and patient mortality and morbidity. The intent of QAPI in addressing adequacy of dialysis is to maximize the number of patients who achieve the goals for adequate dialysis, which includes both successful fluid volume management and clearance of toxins.

**Urea Reduction Ratio (URR)**

Pre- and post-dialysis blood urea nitrogen (BUN) levels were drawn and reported to calculate URR results.

The Renal Network has a goal to maintain the URR rate of 96% of patients with a URR ≥ 65%.

The results provided by the 2011 Lab Data Collection project show that each of our three Networks are above the national mean with compliance to this measure; however, we are below our target.
### Adequacy of Dialysis

#### URR Data

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>IL</th>
<th>U.S.</th>
<th>Our Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean URR</strong></td>
<td>75</td>
<td>75</td>
<td>75</td>
<td>75</td>
<td>74</td>
<td>74</td>
<td>74</td>
<td>74</td>
<td>75</td>
<td>≥ 65</td>
</tr>
<tr>
<td><strong>% Patients with mean URR ≥ 65</strong></td>
<td>96.2%</td>
<td>95.9%</td>
<td>96.2%</td>
<td>96.1%</td>
<td>94.7%</td>
<td>95.0%</td>
<td>95.2%</td>
<td>95.2%</td>
<td>95.2%</td>
<td>96.0%</td>
</tr>
</tbody>
</table>

#### Compliance to the URR Measure

![Diagram showing compliance to URR measure](image-url)
Adequacy of Dialysis

Kt/V

Kt/V was reported for all patients in the Lab Data Collection project.

The Renal Network has a goal to maintain 96% of patients with a Kt/V ≥ 1.2, calculated using the Daugirdas II method for hemodialysis patients.

The 2011 Lab Data Collection results show each of our Network areas are close to our target compliance rate.

### Kt/V Data

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
<th>Our Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Kt/V</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
<td></td>
<td>≥ 1.2</td>
</tr>
<tr>
<td>% Patients with mean Kt/V ≥ 1.2</td>
<td>97.5</td>
<td>97.6</td>
<td>97.5</td>
<td>97.7</td>
<td>96.7</td>
<td>97.2</td>
<td>97.3</td>
<td>97.1</td>
<td>97.2</td>
<td>96.0</td>
</tr>
</tbody>
</table>

### Compliance to the Kt/V Measure

- **Net 4**: 97.5%
- **Net 9**: 97.3%
- **Net 10**: 97.1%
- **U.S.**: 97.2%
- **Our Goal**: 96.0%

Page 11
The FDA notified healthcare professionals (June 24, 2011), that new recommendations for more conservative dosing of ESAs in patients with CKD and ESRD have been approved to improve the safe use of these drugs. The FDA has made these recommendations because of data showing increased risks of cardiovascular events with ESAs in the CKD and ESRD patient population.

The FDA has recommended that Healthcare professionals should:

- Weigh the possible benefits of using ESAs to decrease the need for red blood cell transfusions in CKD and ESRD patients against the increased risks for serious cardiovascular events
- Inform their patients of the current understanding of potential risks and benefits.
- Individualize patient therapy and giving the lowest possible ESA dose to reduce the need for blood transfusions.

The FDA recommends administering ESAs only to reduce the need for blood transfusions and specified a ceiling-hemoglobin of 11 gm/dL in patients with ESRD.
RBC transfusions are undesirable because they:

- Increase sensitization of recipients to human antigens and thereby decrease the pool of potential compatible donors for organ transplantation to the patient.
- Have been associated with communicable diseases such as HIV and Hepatitis B and C
- May be associated with new communicable diseases in the future.
- Are associated with iron overload which may lead to organ damage.

Anemia is present in the majority of Chronic Kidney Disease (CKD) patients. Untreated CKD associated anemia can result in a number of physiologic abnormalities that can reduce the quality of life and decrease patient survival.

The Network goal is to individualize treatment to maintain hemoglobin levels at a range best suited to the patient’s level of activity, symptoms and degree of ESA resistance.
Anemia Management

Hemoglobin (Hgb)

Hemoglobin data parameters were reported using the standard target ranges prior to the FDA recent (June 24, 2011) recommendations

<table>
<thead>
<tr>
<th>Hemoglobin Data (g/dL)</th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Hgb</td>
<td>10.9</td>
<td>11.3</td>
<td>11.0</td>
<td>11.0</td>
<td>11.1</td>
<td>11.0</td>
<td>11.0</td>
<td>11.0</td>
<td>11.0</td>
</tr>
<tr>
<td>% Patients with mean Hgb &lt; 10</td>
<td>13.4</td>
<td>7.5</td>
<td>13.0</td>
<td>13.5</td>
<td>11.5</td>
<td>13.1</td>
<td>12.9</td>
<td>13.2</td>
<td>14.1</td>
</tr>
<tr>
<td>% Patients with mean Hgb in 10-12</td>
<td>76.0</td>
<td>76.7</td>
<td>76.0</td>
<td>74.3</td>
<td>74.0</td>
<td>73.9</td>
<td>74.0</td>
<td>74.5</td>
<td>74.6</td>
</tr>
<tr>
<td>% Patients with mean Hgb &gt; 12</td>
<td>11.0</td>
<td>15.7</td>
<td>11.0</td>
<td>12.2</td>
<td>14.5</td>
<td>13.1</td>
<td>13.1</td>
<td>12.2</td>
<td>11.3</td>
</tr>
</tbody>
</table>

Hgb < 10

Page 14
Hemoglobin data parameters were reported using the standard target ranges prior to the FDA recent (June 24, 2011) recommendations.
Iron Studies: Iron deficiency is an additional factor that may contribute to CKD-associated anemia, since iron is critical for hemoglobin synthesis.

The Renal Network does not have an established goal for these assays; however, it is recommended to increase the number of patients with a Ferritin level \( \geq 200 \) ng and \( \leq 800 \) ng (HD patients), and increase the number of patients who achieve a TSAT \( \geq 20\% \) and \( \leq 50\% \).

### Ferritin Data (ng)

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Ferritin</td>
<td>788.8</td>
<td>1027.1</td>
<td>807.5</td>
<td>909.1</td>
<td>849.0</td>
<td>829.3</td>
<td>854.7</td>
<td>936.9</td>
<td></td>
</tr>
<tr>
<td>% Patients with mean Ferritin within range</td>
<td>50.3</td>
<td>30.0</td>
<td>48.8</td>
<td>39.5</td>
<td>45.8</td>
<td>47.4</td>
<td>45.0</td>
<td>37.4</td>
<td>43.2</td>
</tr>
</tbody>
</table>

### TSAT Data

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean TSAT</td>
<td>31.2</td>
<td>32.9</td>
<td>31.4</td>
<td>31.6</td>
<td>31.5</td>
<td>31.3</td>
<td>31.4</td>
<td>33.1</td>
<td></td>
</tr>
<tr>
<td>% Patients with mean TSAT within range</td>
<td>87.0</td>
<td>90.0</td>
<td>87.3</td>
<td>87.3</td>
<td>88.0</td>
<td>86.4</td>
<td>86.9</td>
<td>89.7</td>
<td>88.6</td>
</tr>
</tbody>
</table>

If your facility uses a standardized anemia management guideline or algorithm, an evaluation of the efficacy of this tool is needed if facility QAPI goals for anemia management are not achieved over consecutive evaluation periods.
Nutritional Status

Network Outcomes and Process Goals
All hemodialysis patients measured for nutrition every month.

80% of hemodialysis patient population achieves an albumin ≥ 3.5 gm/dL bromcresol green method or ≥ 3.2 gm/dL bromcresol purple method (correct for other assay methods).

If a patient has an albumin < 3.5 BCG or 3.2 BCP gm/dL, documentation of actions to be taken to improve nutrition outcomes should be written into the patient’s plan of care.

Serum albumin has been used extensively to assess the nutritional status of individuals, and is highly predictive of future mortality risks. The intent of QAPI in addressing nutritional status is to maximize the number of patients who achieve the goals for this area.

### Albumin Data (gm/dL)

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>IL</th>
<th>U.S.</th>
<th>Our Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Albumin</td>
<td>3.8</td>
<td>3.8</td>
<td>3.8</td>
<td>3.8</td>
<td>3.8</td>
<td>3.8</td>
<td>3.8</td>
<td>3.9</td>
<td>3.9</td>
<td>83.3</td>
</tr>
<tr>
<td>% Patients with mean Albumin within range</td>
<td>83.1</td>
<td>85.2</td>
<td>83.3</td>
<td>83.3</td>
<td>84.4</td>
<td>83.3</td>
<td>83.5</td>
<td>86.9</td>
<td>85.7</td>
<td>80.0</td>
</tr>
</tbody>
</table>

### Compliance to the Albumin Measure

- **Net 4**: 83.3%
- **Net 9**: 83.5%
- **Net 10**: 86.9%
- **U.S.**: 85.7%
- **Our Goal**: 80.0%

Page 17
Disorders of mineral metabolism with CKD have been associated with a high mortality rate. Regulation of calcium and phosphorous levels are essential components of the management of bone and mineral disorders. The intent of QAPI in addressing management of CKD mineral and bone disorder is to maximize the number of patients who achieve the goals for this area. **Dialysis facilities should strive to maintain Calcium levels to avoid hypercalcemia. Phosphorus levels should be maintained at a level ≤ 5.5 mg/dL.**

### Network Outcomes and Process Goals

Reviewing a three-month average of the last serum phosphorus level of the month, 60% of hemodialysis patient population will have a serum phosphorus ≤ 5.5 gm/dL.

Review other recommendations from the NKF-K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease.

---

<table>
<thead>
<tr>
<th>Calcium Data (mg/dL)</th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Calcium</td>
<td>9.0</td>
<td>8.9</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.1</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
</tr>
<tr>
<td>% Patients with mean Calcium 8.4-10.2 mg/dL</td>
<td>82.5</td>
<td>79.0</td>
<td><strong>82.2</strong></td>
<td>80.7</td>
<td>82.5</td>
<td>83.0</td>
<td><strong>82.3</strong></td>
<td><strong>82.6</strong></td>
<td>82.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phosphorus Data (mg/dL)</th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
<th>Our Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Phos</td>
<td>5.1</td>
<td>5.3</td>
<td>5.1</td>
<td>5.2</td>
<td>5.4</td>
<td>5.2</td>
<td>5.2</td>
<td>5.1</td>
<td>5.1</td>
<td>60.0</td>
</tr>
<tr>
<td>% Patients with mean Phos 3.5-5.5 mg/dL</td>
<td>59.3</td>
<td>54.6</td>
<td><strong>58.9</strong></td>
<td>57.1</td>
<td>53.0</td>
<td>57.3</td>
<td><strong>56.5</strong></td>
<td><strong>57.8</strong></td>
<td><strong>57.1</strong></td>
<td>60.0</td>
</tr>
</tbody>
</table>
Compliance to the Calcium Measure

- Net 4: 82.2%
- Net 9: 82.3%
- Net 10: 82.6%
- U.S.: 82.3%

Compliance to the Phosphorus Measure

- Net 4: 58.9%
- Net 9: 56.5%
- Net 10: 57.8%
- U.S.: 57.1%
- Our Goal: 60.0%
An ideal vascular access delivers a flow rate adequate for the dialysis prescription, has a long use-life and minimal complications. Studies demonstrate that the native AV fistula comes closest to achieving these optimum outcomes. Access morbidity may be significantly reduced with the use of native AV fistula.

The intent of QAPI in addressing vascular access is first, to improve the rate of use and preservation of fistulas; second, to decrease the inappropriate use of catheters; and finally, to improve the care provided for all types of vascular access.

The CMS and the Network goal is to achieve a fistula rate of 66% in the prevalent in-center hemodialysis patient population.

Dialysis facilities also need to develop a catheter reduction plan and to adopt strategies for improved access management practices with timely interventions.

The Network & CMS follow the NKF-K/DOQI catheter guideline:
- Less than 10% of the adult hemodialysis population should be maintained on catheters 90 days or longer.
### Vascular Access Data – Prevalent Fistula Use Rates – March 2011

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
<th>Our Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Patients</td>
<td>59.4</td>
<td>64.6</td>
<td>59.9</td>
<td>55.9</td>
<td>63.9</td>
<td>56.7</td>
<td>57.8</td>
<td>59.2</td>
<td>60.4</td>
<td>≥ 66%</td>
</tr>
</tbody>
</table>

### Vascular Access Data – Long Term Catheter Use Rates – March 2011

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
<th>Our Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Patients</td>
<td>9.0</td>
<td>7.5</td>
<td>8.9</td>
<td>9.9</td>
<td>6.4</td>
<td>8.9</td>
<td>8.7</td>
<td>9.0</td>
<td>7.4</td>
<td>≤ 10%</td>
</tr>
</tbody>
</table>

### Vascular Access Data – ALL CATHETER Use Rates – March 2011

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Patients</td>
<td>21.9</td>
<td>17.0</td>
<td>21.5</td>
<td>24.0</td>
<td>19.3</td>
<td>23.0</td>
<td>22.6</td>
<td>22.2</td>
<td>20.2</td>
</tr>
</tbody>
</table>

### How is Your Facility Monitoring Venous Stenosis?

According to the NKF-K/DOQI Guidelines, every dialysis facility should be monitoring vascular accesses for venous stenosis monthly. Early intervention can extend the life of an access, especially if stenosis can be identified before the access completely fails. There are several methods of monitoring for venous stenosis:

- **Physical Assessment**
- **Duplex Ultrasound**
- **Intra-Access Flow**
- **Urea Recirculation**
- **Static Venous Pressures**
- **Unexplained decrease in URR**
Chapter 2: Peritoneal Dialysis CPM Indicators

Topics included in this section:

Adequacy of Dialysis

Anemia Management

Nutritional Status

Bone & Mineral Metabolism
Adequacy of Dialysis

Network Outcomes and Process Goals
Each patient should be measured for adequacy every 4 months. 
≥ 85% of unit’s peritoneal dialysis patient population achieve a weekly Kt/V$_{\text{urea}}$ ≥ 1.7.

Kt/V
The Renal Network’s goal is to maintain 85% of patients with a Kt/V ≥ 1.7.

The results provided by the 2011 Lab Data Collection project show that each of our three Networks are above our target; however, we are below the national compliance rate.

Kt/V Data

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>IL</th>
<th>U.S.</th>
<th>Our Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Kt/V</td>
<td>2.3</td>
<td>2.3</td>
<td>2.3</td>
<td>2.4</td>
<td>2.4</td>
<td>2.3</td>
<td>2.3</td>
<td>2.4</td>
<td></td>
<td>≥ 1.7</td>
</tr>
<tr>
<td>% Patients with mean Kt/V ≥ 1.7</td>
<td>91.6</td>
<td>92.1</td>
<td>91.6</td>
<td>91.6</td>
<td>88.4</td>
<td>92.7</td>
<td>91.6</td>
<td>92.3</td>
<td>91.1</td>
<td>85.0</td>
</tr>
</tbody>
</table>

Compliance to the Kt/V Measure

Page 23
The FDA notified healthcare professionals (June 24, 2011), that new recommendations for more conservative dosing of ESAs in patients with CKD and ESRD have been approved to improve the safe use of these drugs. The FDA has made these recommendations because of data showing increased risks of cardiovascular events with ESAs in the CKD and ESRD patient population.

The FDA has recommended that Healthcare professionals should:

- Weigh the possible benefits of using ESAs to decrease the need for red blood cell transfusions in CKD and ESRD patients against the increased risks for serious cardiovascular events
- Inform their patients of the current understanding of potential risks and benefits.
- Individualize patient therapy and giving the lowest possible ESA dose to reduce the need for blood transfusions.

The FDA recommends administering ESAs only to reduce the need for blood transfusions and specified a ceiling-hemoglobin of 11 gm/dL in patients with ESRD.
RBC transfusions are undesirable because they:

- Increase sensitization of recipients to human antigens and thereby decrease the pool of potential compatible donors for organ transplantation to the patient.
- Have been associated with communicable diseases such as HIV and Hepatitis B and C.
- May be associated with new communicable diseases in the future.
- Are associated with iron overload which may lead to organ damage.

Anemia is present in the majority of Chronic Kidney Disease (CKD) patients. Untreated CKD associated anemia can result in a number of physiologic abnormalities that can reduce the quality of life and decrease patient survival.

The Network goal is to individualize treatment to maintain hemoglobin levels at a range best suited to the patient’s level of activity, symptoms and degree of ESA resistance.
Hemoglobin data parameters were reported using the standard target ranges prior to the FDA recent (June 24, 2011) recommendations.
Hemoglobin data parameters were reported using the standard target ranges prior to the FDA recent (June 24, 2011) recommendations.
Iron Studies: Iron deficiency is an additional factor that may contribute to CKD-associated anemia, since Iron is critical for hemoglobin synthesis.

The Renal Network does not have an established goal for these assays; however, it is recommended to increase the number of patients with a Ferritin level ≥ 100 ng and ≤ 800 ng (PD patients), and increase the number of patients who achieve a TSAT ≥ 20% and ≤ 50%.

**Ferritin Data (ng)**

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>IL</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Ferritin</td>
<td>578.1</td>
<td>649.1</td>
<td>584.3</td>
<td>670.9</td>
<td>629.6</td>
<td>624.5</td>
<td>639.1</td>
<td>664.9</td>
<td></td>
</tr>
<tr>
<td>% Patients with mean Ferritin within range</td>
<td>59.5</td>
<td>64.0</td>
<td><strong>59.8</strong></td>
<td>50.9</td>
<td>59.2</td>
<td>54.3</td>
<td><strong>54.2</strong></td>
<td><strong>54.1</strong></td>
<td><strong>54.0</strong></td>
</tr>
</tbody>
</table>

**TSAT Data**

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>IL</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean TSAT</td>
<td>32.1</td>
<td>35.1</td>
<td>32.4</td>
<td>32.6</td>
<td>32.3</td>
<td>32.4</td>
<td>32.5</td>
<td>32.7</td>
<td></td>
</tr>
<tr>
<td>% Patients with mean TSAT within range</td>
<td>88.9</td>
<td>92.2</td>
<td><strong>89.2</strong></td>
<td>91.0</td>
<td>90.3</td>
<td>88.1</td>
<td><strong>89.4</strong></td>
<td><strong>90.1</strong></td>
<td><strong>90.5</strong></td>
</tr>
</tbody>
</table>

If your facility uses a standardized anemia management guideline or algorithm, an evaluation of the efficacy of this tool is needed if facility QAPI goals for anemia management are not achieved over consecutive evaluation periods.
Serum albumin has been used extensively to assess the nutritional status of individuals, and is highly predictive of future mortality risks. The intent of QAPI in addressing nutritional status is to maximize the number of patients who achieve the goals for this area.

### Albumin Data (gm/dL)

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
<th>Our Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Albumin</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
</tr>
<tr>
<td>% Patients with mean Albumin within range</td>
<td>63.8</td>
<td>64.4</td>
<td>63.9</td>
<td>64.2</td>
<td>54.8</td>
<td>62.7</td>
<td>61.6</td>
<td>64.7</td>
<td>65.1</td>
<td>60.0</td>
</tr>
</tbody>
</table>

### Compliance to the Albumin Measure

![Compliance to the Albumin Measure](chart.png)

- **Net 4**: 63.9%
- **Net 9**: 61.6%
- **Net 10**: 64.7%
- **U.S.**: 65.1%
- **Our Goal**: 60.0%

Network Outcomes and Process Goals

All peritoneal dialysis patients measured for nutrition every month of PD clinic visit.

60% of peritoneal dialysis patient population achieves an albumin ≥ 3.5 gm/dL brom cresol green method or ≥ 3.2 gm/dL brom cresol purple method (correct for other assay methods).

If a patient has an albumin < 3.5 BCG or 3.2 BCP gm/dL, documentation of actions to be taken to improve nutrition outcomes should be written into the patient’s plan of care.
Disorders of mineral metabolism with CKD have been associated with a high mortality rate. Regulation of calcium and phosphorous levels are essential components of the management of bone and mineral disorders. The intent of QAPI in addressing management of CKD mineral and bone disorder is to maximize the number of patients who achieve the goals for this area. **Dialysis facilities should strive to maintain Calcium levels to avoid hypercalcemia. Phosphorus levels should be maintained at a level ≤ 5.5 mg/dL.**

### Network Outcomes and Process Goals

Reviewing a three-month average of the last serum phosphorus level of the month, 60% of peritoneal dialysis patient population will have a serum phosphorus ≤ 5.5 gm/dL.

Review other recommendations from the NKF-K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease.

### Calcium Data (mg/dL)

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Calcium</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
<td>9.0</td>
</tr>
<tr>
<td>% Patients with mean Calcium 8.4-10.2 mg/dL</td>
<td>79.0</td>
<td>76.7</td>
<td>78.8</td>
<td>79.1</td>
<td>80.3</td>
<td>80.0</td>
<td>79.8</td>
<td>78.6</td>
<td>79.1</td>
</tr>
</tbody>
</table>

### Phosphorus Data (mg/dL)

<table>
<thead>
<tr>
<th></th>
<th>PA</th>
<th>DE</th>
<th>NW4</th>
<th>IN</th>
<th>KY</th>
<th>OH</th>
<th>NW9</th>
<th>NW10</th>
<th>U.S.</th>
<th>Our Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Phos</td>
<td>5.3</td>
<td>5.6</td>
<td>5.3</td>
<td>5.0</td>
<td>5.1</td>
<td>5.1</td>
<td>5.1</td>
<td>5.2</td>
<td>5.1</td>
<td>5.1</td>
</tr>
<tr>
<td>% Patients with mean Phos 3.5-5.5 mg/dL</td>
<td>58.2</td>
<td>48.9</td>
<td>57.4</td>
<td>60.1</td>
<td>59.5</td>
<td>59.1</td>
<td>59.5</td>
<td>56.6</td>
<td>57.8</td>
<td>60.0</td>
</tr>
</tbody>
</table>
Chapter 3: Other QAPI Initiatives

**Topics included in this section:**

- Medical Injuries and Medical Errors Identification
- Hemodialysis Reuse Program
- Patient Satisfaction and Grievances
- Health Outcomes: Physical and Mental Functioning and Patient Survival
- Infection Control
Medical Injuries and Medical Errors Identification

The intent of QAPI in addressing medical injuries and identification of medical errors is to minimize the number of occurrences and limit the number of patients and staff who are adversely affected by such occurrences.

The facility must compile events and the QAPI team must review reports and complaints related to any patient or staff injuries, and treatment or medication errors.

The Renal Network invites you to participate in the 5-Diamond Patient Safety Program. There are currently 15 modules under this program, two of which may be used in this area: “Sharps Safety” and “Slips, Trips and Falls”.

Visit our URL for more information:
http://www.therenalnetwork.org/5Diamond/5Diamond.php

Turn to Page 40 for more information on the 5-Diamond Patient Safety Program.
Medical Injuries and Medical Errors Identification

Part of the QAPI activity is to trend any injuries or errors to identify the prevalence of occurrences, commonalities, and causes.

Examples include but are not limited to:

- Patient falls
- Treatment prescription errors
- Medication error or omission
- Equipment related injury
- Intradialytic morbidities
- Intradialytic events as seizures, chest pain, hypotension or cardiac arrest
- Deaths
- Acute allergic-type reactions
- Blood loss >100 ml
- Patient transfer to a hospital emergency room
- Staff needle sticks
Hemodialyzer Reuse Program

If a facility has a dialyzer reuse program, it must be compliant with the quality assurance requirements specific to reuse, located in the Conditions for Coverage, V300-V368. These requirements outline periodic reuse process and practice audits which must be conducted and documented to ensure that the reuse program remains safe and effective.

Any adverse outcomes or patient complaints related to dialyzer reuse must be properly investigated.

Reuse audits must be performed on the required schedule and reported in the QAPI activities. For many of the audits, there is a two-tier system of review required: the review of the process by the person assigned (i.e. reprocessing by the reuse technician), and oversight of that review by another person qualified to do so (i.e. the technical supervisor observing the reuse technician performing reprocessing).
Patient Satisfaction and Grievances

The intent of QAPI in this area is to use patient satisfaction surveys and patient grievance investigations as a means to identify opportunities to improve care.

- Report and analyze complaints and grievances for trends
- Conduct satisfaction surveys annually
- Develop resolutions

Facilities must monitor and track patient grievance reports and outcomes as required in the Conditions for Coverage V765.
Health Outcomes: Physical and Mental Functioning and Patient Survival

The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and patient survival.

- NKF-K/DOQI 36 Quality of Life (QOL) or similar survey recommended annually

**CMS and Network recommends a facility Standard Mortality Ratio (SMR) \( \leq 1.0 \).**

Facilities are expected to use Dialysis Facility Reports to determine comparison or “average” values associated with clinical outcomes.
Infection Control

The intent of QAPI in addressing infection control is to minimize the number of patients and staff who are exposed to or acquire infectious diseases at the facility.

This requires facilities to:

(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;

(B) Develop recommendations and action plans to minimize infection transmission, and promote immunization; and

(C) Take actions to reduce future incidents.
Infection Control

CMS and the Network recommend that surveillance information is available for review, and should include, but not be limited to:

- Patients’ vaccination status (Hepatitis B, pneumococcal pneumonia, and influenza vaccines)
- Viral hepatitis serologies and seroconversions for HBV (and HCV and ALT, if known)
- Bacteremia episodes
- Pyrogenic reactions
- Vascular access infections and vascular access loss due to infection

The Renal Network recommends all dialysis units to report vascular access infections using the National Healthcare Safety Network (NHSN) created by the Centers for Disease Control and Prevention (CDC). Resources, documentation and recorded webinars are available at: http://www.esrdnetwork4.org/NHSN
The Renal Network, Inc. believes it is important for each dialysis facility to incorporate patient safety into their organizational culture. To help promote patient safety values, TRN is implementing the 5-Diamond Patient Safety Program. The goal of this program is to help dialysis facilities better implement patient safety principles among both staff and patients.

This interactive program is designed so that each dialysis facility that completes a module and submits documentation is awarded a diamond.

Many of these modules can be integrated into your QAPI efforts.
Current 5-Diamond Patient Safety modules include:

- Patient Safety Principles*
- Communication
- Constant Site Cannulation
- Decreasing Patient & Provider Conflict
- Emergency Preparedness
- Flu Vaccination
- Hand Hygiene (Infection Control)
- Health Literacy
- Medication Reconciliation
- Missed Treatments
- Patient Self-Managed Care
- Sharps Safety
- Slips, Trips, & Falls
- Stenosis Surveillance
- Transplantation

* Required Module

For more information and to register for this program, visit our 5-Diamond Patient Safety website:

http://www.therenalnetwork.org/5Diamond/5Diamond.php
Additional Information

If a facility has areas of QAPI that do not meet target levels (per MAT) or areas where the facility performance is below average (per data reports), the facility is expected to take action toward improving those outcomes.

The important aspects of the QAPI program are appropriately monitoring data/information; prioritizing areas for improvement; determining potential root causes; and developing, implementing, evaluating, and revising plans that result in improvements in care.

Records of QAPI activities including minutes or another method of demonstrating this analysis and action must be available for review.

Additional resources can be located on the Network websites at:

www.therenalnetwork.org
[click on the “Conditions for Coverage” link]

Or

www.esrdnetwork4.org
[click on the “Conditions (CfC)” link]
Additional Information

Contact your regional Network office if you have any questions.

ESRD Network 4
(Serving Pennsylvania and Delaware)
   40 24th Street, Suite 410
   Pittsburgh, PA 15222
   Phone: 412.325.2250
   Fax: 412.325.1811

ESRD Networks 9 & 10
(Serving Indiana, Kentucky, Ohio and Illinois)
   911 East 86th Street, Suite 202
   Indianapolis, IN 46240
   Phone: 317.257.8265
   Fax: 317.257.8291

This publication was published and distributed under Contract Numbers HHSM-500-2010-NW004C, HHSM-500-2010-NW009C and HHSM-500-2010-NW010C with the Centers for Medicare & Medicaid Services (CMS). The contents presented do not necessarily reflect CMS policy.

The Renal Network, Inc. Publication Number: CPG-2012-2013