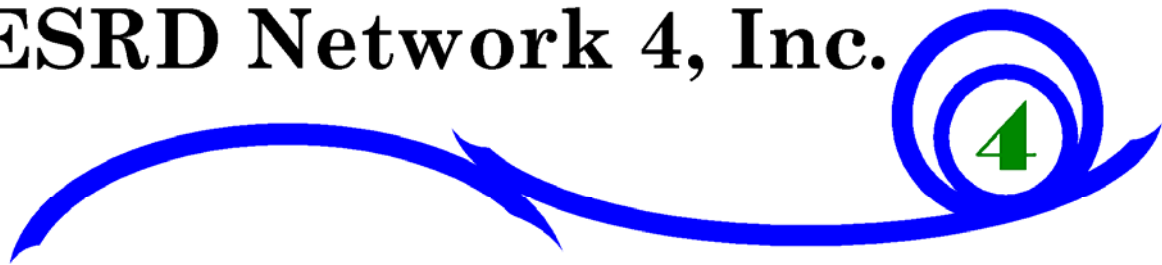


ESRD Network 4, Inc.



: Working for you

Clinical Performance Goals

2009-2010



Health Care Quality Improvement Program



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 CROWNWeb 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 website: www.esrdnetwork4.org. Then click on the “Conditions (CfC)” link and find the MAT tool

The ESRD Network 4, Inc. *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.

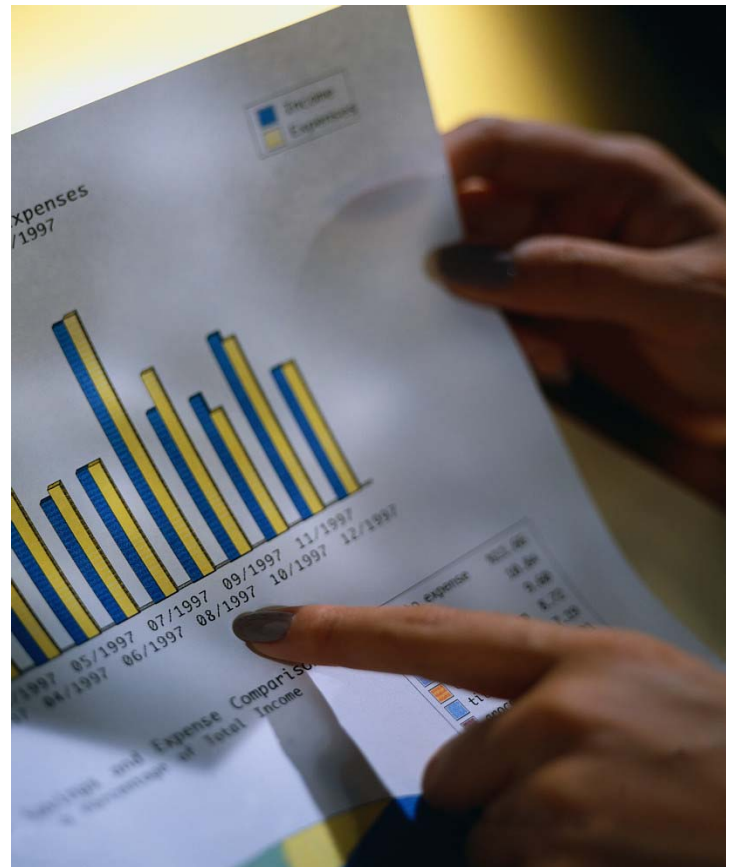
The Network goal is to combine efforts with renal facilities to improve performance in the delivery of quality patient care.

Clinical Performance Measures

The ESRD Clinical Performance Measures (CPM) Project, now in its 15th year, is a national effort led by CMS and the 18 ESRD Networks.

The 2008 National Clinical Performance Measures Report described the findings of several important clinical measures using a random sample of in-center hemodialysis patients (during October-December 2007) and peritoneal dialysis patients (during October 2007-March 2008).

Facilities were 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.



Adequacy of Dialysis

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 include both successful fluid volume management and clearance of toxins. Pre and post-dialysis blood urea nitrogen (BUN) levels were drawn and reported to calculate URR results.

Urea Reduction Ratio (URR)

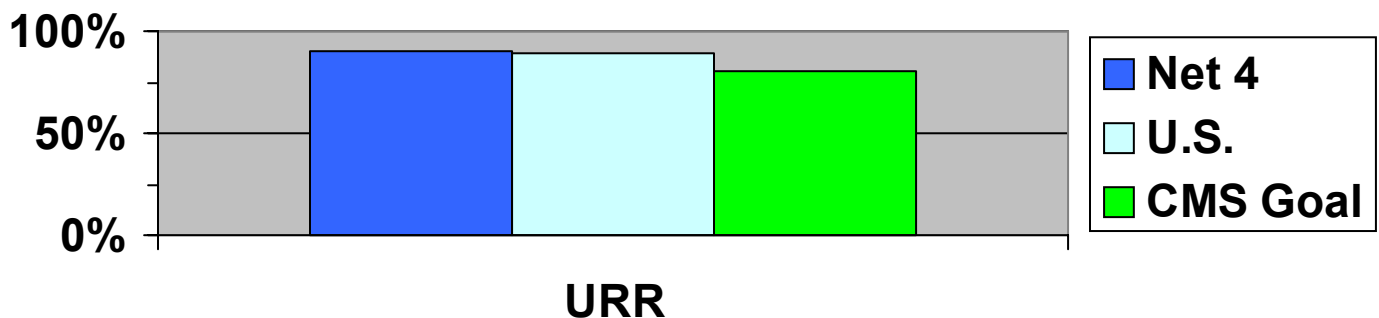
CMS's goal for dialysis units is to maintain 80% of patients with a URR \geq 65%.

The Network's goal is to maintain the URR rate of 90% of patients with a URR \geq 65%.

2008 CPM Network 4 results show that our rate of 90% patients with a URR \geq 65% is greater than the national rate.

	Network 4	U.S.	CMS Goal
Mean URR	74.0	73.0	\geq 65
% Patients with mean URR \geq 65	90%	89%	80%

Compliance to the URR Measure



Adequacy of Dialysis

Kt/V

Kt/V was calculated by using the pre- and post-BUN, post dialysis weight, and time on dialysis.

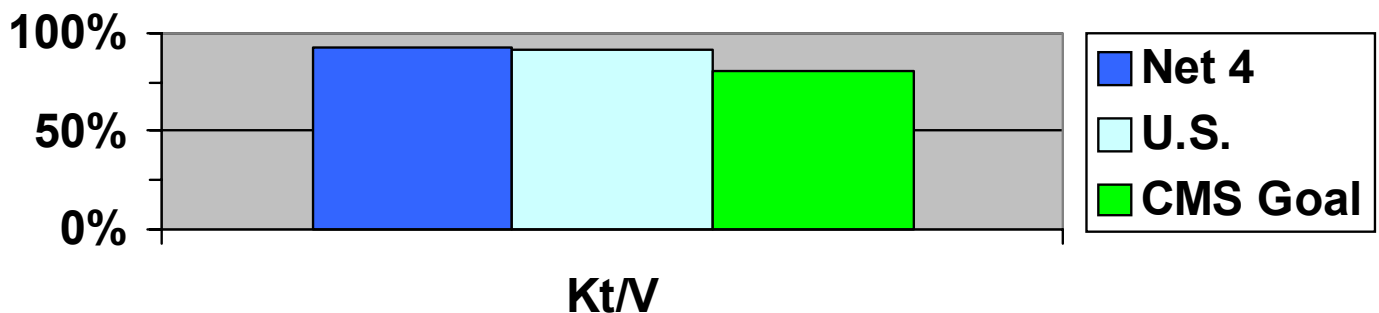
CMS's goal for dialysis units is to maintain 80% of patients with a Kt/V \geq 1.2.

The Network's goal is to maintain 90% of patients with a Kt/V \geq 1.2 (HD) and 1.7 (PD)

2008 CPM Network 4 results show that we had 93% of our patients with a Kt/V \geq 1.2, and the United States had a rate of 91%.

	Network 4	U.S.	CMS Goal
Mean Kt/V	1.57	1.56	\geq 1.2
% Patients with mean Kt/V \geq 1.2	93%	91%	80%

Compliance to the Kt/V Measure



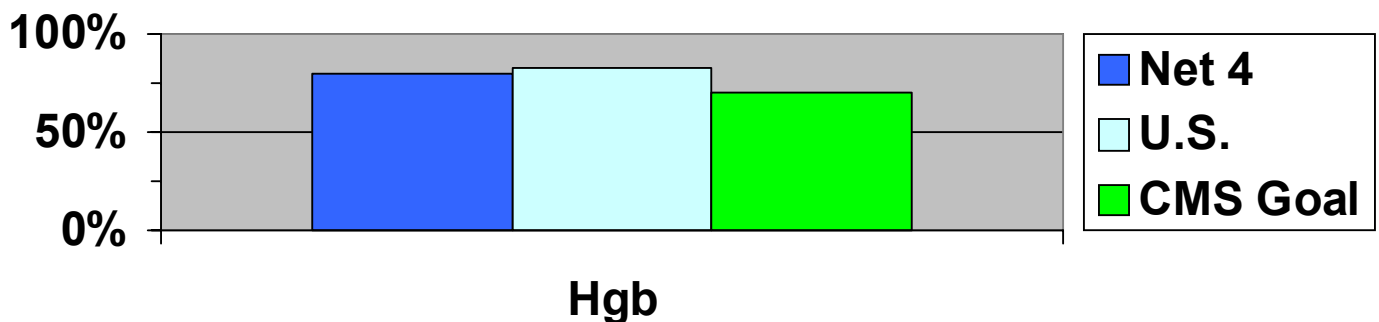
Anemia Management

A normocytic, normochromic 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 intent of QAPI in addressing management of anemia is to maximize the number of patients who achieve the goals for this area.

Hemoglobin (Hgb): CMS's goal for dialysis units is to maintain 70% of patients with a Hgb > 11 g/dL, with an increase in the number of patients within the range of 10-12 g/dL and < 13 g/dL. **The Network's goal is to increase the number of patients with a Hgb within the range of 10 - 12 g/dL, and to decrease the number < 10 g/dL and > 13 g/dL.** 2008 CPM Network 4 results show that we had 56% of our patients with a Hgb within the range of 10-12 g/dL, and the United States had a rate of 50%. The Network exceeded the national rate of Hgb \geq 11.

	Network 4	U.S.	CMS Goal
Mean Hgb	11.8	11.9	
% Patients with a mean Hgb \geq 11 g/dL	80%	82%	70%
% Patients with a mean Hgb 10-12 g/dL	56%	50%	

Compliance to the Hgb Measure (Hgb \geq 11 g/dL)



Anemia Management

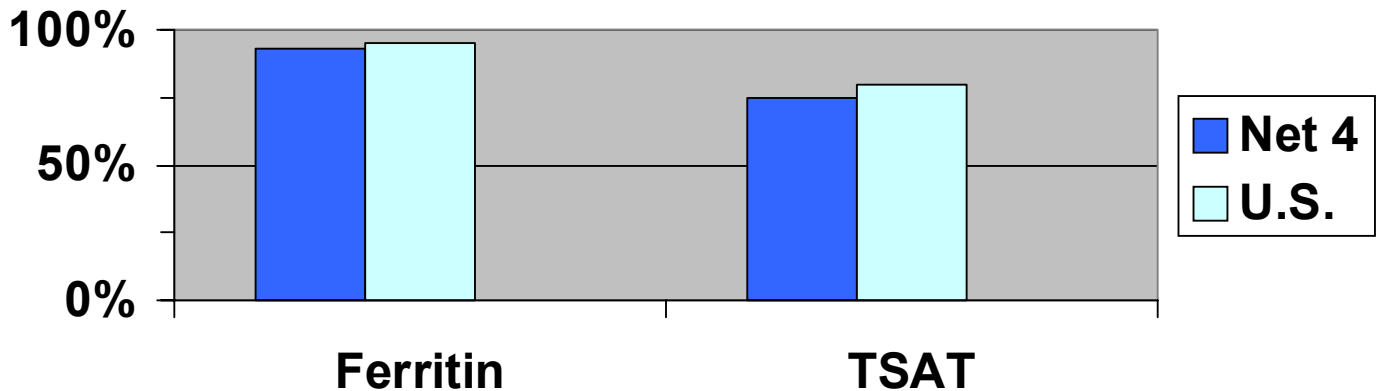
Iron Studies: Iron deficiency is an additional factor that may contribute to CKD associated anemia, since Iron is critical for hemoglobin synthesis.

The Network's goal is to increase the number of patients with a Ferritin level > 200 ng/mL (HD) or > 100 ng/mL (PD). The TSAT goal is to achieve a TSAT \geq 20%.

	Network 4	U.S.
Mean Ferritin (ng/ml)	532	541
% Patients with mean Ferritin \geq 100 ng/ml	93%	95%

	Network 4	U.S.
Mean TSAT %	25%%	27%
% Patients with mean TSAT \geq 20%	75%	80%

Compliance to the Iron Measures



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

Serum Albumin

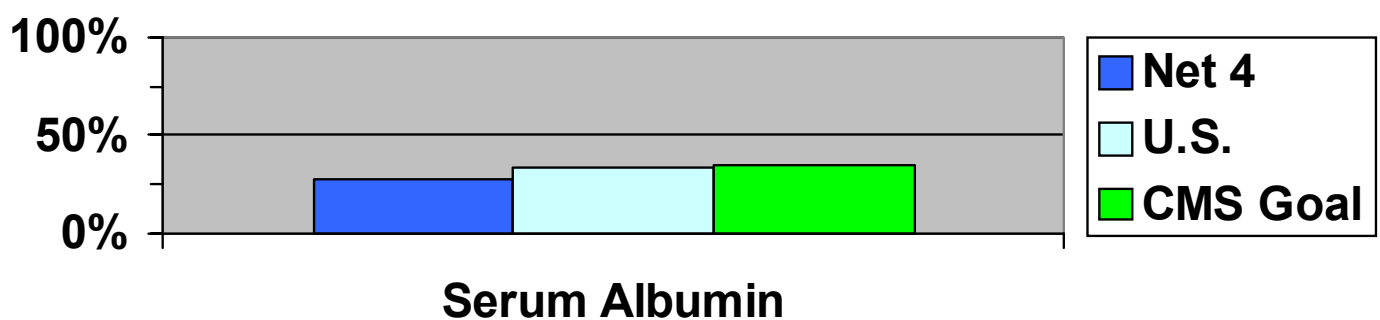
Serum albumin has been used extensively to assess the nutritional status of individuals, and is highly predictive of future mortality risks associated with malnutrition. The intent of QAPI in addressing nutritional status is to maximize the number of patients who achieve the goals for this area.

CMS's goal for dialysis units is 35% of patients to have a mean serum albumin >4.0 gm/dL (BCG) or 3.7 gm/dL (BCP)

The Network's goal for dialysis units is to maintain 35% of patients with a mean serum albumin \geq 4.0/3.7 gm/dL (BCG/BCP).

	Network 4	U.S.	CMS Goal
Mean Serum Albumin BCG (g/dL)	3.8	3.8	-
Mean Serum Albumin BCP (g/dL)	3.4	3.5	-
% Patients with mean Serum Albumin \geq 4.0/3.7 (BCG/BCP)	27%	34%	35%

Compliance to the Serum Albumin Measure



Bone and Mineral Metabolism

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 between 8.4-10.2 mg/dL. Phosphorus levels should be maintained between 3.5-5.5 mg/dL.**

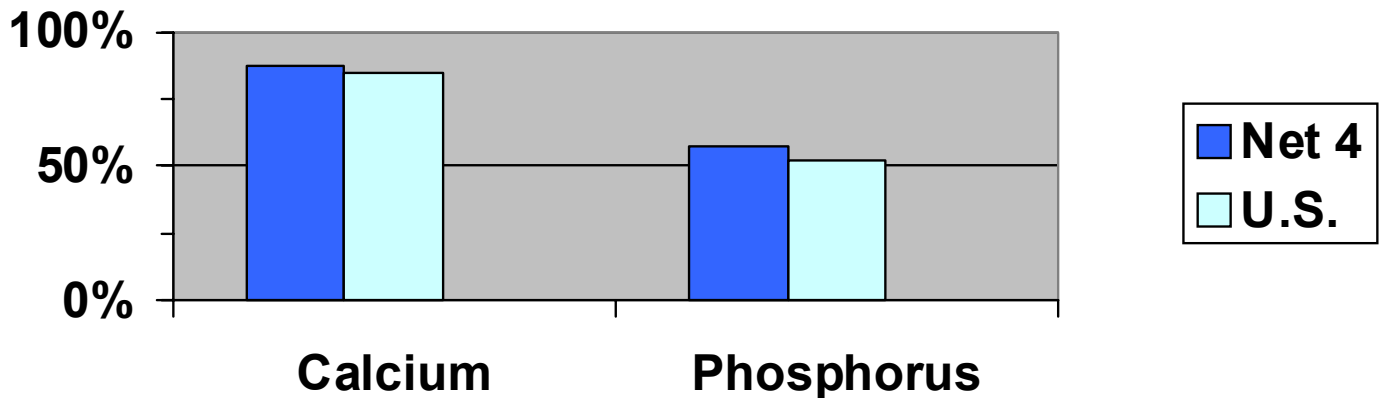
Calcium

	Network 4	U.S.
Mean Calcium	9.3	9.3
% Patients with adjusted Calcium 8.4 - 10.2	87%	85%

Phosphorus

	Network 4	U.S.
Mean Phosphorus	5.0	5.2
% Patients with mean Phosphorus 3.5 - 5.5	57%	52%

Compliance to the Bone and Mineral Measures



Vascular Access

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.

The 2008 CPM Network 4 results show that we had 48% of our patients with an AVF, and the United States had a rate of 49%.

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

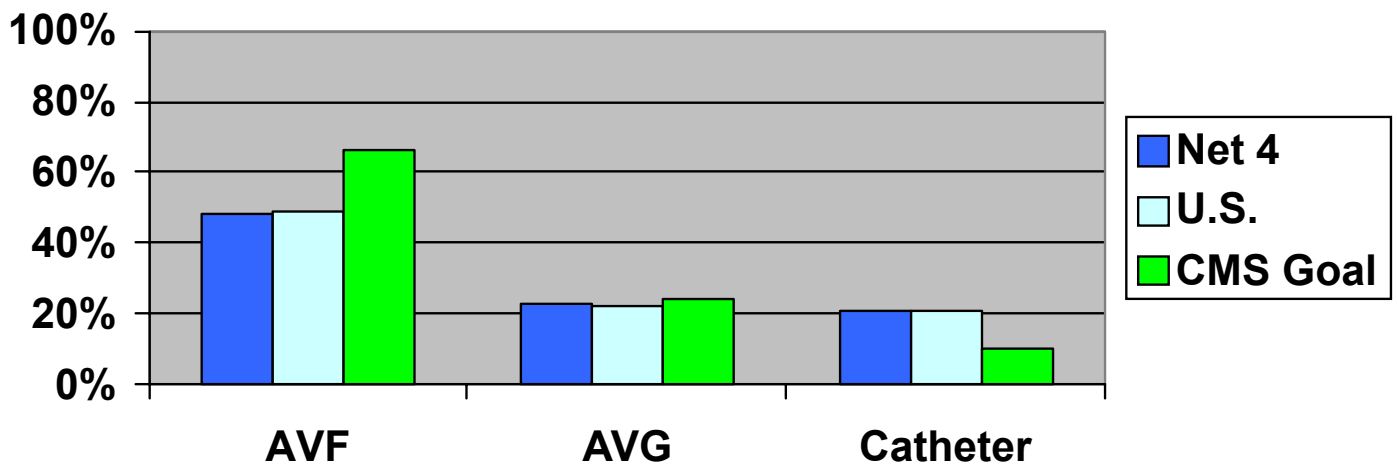
The Network & CMS follow the NKF-K/DOQI catheter guideline:

- **Less than 10% of the adult hemodialysis population should be maintained on catheters 90 days or longer.**

Vascular Access

	Network 4	U.S.	CMS Goal
% Prevalent Patients with AVF	48%	49%	66%
% Prevalent Patients with AVG	23%	22%	< 24%
% Prevalent Patients with Catheter	21%	21%	< 10%

Compliance to Vascular Access Measures



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

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.

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.

- 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, 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.



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; 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 website at www.esrdnetwork4.org

Click on the “Conditions (CfC)” link

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