

III. CMS NATIONAL GOALS AND NETWORK ACTIVITIES

A. IMPROVE THE QUALITY AND SAFETY OF DIALYSIS RELATED SERVICES PROVIDED FOR INDIVIDUALS WITH ESRD

➤ Quality Improvement Work Plan

The major function and responsibilities of all ESRD Network Organizations focus on quality improvement initiatives. These initiatives assist ESRD providers to develop, maintain and modify, as needed, its' internal processes for patient safety and quality of care to achieve better patient outcomes. The Network of New England (#1) has developed a Quality Management Program to accomplish these objectives.

This work plan contains information about targeted clinical or patient experience areas selected by the Centers for Medicare & Medicaid Services (CMS) and the Network Medical Review Board (MRB) that indicates opportunities for improvement or are of such critical importance that ongoing surveillance is required. The work plan at a minimum is updated twice a year after approval from CMS Project Officer. Revisions to specific sections are made during the year as tasks are accomplished or modifications to the plan become necessary. It is considered by the Network Board and staff an essential dynamic tool that provides a quality improvement road map for Network #1.

This Quality Improvement Work Plan (QIWP) is collaboratively developed by the Network of New England's Medical Review Board and professional staff to provide a structured process during the CMS contract year regarding the QI activities that are conducted to support specific national and New England goals. There were four major QI strategies addressed:

- Vascular Access: Fistula First National Initiative
- National CMS Clinical Performance Measures and Lab Data
- Local Quality Improvement Projects, to include catheter reduction in incident and prevalent hemodialysis patients
- Facility-Level Quality Assessment Activities (described in section D)

Each QI strategy is addressed separately.

➤ National Fistula First Vascular Access Improvement Initiative

Background

In July 2003, CMS committed the Networks to a system-wide national improvement project on vascular access management. Fistula First became the first breakthrough initiative of the Centers for Medicare & Medicaid Services (CMS). A National Coalition, consisting of all stakeholders in the

renal community, was established collaboratively to increase awareness and improvement in the rate of use of AV fistulas in hemodialysis patients. As of December 2008, due to the efforts put forth by the hemodialysis providers, nephrologists and vascular surgeons, the U.S. AVF prevalent rate has increased to 48.6%, which is a 16.2% improvement from the baseline rate of 32.4%. Vascular access data is obtained from all providers on a monthly basis to allow for close assessment of provider changes in vascular access management. The large dialysis organizations download data directly to CMS and the independent or hospital dialysis providers send their data to the Network. The Network staff enters the data for analysis on a monthly basis. CMS had established a new goal in 2007 for this initiative; to have a 66% Prevalent AVF rate nationally by March 2009. The Network of New England by the end of 2008 had a prevalent AVF rate of 55.9%.

Partnerships

In the first quarter of 2008, this Network, under the direction of the Medical Review Board shared aggregate vascular access data with each of the Quality Improvement Organizations (QIO) in New England. The data helped the QIO to have a baseline for their state's CKD population vascular access rate. Articles regarding the Fistula First Initiative, directed at the primary care physician, were written and shared. These steps were to lay the ground work for the QIO to become involved in the special project for improvement in the CKD populations care under the 9th Scope of Work. The Network also reached out to local CT hospitals to demonstrate the importance of early placement of the AV fistula and the many adverse effects of catheters and PICC lines to CKD patients.

Vascular Access Surveillance and Intervention

Network staff provided feedback reports to all participating providers each quarter of 2008. Comparable vascular access data by state and nation was also distributed so that the providers could compare their AVF rates to other dialysis providers. New England's prevalent AV fistula rate improved slightly each month and the prevalent catheter rate has decreased 3% to 27%. The Medical Review Board investigated catheters that are in use > 90 days the rate decreased to 12.5%, a decrease of 1.5% suggesting that a permanent access has become fully functional in a greater number of patients.

Of the 159 dialysis providers, 113 (71%) New England hemodialysis providers had a prevalent AV fistula rate equal or greater than 50% as of Dec. 2008 (Table E). The majority of the 46 providers under 50% AVF improved during 2008. The providers with less than 10% AVF rate are hospitals with less than 5 patients. The MRB has and will continue to focus intervention with those providers who are < 40% and have a high prevalent catheter rate. In order to reach the long term AVF Network goal, the MRB has determined that additional focused intervention will be needed for providers with < 50% AVF rates as a future strategy in 2009.

Table E: December 2008 Prevalent AVF rate by Percent Group

Prevalent AV Fistula Percentage Rate	Number Of Facilities In This Range
10% or less	2
30 to 39%	8
40-49%	36
50-59%	55
60-69%	37
70% or higher	21
Total Providers Reporting	159

Source: Provider specific vascular data reports Dec. 2008

Table F: Percentage Change of Prevalent AVF, by State and Network Between Jan. 2008 and Dec. 2008

STATE	Jan. '08 Prevalent AVF rate	Dec. '08 Prevalent AVF rate	Percentage Change
CT	50.6%	54.0%	+3.4%
MA	53.7%	56.2%	+2.5%
NH	64.1%	67.2%	+3.1%
RI	56.2%	58.0%	+1.8%
ME	57.4%	58.6%	+1.2%
VT	47.4%	46.3%	- 1.1%
Network	53.8%	55.9%	+2.1%

Source: Monthly provider and vascular access reports

The greatest rate of improvement was shown by the state of Connecticut followed closely by New Hampshire (Table F). The clinical managers of dialysis units with <50% prevalent AV fistula rates received a letter of concern from the Medical Review Board requesting a plan of improvement. These plans were evaluated and technical assistance provided by Network QI staff. The Network's Quality Managers conducted site visits to providers with < 40% prevalent AVF rates. A few of these providers have unique ESRD populations, serving patients that can only have an indwelling catheter due to co-morbidities, drug addiction or severe peripheral vascular disease. The hospital providers often have a small patient population starting chronic hemodialysis with a catheter prior to transfer to their local hemodialysis clinic and out-patient vascular surgery. There are significant barriers to improvement in 5 providers <40% AVF. The other 5 have used strategies suggested by the Network and have increased their AVF rates.

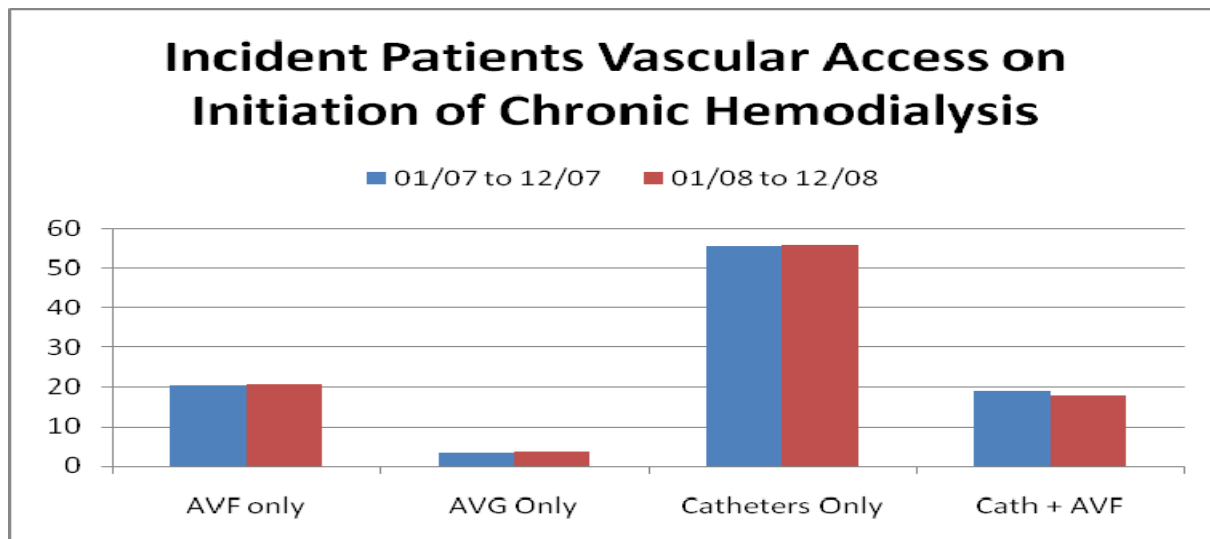
Physician Profile Reports

The Network staff met with the Medical Review Board (MRB) in Q1/08, Q2/08 and Q4/08 for ongoing provider intervention development. Fistula First updates were delivered at each meeting

and the MRB responded with various new strategies, which the QI staff implemented. The MRB remains concerned about the high rate of incident and prevalent catheters.

One of the strategies that were carried out was the development of a nephrology practice report card, utilizing the data from the ESRD Disease Medical Evidence Report (Form 2728). The provider profile report contains the individual nephrologist by UPIN number and the number of incident patients he/she signed for in 2007, the length of time the patient was followed and what vascular access the patient initiated chronic hemodialysis. In March 2008 the reports were sent to 159 hemodialysis Medical Directors, each received a report specific to the clinic with UPIN numbers of the referring nephrologists. Comparative data by state and Network was also included. The purpose of these reports was to stimulate practice changes for earlier referral of vascular access creation in the CKD patients in the hope that the incident catheter would be reduced and incident AV fistulas would increase.

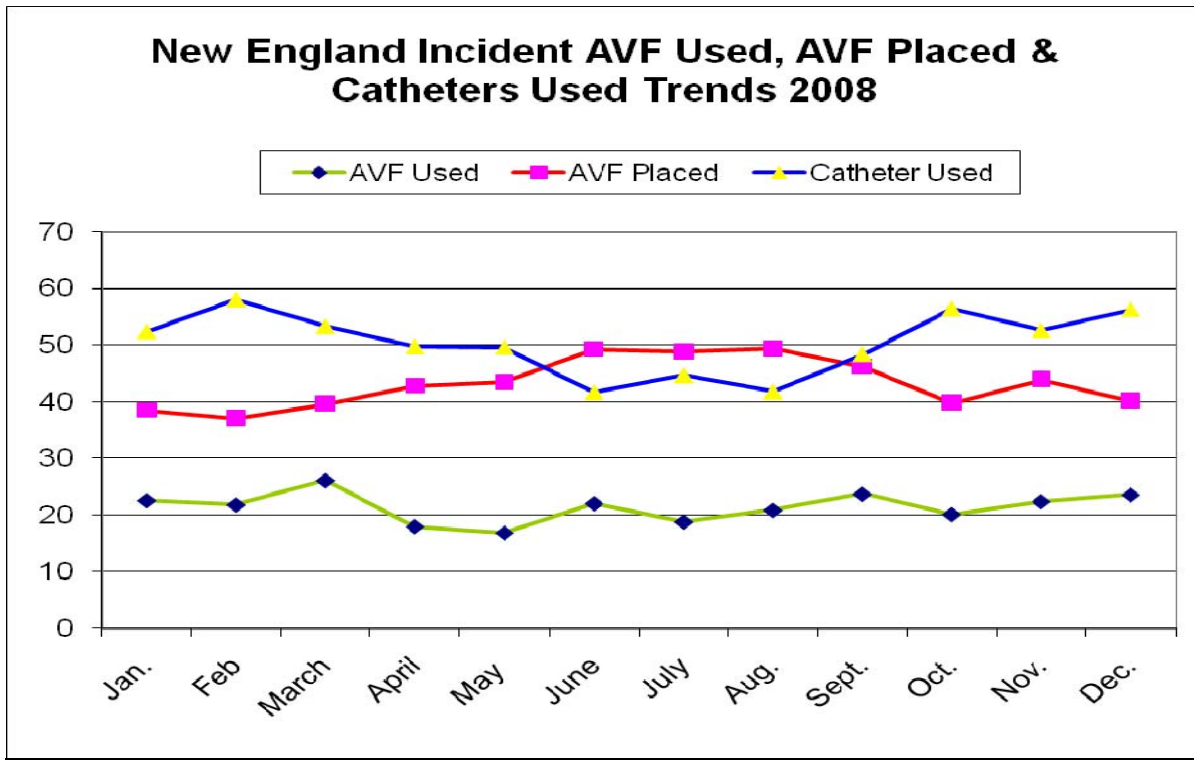
Figure 10



Source: 2728 forms submitted 2007 to 2008

Figure 10 above illustrates that there has been very little change in what type access the incident hemodialysis uses to initiate chronic hemodialysis. On average 20% incident patients in New England start hemodialysis with an AV fistula, 18% start with a catheter and AV fistula in place and on average 56% start with a catheter only. The NKF-KDOQI guidelines suggest that 10% of incident patients will have a catheter only and 50% of incident patients should have an AVF. Combined the AVF only and catheter with AVF and it equals 48% for the past two years approaching the KDOQI guideline however with more than half of incident patients starting with a catheter only, there remains much room for improvement. Figure 11 illustrates the ongoing challenge of the low percent of AVF's placed in new hemodialysis patients in New England and the high rate of catheters used to initiate chronic treatment.

Figure 11: Percent of Incident AVF Used, AVF Placed and Catheters used to initiate treatment 2008:

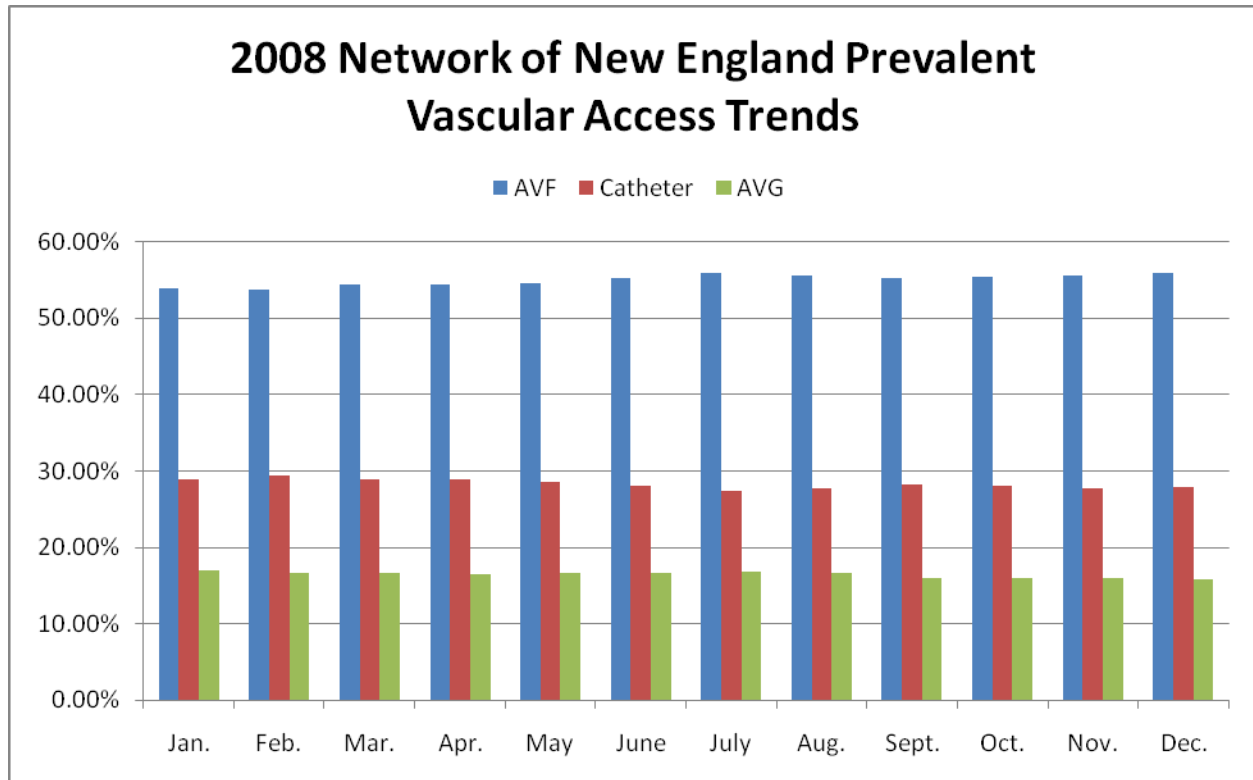


Source: CMS Form 2728

The MRB determined that the CKD population stages 3 & 4 and their caregivers were not receiving the vascular access message, “Fistula First and Catheter last”. Network #1 staff communicated with all the New England Quality Improvement Organizations (QIO’s) to request their support in the Fistula First Initiative. The collaboration with the QIO’s has not resulted in improving the education of both hospitals and physician office practices of reducing catheter use and increasing vein mapping for AVF evaluation

Network #1 has provided to each of New England’s QIO’s both state and national vascular access data, educational tools and CKD vascular access management articles for their web sites or hospital newsletters. The tools and articles stressed avoidance of catheters for the initiation of chronic hemodialysis and encouraged vein preservation and early referral for vascular access.

Figure 12: New England Prevalent Vascular Access Network Trends 2008



Source: Monthly provider reports

Prevalent Population

As shown (Figure 12), by Dec. 2008 the prevalent AVF rate is up to 55.9% and the prevalent catheter rate decreased to 27.8% with a decrease in AV grafts to 15.87%. Since the incident rate drives the prevalent rate, a further decrease in the prevalent catheter rate will not be seen until the incident catheter rate can be reduced. The awareness, educational endeavors and technical assistance conducted have concentrated on the current chronic population, the dialysis facilities, the nephrologists and the vascular surgeons. The MRB will continue these activities. However, new strategies need to be expanded into areas that are not normally in the Network's purview such as, the acute care hospitals and staff, the primary care physician's office, and the pre ESRD patients and their caregivers. The emphasis has been on education regarding vein preservation and earlier referral to the nephrologists and vascular surgeon for AV fistula evaluation. The Medical Review Board recognizes that nearly 50% of all patients start dialysis emergently and often catheters cannot be avoided. However AV fistula evaluation can be done in the hospital once the patient is stabilized. The other 50% of CKD patients that are being followed by a primary physician or nephrologists will benefit from early referral for AV fistula evaluation so that maturation and or revision can take place prior to initiating hemodialysis.

A synopsis of 2008 major projects carried out or started for the Fistula First Breakthrough Initiative:

- ***Communication and Education Regarding Fistula First*** was accomplished in a number of different venues. The Network's website maintains current data on each New England's state progress as well as national comparative data. There are links to the fistulafirst.org site and educational resources for vascular management. The chairman of the Medical Review Board gave an update on the Fistula First initiative during the Network Annual meeting in October. The Annual meeting was the Network's 20th meeting. This milestone was an impetus to look at the history of vascular access. The Network was honored to have Dr. James Cimino speak on his work in the development of the first arteriovenous fistulae in 1966. The attendees gave a standing ovation for this pioneer to recognize his contributions to one of the most important advances in the history of dialysis.
- Commendation awards were also given to publicly recognize the dialysis clinics with prevalent AVF rates consistently equal or higher than 60% for the entire year. Providers with at least a 15% improvement over the course of the year also received a commendation. Special recognition was given to the providers that had achieved $\geq 66\%$ prevalent AVF rate. Fistula First educational posters, an educational booth and vascular management tools and articles were all part of the annual meeting.
- The QI manager wrote updates on the progress of the Fistula First initiative for Network Notes Newsletter. Quarterly feedback reports were sent to all Clinical Managers and Medical Directors. Vascular management tools and quality improvement tools were sent to providers with less than a 40% AVF rate. The Network produced in 2006, a patient education video, "The Patient Speaks", it continues to be requested from regions throughout the country. The surgeon's educational video was also mailed out to surgeons or dialysis clinics who requested a copy. The Network developed vascular passports and vein preservation cards which was the Renal Physicians Association tool kit for CKD care. These tools are very popular and copies have been mailed to renal providers and physician's offices throughout the USA.
- Network staff also participated with group and individual conference calls with CMS/NW EDs/QID/PSCs/LDOs representatives throughout 2008 and completed all required CMS assignments in preparation for the scheduled conference calls. The QI manager served on the National Task force for the Fistula First Breakthrough Initiative and participated in planning conference calls throughout 2008. The QI manager was the liaison to the other Network's QI departments for the provider education task force.
- An educational day was held for patient care technicians in Sturbridge, MA on April 24th, 2008. It was very well attended and the evaluations indicated a strong need for more education and training. The QI manager also gave a presentation on vascular assessment and cannulation in CT and the feedback was excellent. Staff education is a strong component to improving vascular access management.
- ***Education and Communication with Other Organizations:***
 - The QI manager gave a presentation on vascular access assessment and cannulation to the patient care staff and Medical Director of a newly opened hemodialysis clinic in CT.
 - Each Quality Improvement organization received vascular access data for the states they cover as well as comparative national data.

- Articles directed at hospitals and primary care physicians were either placed in hospital newsletters or on the QIO's website.
- ***Expanded the Data Base:*** The Network staff continues to increase the database of New England vascular surgeons and interventional radiologists when the Network Directory is updated. This expanded database was used to mail profile reports to twenty one high volume vascular and general surgeons from each of the New England states. The reports were based on Medicare claims data for vascular access procedures. The surgeons with the largest amount of claims data received the reports with a cover letter acknowledging that since the report only included Medicare claims data that it was understood to be a limited representation of their vascular surgery. The report was a comparative “snap shot” of the placement of vascular accesses in 2004 and 2006 for each surgeon's Medicare patients. A feedback form was included requesting that the surgeon share practice patterns unique to their area. State and Network vascular access data was also included in the mailing.
- ***Collaboration with Other Organizations:*** Both Fresenius Health Care and DaVita are large dialysis organizations (LDOs) that have met with the Network staff and shared their strategies to increase AVF rates as well as reduce the rate of catheter use. The LDOs have distributed Fistula First tools and patient education tools throughout their clinics. Several conference calls have been held with the QIOs to explore possible collaborative efforts on the CKD project for their 9th scope of work. The QI manager has held on site focused interventions or telephone coaching which help facilitate the development of strategies to improve AVF rates in VT and CT. This Network has identified a Primary Care Physician (PCP) in New York that is a champion for educating PCP's about the importance of shared management with nephrologists on CKD cases that have reached CKD Stage 3 or 4. He has helped this Network develop materials for PCP's.
- ***Website Development:*** Network #1 website has been enhanced to include information on Fistula First. The site has been improved with current Fistula First data and links to the national sites for tools for improvement for professionals and patient education.

➤ National CMS Clinical Performance Measures Project

Background

The ESRD Clinical Performance Measures (CPM) Project, now in its fifteenth year, is a national effort conducted by CMS and its eighteen ESRD Networks to give dialysis providers, renal community, public policy agencies, and consumers comparative clinical improvement measures for performance evaluation. Since 1994, the project has documented continued improvements in dialysis management; specifically in areas of adequacy of dialysis and anemia management. The providers of dialysis services are to be commended for their ongoing efforts to improve patient care.

Since the onset of the project, on an annual basis, a random 5% sample of adult ESRD patients (> 18 years) has been drawn from each Network. In 2000, patients (ages > 12 and < 18 years) were added to the patient sample. The final 2008 CPM report was given to the Networks on February 24, 2009. The national patient sample size for the 2008 CPM Report (2007 data) consisted of 8,730 in-

center hemodialysis patients, and 1,472 peritoneal patients. The sample size selected for Network #1 was 484 hemodialysis patients, and 56 peritoneal dialysis patients. The total pediatric hemodialysis patients reported (not defined by Network) were 740 and for peritoneal dialysis patients 753. The CPM's were developed in the areas of hemodialysis and peritoneal dialysis adequacy, vascular access and anemia management. The serum albumin was also chosen as an indicator for assessing nutritional risk.

Each year, the Network staff coordinates the work effort to assist providers in the abstraction of CPM data. In July 2004, Networks were notified by CMS that the Large Dialysis Organizations (LDO's) would submit electronically to CMS most of the data required for the CPM data file. The small Dialysis Organizations (non-LDO's) continue submitting data via the paper forms and the data was entered by Network staff into a standardized software program for aggregation and analysis by CMS. This CPM data collection process begins in May and is completed in October. Data collection for the 4 Veterans Administration hospitals was conducted in August 2008 and completed by October 2008 for a total of 72 hemodialysis forms and 0 peritoneal forms.

Hemodialysis patient data for the last quarter of 2007 (October, November, December) was reported. The peritoneal patient data was from the last quarter of 2007 and the first quarter of 2008. The data represents clinical information designed to reflect values for the four major domains of care.

- Pre- and post- dialysis blood urea nitrogen (BUN) levels were drawn and reported to calculate urea reduction ratios (URR) for adequacy of dialysis.
- KT/V for adequacy was calculated by using the pre- and post- BUN, pre- and post- dialysis weight, time on dialysis and the type of dialyzer used at the time the BUNs were drawn.
- Hematocrits and hemoglobins were reported, plus Erthropoetin Stimulating Agents (ESA) and iron related measures to determine status of anemia management.
- Patient's serum albumin levels were reported as well as the primary vascular access type and screening for stenosis. National comparative findings by the percent achieving the target measurement for adult ESRD patients (≥ 18 years) receiving dialysis in the 2007 observation study period are as follows in Table G:

Additional measures related to anemia management for hemodialysis patients were also collected. The national median transferrin saturation was 27% (Network #1, 27%). The national median for serum ferritin concentration (ng/mL) was 541 ng/mL, (Network #1, 499 ng/mL). Seventy-one percent of patients nationally were prescribed iron IV. Nationally, 92% of all patients were prescribed (ESA). For Network #1, the percent of patients prescribed is 93%. ESA administration was down from 94% nationally and 94% for Network #1 from the previous report. This reduction is due to the new Medicare payment formula.

Table G: CMS Report Comparative Hemodialysis Data for Network # 1

	Network Target	National Data+ 2007	National Data+ 2008	Network Data+ 2007	Network Data+ 2008
Mean URR % \geq 65	90 %	87%	89%	91%	90%
Mean KT/V \geq 1.2	90 %	90%	91%	95%	93%
Mean Hemoglobin \geq 11 gm/dL	80 %	84%	82%	83%	85%
Mean Tsat % \geq 20%	80 %	79%	80%	80%	81%
Mean Serum Ferritin % \geq 100 ng/mL	80 %	95%	95%	95%	96%
Prevalent Pts with Serum Albumin \geq 3.5/3.2 gm/dL BCG/BCP	80 %	81%	82%	79%	81%
Prevalent Pts with Serum Albumin \geq 4.0/3.7 gm/dL BCG/BCP	32 %	34%	34%	31%	35%
Prevalent Pts with Catheter \geq 90 days	Decrease 1% annually	22%	21%	20%	18%
Prevalent Pts with AVF	54.6% by 3/08	45%	49%	57%	58%

+Source: 2006 Report has 2005 data. CMS/CPM 2007 Report has 2006 data. CMS/CPM 2008 Report has 2007 data.

Data Validation for the National ESRD Clinical Performance Measures

This Network conducted a data validation in August and October of 2008 for the 2008 National CPM Data Project. The hemodialysis and peritoneal dialysis cases selected for the abstraction were defined by CMS. The hemodialysis validation sample was drawn from a 5% Network random sample of the original hemodialysis patient selected. The peritoneal validation sample was drawn from a 5% National random sample of the original peritoneal patients selected.

A total of 22 providers were selected for data validation of their 2007 CPM data. A total of 23 medical records (17 HD and 6 PD) were reviewed by the Medical Quality Manager. Selected records reviewed were entered into a specific validation data entry program and submitted to CMS for analysis. The Medical Quality Manager did a random cross check with the original database and found a close correlation between both files.

➤ Annual Lab Data Collection

The only current source of provider level clinical information is available from the voluntary lab data collection project which this Network Organization has participated in for the past several years starting in 1999.

Network #11 coordinates the project by working with independent dialysis facilities and the Large Dialysis Organizations (LDO's) to collect data on nearly 100% of patients in all dialysis facilities in Network 11 and other ESRD Networks. For the Quarter 4 (Q4) 2008 collection period conducted in 2009, all of the 18 Network Organizations participated in the project

Since 2003, (Q4 2002), Network 11 has collaborated with Computer Sciences Corporation (CSC) and CMS to coordinate lab data collection for all Networks. Large Dialysis Organizations submit data to CSC. The data is formatted according to Network 11 specifications and sent to Network 11. Each participating Network collects data from non-LDO facilities and submits the data together with a patient demographics file to Network 11. Network 11 merged the data and produce facility-specific reports for each Network. These reports provide the facility with state and Network comparisons. Reports produced include the following:

- Facility Characteristics
- HD Quality Indicators (tabular and graphic)
- PD Quality Indicators (tabular and graphic)
- HD Percentile Ranking
- PD Percentile Ranking
- HD Means and Median Report
- PD Means and Median Report

The success of this project depends on the local voluntary data collection provided by independent and hospital dialysis facilities for 3 months (October, November, and December). The retrospective lab information patient specific data collection spread sheets have been prepared by Network #1 and sent to participating providers. Patient specific information is returned to the Network to be compiled into a data file then sent to Network 11 for analysis with the LDO data. The data collection process for the 55 non-LDO providers in 2008 was a labor-intensive activity spanning approximately four months of Network staff time to complete.

When the provider specific data is received from Network 11, a unique provider specific report is prepared and distributed to independent and hospital dialysis providers in New England to allow each provider to see its performance compared to the state and Network #1.

Due to increased security requirements to protect Patient Health Information (PHI), a new process was used to collect this data. Network #1 purchased thumb drives for each provider, which is password protected because it contains patient information for only its specific provider. Confirmation of receipt of the data is required by calling the Network staff to get the password. Each provider returns the thumb drive populated with the required information.

➤ Network #1 Indicator Measures

The Medical Review Board annually evaluates comparative data to benchmark the clinical performance indicators of New England as compared to national and other Network results. Based on the Lab Data Project which represents all patients, the Medical Review Board selected these clinical measures for focused QI activity: Anemia (Hgb), Nutrition (Serum Alb), and Vascular Access (catheter). The Network target goals are reviewed and adjusted by the BOD/MRB on an annual basis.

The data result difference between the CMS/CPM rates and the Lab Data Project rates is of interest to the MRB. Since the Lab Data Project is based on 100% patient sample at the provider level and is more recent (2008 data), the MRB relies on this data for QI intervention activities (Tables G and H).

**Table H: Comparative Trend Data by Clinical Indicator
Hemodialysis Patients**

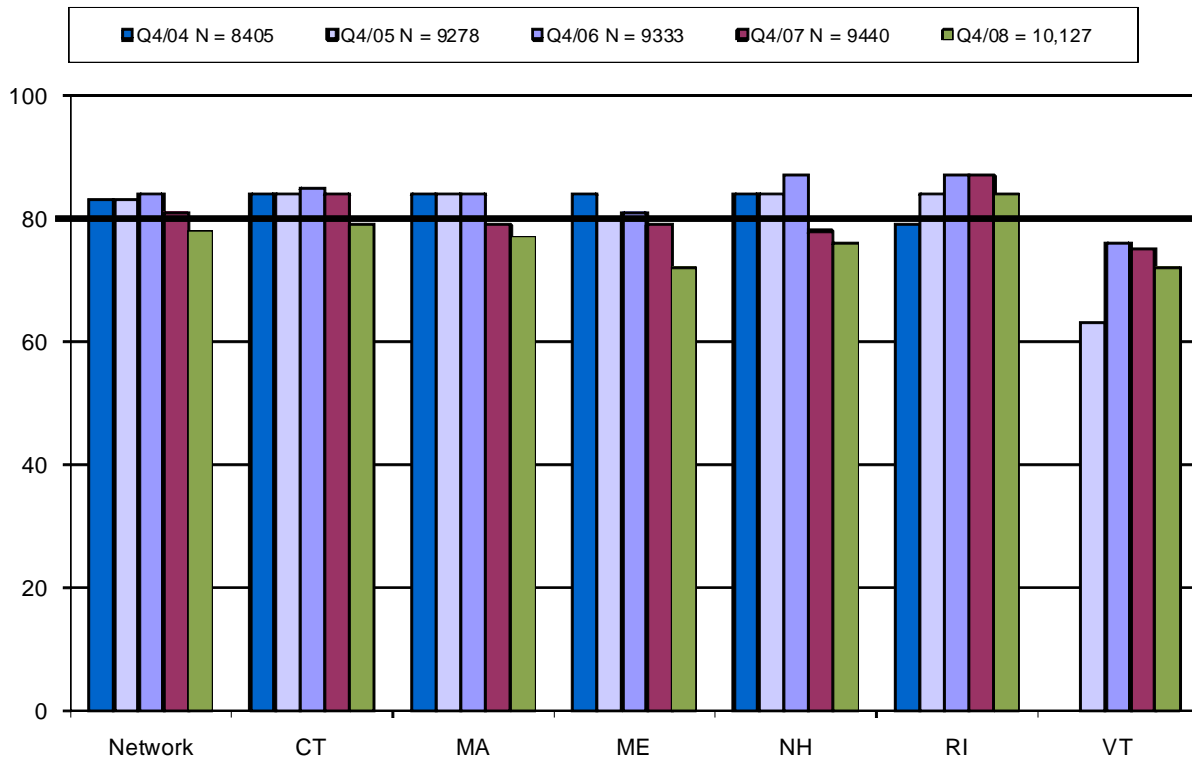
INDICATOR	Target		Network Lab Data 2004+ 8,485 Patients	Network Lab Data 2005+ 9,278 Patients	Network Lab Data 2006+ 9,333 Patients	Network Lab Data 2007+ 9,440 Patients	Network Lab Data 2008+ 10,127 Patients
	CMS	Network					
Mean URR % \geq 65	80%	90%*	91%	89%	91%	91%	91%
Mean KT/V \geq 1.2	84%	90%*	91%	93%	94%	95%	95%
Mean Hemoglobin \geq 11 gm/dL (Anemia)*	80 %	80%	83%	83%	84%	81%	78%
% Pts with mean Hgb 10-12 g/dL	N/A	80%	-	-	47%	54%	60%
% Pts with mean Hgb < 10 g/dL	N/A	10%	-	-	4%	5%	5%
% Pts with mean Hgb between 12.1 – 12.9 gm/dL	N/A	N/A			34%	31%	29%
% Pts with mean Hgb \geq 13 gm/dL	N/A	10%	-	-	15%	10%	6%
Mean Tsat % \geq 20%	80%	80%	77%	76%	79%	80%	84%
Mean Serum Ferritin % \geq 100 ng/mL	80%	80%	83%	84%	85%	87%	73%
Prevalent Pts with Serum Albumin \geq 4.0/3.7 gm/dL BCG/BCP (Nutrition)*	35%	32%**	35%	30%†	31%	35%	34%
Prevalent Pts with Serum Albumin \geq 3.5/3.2 gm/dL BCG/BCP (Nutrition)	80%	80%	84%	80%	80%	83%	81%
Prevalent Pts with Catheter* \geq 90 days (Vascular Access)***	10%	Reduce 1%/yr	FF data 2004 14.66%	FF data 2005 14.15%	FF data 2006 13.88%	FF data 2007 12.5%	FF data 2008 12.5%
Prevalent Pts with AVF***	66% by 2009	\geq 54.6% by 3/08♦	Net 45.2% (4,179) Nat 37.4% (102,593)	Net 47.2% (4,579) Nat 41.0% (117,742)	Net 50.1% (5,076) Nat 45.0% (138,151)	Net 53.8% (5,523) Nat 48.5% (157,107)	Net 55.5% (5,949) Nat 51.2% (165,127)

*Adjusted higher by BOD/MRB on 11/07/2006
 ◆ Adjusted higher by BOD/MRB on 11/7/06. Adjusted again 11/13/2007
 **Stretch Goal 35%
 +Denominator for each indicator varies due to the variation in voluntary reporting. Source: Lab Data Collection
 ***Fistula First Provider Vascular Reports 12/04, 12/05, 12/06, 12/07, 12/08

Anemia

Anemia develops for all patients with chronic kidney disease (CKD) and is a risk factor for clinical complications and quality of life in 2008. K/DOQI recommends a target level of Hgb 11.0-12.0gm/dL. This Network’s Hgb levels ≥ 11 gm/dL in hemodialysis patients has decreased since the last data collection, and a reduction in peritoneal dialysis patients was noted. State variation in the level of Hgb in both types of patients is also of concern (Figures 13 and 14). Recent change in reimbursement protocols by CMS for Epogen, an intravenous medication used to treat anemia, may be contributing to this pattern change. The MRB has concerns about some recently adjusted treatment protocols for anemia management that specifically address Hgb levels and Epogen dose. Warnings issued by the FDA in 2007 and 2008 on Hgb levels have also contributed to confusion and caution on dosing protocols. Fragmented management of the Epogen dosing formula when dialysis patients are hospitalized has been observed. This may also be attributing to the challenges of dialysis providers to maintain the targeted Hgb when the patients return from an extended hospital stay.

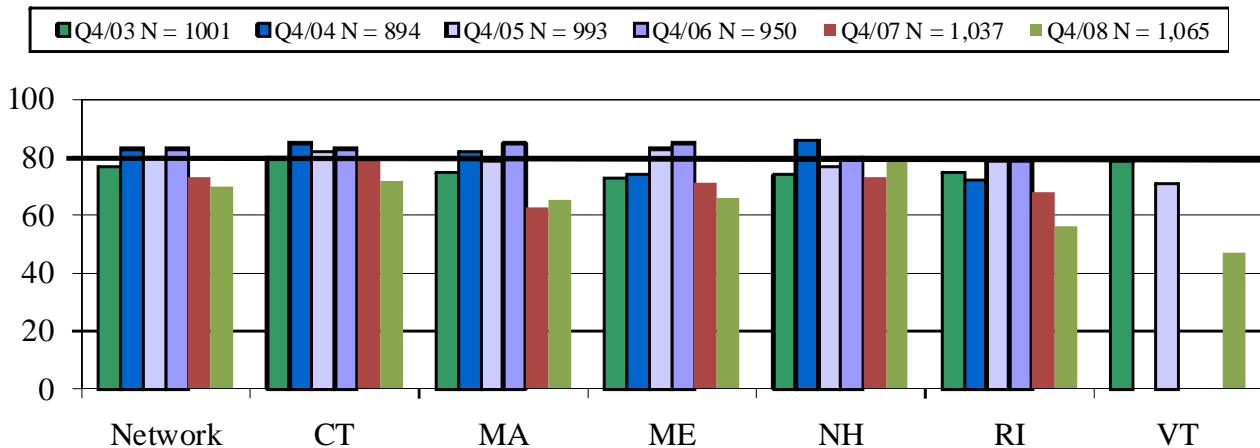
Figure 13: Hemodialysis - % of Patients with Hemoglobin ≥ 11 gm/dL



Source: Lab Data Collection – Data Used from 4th Quarter of Previous Year.

The goal for 2008 was to sustain the percent of patients with Hgb \geq 11gm/dL at 80%. NOTE: The recent FDA black box warning on risks associated with Erythropoiesis Stimulating Agents (ESAs) are having an impact on anemia treatment protocols that are causing lower Hgb levels. The MRB in March 2006 adjusted its goal to 80% until this matter is further researched. The MRB will begin to evaluate trends focusing on the following indicators for hemodialysis and PD patients. Hgb level \geq 13 gm/dL in 10% of dialysis patients, Hgb levels between 10-12 gm/dL in at least 80% of dialysis patients and Hgb levels $<$ 10 gm/dL in 10% of dialysis patients. New goals will need to be established in 2009.

Figure 14: Peritoneal - % of Patients with Hemoglobin \geq 11 gm/dL



Source: Lab Data Collection – Data Used from 4th Quarter of Previous Year for all quarters and rounded.

Activity Description: Provider specific trend data from voluntary lab data were used to generate new feedback reports. Intervention was performed for the lowest 10% of providers with poor Hgb rates ($<$ 80%) for at least two of the last report periods. These interventions are based on scripted phone interviews with facility nurse manager, conducted by Network QI staff. In addition the high performers, the top 5% of providers, were requested by phone to share their treatment models as best practice models.

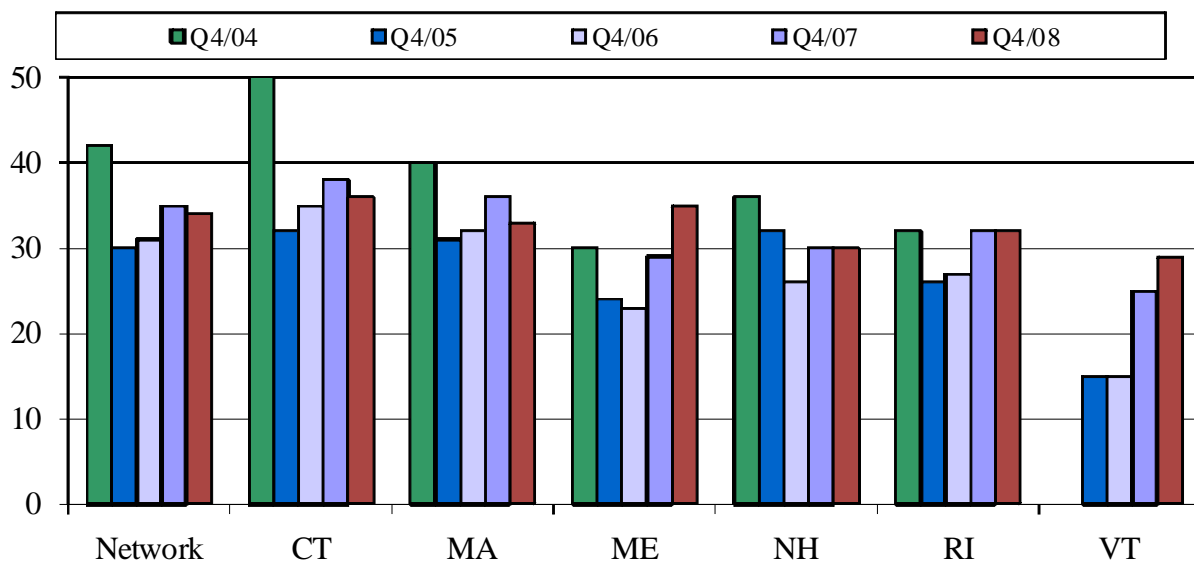
There were 10 providers that met the project selection criteria. The findings from the interview indicated that only 3 providers were still below 80 % Hgb \geq 11 gm/dL (75%, 77% and 75%). Those providers submitted a Quality Improvement Plan, which was reviewed and evaluated by Network QI staff. The Network staff gave feedback with procedure recommendations to these providers. Quarterly checkup by phone reviewing data results were conducted. These 3 providers improved in 2008. The other improved providers were re-measured in early 2008 to determine if they sustained improvement. The 10 highest providers reported the most important factor is having a designated anemia coordinator. Both DaVita and FMC have established new anemia protocols, based on CMS new EPO payment protocol.

Nutrition Management

Serum Albumin is considered a marker for the measurement of the nutritional status of dialysis patients. Prevention of malnutrition begins in the early stages of Chronic Kidney Disease (CKD) because patients experience a loss of appetite and are often suffering from nausea related to renal disease. These problems become more complicated with the onset of dialysis because the treatment itself causes electrolyte imbalance and protein loss. Malnutrition has been reported in 44% of predialysis patients, 30% of hemodialysis patients and 40% of peritoneal patients. There are two methods to test Serum albumin levels (BCG and BCP) each having a slightly different reference range which results in the benchmark level being different. Because malnutrition has a significant effect on survival, the New England Network’s Medical Review Board has determined this is an area of challenge for this Network and continues to be investigated to improve nutrition management (Figure 15).

A stabilized Serum albumin of $\geq 4.0/3.7$ g/dL is associated with improved outcomes for chronic dialysis patients. Patients with a pre-dialysis treatment serum albumin that is low should be evaluated for the cause of possible protein-energy malnutrition and /or inflammation should also be explored. Recent research is revealing a more complex cause and effect relationship of malnutrition, which cannot be resolved by increased protein and exercise. More in depth patient assessments are needed to rule out inflammation sources such as dental complications. Both inflammation and nutritional factors are responsible for low serum albumin.

Figure 15: HD - % Serum Albumin Optimal ≥ 4.0 BCG / 3.7 BCP gm/dL



Source: Lab Data Collection – Data Used from 4th Quarter of Previous Year.

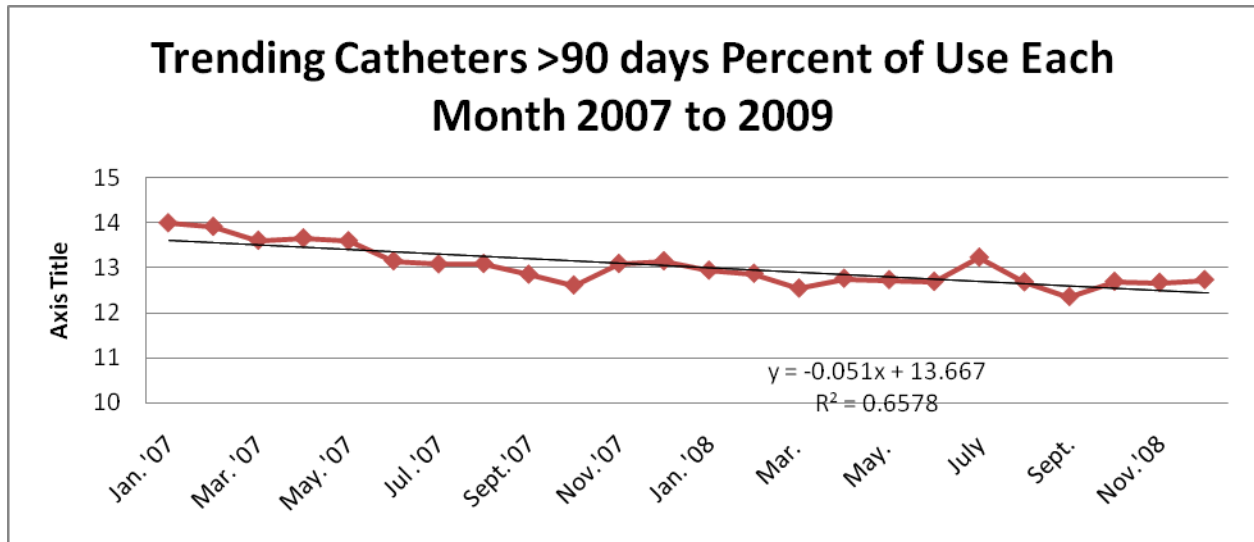
Activity Description: The MRB set a target of 32% (stretch goal of 35%) of hemodialysis patients having a serum albumin of $\geq 4.0/3.7$ g/dL by June 2008 and 35% of hemodialysis patients by June 2009. The results from the lab data collection for the last quarter of 2008 is 35% for serum albumin $\geq 4.0/3.7$ gm/dL and 81% for serum albumin $\geq 3.5/3.2$ gm/dL, the target being 80%.

Using the voluntary lab data submitted by providers, the Network identified 17 providers that consistently had low serum albumin levels below the target of 32% of $\geq 4.0/3.7$ g/dL in 2007. During 2008, the Network QI staff provided technical assistance to these providers. By mid 2008, the number of low providers dropped to 12 providers. Structured interviews were conducted with the dietitian in each of these clinics. Recommendations for internal changes were developed. By December 2008, there were 8 providers still below the Serum Albumin target. Major barriers are: lack of funds to obtain nutritional supplements. It was also observed that there is a lack of follow-up with patient interviews in the clinics where dietitians are assigned on a part time basis.

Catheter Reduction in Hemodialysis Patients

Use of catheters for long term vascular access should be discouraged due to the increased morbidity associated with infections, susceptibility to thrombus and inconsistent delivery of blood. A catheter placed in a prevalent hemodialysis patient greater than 90 days is considered long-term and should be evaluated by the medical team. The increased complications due to long-term catheters create a greater need for medical or surgical interventions and hospitalizations reducing the quality of life for these patients. Long-term catheters should be the last choice for vascular access except in a specific subset of patients such as some pediatric patients soon to be transplanted and those patients with severe co-morbidities such as congested heart failure (CHF), severe peripheral vascular disease (PVD), the very elderly, patients with inadequate vascular anatomy, or patients with limited life expectancy. Catheter placement should be used in conjunction with a plan for a different permanent access. The Medical Review Board of the Network of New England has determined that the prevalent long term catheter rate needs to be reduced. Historically, the National CPM Project collected annually on a random 5% sample of ESRD patients, indicates this Network has a prevalent catheter rate for of 24%. The Fistula First provider specific reports show this Network's prevalent catheter rate has averaged 27.7% in 2008. However, this same report shows NW 1 having a > 90 day catheter rate of 14% in Jan. 2007 reduced to 12.7% by Dec. 2008 (Figure 16). The Medical Review Board goal was to reduce the >90 day prevalent catheter rate 1% annually. Nephrologists are to be encouraged to have patients with a catheter evaluated for an AV fistula if medically suitable or if that is not feasible than an AV graft should be considered.

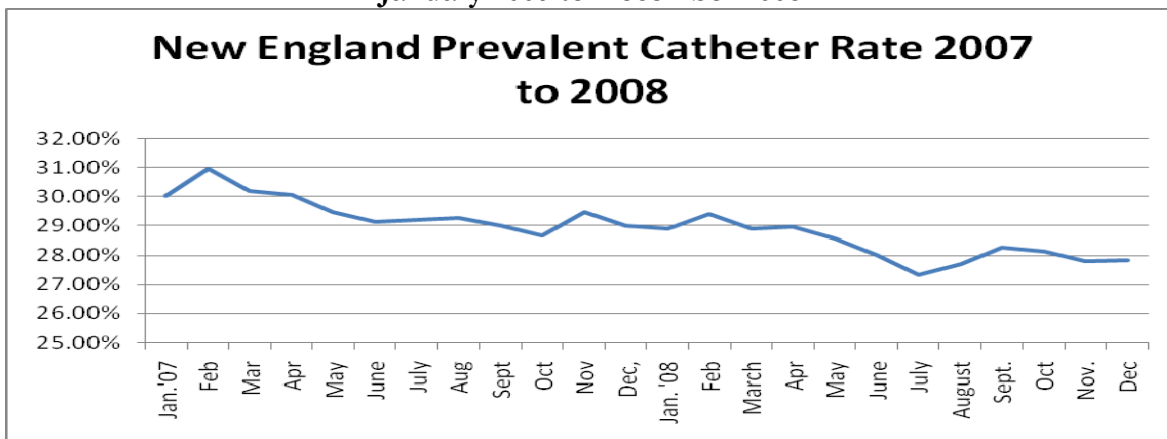
Figure 16: Trending Catheters > 90 days Percent of Use in 2007 to 2008



Source: Provider Reports based on monthly provider reports

The Network’s specific quality improvement projects (QIPs) are selected by the Medical Review Board and/or the Board of Directors based on available data documenting chronic high catheter rates in New England. The data from the CPM report, Medical Evidence Forms and Fistula First Dashboard all contain proof that the catheter utilization in this Network is at an unacceptable rate. The NKF KDOQI Guideline # 30-A, for vascular access (opinion-based guideline), recommends less than 10% of chronic hemodialysis patients should be maintained on catheters as their permanent dialysis vascular access. The downward trend of prevalent catheters is displayed in Figure 17. The rate fell from a high of 31% to 27.7% by Dec. 2008. This is improvement. However there remains more opportunity to improve to reach the KDOQI recommendations.

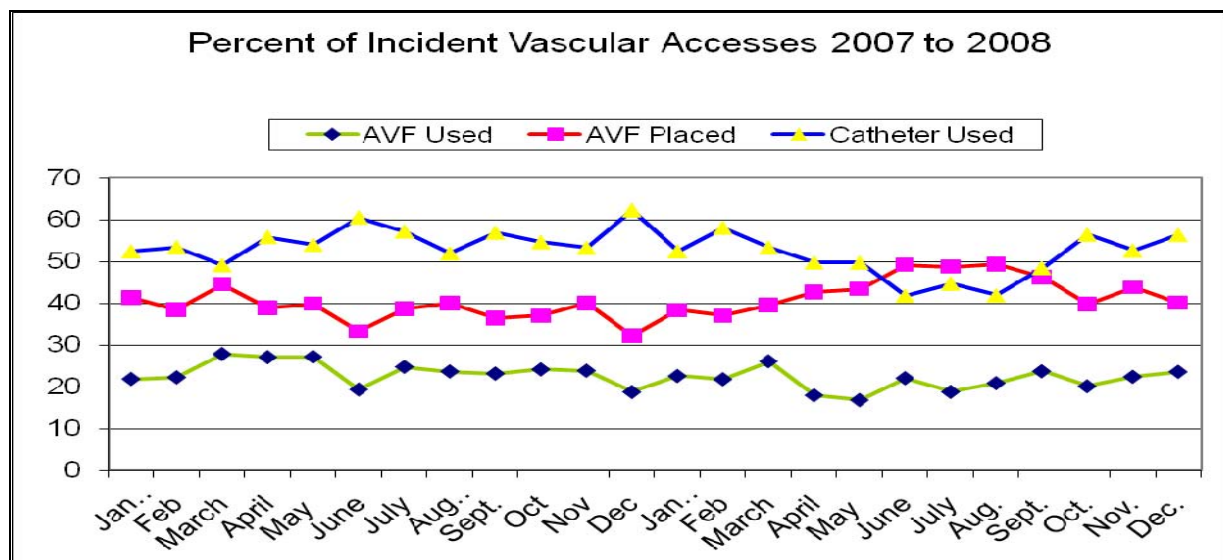
Figure 17: Network of New England Prevalent Catheter Rates January 2007 to December 2008



Source: Fistula First monthly provider vascular reports

The data reported on the Medical Evidence Form has been used to generate a physician practice performance report for the past two years. The Medical Evidence Form provides information on how long a patient has been in the care of a Nephrologist prior to the first chronic dialysis treatment, and the type of access used at initiation of chronic dialysis. Physician Profile Reports were mailed to each Medical Director in March 2008 with an evaluation tool. The intent of the report was to stimulate the nephrologists' to review practice patterns and to develop strategies to increase the incident AVF rate and reduce the catheter only rate if feasible (Figure 18). The feedback was favorable from the Medical Directors. Several planned to use it in the physician practice quality improvement activity.

Figure 18: The Percent of New England patients that initiated chronic hemodialysis with either an AVF or catheter and the percent of AVFs placed used or not



Source: Fistula First provider monthly reports

OTHER QUALITY IMPROVEMENT ACTIVITIES IN 2008

➤ ESRD Regulations

There were many concerns and questions regarding the new ESRD Conditions of Coverage which became final in October 2008. The Network held an educational program for the providers of New England on November 13th in Sturbridge, MA. The program included:

- An overview of the Conditions of Coverage
- The Increased Responsibilities of the Medical Director & leadership
- Quality Assessment and Performance Improvement
- Comprehensive Patient Assessment and Plan of Care
- Patient's Rights
- Facility and Patient Safety

A template for Quality Assessment and Performance Improvement (QAPI) both in hard copy and on a CD were part of the handouts. The audience was given time for questions and to have their concerns addressed by the expert panel.

There were number of inquiries to the Network in 2008 concerning dialysis regulations for specific states. Many clinicians wanted to know if the Federal regulations superseded their state regulations. The Network staff explained that if their state regulations were more stringent than the Federal conditions then the state regulations superseded. As new dialysis providers join the Network of New England, the QI staff assisted the facility professionals with information about dialysis regulations. Several providers were given assistance and advice during their state survey.

The types of inquiries involved topics listed below and responses varied according to the specific state:

- Dialysis regulations for individual states mailed to providers
- Guidelines for patient discharge for non-adherence or threat of violence, counseled and sent the DPC tool kit
- Physical plant standards in dialysis clinics
- Staffing guidelines
- Improve understanding of how the SMR and crude mortality are derived
- Guidelines on treating dialysis pts. with MRSA or VRE
- Natural disaster drills and emergency planning

➤ **Infection Control Issues**

Clinical inquiries often focused on infection control issues in 2008. The most common issues addressed by the Network QI staff were:

- Calculation of infection rates
- Caring for patients with C-difficile, MRSA, VRE or TB
- CDC guidelines on Hepatitis A, B and C
- OSHA regulations concerning staff protection
- Changing patients surgical dressings in the dialysis unit
- Influenza and pneumococcal vaccinations
- Regulations concerning the patient isolation room

➤ **Clinical Technical Assistance**

The Network of New England is fortunate to have very knowledgeable multidisciplinary members on the Board of Directors and Medical Review Board. Those members have volunteered to assist the Network staff and its peers with clinical questions and other issues that might be beyond the scope of the resources in the Network office.

While the Network can provide educational resources, staff always advises patients to check with their own physicians for comprehensive and specific answers to their questions. Many website resources are from professional and well-recognized reliable sources. Utilizing the team approach,

Network of New England has a Patient Services Manager and two Medical Quality Managers (RNs) along with the Network staff, to handle a number of clinical inquiries during 2008. These included:

- Acute dialysis issues that impact chronic dialysis patients
- Adequacy of dialysis
- Advance Practice Nurses/Physicians' Assistants in nephrology settings
- Articles on a variety of subjects (vascular access, infection control, cost containment, quality improvement, miscellaneous clinical issues, etc.)
- Behavior problems (management of patients/educational guidelines for staff)
- CQI resources (articles, educational programs, tool sheets)
- Dialysis of patients in rehabilitation centers or skilled nursing facilities
- Educational websites for staff and patients
- JACHO survey procedures
- Intermediary issues – referred to Intermediary Specialist, at CMS/Boston
- LPN practice
- OSHA regulations
- Pediatric issues
- Safety/security issues in dialysis facilities
- Staffing opportunities
- Water treatment management

➤ **Acute Dialysis Programs**

While acute dialysis facilities are not in the scope of work for Network #1, Network #1 receives requests for assistance from acute care staff seeking educational information. Network #1 provides as much information as possible, since the staff caring for acute dialysis patients has a large impact on ESRD care. Network #1 also sends meeting brochures to acute dialysis staff for the Network educational programs. In addition, Network staff communicate with the specific health departments when there are any dialysis water treatment issues that would affect acute dialysis facilities. Ultimately, the Health Department for each state is responsible for maintaining communication with acute inpatient hospital dialysis services.

➤ **Assisting Facilities with Continuous Quality Improvement Activities**

There has been an increase in requests for assistance with quality improvement management techniques, particularly for new dialysis Nurse Managers. The Network staff assisted providers with in depth QI information, which includes sample run charts, tracking/trending sheets, and QI tools from other QI sources. Network #1 continues to incorporate the principles of Quality Improvement in each Annual Network Meeting.

➤ **Achieving Network #1 Goals in Quality of Care and Safety**

The outcome and process measurements reported in the national clinical indicator projects and the Lab Data project demonstrates an increased number of patients in New England achieving acceptable K-DOQI benchmarks. In the past 3 years this Network has exceeded the CMS target of patients having a URR > 65% KT/V \geq 1.2 and Hgb > 11. Collective educational efforts by physicians, administrators, and dialysis patient care teams, and the collaborative role of Network #1 has contributed to improvement in these CMS indicator targets. This Network has made improvements in anemia and \geq 90 day catheter reduction. Network #1 successfully completed, and CMS approved the Annual QI Work Plan. However, this Network did not achieve the CMS goal for Fistula First in 2008.

The Medical Review Board has been increasingly aware of the benefits of collaboration within the renal community. Toward that end, Network #1 has worked diligently to survey the environment for quality improvement partnership opportunities and to nurture established relationships with those responsible for direct patient care. The Fistula First initiative offers new challenges to expand relationships with Vascular Surgeons, Intervention Radiologists, Acute Care settings, and Quality Improvement Organizations.