III. CMS National Goals and Network Activities

The Medical Review Board, Board of Trustees and the Council reviewed national CMS goals promulgated in TARC's contract. The committees then formulated sub-goals and activities for the contract year. The sub-goals are used to focus attention on and promote action in specific areas of nephrology practice to attain national goals and improve the quality and delivery of health care services.

A. Improve the quality and safety of dialysis-related services provided for individuals with ESRD

a. Develop criteria and standards relating to the quality and appropriateness of patient care;

b. Conduct on-site reviews of facilities and providers, as necessary, utilizing standards of care established by the Network;

c. Identify facilities not meeting Network goals, assist facilities to develop appropriate plans for correction, and report to the Secretary (CMS) facilities and providers that are not providing appropriate medical care; and

d. Improve collaboration with providers to ensure goal achievement through the most efficient and effective means possible.

   i. Facilities will maintain expected levels of performance in national clinical performance indicators for anemia management (80% Hgb ≥ 11 gm/dL), dialysis adequacy (80% URR ≥ 65%), fistula use (66%), and reduction in use of access catheters by 3% each year.

   ii. Facilities will replace within 90 days of placement temporary catheter accesses.

Supportive Activities

In 2003, CMS launched with all Networks the National Vascular Access Improvement Initiative, now called the Fistula First Breakthrough Initiative. The project was based on the NKF-KDOQI guidelines, which stated that 40% of prevalent hemodialysis patients should use an arteriovenous fistula and 50% of the incident patients should use an arteriovenous fistula. Hemodialysis patients with fistulas have improved morbidity and mortality outcomes.

Since 1997, TARC collected vascular access data from all facilities as part of TARC's local Hemodialysis Improvement Project (HIP). Although the local project was terminated in 2003, the vascular access data collected served as historical reference information. The national project developed a new *Fistula First* data collection tool. The charts and graphs in the following sections used data from both sources: HIP data from 1999 through June 2003 and *Fistula First* data from December 2003 to the present.

Network Results

Improve Fistula Rates

TARC's fistula rates have increased in small increments since 1997 when the DOQI guidelines were published. The goal of the *Fistula First* project was to have 40% of prevalent patients using a fistula by 2006. This goal was raised by CMS and is now set at 66% by June 2009.

Since the inception of the *Fistula First* initiative in 2003, TARC has sponsored educational programs for vascular surgeons, nephrologists, and nurses in New Jersey, Puerto Rico and the US Virgin Islands. A DVD entitled, *Creating AV Fistulas In All Eligible Hemodialysis Patients* was distributed to vascular surgeons requesting additional copies. TARC developed a newsletter entitled *Fistula Gram,* which was distributed to the dialysis facility medical directors, all county medical societies; the chiefs of medicine at acute-care hospitals; and the chiefs of surgery at acute-care hospitals. Dialysis facilities were provided quarterly vascular access feedback reports that were mailed to every facility's medical director and administrator.

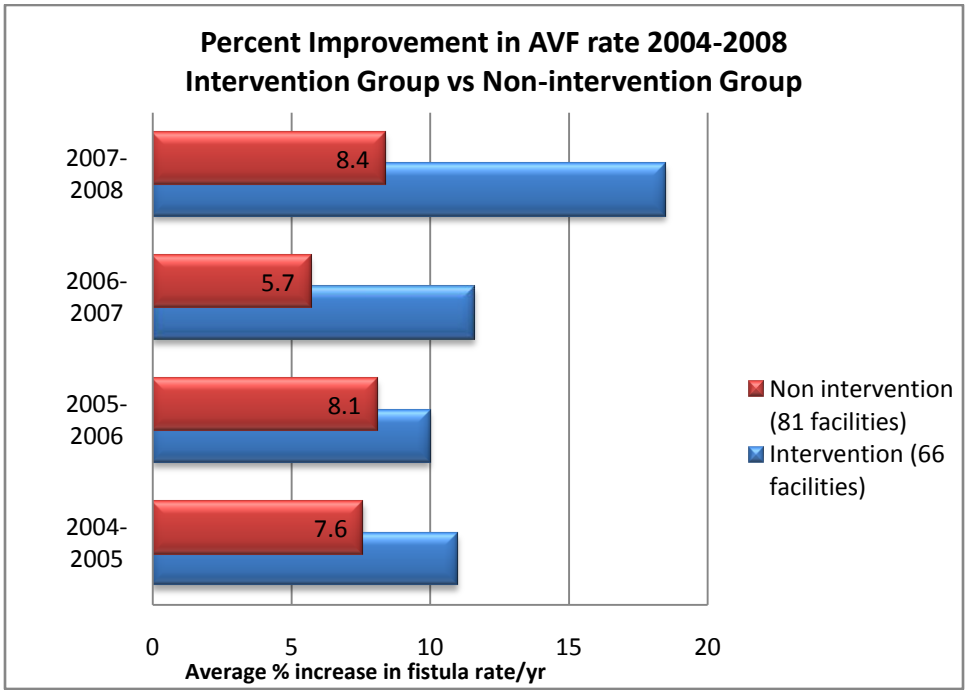
TARC continued to focus on this initiative and develop new strategies to continue to have the message implemented. TARC reviewed results of facilities with low fistula rates or elevated catheter rates and performed site evaluations at these facilities. The focus of the facility visits was to increase fistulas and decrease catheter use, stressing fistula maturation, early referral for fistula placement and referral to the surgeon with the best outcomes. In 2008, 54 site visits were conducted; 40 level I visits (meetings with facility staff by TARC quality improvement staff), 11 level II (repeated visit from TARC quality improvement staff), 2 level III (TARC executive director/quality improvement administrator with high level facility administration)and 1 level IV. (sanction recommendation to New York CMS regional office). Targeted facilities included dialysis centers with >30% prevalent catheter rate.

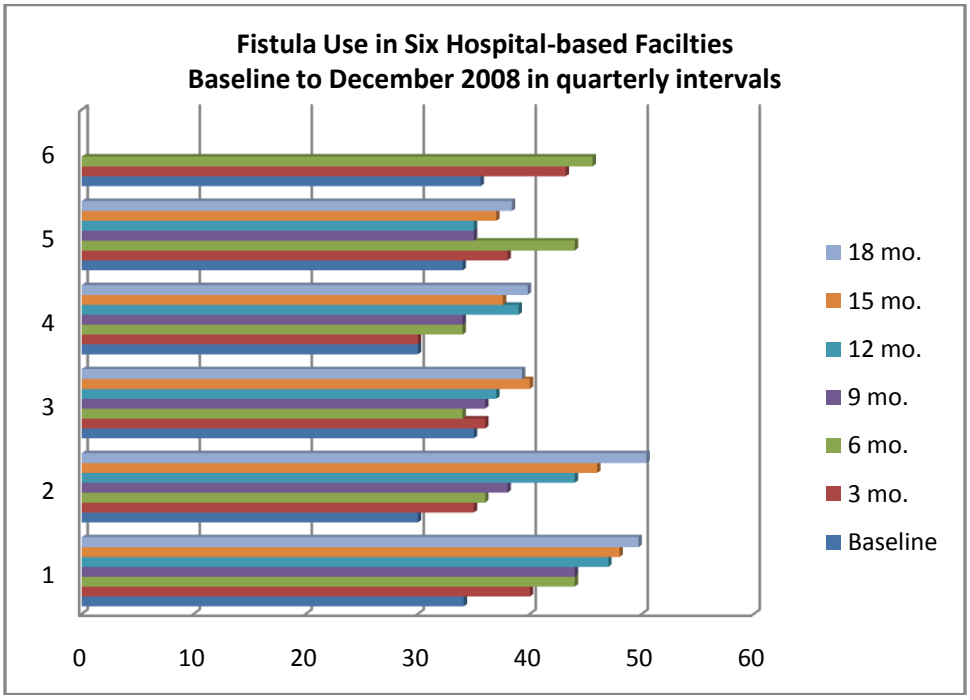
Attribution

The Fistula First Breakthrough Initiative activities in 2004-2006 included all Network facilities and consisted of multiple nursing, physician and surgeon educational programs in New Jersey, Puerto Rico and the U.S. Virgin Islands. Vascular access data was collected from 100% of Network facilities and quarterly progress reports were distributed to the medical directors and administrators at all facilities. The FistulaGram was developed and distributed to hospitals, surgeons, dialysis facilities and other healthcare organizations.

By the end of 2005 there was a clear line between the early adopters and those failing to meet TARC goals. During the first quarter of 2006, under the direction of the Boards TARC staff began conducting site visits at facilities with <30% AVFs and >40% catheters.

As is evident in the chart below, from 2004 through the end of 2005 both groups were making progress. The group that became the intervention group had an average AVF rate of 35.6% (12/05) while the early adopters had an average AVF rate of 43%. The rate of improvement was fairly consistent in both groups until 2006 when the intervention changed. The year following the site visits the improvement rate for the lower performing units increased from 11.6% to 18.5% while the non-intervention group remained constant.





The graph above shows the results of 6 hospital-based facility visits conducted in 2007-2008. The vascular access data showed that site 1 had a 5.4% fistula increase from baseline (34.1% to 39.5%) in the first 3 months post-site visit and a 15.6% increase (34.1 to 49.7%) at 18 months.

Site 2 had a baseline AVF rate of 30%, the rate increased to 34.7% after 3 months and was 50.4% at 18 months. A 20.4% improvement was observed at 18 months post-intervention.

Site 3 consists of a hospital-based facility and a freestanding satellite. Both facilities continued to struggle and failed to achieve TARC goals and maintain sustainability. The AVF rate at the hospital facility in March 2008 was 28.4%, in December it was 33.7%, in November it was 38.7%. The same is true of the satellite facility, the AVF rate in March 2008 was 43.4%, in December it was 48.5%, and in July it was 48.7%. TARC continues to work with these facilities but has failed to gain the full attention of hospital administration.

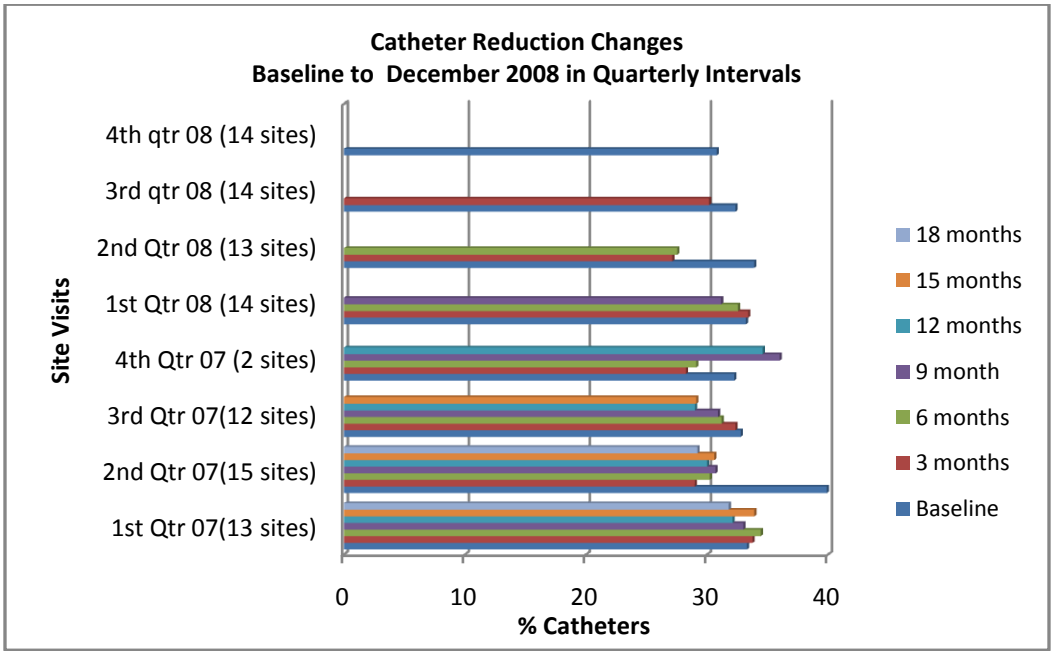
The next group (site 4) of facilities was the most challenging where 3 dialysis facilities, collectively, treat 190 beneficiaries. In March 2008 the medical director of the dialysis unit was asked to report to the Medical Review Board his plan to improve the fistula rate and decrease the catheter rate. The hospital chief executive officer was asked to send a representative to the Board of Trustees meeting and report how the hospital would support the Fistula First Initiative. Since March 2008 the average fistula rate for all three facilities increased by 1.3% demonstrating a lack of commitment from all parties.

Site 5 demonstrated remarkable improvement at 9 months but could not sustain improvement. A second level III site visit was scheduled for 1st quarter 2009.

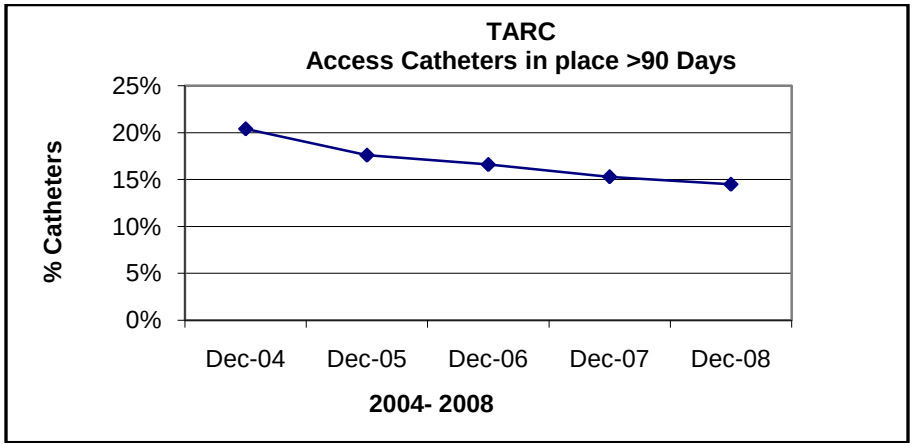
The sixth site is a hospital-based facility that demonstrated a strong hospital commitment to the program and increased the fistula rate by 10% within the first 6 months.

Catheter Reduction

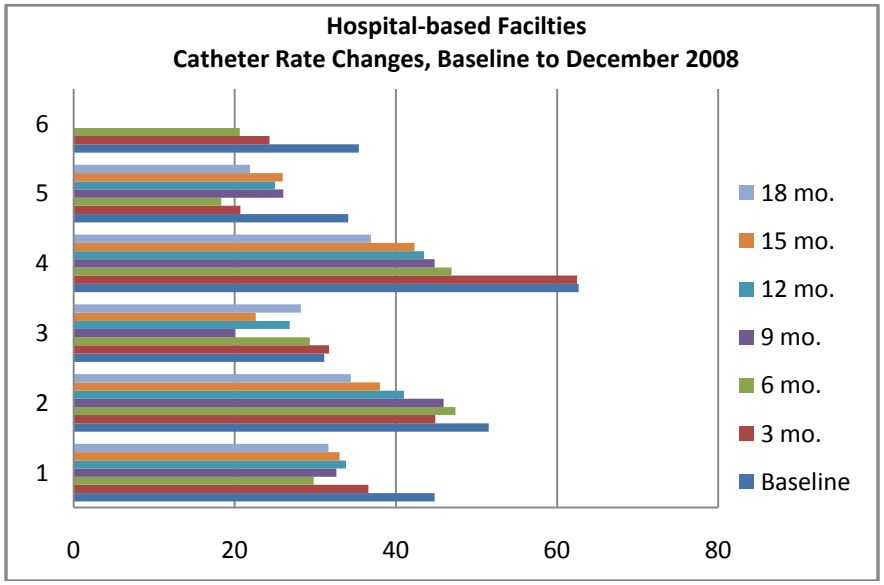
The USRDS Morbidity and Mortality Study Wave 1 showed that patients receiving catheters and grafts have greater mortality risk than patients dialyzed with fistulae. In December 2008, 4,166 patients used catheters as the primary access, which is a decrease of 1.7% from the previous year. However, that number constitutes 28.7% of the total hemodialysis population. Most authors suggest that catheter prevalence in the caseload should be in the area of 10%.



The graph above shows sustained improvement at almost all facilities visited since the first quarter 2007. Highlights of the 2008 site visits include: average baseline catheter rate of 14 facilities visited during first quarter was 33.2% and at 9 months an average rate of 31.2%, which was an average decrease of 2.0%. Thirteen facilities were visited in the second quarter when the average baseline catheter rate was 33.9% and which decreased to 27.5% at 6 months. During the third quarter, 14 sites were visited where the baseline average rate was 32.4% which decreased to 30.2% after 3 months. TARC will continue to evaluate the effectiveness of site visits by collecting monthly vascular access data from 100% of facilities.



The chart above shows the decrease in the percentage of catheters used >90 days from December 2003 through December 2008. TARC will continue to work with facilities and encourage removal of all medically inappropriate catheters.



The graph above depicts the results of 6 hospital-based facility visits conducted in 2007-2008. As is evident, the catheter rate decreased post-site visits. Site1's baseline catheter rate was 44.8% and 31.6% at 18 months; site 2 decreased the catheter rate from 51.1% to 34.4% at 18 months; site 3 baseline rate was 31.1% decreased 2.9%by 18 months; site 4 had a baseline catheter rate

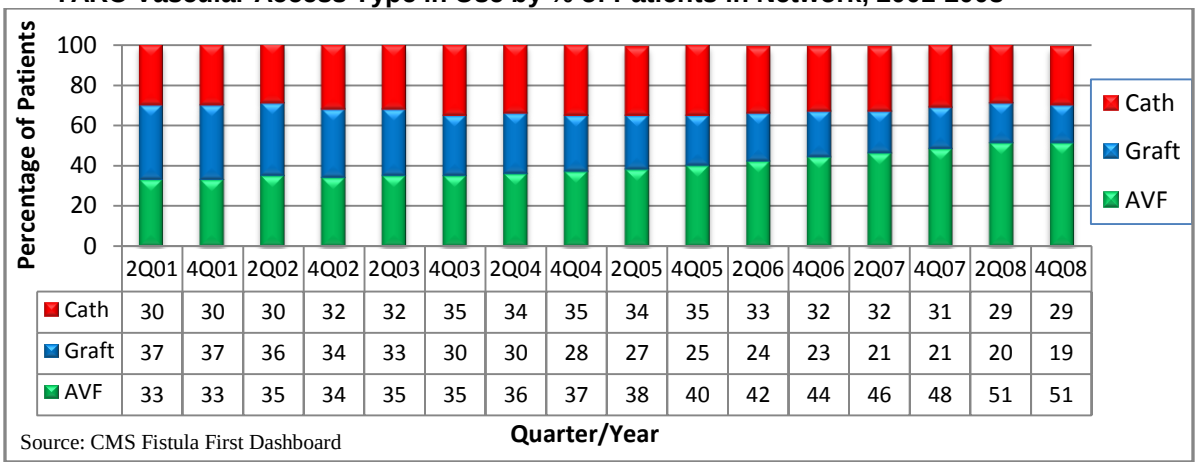
of 62.7% and at 18 months had decreased the catheter rate to 36.9%; site 5 decreased the catheter rate from a baseline 34.1% to 21.9% at 18 months. Site 6 had a baseline catheter rate of 35.4% which decreased to 20.6% at 6 months.

Fistula First Initiative

From June 1999 to December 2008, TARC's prevalent fistula rate increased from 31% to 51.4%, catheter rates continued to decline from 32.4% to 28.7%.

TARC plans to meet the 3.3% goal by June 2009. TARC's Board of Trustees challenged facilities to decrease catheter use by 3% annually. As of December 2008, TARC decreased catheter use by 1.7% and plans to meet the challenge by June 2009.

TARC Vascular Access Type in Use by % of Patients in Network, 2001-2008



	2Q01	4Q01	2Q02	4Q02	2Q03	4Q03	2Q04	4Q04	2Q05	4Q05	2Q06	4Q06	2Q07	4Q07	2Q08	4Q08
Cath	30	30	30	32	32	35	34	35	34	35	33	32	32	31	29	29
Graft	37	37	36	34	33	30	30	28	27	25	24	23	21	21	20	19
AVF	33	33	35	34	35	35	36	37	38	40	42	44	46	48	51	51

Source: CMS Fistula First Dashboard

Fistula Data by Facility Management

Type of Facility	Baseline 3-08	12-08	% Improvement
Large Dialysis Organization	48.6%	50.2%	1.6%
Independent facilities	50.4%	53.1%	2.7%
Hospital-based facilities	48.0%	50.5%	2.5%

Catheter Data by Facility Management

Type of Facility	Baseline 3-08	12-08	% Decrease
Large Dialysis Organization	29.6%	28.6%	-1.0%
Independent facilities	31.5%	28.9%	-2.6%
Hospital-based facilities	32.8%	29.2%	-3.6%

Fistula Data by Corporate Provider

Provider	Baseline 3-08	12-08	% Improvement
DaVita	47.8%	51.0%	3.2%
Dialysis Clinic Inc.	58.6%	56.3%	-2.3%
Fresenius New Jersey	53.6%	54.2%	0.6%
Renal Care Group	47.2%	51.4%	4.2%
Fresenius Puerto Rico	45.5%	45.5%	0.0%
Atlantis Puerto Rico	40.0%	43.1%	3.1%

Catheter Data by Corporate Ownership

Provider	Baseline 3-08	12-08	% Decrease
DaVita	30.6%	27.5%	-3.2%
Dialysis Clinic Inc.	28.7%	32.0%	+3.3%
Fresenius New Jersey	27.7%	27.4%	-0.3%
Renal Care Group	27.9%	25.0%	-2.9%
Fresenius Puerto Rico	32.6%	33.4%	+0.8%
Atlantis PR	38.2%	34.7%	-3.5%

Area-specific Data

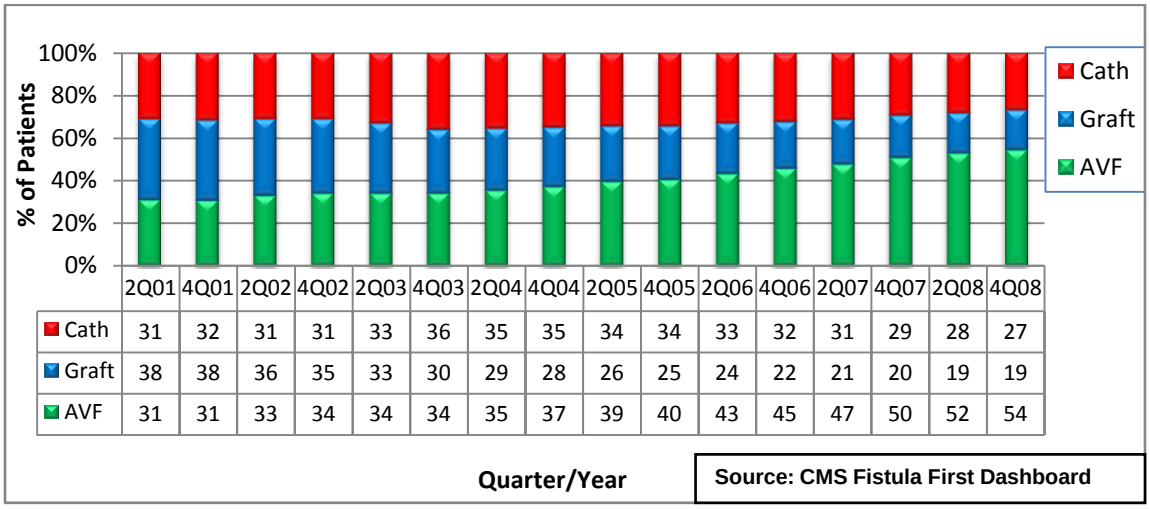
New Jersey

New Jersey has several champion vascular access teams that include the dialysis unit medical director as team leader, a skilled vascular surgeon, dedicated dialysis unit staff and a supportive interventional radiologist. All team members play an important role in improving patient outcomes. New Jersey had 15 facilities that achieved the 66% AVF goal in 2008; 44% of New Jersey facilities had AVF rates >55% by December 2008.

The fistula rate increased from 27% to 51.4% between June 1999 and December 2008. Although it is not displayed in the graph below, the percentage of patients with a "catheter only," which excludes patients with maturing permanent vascular access, decreased from 20.2% to 18.8% - an improvement of 1.4%.

The prevalent catheter rate increased from 28% to 36% from June 1999 to December 2003 and decreased to 28.7% by December 2008. The net decrease accounts for both catheters-alone in use as well as those that had a maturing fistula not yet in use.

New Jersey Vascular Access Type in Use by Percent of Patients, 2001-2008



	2Q01	4Q01	2Q02	4Q02	2Q03	4Q03	2Q04	4Q04	2Q05	4Q05	2Q06	4Q06	2Q07	4Q07	2Q08	4Q08
Cath	31	32	31	31	33	36	35	35	34	34	33	32	31	29	28	27
Graft	38	38	36	35	33	30	29	28	26	25	24	22	21	20	19	19
AVF	31	31	33	34	34	34	35	37	39	40	43	45	47	50	52	54

Quarter/Year

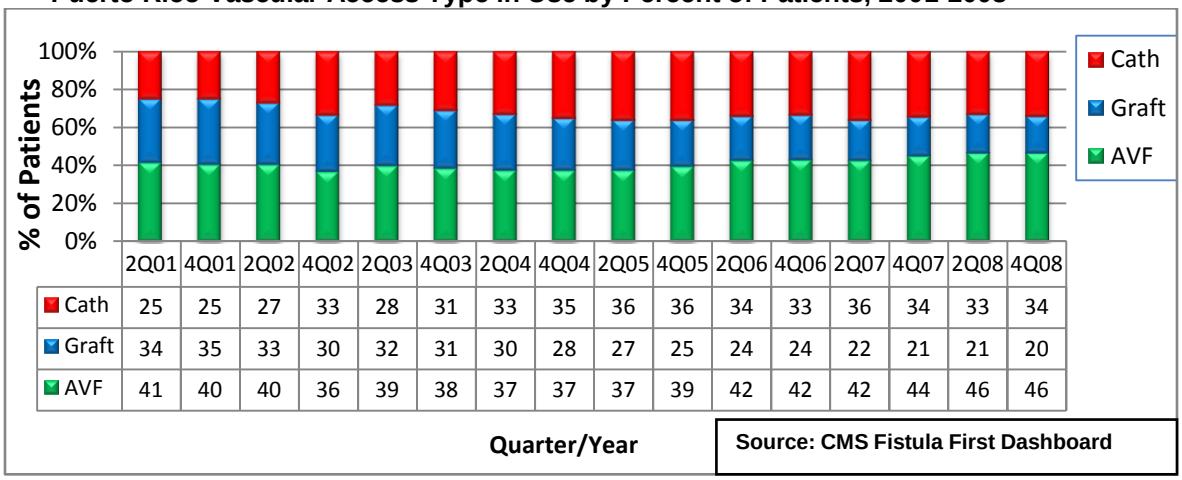
Source: CMS Fistula First Dashboard

Puerto Rico

Regional variation was observed in the distribution of access types in use. Historically, the majority of hemodialysis patients in Puerto Rico had arteriovenous fistulas and, although the majority of these patients still have fistulas, there has been a general increased use of catheters

in recent years. The prevalent rate of patients using fistulas decreased from 44% to 36% from June 1999 to December 2002 and increased to 46.1% by December 2008. The catheter rate increased from 24% to 36% by December 2005 and decreased to 33.6% by December 2008.

Puerto Rico Vascular Access Type in Use by Percent of Patients, 2001-2008



	2Q01	4Q01	2Q02	4Q02	2Q03	4Q03	2Q04	4Q04	2Q05	4Q05	2Q06	4Q06	2Q07	4Q07	2Q08	4Q08
Cath	25	25	27	33	28	31	33	35	36	36	34	33	36	34	33	34
Graft	34	35	33	30	32	31	30	28	27	25	24	24	22	21	21	20
AVF	41	40	40	36	39	38	37	37	37	39	42	42	42	44	46	46

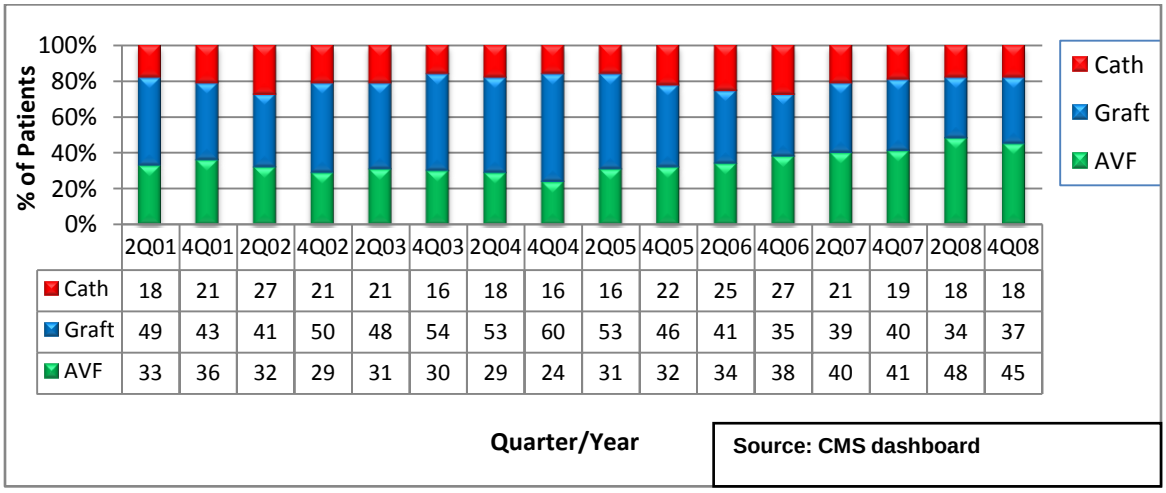
Quarter/Year

Source: CMS Fistula First Dashboard

Virgin Islands

The trend in the Virgin Islands showed an increase in the use of fistulas and decrease in graft use. Rates fluctuated more widely here because the number of patients was much smaller than in other areas. The prevalent fistula rate was highest in 2008 at 47.5%, an increase of 5.2% above baseline. This was in part due to the addition of a dedicated vascular surgeon. The catheter rate increased from 21% to 27% from June 1999 to December 2006 and decreased to 17.9% in December 2008.

Virgin Islands Vascular Access Type in Use by % of Patients, 2001-2008



	2Q01	4Q01	2Q02	4Q02	2Q03	4Q03	2Q04	4Q04	2Q05	4Q05	2Q06	4Q06	2Q07	4Q07	2Q08	4Q08
Cath	18	21	27	21	21	16	18	16	16	22	25	27	21	19	18	18
Graft	49	43	41	50	48	54	53	60	53	46	41	35	39	40	34	37
AVF	33	36	32	29	31	30	29	24	31	32	34	38	40	41	48	45

Quarter/Year

Source: CMS dashboard

2008 ESRD Clinical Performance Measures Project

Annually, in order to identify and track opportunities for improvement in dialysis facilities, the clinical performance measures project collects data for a national set of measures with a random sample of dialysis patients in clinical areas that include dialysis adequacy, anemia management, nutrition, bone management and vascular access.

The sample included hemodialysis patients, peritoneal dialysis patients and pediatric patients. Veterans Administration hospitals provided data for 100% of their population while all other facilities extracted data for a ≤5% scientifically selected sample of patients.

The 2008 iteration of this project was its fifteenth year having been conducted in more than 3,500 dialysis facilities nationwide. CMS characterized the project as a 'snap-shot' description of peritoneal and in-center dialysis patients.

Through this data collection effort, TARC had access to data from an additional source for the same collection period. Clinical performance measures data (5% sample) were reviewed with lab data collection data, which included 100% of the patient population. Large dialysis organizations' laboratory data were provided to TARC electronically through CMS. Other facilities submitted data to TARC on forms, spreadsheets or on a flash drive.

The Medical Review Board, Patient Advisory Committee and Board of Trustees discussed the report and selected information was shared with facilities at the annual Council meeting.

Facility-specific statistics provided through the lab data collection effort were analyzed to assist in anemia management, bone management and an evaluation of treatment adequacy as well as compared to preliminary clinical performance measures data.

Number of Clinical Performance Measures Participants by area, 2008

Area	No. Dialysis Facilities	No. Hemo Dialysis patients	No. Hemo Pediatric Patients	No. Perit. Dialysis Patients	Total No. forms
New Jersey	121	357	17	36	410
Puerto Rico	41	119	13	32	164
US VI	3	9	0	0	9
Network	165	485	30	68	583

On June 4, 515 hemodialysis forms and 68 peritoneal dialysis forms were sent to dialysis facilities for completion. All forms were received and data entry completed by August 29. The veterans' administration facilities received and completed forms by September 22 for their entire patient population of 82 hemodialysis and 1 peritoneal dialysis patients.

A total of 583 forms were submitted for the ≤5% sample study not including the veterans administration facilities or the reliability forms. Data from 26 of the 583 forms were re-abstracted as part of the reliability testing for the project. Reliability forms from 17 hemodialysis and 9 peritoneal dialysis patients were received and data entry was completed by September 22.

Facilities were encouraged to compare national information from the *Clinical Performance Measures Project Annual Report* with local data and to examine their own patient-care practices and processes. TARC's Medical Review Board and Board of Trustees used the information to

identify progress over time and compare the results from New Jersey, Puerto Rico, and the Virgin Islands to other areas of the country.

Annually, the clinical performance measures report is distributed to each facility to provide comparative clinical data that can be reviewed against facility performance. If results were less than the national average or less than the threshold established by the Medical Review Board, facility caregivers were to develop internal improvement efforts in the area. Overall, the goal of the project was that, collectively, providers would achieve the following intermediate outcomes for prevalent adult, in-center hemodialysis patients:

- Dialysis adequacy: Urea reduction ratios ≤65% (or 1.2 Kt/V)
- Anemia management: Hemoglobin values 11–12 gm/dL

Dialysis Adequacy

The dialysis adequacy goal stated that 80% of prevalent adult hemodialysis patients would have a urea reduction ratio ≥65%. CPM 2008 data showed that the goal was met and exceeded. The United States as a whole attained 89% of patients with adequacy ≤65% and TARC reached a similar level of achievement. The chart below shows data from the lab data collection and the 2008 CPM data collection.

Percent of Hemodialysis Patients with URRs ≥65%
for available periods in 2003-2008

Goal: 80 % of patients will have a URR of ≥ 65%

Area	2003 CPM	2004 CPM	2004 Lab	2005 CPM	2005 Lab	2006 CPM	2006 Lab	2007 CPM	2007 Lab	2008 CPM
New Jersey			89.2		88.8		89.4		90.1	
Puerto Rico			89.3		88.9		89.9		90.1	
Virgin Islands			80.9		85.4		77.6		76.9	
Network	**84**	**86**	**89.1**	**88**	**88.8**	**88**	**89.4**	**88**	**89.9**	**89**

Source 2003-2008 CPM data, Lab Data Collection

Anemia Management

It has been acknowledged that anemia management has more influencing factors than does treatment adequacy. Some of the influencing factors are outside the control of the nephrology health care team and patient. TARC continued to encourage facilities to monitor anemia status closely, refer patients early when co-morbidity is suspected as causing or influencing the anemia and continue efforts to achieve the goal. Preliminary CPM data is accurate only at network level and cannot be extrapolated to the facility level because the power of the sample size is insufficient.

In the United States, 82% of adult in-center hemodialysis patients had mean hemoglobin values of ≥11 gm/dL; TARC's percentage was 83%, which is slightly above the national average.

Iron administration is a necessary adjunct to erythropoietin therapy. National iron management data showed that 80% of patients had a mean TSAT ≥20% and 95% had ferritin levels ≥100ng/mL. TARC had 82% of patients with a mean TSAT ≥20% and 96% with ferritin values ≥100ng/mL.

TARC's percentage of patients with TSAT ≥20% was 4% higher than the previous year. TARC had addressed iron management with facilities during the 2007 annual meeting in a presentation by Dr. Steven Fishbane, who has studied the subject extensively. Nationally, 71% of patients received intravenous iron and in TARC's area, 74% of patients received intravenous iron.

The anemia management goal was 80% with a hemoglobin value of ≥11 gm/dL. The chart below shows data from the 2008 CPM data collection. This goal was met.

Percent of Hemodialysis Patients with Hemoglobin Values ≥11 gm/dL for available periods. 2003-2008

Goal: 80% of patients will have a hemoglobin ≥ 11 gm/dL

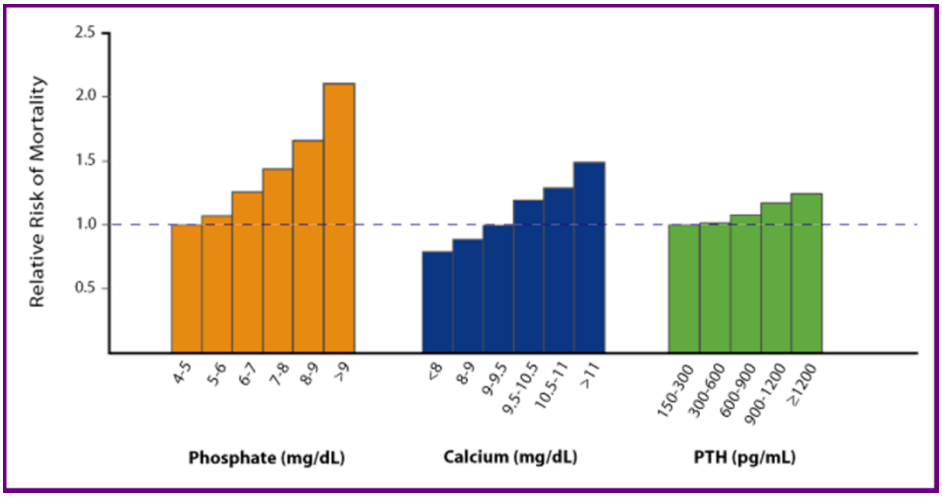
Area	2003 CPM	2004 CPM	2004 Lab Data	2005 CPM	2005 Lab Data	2006 CPM	2006 Lab Data	2007 CPM	2007 Lab Data	2008 CPM
New Jersey			84.0		83.5		84.7		81.2	
Puerto Rico			78.5		77.6		85.1		81.7	
Virgin Islands			63.8		70.8		66.7		65.8	
Network	**79**	**82**	**82.3**	**84**	**81.8**	**81**	**84.5**	**83**	**81.1**	**82**

Source 2003-2008 CPM data, Lab Data Collection

Bone Management

The KDOQI guidelines state: *In CKD patients with kidney failure (Stage 5) and those treated with hemodialysis or peritoneal dialysis, the serum levels of phosphorus should be maintained between 3.5 and 5.5 mg/dL. Prolonged hyperphosphatemia causes soft-tissue and vascular calcification due at least in part to an increase in calcium-phosphate product and is associated with increased morbidity and mortality.*

Relative Risk of Mortality Related to Levels of Phosphorus, Calcium, and PTH



TARC Boards utilized two data sources to determine the focus of the bone management initiative, 2007 CPM data collection and 2007 lab data collection. The CPM data collection shows results from 5% network sample during the last quarter 2006 and the lab data collection from 100% sample from the same time period.

According to the 2007 CPM data collection, 51% of TARC patients had a phosphorus level between 3.5-5.5 mg/dl. The lab data collection reported that 63.6% had a phosphorus ≤5.5 mg/dl, which included patients with phosphorus levels <3.5 mg/dl. Based on the lab data collection 95% of TARC patients had a calcium level ≤10.2mg/dl. The CPM data was reported differently and showed that 86% of patients had a calcium within target range (8.4 -10.2 mg/dl).

The intervention developed focused on increasing the current rate of improvement by 3-5% annually because of the high mortality rate associated with elevated phosphorus levels

TARC calcium and phosphorus levels reported in CPM and electronic laboratory datasets, Q4 2006, Q4 2007

Results	2006 CPM	Lab data 2006	2007 CPM	Lab data 2007	2008 CPM
% pts Ca 8.4-10.2	81		86		81
% pts PO4 3.5-5.5	51		52		53
% pts PO4 ≤5.5		62.2		63.6	
% pts Ca ≤ 10.2		95.3			95.8

Source 2006-2008 CPM data, Lab Data Collection

TARC launched a pilot program in May 2008 based on 2006 and 2007 electronic lab data and selected 7 New Jersey facilities that had ≥14.9% patients with a phosphorus level ≥7mg/dl for 2 consecutive years. After 3 months, eighty-six percent of the 7 facilities had decreased the percentage of patients with a PO4 ≥7. Three of the 7 facilities had met the 20% reduction goal with 1 champion unit that decreased the percentage of patients from 21.3% to 12.6%.

In October 2008 TARC launched the network-wide initiative and will begin collecting monthly data in January 2009.

Albumin Management

The final clinical indicator concerns nutrition. Nutritional status, measured by albumin levels, of hemodialysis patients was assessed. There are 2 commonly used albumin measurement methods, which have slightly different results - bromcresol green (BCG) and bromcresol purple (BCP).

TARC's percentage of prevalent patients with mean serum albumin level of ≥ 4.0/3.7 gm/dL (BCG / BCP) was 34%/85% for prevalent patients and mean serum albumin level of ≥ 3.5/3.2 gm/dL (BCG / BCP). The national percentages were 34% and 82% respectively.

Percent of Hemodialysis Patients with Albumin Values >4.0 gm/dL for available periods, 2003-2008

Prevalent patients with an albumin of 4.0/3.7gm/dL or 3.5/3.2 gm/dL (BCG / BCP lab method)

Albumin Results	2003 CPM	2004 CPM	2005 CPM	2006 CPM	2007 CPM	2008 CPM
≥ 4.0/3.7 gm/dL	33	33	31	33	33	34
≥ 3.5/3.2 gm/dL	78	77	79	75	81	85

Source 2003-2008 CPM data

Vascular Access Reporting

The Centers for Medicare & Medicaid Services (CMS) required data collection for three clinical performance measures derived from the original and revised NKF-KDOQI *Guidelines for Vascular Access*. The goal for prevalent fistula use was set at 66% by June 2009.

According to the 2008 CPM report, the percentage of incident and prevalent patients with fistulas was 42% and 49% nationally; TARC had 48% and 49% respectively. By increasing fistula use, the desired secondary effect is usually a reduction in catheter use.

The second goal related to vascular access was to decrease catheter use. The Medical Review Board and the Board of Trustees challenged facilities to decrease catheter use by 3% annually. NKF-KDOQI recommends no more than 10% of patients should have primary vascular access via catheter.

December 2008 vascular access data reported 28.7% with catheter accesses, a decrease of 1.7% from baseline March 2007. The 2008 CPM data reported that 27% of prevalent patients in the United States had a catheter; TARC had 28% catheter rate a 6% decrease from 2007. TARC continued to target facilities with high catheter use and encouraged them to decrease catheter use, provided education and resources to assist in this process, and monitored progress.

The data supplied in the graphs below were obtained from two sources. The first source was the *Fistula First* dataset, a required submission to TARC from all facilities with monthly aggregate access totals. The second source was the CPM data, which is a random patient sample of only 5%. The discrepancies noted below derive from the different populations included in each data collection set as well as sample size.

Percent of prevalent hemodialysis patients with a fistula access for available periods by area, 2003-2008

Goal: 66% or more prevalent hemodialysis patients will have a fistula for access

Area	2003 CPM	2004 CPM	2005 CPM	12/05 FF	2006 CPM	12/06 FF	2007 CPM	12/07 FF	2008 CPM	12/08 FF
New Jersey				39.96		45.06		49.58		54.0
Puerto Rico				38.59		42.07		44.03		46.1
Virgin Islands				32.24		37.50		41.24		48.5
Network	**36**	**35**	**34**	**39.51**	**39**	**44.16**	**44**	**48.01**	**49**	**51.8**

Source: CPM / Fistula First database

Percent of prevalent hemodialysis patients with a catheter access for available periods by area, 2003-2008

Goal: Decrease catheter usage by 3% annually

Area	2003 CPM	2004 CPM	2005 CPM	12/05 FF	2006 CPM	12/06 FF	2007 CPM	12/07 FF	2008 CPM	12/08 FF
New Jersey				34.15		32.26		29.29		27.1
Puerto Rico				36.13		33.29		34.34		33.6
Virgin Islands				21.71		27.17		18.56		17.9
Network	**32**	**37**	**34**	**34.52**	**35**	**32.47**	**34**	**30.46**	**28**	**28.7**

Source: CPM / Fistula First database

2008 ESRD Clinical Performance Measures Project-Peritoneal Dialysis Adequacy

The peritoneal dialyses clinical performance measures were designed to assist providers improve the care delivered by highlighting opportunities for improvement. The patient sample had sufficient power to produce only network-wide and national statistically valid results.

Clinical information reported to TARC for the October 2007–March 2008 period included hemoglobin levels, serum albumin values, blood pressure measurements and calculated dose of delivered dialysis. Data were abstracted from 68 peritoneal dialysis patients' medical records in area facilities; nationwide, 1,472 adult peritoneal dialysis patients >18 years were examined.

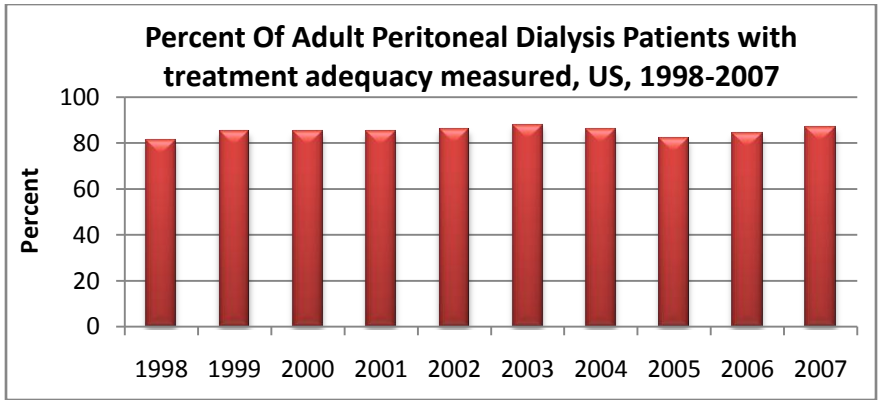
In anemia management, 79% of the sampled peritoneal dialysis patients had mean hemoglobin values ≥11gm/dL. Sixty-two percent of peritoneal patients had a mean serum albumin level of 3.5

gm/dL with the BCG method or 3.2 gm/dL with the BCP method. Nineteen percent of the sample had a mean serum albumin value of at least 4.0 gm/dL (BCG) or 3.7 (BCP).

Year	CAPD patients with Kt/V 2.0 (%)	CCPD patients with Kt/V 2.1 (%)		Year	CAPD patients with Kt/V 2.1 (%)	CCPD patients with Kt/V 2.1 (%)
2008	72%	65%		2003	71%	66%
2007	75%	64%		2002	68%	70%
2006	72%	59%		2001	68%	62%
2005	73%	59%		2000	65%	60%
2004	70%	65%		1999	56%	52%

CPM data showed that 87% of the sampled adult peritoneal dialysis patients had both a weekly Kt/V urea and a weekly creatinine clearance measurement reported at least once during the six-month period. It must be noted that this finding did not demonstrate that adequacy had been achieved in 87% of peritoneal patients, only that some measurement was taken to quantify the dose delivered.

Findings included 72% of CAPD patients had a mean ≥2.0 Kt/V adequacy measurement which met NKF-KDOQI guidelines. Sixty-five percent of cycler patients had a mean weekly 2.1 Kt/V.



Source: HIP/CPM

K/ DOQI guidelines for PD adequacy include:
Kt/V urea ≥2.0; creatinine clearance ≥60L/week/1.73m² for CAPD patients
Kt/V urea ≥2.1; creatinine clearance ≥63L/week/1.73m² for CCPD with day dwell patients
Kt/V urea ≥2.2; creatinine clearance ≥66L/week/1.73m² for Cycler PD patients

National Pediatric Population CPM results

All pediatric patients <18 years who were identified as receiving in-center hemodialysis on December 31, 2008, were included in the study. TARC's total number of pediatric patients was 30 of the national 693 records abstracted.

The findings were as follows:

- 90% of the pediatric in-center patients had a mean delivered calculated, single session Kt/V ≥1.2 using the Daugirdas II formula;
- 31% were dialyzed using a fistula, 5% with a graft, 63% with a chronic catheter;
- 54% of the catheter patients had continuously dialyzed with a catheter for ≥90 days; and

- 57% of patients with a fistula or graft were routinely monitored for the presence of stenosis.

In anemia management, 65% of patients had mean hemoglobin value of ≥11 gm/dL. Nutritionally, 86% had a mean serum albumin ≥3.5/3.2 gm/dL, 54% had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) during the three-month study.

Effectiveness

CMS/TARC Goal Attainment Progress

Preliminary 2008 CPM data (Oct-Dec 2007) were received on December 4, 2008. The following table is a comparative analysis of TARC data with national averages.

2003- 2008 TARC and National CPM Comparative Data (%)

Measure	Goal	CPM Year						U.S.
		2003	2004	2005	2006	2007	2008	
Hgb ≥11.0 g/dL	80	79	82	84	81	83	83	82
URR ≥65%	80	84	86	88	88	89	89	89
Alb ≥4.0/3.7 g/dL	35	33	33	31	33	33	34	34
TSAT ≥20%	80	79	80	74	78	78	82	80
Ferritin ≥100ng/mL	80	90	91	95	95	95	96	95
% Prevalent fistula pts	66	36	35	34	39	44	49	49
% Incident fistula pts.	50	24	38	43	48	38	48	42
Prev patients with catheter ≥90 days	<10	24	29	31	29	26	23	21
% pts. with AVG and stenosis monitoring	100	46	73	57	55	73	72	71
% pts adjusted calcium 8.4-10.2 mg/dL					81	86	81	85
% pts with mean phosphorus 3.5-5.5 mg/dL					52	51	53	52

The chart above shows the effectiveness of TARC's interventions, which included:

- The percentage of patients with a hemoglobin value ≥11gm/dL exceeded the 80% goal;
- TARC exceeded the 80% dialysis adequacy goal at 89%;
- Thirty-four percent had an albumin level of 4.0 gm/dL. TARC provided, through a state grant, funding for nutritional supplements to improve this indicator;
- Eighty-two percent had a TSAT value ≥20%;
- Ninety-six percent had a ferritin value ≥100;
- CMS established the prevalent fistula rate 66% goal; 2006 CPM data showed that TARC had a prevalent fistula rate of 44%. In 2007, vascular access data showed that TARC's fistula rate was 48% and in December 2008 the rate was 51.4%
- The Medical Review Board and the Board of Trustees challenged dialysis facilities to decrease the catheter rate by 3% annually. TARC aggressively worked toward attaining this goal and decreased the catheter rate by 2%;
- NKF-KDOQI recommends no more than 10% of hemodialysis patients should have a catheter access and catheters used as a bridge to a permanent vascular access should only remain in place for ≤90 days. TARC provides technical assistance to decrease catheters ≥90 days by 3%;
- TARC encouraged vascular access monitoring through distribution of educational materials;

- Eighty-one percent had an adjusted calcium in target range;
- Fifty-two percent had a mean phosphorus level between 3.5-5.5 mg/dl.

Clinical Performance Assistance Provided

TARC recognized that different facilities might identify different root causes and pathways for a lack of success to achieve successful outcomes. TARC implemented several strategies to improve the fistula rate, decrease the catheter rate, improve the percentage of patients in target range for anemia management and decrease the number of non-tunneled catheters and subclavian catheters used. TARC provided many tools and resources to achieve the fistula placement goal for existing and new patients.

Fistula and Catheter Use

TARC reviewed prior efforts to reduce catheter access use and developed new strategies to address needed improvement. TARC identified dialysis facilities that had >30% catheter rate. Catheter rates, in these facilities, ranged from 57% to 30%. TARC staff met with the medical director, attending nephrologists, vascular surgeon and nursing leadership to identify barriers and develop a comprehensive plan of action to improve outcomes. Thirty-five facilities were placed on quality assessment improvement plans (QAIP); as of December data the percentage of facilities with catheter rates >30% dropped from 46% to 36% in 12 months.

Anemia Management

In 2006, 25 dialysis facilities failed to meet the goal (80% of patients Hgb≥11 gm/dL) and submitted a quality assessment improvement plan. These facilities remained on the QAIP through first quarter 2007. Facility monthly data were evaluated and those still not meeting the goal were contacted and technical assistance provided.

Due to the controversy surrounding ESA dosing the Boards modified the criteria for TARC intervention but not goal attainment. This meant that the goal would remain unchanged (≥80% Hgb ≥ 11gm/dL) but intervention would occur when ≥80% had a Hgb ≥10gm/dL. TARC reviewed the data and 8 facilities remained on an improvement plan.

Five of the 8 facilities demonstrated sustained improvement for 6 months and at year-end 3 facilities showed improvement but were not able to demonstrate sustainability. TARC provided technical assistance until sustained improvement was achieved for 6 months. In June 2008 the remaining 3 facilities completed the QAIP; the 25 facilities will be re-evaluated for sustainability when the 2009 electronic lab data is available.

Non-tunneled and Subclavian Catheters

Vascular access with catheters is required in a small number of cases and is not the preferred method if other alternatives are available. New cases may require short-term use until a permanent access with a fistula or graft is mature enough to use. Long-term use of catheters is discouraged because of the high infection rate; cuffed catheters and catheters placed in the internal jugular are recommended.

NKF-KDOQI guidelines for vascular access have become the standard of care for the renal community and they recommend:

- *Tunneled cuffed venous catheters are the method of choice for temporary access of longer than 3 weeks' duration;*

- *The preferred insertion site for tunneled cuffed venous dialysis catheters is the right internal jugular vein;*
- *Subclavian access should be used only when jugular options are not available;*
- *The subclavian insertion site should not be used in a patient who may need permanent vascular access.*

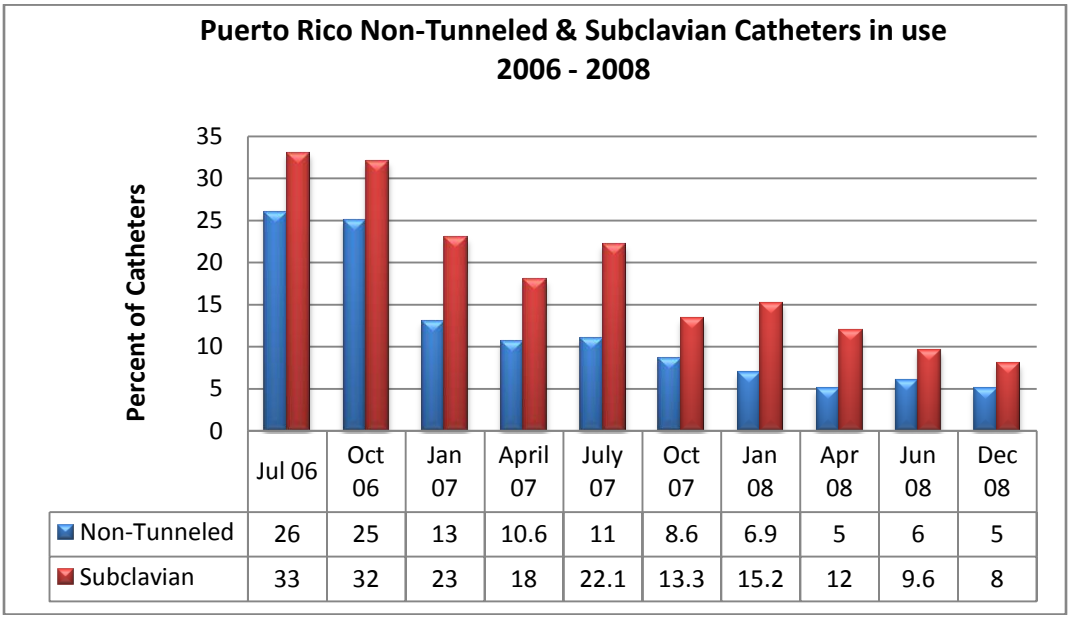
In July 2006, a cluster of 8 facilities in the northern section of Puerto Rico were observed to have non-tunneled catheters in 26% (384) of the patients with catheters (n=1,461). Eighty-one percent (313) of the non-tunneled catheters were placed in the subclavian vein, which is a practice not usually seen in this patient population. Other observations included:

- 81% (313 patients) of the non-tunneled catheters were placed in the subclavian vein;
- 54% (208 patients) had non-tunneled catheters in the subclavian vein for >90 days;
- Of the tunneled catheters (167) 66% were placed in the subclavian vein.

TARC obtained in August 2006 a small sample of comparative New Jersey data and found that only 14 patients or 1% of the 1,246 catheter population had non-tunneled catheters in use as primary vascular access, which confirmed the need to alter practice patterns among a certain group of facilities.

The 8 facilities have been on an improvement plan since 2006. In 2007 TARC continued to provide technical assistance, performed site visits at 29% of the facilities in Puerto Rico, conducted meetings with 3 local fiscal intermediaries, a representative from the office of the secretary of health, and met with hospital administration at one of the largest providers of vascular access on the island to decrease non-tunneled and subclavian catheters.

In 2008, TARC continued to track facilities to determine if they were able to maintain sustainability with decreasing non-tunneled and subclavian catheters. In June 2008, the medical review board noted a continued declining trend in both non-tunneled and subclavian catheters. The boards recommended a review of the facilities in 6 months (December 2008). The chart below shows facilities have continued the downward trend during the 6-month period.



	Jul 06	Oct 06	Jan 07	April 07	July 07	Oct 07	Jan 08	Apr 08	Jun 08	Dec 08
Non-Tunneled	26	25	13	10.6	11	8.6	6.9	5	6	5
Subclavian	33	32	23	18	22.1	13.3	15.2	12	9.6	8

TARC will continue oversight until the vascular access non-tunneled and subclavian catheters are used according to the NKF-KDOQI guidelines.

Technical and Collaborative Assistance Provided

The dialysis community discovered it could no longer continue to practice in an isolated area of medical care. Collaborative assistance is being sought from new sources, not only by the renal community and Networks, but also by all healthcare providers. TARC recognized this need and continued to develop programs to increase the knowledge and skills of the renal community. Beneficiary education, as well as staff, physician, and community education continues to be a major role of Networks.

TARC provided technical assistance, guidance and appropriate referrals for facilities and consumers. One of the key areas of need identified during site visits was the inability of facilities to lower the barriers that prevented improved outcomes. TARC provided tools and resources, shared experiences of other centers and suggested alternate courses of action to move beyond the barriers.

During site visits, meetings and mailings, TARC provided copies of *Fistula First* change concepts, data analyses, disaster preparedness, anemia management data and other valuable tools and resources.

All of these efforts were directed toward the ultimate goal of providing an environment of care that is not only safe but will produce optimum outcomes for all beneficiaries.

Educational Materials

An integral part of TARC's goal attainment effort is sought through consumer education. TARC continued to provide educational materials through newsletters and brochures directly mailed to each dialysis facility. Engaging patients and promoting active involvement with the renal team was considered essential and remained a priority.

TARC distributed to all dialysis facilities educational resources developed by the *Fistula First Breakthrough Initiative*, other Networks, CMS, ANNA, homeland security, the National Kidney Foundation and the Centers for Disease Control. Information distributed included: advanced care planning, complaints and grievances, home dialysis, diabetes, disaster preparedness, patient emergency cards, hepatitis, influenza, pneumococcal, immunizations, Medicare Part D, Medicare prescription plans, Medicare Advantage plan, transplantation, end of life and palliative care, , vocational rehabilitation, low income home energy assistance program, NKF coffee house conversations, Conditions for Coverage, vascular access, treatment modalities, DPC and addressing conflict situations, TARC and web site information, patient safety, Patient Advisory Committee, *Dialysis Facility Compare*, and the *CMS Guide-Emergency Preparedness for Dialysis Patients and Facilities*. TARC created and distributed to the dialysis facilities an English and Spanish CD with patient and staff education and quality improvement information.

Patients who participate in their healthcare decisions derive many positive benefits. TARC knows each consumer should be afforded the opportunity to become educated about their disease and treatment options so they may participate in their healthcare decisions. A degree of control and empowerment results in a greater sense of well-being and positive outcomes. Consumers educated about their rights and responsibilities take greater ownership of their care and treatment.

Consumers educated in the grievance procedure know they are not helpless when their care presents a troublesome situation. Consumers educated about quality indicators are able to track treatments and know what the measures mean. All of these facts help to make consumers know that they are part of a health care team that strives to achieve the optimum level of health for each patient. The continuum of care for consumers spans a wide range of providers. TARC, through the provision of educational materials, helped to clarify some of the confusing elements found in renal replacement therapy system.

A collaborative effort between TARC and the interdisciplinary teams at facilities selected for focused oversight proved successful. All groups continue to be monitored by TARC; the effort improved access rates, anemia management and non-tunneled and subclavian catheter rates at the facility level.

Consumer Impact

Delivering safe and effective care yields significant benefits to consumers through better management of the co-morbidities that affect consumers. Identifying models for appropriate clinical management provides consumers with a better quality of life, reduced hospitalization and fewer debilitating conditions.

Morbidity and mortality data showed that patients with a fistula access have improved quality of life, reduction of infections, and hospitalizations. TARC contributed to improvement in the quality of care at facilities noted for poor performance and outcomes with the dissemination of knowledge and resources necessary to improve the level of care delivered to patients.

Consumers benefited from their providers becoming informed about and responding to TARC-specific goals, which focused on quality renal replacement services. Existing or potential providers used TARC data to plan expansion programs and/or new facilities, assisted consumers by making treatment available in more locations or on additional shifts. Since the ultimate purpose of both TARC and facilities is to serve renal consumers, all renal-related educational materials enhance patient care delivery.

B. Improve the independence, quality of life, and rehabilitation (to the extent possible) of individuals with ESRD through transplantation, use of self-care modalities, as medically appropriate, through the end of life

The following statements approved by the Boards guided TARC's implementation efforts:

A Encourage the participation of patients, providers of services and ESRD facilities in vocational rehabilitation programs.

B Evaluate procedures used by facilities and providers to assess the appropriateness of patient treatment type.

1. Facilities will post in prominent place posters describing treatment modalities provided by TARC;
2. Facilities will provide treatment schedules that allow patients to work or refer to another facility with this ability;
3. Encourage the use of the treatment settings most compatible with the successful rehabilitation of the patient;
4. Facilities will assign specific staff with the responsibility for home designee. transplant designee and vascular access coordinator functions; and
5. Facilities will post in prominent place TARC's patient rights and responsibilities statement and distribute annually paper copies provided by TARC.

Supportive Activities

The *Consumer Rights and Responsibilities* flyer was distributed to all facilities in English and Spanish. Facilities were asked to display the material in a prominent place such as the waiting room and to distribute paper copies to all patients.

In addition to paper copies, TARC *Consumer Rights and Responsibilities* and the *Consumer Grievance Procedure* were posted on the TARC Web site in English and Spanish. When a new facility is approved as an ESRD provider by CMS, a package of resource materials is sent. Copies of the *Consumer Rights and Responsibilities* and *Grievance Procedure* are included.

TARC created and distributed to the dialysis facilities an English and Spanish CD with patient and staff education and quality improvement information. Patient educational information includes: complaints and grievances, rehabilitation, TARC, treatment modalities. Paper copies of the patient rights and responsibilities statement are distributed to the dialysis facilities annually.

Vocational Rehabilitation

Individuals with chronic kidney disease can live long, productive lives even though kidney failure is not a curable disease. Rehabilitating the patient with end-stage renal disease is admittedly difficult in certain situations. Improving outcomes of kidney disease usually requires that patients learn to manage their illness, report their symptoms accurately and advocate on their own behalf. TARC encouraged patients to become more informed partners in their own care.

Rehabilitation involves more than working to improve the clinical and functional status of dialysis patients; it is a comprehensive approach to care with the goal of helping patients resume

productive activities and independent living. The TARC Web site provided links to the Life Options Web site and other resources to assist patients achieve maximum rehabilitation potential.

The Life Options Rehabilitation Program contains on its Web site a program that was developed to help people live long and well with kidney disease by identifying and addressing the challenges with the goal of improving longevity and quality of life. Life Options developed rehabilitation and training resources for facility in-service programs. TARC promoted the utilization of this site.

The list of vocational rehabilitation offices in New Jersey, Puerto Rico and the Virgin Islands was sent to each facility and placed on the Web site.

Many dialysis facilities maintained activities with an active team approach to promote a vocational rehabilitation program by:

- Use of a centrally-located bulletin board that featured stories or topics regarding rehabilitation;
- Assess consumers' physical status, mental health and general well-being on a regular basis;
- Assess patient, family and staff attitudes toward rehabilitation;
- Screen for employment status or potential;
- Assessing job skills and suitability for vocational rehabilitation;
- Provide information about end-stage renal disease to employers as requested;
- Make information available about the benefits of working;
- Inform consumers annually about treatment modalities to accommodate work and life interests; and
- Utilize redesigned Life Options Web site (www.lifeoptions.org) which offers downloadable materials that can be reproduced.

Consumer Education

Consumers can be motivated to learn more about kidney disease and its treatment so that they will become more involved in self-advocacy, self-management and self-care. Helping consumers to set goals, share success stories and support independence are examples of encouragement activities that can ultimately improve quality of life on dialysis. Consumers need to participate in decisions about their own care. In order to do this, they must first understand the disease and its treatment.

Educating consumers is the key to developing this understanding. Educational goals must be geared to the needs and readiness of the consumer to achieve positive outcomes. Learning style and any barriers to learning, e.g., vision, hearing or language problems, must be addressed. Learning about kidney disease and all the treatment options can help consumers maintain a sense of control despite the challenges. It is critical to involve family members in educational efforts. Increased personal control, often gained through patient and family education, has been linked to improved adherence to treatment regimens and better quality of life.

Patient teaching about medications, diet, exercise, compliance with treatment schedules, and maintaining or restarting employment or school attendance were all favored as means to enhance rehabilitation. TARC encouraged patient care planning that would address attainment of the highest quality of life possible for each patient.

Summary of educational and other materials provided to facilities and/or consumers

Whenever possible, TARC provided educational material, technical assistance and guidance or made referrals to appropriate resources to assist facilities and consumers improve the quality of care and life for consumers. TARC made efforts to be sensitive to local renal community needs and familiarized others with its role, which includes coordinating activities and participating with the larger renal community. TARC received requests for information and assistance by letter, fax, phone call, the Web site and e-mail.

TARC held several educational programs in addition to the transplant designee programs sponsored by the Saint Barnabas Health Care system on April 1st and 15th. TARC's *Annual Council Meeting* was held in New Jersey on October 22. The meeting addressed quality improvement, understanding disparities in chronic kidney disease, hyperphosphatemia and hypertension management. An educational meeting was held in Puerto Rico on October 1st about Improving fistula maturation, infection control, water treatment and maximizing outcomes in the management of hyperphosphatemia.

In 2008, several WebEx educational programs about quality assessment and performance improvement were provided for dialysis facilities in New Jersey, Puerto Rico and the Virgin Islands during the months of March and August 2008.

TARC provided a presentation at the Council of Nephrology Social Workers annual spring meeting on May 1st, on the role of TARC, patient involuntary discharge, patient provider conflict management and the DPC toolkit and the role of the social worker in home therapies.

TARC sponsored an ANNA WebEx about transplantation on October 8th for dialysis facilities in New Jersey, Puerto Rico and the U.S. Virgin Islands. TARC also presented a session at the ANNA Garden State Chapter 125, annual spring program on Thursday, May 15, 2008, about the conditions for coverage and patient involuntary discharge.

In 2008, TARC planned and organized two patient education programs. On April 27, TARC in collaboration with FMC Five Points Dialysis Center and FMC Maplewood Dialysis Center provided a presentation to the dialysis patient and family education and support group about TARC structure and function, vascular access and the fear of cannulation. On September 30th in Puerto Rico, TARC presented information about vascular access, patient rights and responsibilities and information about TARC.

The Patient Advisory Committee collaborated with the New Jersey Renal Coalition to plan and organize the patient education programs that were held on June 17 and November 13, 2008, about secondary hyperparathyroidism, vascular access and fear of cannulation. The committee reviewed and determined patient educational handouts and materials for the programs.
TARC staff received numerous telephone calls from both stage 5 and earlier stage chronic kidney disease consumers with questions about Medicare coverage rules and regulations. Some information was provided directly, other consumers were referred to their nephrology social workers and TARC Web site while others were referred to CMS or other responsible agencies.

Materials were distributed to facility medical directors, head nurses, administrators and quality improvement coordinators during facility visits, in hardcopy mailings or e-mail; several were given as handouts at TARC meetings. In addition to mailings, staff responded to individual requests for data and information throughout the year.

Home Dialysis

Home dialysis as a selected modality continued to decline in the number of patients who chose this setting despite the increasing caseload and nursing shortage.

TARC Percentage of Home Patients by year

Home Dialysis Patients (%)				
2008	6		2001	9
2007	6		2000	10
2006	7		1999	12
2005	7		1998	14
2004	7		1997	16
2003	8		1996	18
2002	9			

Source: SIMS database

Home hemodialysis has not been a popular modality for many years. However, in 2008, there were 59 patients receiving home hemodialysis compared to 44 in 2007. Nationally, home dialysis is gaining momentum and an increase in this form of therapy may be realized in future years.

Sixteen providers in New Jersey treated 57 home hemodialysis patients. Two facilities provided home hemodialysis services in Puerto Rico. No facilities offered home hemodialysis in the Virgin Islands.

TARC recognized three variables that affected the number of home dialysis patients: a lack of patient education in home therapies, a shortage of nephrologists comfortable with prescribing peritoneal dialysis and a shortage of qualified nurses available to provide education and training for home dialysis modalities.

During educational meetings and facility visits, TARC reminded facility staff to consider patients for home dialysis and refer patients accordingly. TARC developed and distributed to all facilities a *Treatment Options* poster that facilities are required to post in the patient waiting room. The poster describes the pros and cons of hemodialysis, peritoneal dialysis and transplantation.

For the past several years TARC sponsored the home designee program which has had little impact on the promotion of home dialysis therapies. TARC redesigned its approach to home dialysis improvement and decided to focus future efforts on social workers; an awareness meeting was held May 1, 2008.

TARC believes that home dialysis is beneficial for many consumers and continued to develop programs to assist the consumer in making an educated modality decision. Patients were encouraged to pursue home dialysis as an option.

Kidney Transplantation

Consumers must receive information about all treatment modality options prior to initiation of renal replacement therapy and at regular intervals following initiation of therapy. While some consumers may have had ample time to learn about treatment modalities before starting treatment, others have had little time between diagnosis and initiation of treatment. All consumers must know that the option to be evaluated for a modality change is available at any time.

Long waiting lists for organs are problematic both in Network 3 and throughout the country. TARC's 6 transplant facilities had a total of 2,861 people on their kidney transplant waiting list on December 31, 2008,▲ which is a slight decrease from 3,129 people on the waiting list in 2007. The list included patients from outside TARC's boundaries as well because patients are not limited to local centers but may register at any accredited center.

Many factors affected the actual number of kidney transplants performed: availability of transplant surgeons, operating room schedules, intensive care facilities, specialized nurses and other ancillary staff. The major factor was the number of organs available. Historically, most people on transplant lists have had to wait for cadaveric kidneys.

Interstate transplant referral patterns have been operative for many years. Dialysis consumers sought transplant services not only at one of the six local programs but also at those in neighboring or distant states. For example, some New Jersey dialysis consumers received cadaveric organs or transplant work-ups in New York, Maryland, and Pennsylvania. A number of Puerto Rico consumers received kidney transplants in Texas and Florida.

The vast majority (86.7%) of the Medicare-approved and veterans administration dialysis programs in the Network at year's end had a minimum of one patient who received a kidney transplant. The range in number of dialysis consumers who received a transplant from those dialysis facilities ranged from 1 to 24 consumers.

Transplant designees served as the initial link between the consumer and the ultimate goal of transplantation. Their responsibilities include: educating the dialysis patients about transplantation, reviewing cases for medical suitability, reporting referrals to the transplant surgeons and documentation of transplant discussions in the medical record. Dialysis providers, by pursuing this activity, sought to make the option of a transplant work-up available to medically-suitable consumers. Unfortunately, during 2008, the number of organs available and suitable for use was still lower than those needed or desired by TARC's dialysis patients.

Immunizations

TARC distributed to dialysis facilities information to inform their patients about the flu, hepatitis and pneumonia immunizations. This information included *Importance of Influenza Vaccination for Health Care Personnel*, the *CMS 2008-2009 Influenza Season Resources for Health Care Professionals*, and the recommended immunization schedule for chronic kidney failure and ESRD patients. TARC distributed the *CDC Recommends Shingles Vaccine* and invited facilities to participate in the COCA Conference Call: Seasonal Influenza Update on October 28, 2008. TARC's Web site contains vital information on immunization.

Volunteerism

TARC together with dialysis facilities encouraged patients to volunteer at their local food kitchen, American Red Cross and to join the Patient Advisory Committee, all of which would help improve their quality of life and also help others. Psychologically, efforts to help others despite one's own disability often result in unanticipated benefits and greater well-being.

Effectiveness

TARC had a total of 637 transplants, 538 in-center patients, 99 home dialysis patients, over 400 transplant and home dialysis designees providing treatment, modality education. Home dialysis

▲ Source: SIMS database

was chosen by 6.7% of the entire patient caseload. TARC saw a 26% increase in the number of home hemodialysis patients, while the number of peritoneal dialysis patients decreased by 2.2%. A *Treatment Options* poster was distributed to 100% of TARC's facilities. Ninety-seven percent of facilities site-visited had a vascular access coordinator.

During 2008, 55 site visits were made, which was 36% of all TARC facilities. Treatment option posters, *Consumer Rights and Responsibilities* and *Consumer Grievance Procedures* were posted in clear view at 100% of the facilities visited.

In an effort to evaluate the effectiveness of TARC's site visits, which are labor intensive, TARC developed an evaluation tool using a Likert scale of 1- 5 (low - high). Summary scores ranging from 12-15 indicated the evaluator considered the site visit to have been "highly effective." Scores <11 indicated the site visit could have been more informative. Thirty-seven responses were received and 94% of the evaluators rated the visits as highly effective.

TARC continued to encourage rehabilitation and individualized care planning. Vocational rehabilitation is an ongoing process that needs repeated attention to continue its development. Material was distributed to facilities for use with consumers; other resources were made available both through mailings and on the Web site.

Dialysis facilities in New Jersey reported 3,012, patients between the ages of 18 to 54. Sixty-six patients received services from a vocational rehabilitation program and 1,006 were employed (full or part time); 103 patients attended school (full or part time). In Puerto Rico, there were 1,299 patients between the ages of 18 and 54 years. Fifty-seven patients received services from a vocational rehabilitation program, 207 patients were employed (full or part time) and 32 patients attended school (full or part time). Of the 74 Virgin Islands dialysis patients in the same age range, 3 patient received services from a vocational rehabilitation program, 28 patients were employed (full or part time) and 1 patient attended school (full or part time).

TARC had a total of 4,385 patients in the 18-54 age group; 126 patients received services from a vocational rehabilitation program. Those employed numbered 1,241 and 127 patients attended school (full or part time). TARC had 34% of patients who received services from a vocational rehabilitation program, were employed (full or part time), and/or attended school (full or part time), this represents a decrease of 3% since 2007.

Consumer Impact

Lifestyle changes are inevitable for stage 5 chronic kidney disease consumers but, to the extent possible, these should be minimized. Material was distributed to facilities for use with consumers, and other resources were made available through several mailings and on the Web site.

Consumers must be afforded the opportunity to become educated about their disease and treatment options so they may actively participate in their healthcare decisions. All efforts were made to provide consumers with the knowledge to choose the desired modality. Treatment option posters were distributed to 100% of Network facilities. Consumer rights, responsibilities and grievance procedures were provided to facilities to encourage early problem resolution. End-of-life material was made available on the Web site.

TARC encouraged consumers to take an active role to improve mental health and quality of life through self-management and rehabilitation, education, exercise and employment. TARC continued to encourage rehabilitation and individualized care planning.

C. Improve patient perception of care and experience of care and resolve patient complaints and grievances

a. Implement procedures for evaluating and resolving patient grievances.

1. Each facility will post in prominent place TARC's grievance policy and distribute annually paper copies provided by TARC.
2. Each facility will fully document all involuntary discharges and notify TARC of each occurrence.

Supportive Activities

The consumer grievance flyer was distributed to all facilities in English and Spanish. Facilities were asked to display the material in a prominent place such as the waiting room, and distribute paper copies provided to all patients. In addition to paper copies, TARC *Consumer Grievance Procedure* was posted on the web site in English and Spanish. When a new facility was approved by CMS as an ESRD provider, a package of materials is sent which contains the *Consumer Grievance Procedure*.

A patient education brochure titled *I Am A Kidney Patient What Can I Do If I Have a Complaint* describes in basic terms the complaint process and how to contact TARC. The brochure was translated into Spanish and distributed to all facilities in English and Spanish. Additionally, TARC promoted an increase in beneficiary awareness of TARC functions and responsibilities through patient education programs, the Patient Advisory Committee newsletter, *Kidneys R Us,* and the *What is TARC* poster.

Patient Advisory Committee

The Patient Advisory Committee consists of patients from dialysis facilities in TARC's area and represents all modalities. Members have a genuine concern for quality of care issues. The committee serves as a link between patients and TARC, encourages patients to be involved in their healthcare, share skills, knowledge and experience, attend meetings and conference calls.

The committee supported TARC's mission to improve the quality of care provided to patients and represented the entire patient population. The committee provided consumer advice to the Medical Review Board and the Board of Trustees. The committee was involved in creating the patient newsletter, *Kidneys R Us,* and assisted with the development and promotion of educational materials and resources for patients.

In 2008, the committee developed, reviewed and organized the content for the newsletter, which was distributed in April, September and December. The newsletters were translated into Spanish and distributed to all the facilities. Content included: the patient advisory committee and how to join, phosphorus and calcium, dialysis cookbooks and recipes, the patient's poet corner with a poem "I'm In Charge" *by Nick Palmeri,*,exercise, traveling on a dialysis cruise ship, how to get a medical alert bracelet, transplantation and diabetes. Information about TARC, the patient's toll free number and the Web site were included in every newsletter.

The committee collaborated with the New Jersey Renal Coalition to review and determine patient educational handouts and materials for the patient education programs that were held on May 22 and October 11, 2007, and in June 17th and November 13, 2008, on "Your Achy Breaky Heart: What You Need to Know About Secondary Hyperparathyroidism", "What you Should Know About your Vascular Access" and "Fear of Cannulation."

Evaluate and Resolve Patient Grievances

TARC may receive a written or oral complaint or grievance from a stage 5 chronic renal failure consumer, consumer representative, family member, friend, or others concerning either dialysis or transplant providers.

Referrals of ESRD consumer complaints or other concerns may be received from professional review organizations, state agencies, Medicare hotline numbers and Medicare intermediaries. When an oral grievance is received, the person taking the grievance will usually ask the consumer to document it in writing. During complaint investigations, consumers may designate representatives to act on their behalf. Immediate investigation is started for a potentially life-threatening issue.

Consumers were encouraged to use facility internal processes prior to referring a grievance to TARC because local problem solving can preclude escalation to a more serious level. When a patient did not wish to use the facility process (it is not mandatory that consumers use the facility grievance process), they contacted TARC for assistance.

TARC's responsibility for complaints/grievances is to review issues raised and determine the required action, i.e., investigation or referral. Attempts were made to resolve complaints or grievances by acting as an investigator, facilitator, referral agent, or coordinator between a patient and the provider.

Quarterly, TARC reviewed and analyzed contact information at internal quality improvement meetings. Data were evaluated for trends, interventions formulated and discussed with the patient committee and Boards if indicated. TARC noted an increase in the number of calls concerning involuntarily discharged patients due to abusive and/or disruptive patient behavior.

TARC staff worked with facility leadership to avoid involuntary discharge and recommended the use of the Dialysis Patient Provider Conflict Resolution tool kit. In 2008, TARC tracked the incidence of involuntary discharge to evaluate the extent of the problem. An educational program was held for dialysis social workers and nurse managers on conflict resolution management, complaints and grievances and involuntary discharge on May 1, 2008.

Patient Complaints and Grievances Categorized in the Standard Information Management System (SIMS)

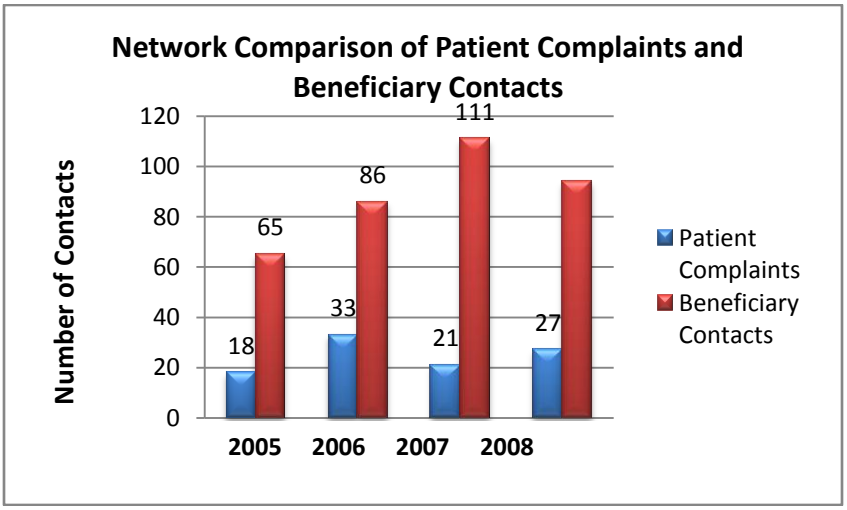
There were 43 complaints which TARC addressed and many more concerns and issues. An aggregate summary of actions follows:

2008	Beneficiary Inquiries	Complaints	Data proces-sing	Facility concerns	Facility Inquiries	Other Inquiry	Total
Abusive	0	3	0	1	1	0	5
Data Request	0	0	2	0	1	1	4
Disruptive	0	0	0	4	0	0	4
Information	42	0	7	4	40	29	122
Non-Compliant	0	0	0	3	1	0	4
Other	0	0	5	1	1	5	12
Patient Transfer/ Discharge	3	14	13	14	6	7	57

2008	Beneficiary Inquiries	Complaints	Data proces-sing	Facility concerns	Facility Inquiries	Other Inquiry	Total
Physical Environment	0	2	0	2	0	0	4
Pre ESRD Inquiry	1	0	0	0	0	0	1
Professional Ethics	0	7	0	2	0	0	9
QI Projects	0	0	35	1	7	0	43
Reimbursement /Financial	8	3	0	0	1	2	14
Request for Educational Materials	6	0	0	1	5	1	13
Request for Forms	0	0	14	0	4	8	26
Request for Technical Assistance	4	0	66	3	29	18	120
Staff Related	0	3	0	0	1	0	4
Treatment/ Quality of Care	3	11	0	2	0	0	16
Vision	0	0	12	0	0	0	12
Total	67	43	154	38	97	71	470

A total of 470 contacts were entered in the SIMS database; of those, beneficiaries initiated 20%. Forty-five percent of the beneficiary calls were information inquiries. Beneficiary complaints resolved included scheduled dialysis treatment times, dialysis reimbursement, blood pressure problems, treatment during dialysis, access infections, dialysis facilities with a bed, transportation problems, involuntary discharge, fluid weight loss during dialysis, physical environment, medication administration, facility admission policy, dietary questions, dialysis machine alarms, chest pain on dialysis, and professionalism of staff members. Information requests, either facility or beneficiary-initiated, accounted for 63% of all complaints.

Beneficiary concerns and inquiries were addressed internally by TARC. Referrals for beneficiary concerns were made, when indicated, to other agencies, when appropriate.



Contacts from consumers and facility staff are grouped into certain categories. Grievances are requests for formal investigation, usually related to a quality of care issue, of a serious complaint involving a facility, physician or other provider. Complaints are requests for assistance about, but not limited to, care or treatment issues. Inquiries are requests for information, advice, referral, or educational material that do not require problem resolution. Facility concerns are staff requests for guidance or advice/assistance in handling difficult situations that are patient-related (clinical or behavioral). Facility inquiries are staff requests for information, advice, referral, or educational material.

In 2008, TARC promoted an increase in beneficiary awareness of Network functions and responsibilities. Beneficiaries and their families were provided information through patient education programs, the Patient Advisory Committee newsletter, and the "*What is TARC"* poster. TARC encouraged open lines of communication through education and information about how to contact TARC as well its toll free telephone number. The patient service coordinator assumed a proactive role in the facilitation and resolution of patient and/or facility situations and organized the Patient Advisory Committee meetings.

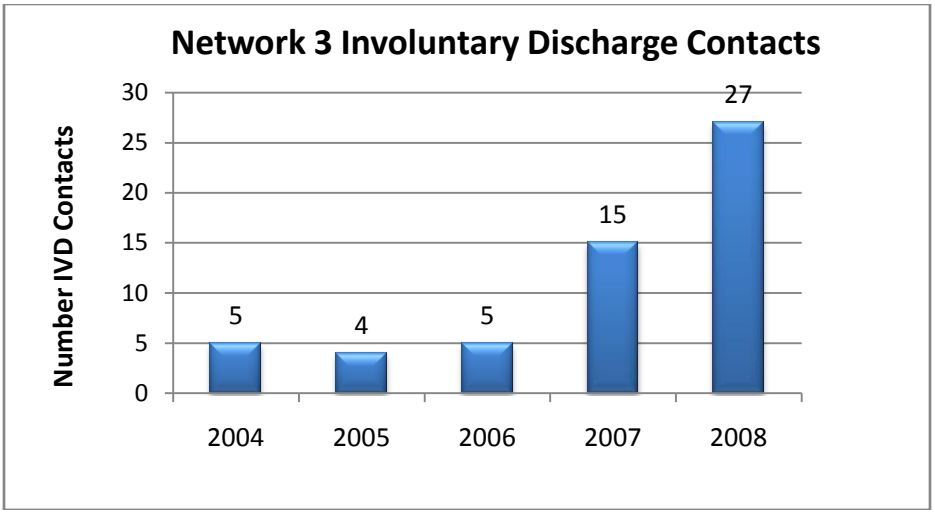
TARC distributed the *What is TARC?* poster in English and Spanish and *I Am A Kidney Patient What Can I Do If I Have A Complaint?* brochure. During site visits, TARC staff ensured proper posting of TARC information; patients were interviewed and asked if they were aware of TARC resources and contact information to evaluate the effectiveness of educational tools. The Patient Advisory Committee collaborated with the New Jersey Renal Coalition to present 2 patient education programs in 2008. These programs distributed information about the complaint/grievance process, presented the role and function of TARC which has contributed to the increase in the number of beneficiary complaints. A program in Puerto Rico provided patients with information about TARC and the complaint/grievance brochures in Spanish.

Additionally, TARC distributed copies of the grievance procedure to all facilities in New Jersey, Puerto Rico, and the Virgin Islands. Facilities, in turn, made these available to consumers on patient bulletin boards, handouts in waiting rooms and in orientation packets. Facilities met their obligation to distribute the Network grievance procedures and address issues of patient concern at the facility level.

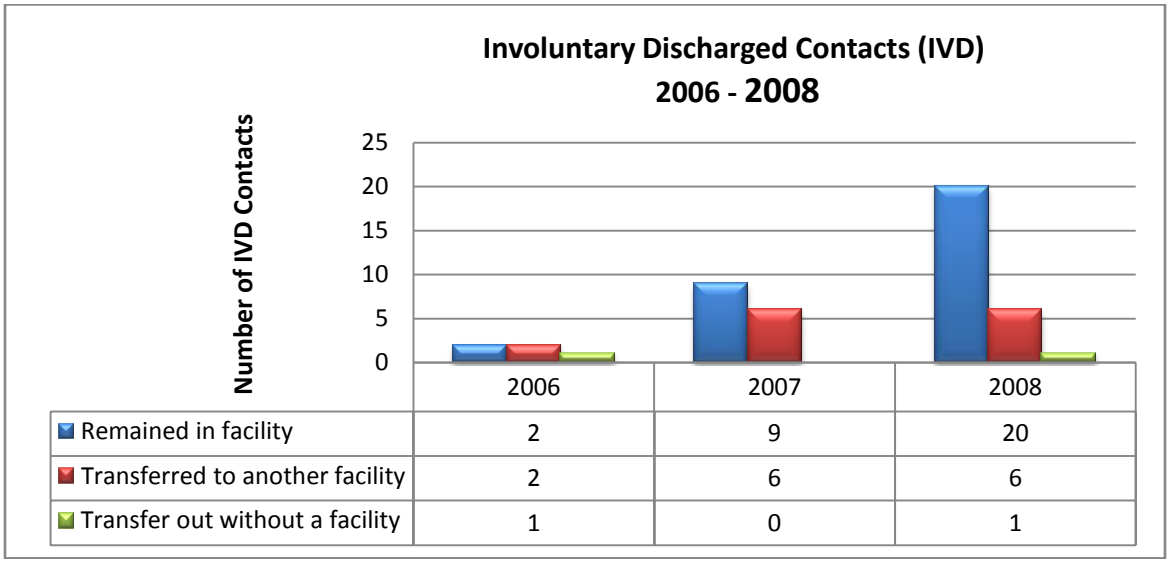
No formal grievances were filed.

INVOLUNTARY DISCHARGE (IVD) CONTACT COMPARISONS

TARC started tracking potential involuntary discharge (IVD) patients from 2004 through 2008 and noted a significant increase in the last two years. The number of IVD contacts has almost doubled from 2007 to 2008. TARC's goal was two-fold: 1) work with the facility to preclude the involuntary discharge of the patient, 2) provide education and encourage the use of the DPC toolkit to prevent the issue from escalating to the point of IVD.



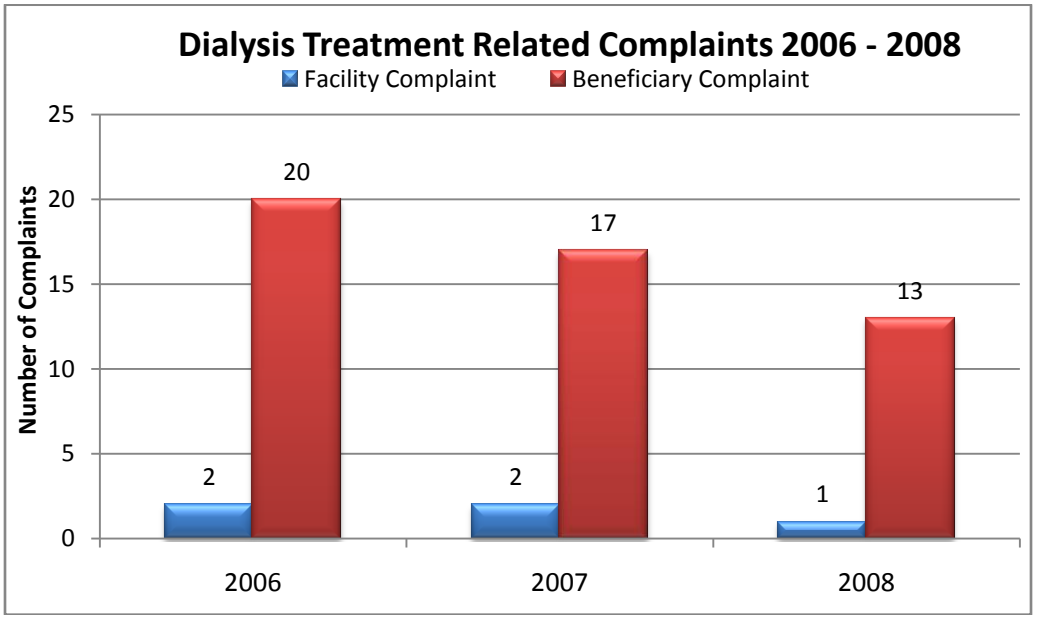
The graph above represents the number of contacts received by TARC regarding potential involuntary discharge (IVD) patients from 2004 through 2008. TARC has noted a significant increase in the number of IVD contacts in the last two years. In 2008, 97% of all the attempted IVD patient issues have been resolved and the patient remained in the facility or was transferred to another facility.



	2006	2007	2008
Remained in facility	2	9	20
Transferred to another facility	2	6	6
Transfer out without a facility	1	0	1

The graph above represents the number of IVD patients that remained in their facility after TARC intervention. Patients with unresolved issues or irremediable behavior were transferred to another facility. In 2007, all patients either remained in their facility or were transferred to another facility. In 2008, one patient of twenty-seven was transferred out without acceptance into another facility. TARC will develop a DPC poster for patients and staff to be displayed in the dialysis facility in next quarter

TARC noted a significant increase number of IVD contacts in 2008 as compared to 2007. Ninety seven percent of the IVD contacts were resolved through intervention. The number of patients remaining in their facility has significantly increased due to the cooperation of the facilities resolving conflict issues with the patient.



The above chart shows the number of beneficiary and facility contacts with concerns regarding treatment-related quality of care issues. In the third quarter 2008, the number of contacts increased to 6 beneficiary contacts compared to 3 in the first and second quarters. The total number of treatment related/quality of care issues for 2008 is thirteen. TAR noted the decrease in the number of beneficiary contacts regarding treatment-related quality of care issues.

Web Site

TARC's Web site provided a question and answer section for patients. Patients asked directly for information and had questions answered that related to their renal disease or dialysis. The questions were first answered by the quality improvement coordinator, reviewed by the executive director and by a medical review board physician for clarity and accuracy of information provided to consumers. Consumers who had Spanish as their primary language also used the site since the entire content is available in Spanish.

The questions originated from anyone with a renal-related issue, not just consumers within TARC's boundaries; subjects included transplant, dialysis and 'other renal.' The issues were diverse and included protein in urine, renal cysts, vascular access including fistulae, grafts and buttonhole technique, acute renal failure, quality of life and termination of dialysis.

Within the dialysis area, peritoneal dialysis, medications, congestive heart failure, vascular access aneurysm, creatinine clearance, life expectancy on dialysis and dialysis modalities were examples of issues addressed. The 'other renal' field contained such topics as new diagnosis of kidney disease, polycystic kidney disease, diabetes, hepatitis B blood results, and infections. In the 'no relation to renal' field, the subjects ranged from pregnancy, leukemia, hypertension, hypotension, heart transplantation to blood donation.

The report generated gave an overview of the number of visitors to the Web site, by period:

Measure	1Q	2Q	3Q	4Q	Total
Visitors	18,262	14,787	18,874	14,669	66,592
Visits	29,843	25,543	35,239	26,791	117,416
Pages Viewed	149,198	100,925	157,117	149,673	556,913

Consumer Impact

Consumers should be afforded the opportunity to become educated about their disease and treatment options, standards of care, rights and responsibilities as well as those of caregivers so all participate in healthcare decision processes. Appropriate clinical management provides consumers with a better quality of life, reduced hospitalizations and less morbidity. TARC continued to contribute toward these outcomes.

D. Improve collaboration with providers and facilities to ensure achievement of goals A through C through the most efficient and effective means possible, with recognition of the differences among providers and associated possibilities/capabilities.

Establish and Improve Partnerships and Cooperative Activities

CMS encourages Networks to establish and enhance partnerships with other health agencies and groups. TARC collaborated with CMS regional offices, state survey agencies, New Jersey and Puerto Rico Departments of Health, other sections of government, quality improvement organizations, the New Jersey Renal Administrators Assn., American Nephrology Nurses Association (ANNA), Council of Nephrology Social Workers, insurance carriers, and interested agencies to improve the quality of care provided to consumers.

These activities included sharing information with other agencies and referring appropriate quality of care issues. Members of ANNA, insurance carriers and the quality improvement organization actively participated in the chronic kidney disease coalition task forces to improve fistula placement and identify early kidney disease.

Health and safety problems and complaints were referred to the appropriate state agency for investigation and resolution. TARC held telephone conferences with state agency personnel in New Jersey, Puerto Rico and the New York Regional Offices for the Virgin Islands. TARC is collaborating with the New Jersey QIO on the care transitions initiative. TARC sent the state agencies copies of TARC's annual report and pattern analysis reports.

TARC met its responsibility to partner with other governmental agencies and contractors to enhance the safe and therapeutic delivery of renal services.

Coalition

In March 2005, CMS introduced the *Strategic Partnership for Change* initiative to ESRD Networks. The goal of the program was to *…ensure optimum quality of care along the continuum of Chronic Kidney Disease (CKD/ESRD) and End Stage Renal Disease by using coalition and partnership building as strategic tools*. The coalition structure and mission were introduced to the TARC's renal community.

The New Jersey Renal Coalition was formed with two tasks forces - the professional and patient/consumer education groups. Members included nursing administrators, insurance carriers, the New Jersey Department of Health, New Jersey Healthcare Quality Strategies Organization, American Nephrology Nurses Association, American Dietetic Association, New Jersey Hospital Association, New Jersey Nephrology social workers and other interested groups. The task forces met quarterly in person or by conference call. Periodically, the groups met jointly to discuss projects and progress. In July 2008 the members decided to combine the two task forces and continue activities as one

The quarterly vascular access medical director report cards were distributed to all dialysis facilities in New Jersey. The quarterly report ranked the facility within the state by prevalent fistula and catheter rates. The report also included the percentage of incident patients starting dialysis with a catheter or functioning fistula.

The patient education task force held two patient education programs in June and November 2008, partnering with the Renal Support Network and the New Jersey Healthcare Quality

Strategies organization. A patient guest speaker from the Renal Support Network spoke on *Your Achy Breaky Heart: What You Need to Know About Secondary Hyperparathyroidism*, and coalition members presented *What You Should Know About Your Vascular Access* and *Fear of Cannulation.* The target audience selected for the initial programs was southern and northern New Jersey.

Transplantation

TARC participated in planning the transplant designee conferences held in 2 locations in New Jersey. The program was developed in collaboration with the Saint Barnabas Healthcare system and held on April 1 and April 15, 2008. TARC staff shared its annual report with organ procurement organizations serving the various geographical sections of New Jersey, Puerto Rico and the US Virgin Islands.

Emergency/Disaster Preparedness and Response

In 2008, TARC continued to enhance the Patient and Provider Continuity and Contingency Plan, a network-specific plan that outlines TARC's responsibilities related to emergency and disaster preparedness and response.

Contents included information for New Jersey, Puerto Rico and the U.S. Virgin Islands:

- TARC's emergency disaster preparedness and response policy;
- Universal codes for Networks; Emergency Network staff contacts;
- Facility contacts by state, county and affiliation (large dialysis organization, hospital based or independent);
- Emergency state contacts; NJ/PR/VI utility contacts; NJ/PA generator retail locations;
- List of patients by zip codes and age group; and List of Network executive directors; and
- Back-up agreement with Network 13.

TARC staff participated in the national Kidney Community Emergency Response Coalition and participated on the NJ Special Needs Advisory Panel. On June 10, 2008, TARC held the second renal community/state office of emergency management (OEM) meeting introducing the renal county representative to the respective county OEM representative, opening the doors of communication and assisting the facilities to meet the new conditions for coverage that require facilities to meet with the local OEM annually.

In July 2008, New Jersey OEM introduced the NJ Special Needs Registry for Disasters (Register Ready) in six southern New Jersey counties. To date over 300 dialysis patients have registered.

In September 2008, TARC staff attended an emergency management meeting hosted by Robert Wood Johnson University Hospital to discuss the special needs of the dialysis patient. The hospital was developing plans to provide emergency back-up services for local dialysis facilities.

TARC participated in the southern region Medical Coordination Center program and presented a slide presentation to the members on the impact of hurricanes on the renal community and the lessons learned from Katrina and other major storms.

Water Treatment

TARC assisted local water companies by alerting facilities when the routine disinfection process changed from chloramines to free chlorine and vice versa and/or if the water was supplied through a different source.

A representative of the water company was included in the ESRD Disaster Preparedness Planning Committee.

Effectiveness

TARC's collaborative activities strengthened relationships with organizations within and outside the renal community. Opening the doors of communication with outside agencies helped increase awareness of the special needs of the dialysis consumer and treatment facilities.

TARC held quarterly conference calls throughout the year with representatives from each state survey agency. Issues discussed included quality improvement activities, complaints and grievances, patient safety, quality of care issues and the Fistula First Initiative. The New Jersey and Puerto Rico state agencies added Fistula First inquiries to the survey process.

The CMS Regional Office in New York and the Virgin Islands Medical Institute worked collaboratively with TARC on quality of care and patient safety issues.

TARC also partnered with public utilities to notify dialysis centers in a geographic region of changes to the water treatment process.

TARC staff worked with the Community Education and Clinical Practice task groups of the National Fistula First Breakthrough Initiative, assisted with material preparation and participated in the monthly core group conference calls.

The New Jersey Renal Coalition raised the awareness of those outside the renal community and included a few new partners. State agencies, insurance carriers, Healthcare Quality Strategies organization, hospital staff, American Nephrology Nurses Association, American Dietetic Association, New Jersey Renal Administrators, all participated in coalition activities.

Consumer Impact

Collaboration and partnerships have become integral to TARC's activities and will play an even more vital role in the future. The heart of the renal care team remains the patient. One of TARC's primary roles is to ensure appropriate care across the continuum of care by building new partnerships. Continuity, collaboration and communication and their influences on the care of the patient population are vital to the program's success.

E. Improve the collection, reliability, timeliness, and use of data to measure processes of care and outcomes; to maintain a patient registry; and to support the goals of the ESRD Network Program.

a. Collect, validate and analyze data for the preparation of reports and assure the maintenance of a national ESRD registry.

b. Submit an annual report to the Secretary.

- Each facility will monitor forms submission and maintain the required timeliness and accuracy rates of 90%.
- Each facility will promptly address data discrepancies identified by TARC.

Supportive Activities

The goal of improving standardization of information management within TARC consists of several measures.

SIMS

SIMS is an integrated system that provides communication and data-exchange links among the Networks, facilities, and CMS. Each Network has a local database where patient, facility, and facility personnel data are entered and maintained. Through an automated data transfer application, the SIMS database was replicated to the central repository on a nightly basis. Replication was checked daily to assure that the process occurred successfully. The replication process was monitored, performed reliably on a daily basis and was documented on a quarterly basis in TARC's logs.

SIMS has the capability to produce various reports used by facilities to ensure facility-reporting accuracy. In particular, the annual CMS-2744 form was completed, and used to validate patient activity throughout the year. The validated data is patient-specific and provides elements such as age, race, sex, ethnicity, diagnosis and modality/setting of care, as well as patients' county and state of residence. This information was used to reconcile TARC's database.

SIMS was also used for receiving and processing notifications from CMS. Notifications are records in which particular elements, such as patient date of birth, date of death, first name, HIC number, most recent transplant date, most recent transplant failure date, sex, social security number, or surname are found to be different than what is on file with the Social Security Administration. TARC sent these records to the appropriate facility once each month, where the facility verified the data, and returned to the Network office the correct information.

All data discrepancies were reviewed for validity and accuracy through notifications and discrepancies were resolved within the SIMS database. This process was run on a monthly basis. Data clean-up activities were also run on a monthly basis; utility logs showed resolved queries and any that needed to be addressed.

To accomplish accurate and timely data reporting, all facilities notified TARC of all patient status changes on a monthly basis. Any changes in the dialysis caseload were noted, including:

- Newly-diagnosed consumers who started a regular course of dialysis;
- Changes in modality during the month (e.g., hemodialysis to CAPD);
- Changes in setting during the month (e.g., facility patient who started home dialysis);
- Transfers into or out of the facility during the month;
- Returns to dialysis after renal transplant grafts failed;

- Restarts to dialysis after temporarily regaining kidney function;
- Patient deaths;
- Discontinuation of dialysis treatment;
- Patients who became lost to follow-up; and
- Patients who regained native kidney function to the extent that dialysis was stopped.

Data Reconciliation

Input forms employed to maintain TARC's patient-specific data system included:

- Monthly Caseload Changes/Census form
- End Stage Renal Disease Medical Evidence Report: Medicare Entitlement and /or Patient Registration (CMS-2728)
- ESRD Death Notification form (CMS-2746)

Forms used to check and reconcile data that were submitted as required, included:

- ESRD Facility Survey (CMS-2744)
- Accretions lists from CMS
- Notifications from CMS
- Federal REMIS web site

TARC staff validated and monitored the accuracy and timeliness of data submissions from all dialysis and transplant programs in New Jersey, Puerto Rico and the Virgin Islands. Facility compliance was monitored for each of the federal medical information system forms listed. Semiannually, the data file was run through customized programming. Two aspects of facility feedback were generated for each of the required forms:

- Compliance rate summary report
- Detail of each form submitted

The compliance rate summary report presented calculations of the total number of forms transmitted, the number of forms submitted that were within the 30 or 45 day goal, the number of forms with errors and the percent compliance by each facility. The detail report generated patient-specific information on each form.

Forms compliance reports were distributed to facility administrators with the request that they positively recognize those employees who achieved the reporting goal of submitting forms within 30 or 45 days of events. Alternately, if the compliance reports reflected forms that were overdue and outstanding, administrators were expected to follow-up with their employees to correct factors that affected non-compliance.

CMS Notifications

CMS notifications are requests for patient database validity information. Each month notifications were sent to those facilities where discrepancies were noted by CMS. Facilities then reviewed the element in question and either reported the value as correct or provided to TARC with the corrected data element. The corrected/validated information was entered in the SIMS database, which ensured accurate data in the national database and REMIS.

End Stage Renal Disease Medical Evidence Report: Medicare Entitlement and /or Patient Registration (CMS-2728)

End Stage Renal Disease Medical Evidence Report: Medicare Entitlement and /or Patient Registration (CMS-2728) is the initial reporting form for all persons with end-stage renal failure who began a regular course of dialysis or had a renal transplant as a first form of therapy. The

form was completed and submitted to TARC by facilities and veterans' administration hospitals according to federal regulations. Submission is expected within 45 days of the start of renal replacement therapy whether or not the patient applied at that time for financial coverage under the federal Medicare program.

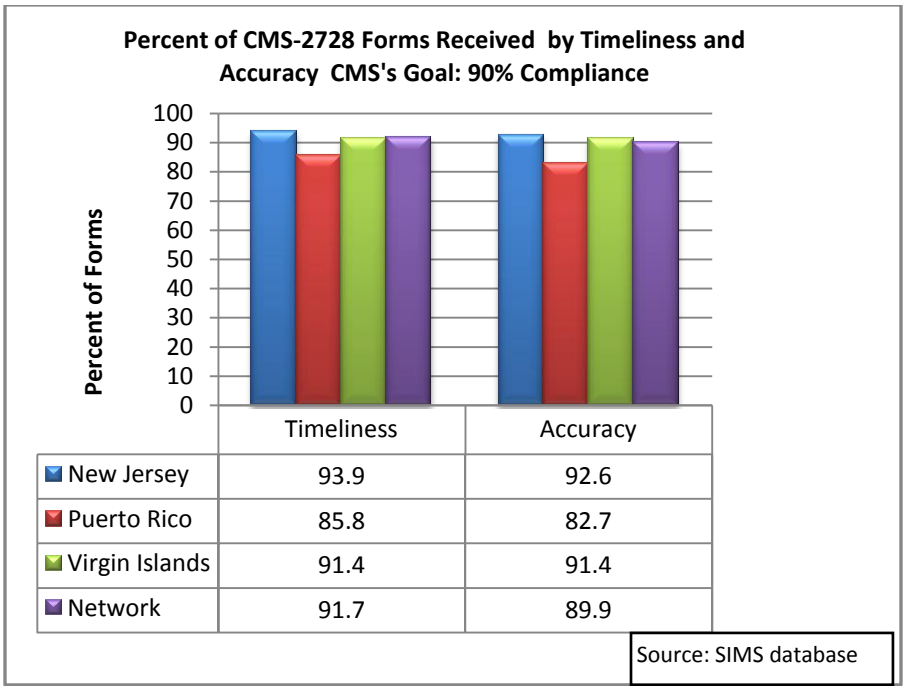
TARC staff entered data from the forms into computer software supported by the federal government. If data required on the form were missing or incompatible with CMS software, the form was rejected by the software and returned to the facility for correction.

TARC's dialysis facilities submitted 5,300 initial forms during the year; of these 4,858 (91.7%) were on time and 4,764 (89.9%) were accurate.

New Jersey facilities submitted 3,816 forms, of which 3,532 (92.6%) were completed accurately and 3,582 (93.9%) met CMS's timeliness criterion.

Facilities in Puerto Rico submitted 1,425 forms of which 1,223 (85.8%) were on time and 1,179 (82.7%) were completed accurately.

Fifty-eight forms were received from the Virgin Islands of which 53 (91.4%) were on time and 53 (91.4%) were accurate.



	Timeliness	Accuracy
New Jersey	93.9	92.6
Puerto Rico	85.8	82.7
Virgin Islands	91.4	91.4
Network	91.7	89.9

Source: SIMS database

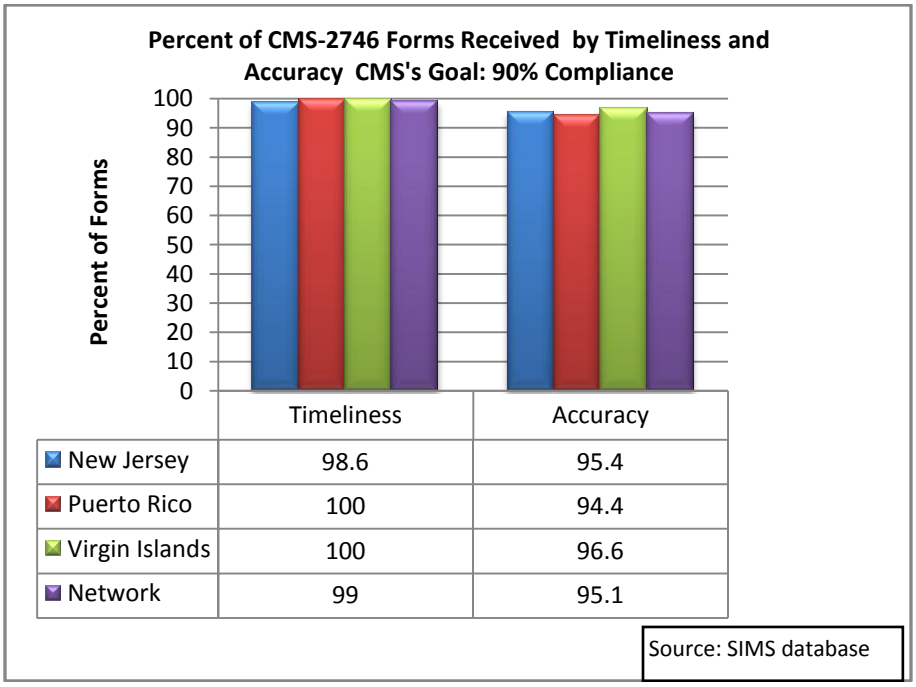
ESRD Death Notification form (CMS-2746)

The ESRD Death Notification form is due within 30 days of a patient's death. TARC's facilities submitted 3,760 death notification forms during the year, of which 3,521 (98.6%) were on time and 3,577 (95.1%) were accurate.

New Jersey dialysis units submitted 2,698 death notification forms during the year, of which 2,659 (98.6%) were on time and 2,574 (95.4%) were accurate. New Jersey exceeded both the accuracy and timeliness requirements.

Puerto Rico's dialysis programs submitted 1,033 death notification forms of which 1,033 (100%) were on time, and 975 forms (94.4%) were completed accurately. Puerto Rico exceeded the goal for accuracy and timeliness.

The 3 Virgin Island facilities submitted 29 death forms of which 29 (100%) were received on time and 28 forms (96.6%) were completed accurately. Virgin Islands facilities exceeded the goal for accuracy and timeliness.



In addition to receiving, processing, and transmitting data reported on the federal medical information system forms, TARC maintained a patient tracking system (SIMS) that tracked end-stage renal disease consumers through changes in treatment modality and setting. Changes in provider were also tracked. These activities were necessary to support federal quality projects and special studies. Monitoring patient events was also necessary for the reconciliation of the annual federal ESRD Facility Survey, preparation of facility profiles for goal achievement in home dialysis use and referral, and local quality of care improvement efforts.

Data accuracy and forms timeliness was reviewed biannually and documented. Both federal forms were profiled for compliance rate analysis.

UNOS

Renal transplant registrations and follow-ups were resolved through updates and verifications within the SIMS and UNOS databases. Data were received monthly from UNOS and entered into the SIMS database. Discrepancies were reviewed with transplant facilities and accurate reconciliation of patients was obtained through the SIMS report summary.

VISION

CMS requires that patient and physician signatures on 3% of all CMS-2728 (Medical Evidence Reports) forms submitted through VISION be verified annually. TARC received 2,125 CMS-2728 forms through VISION and thus were required to verify 64 forms; 66 forms were randomly requested and received from 33 facilities, all of which were signed by the physician. Patient signatures were verified on 65 forms, and after investigation, it was found that the remaining form was for a patient who had expired before signing the form.

REMIS

The federal REMIS system is an important component of the CROWN system and is based on federal billing records. Data entered into SIMS by TARC staff can be viewed there, as can data sent from sources such as CMS, the Social Security Administration, and UNOS. The data can be used to resolve discrepancies and complete patient event histories.

Network staff used the Alerts tool in REMIS to identify incorrect patient identifiers and maintain a more accurate data set. Out-of-area transfers were verified in this database.

Effectiveness

All tracking databases must have current, accurate information and facility cooperation is essential to this effort.

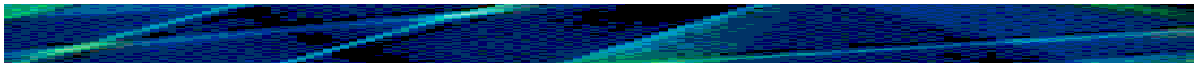
TARC provided facilities with forms compliance comparative data from 2005 to 2008 and held on-site remedial training for the nurse manager and the person responsible for completing the forms for facilities failing to attain an 80% combined compliance rate. TARC required 6 facilities to attend the two-hour program, which was held on May 20th and May 22nd, 2008. On August 26th, 2008, TARC provided an educational meeting for forms compliance for new facilities and new staff completing the forms. Technical assistance was provided to facilities that requested a review. During site visits, TARC staff discussed the commonly omitted items with the employee responsible for completing forms.

TARC continued to support VISION software by training facility staff in existing facilities when assigned staff changed. No new VISION facilities were trained in 2008.

Consumer Impact

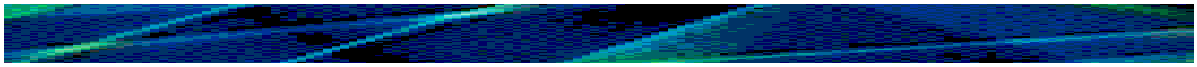
An accurate database is essential for the analysis of clinical indicators. Performance analysis activities utilize current, reliable data to monitor clinical patient outcomes. TARC's efforts to improve data accuracy enhanced data reliability and assured appropriate facility review with improvement plan oversight.

Accurate and timely reporting of patient data is essential for determining the starting date of Medicare coverage. TARC continued to maintain a database high in accuracy and timeliness.



IV. Sanction Recommendations

Upon recommendation of the Medical Review Board and the Board of the Trustees a recommendation for sanction was forwarded to the CMS New York Regional Office for one dialysis facility.



V. Recommendations For Additional Facilities

In all three geographic areas, access to dialysis therapies is within reasonable travel distances from ESRD consumers' homes. No additional New Jersey, Puerto Rico, or Virgin Islands dialysis facilities were recommended.