III. CMS National Goals And Network Activities

The Medical Review Board, Board of Trustees and the Council reviewed the 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. The project was based on the K/DOQI 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 Although the local project was terminated in 2003, the vascular access data collected served as historical reference information.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.

♦ The Institute of Medicine's definition of quality: *The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.*

Network Results

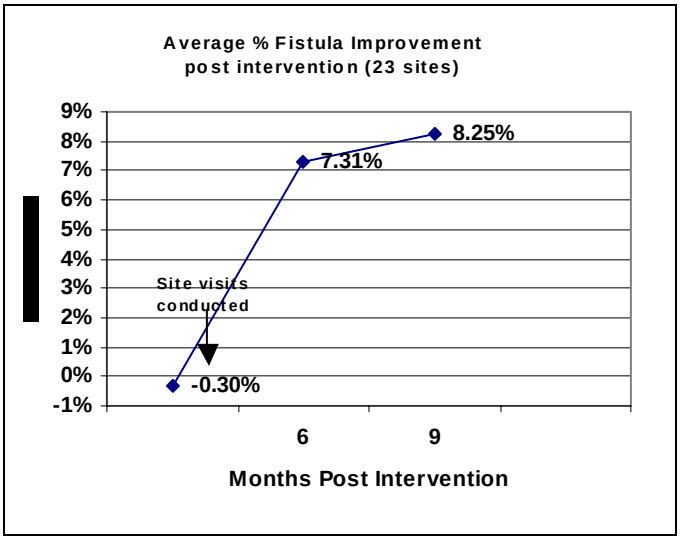
TARC's fistula rates have increased in small increments since 1997 when the DOQI guidelines were published. The goal of the *Fistula First* project was to have 40% of prevalent patients using a fistula by 2006. This goal was raised by CMS and is now set at 66% by 2009.

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 each vascular surgeon within the network area. 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 has continued to look at this initiative and develop new strategies to continue to have the message implemented. TARC evaluated 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 the current facility process for increasing fistulas and decreasing catheters, especially catheters in place >90days. In 2006, 40 facilities were visited. Targeted facilities included dialysis centers with >30% prevalent catheter rate and >100 patients. The criteria were later modified by the Medical Review Board to include facilities with <100 patients.

Twenty-three dialysis facilities were visited in January and February 2006. Eleven facilities were owned and operated by one large dialysis organization, six were hospital-based programs and six were independently owned. The average percent increase in fistula rates for the twelve months prior to the site visits was -0.30%.

The chart below shows the average percent increase in the prevalent fistula rate and the sustained improvement during the nine months following the intervention. The average increase in the prevalent fistula rate at six months was 7.31% above baseline; the momentum was sustained and at nine months the prevalent fistula rate increased by an average of 8.25%. TARC plans to continue to provide technical assistance to each facility and promote sustainability by tracking fistula rates monthly and providing quarterly rapid-cycle feedback reports.

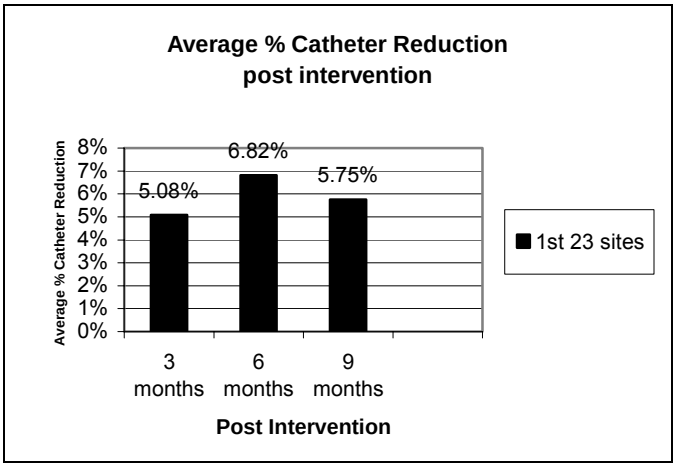


A second site visit was conducted at four facilities that failed to show sustained improvement in fistula and/or catheter rates, which included one hospital-based facility and three LDO facilities. At each meeting, the medical director, referring nephrologists, vascular surgeons, nursing leadership and regional managers were asked to attend. Barriers to improved outcomes were fairly consistent and were related to the willingness and ability to develop non-traditional methods to overcome known problems. TARC staff assisted facilities to identify appropriate change concepts and develop a comprehensive, coordinated plan of action, which included the following steps:

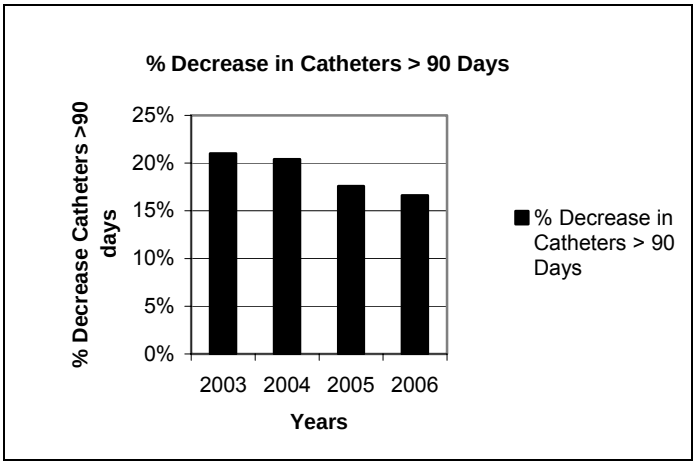
- Select a champion surgeon and establish outcome-based criteria for fistula surgery;
- Track surgeon outcomes and report outcomes to staff nephrologists;
- Arrange transportation for patients who have problems getting to appointments;
- Ask the surgeon to provide educational programs for dialysis staff on access evaluation and cannulation;
- Invite the vascular surgeon to performance improvement meetings; and
- Consider setting up vascular access clinic days to accommodate patients who resist making an additional trip to the physician's office.

These site visits were conducted in October and November; follow-up data are not available at the time of this report. TARC monitors quarterly vascular access rates and will seek the advice of the Medical Review Board if sustained improvement is not achieved.

Many authors have associated catheter rates with increased morbidity and mortality. In December 2006, 4,362 patients used catheters as primary access, which is a decrease of 2.0% from the previous year. However, that number constitutes 32.47% of the total hemodialysis population. Most authors suggest that catheter prevalence in the caseload should be in the area of 10%.



The chart above shows the average percent decrease in catheter rates at the 23 facilities visited during the first quarter of 2006. Three months after the site visits were completed the average decrease in catheter rate was 5.08%; at six months, the decrease improved to 6.82% but the improvement was not sustained. A slight decrease at nine months to 5.75% was seen. TARC will continue to evaluate the effectiveness of site visits by collecting monthly vascular access data from 100% of eligible facilities.



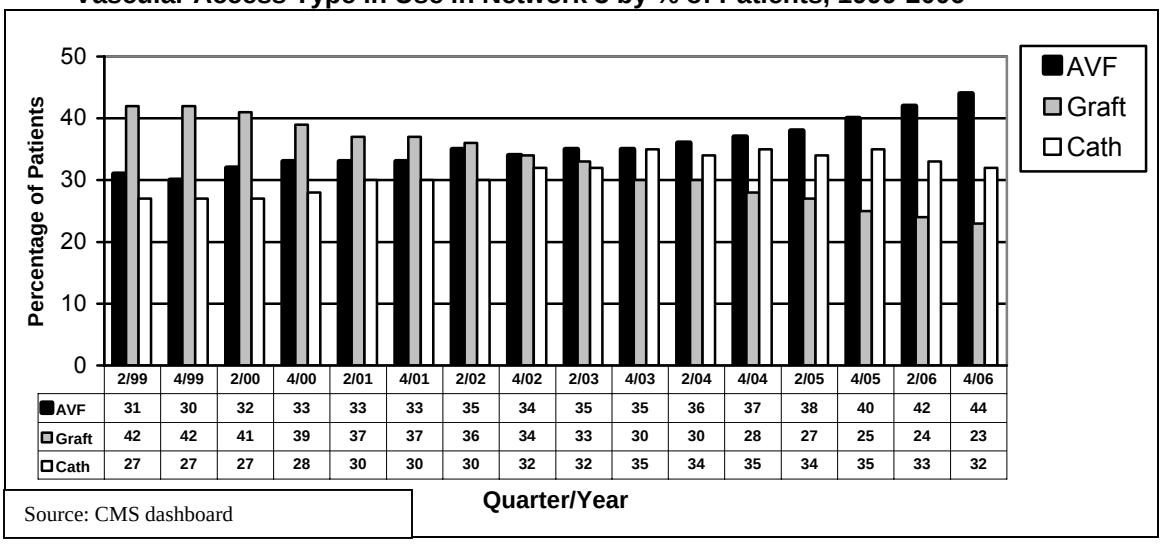
The chart above shows the decrease in catheters used >90 days from December 2003 through December 2006. TARC will continue to work with facilities and encourage removal of all medically inappropriate catheters.

Fistula First Initiative

From June 1999 to December 2006, TARC's prevalent fistula rate increased from 31% to 44.16%; catheter rates continued to increase during this period from 27% to 35% in December 2003 and then decreased to 32.47% by the end of the period.

TARC exceeded the 4% CMS annual goal and increased fistula use by 4.9% over baseline data.

Vascular Access Type in Use in Network 3 by % of Patients, 1999-2006



	2/99	4/99	2/00	4/00	2/01	4/01	2/02	4/02	2/03	4/03	2/04	4/04	2/05	4/05	2/06	4/06
AVF	31	30	32	33	33	33	35	34	35	35	36	37	38	40	42	44
Graft	42	42	41	39	37	37	36	34	33	30	30	28	27	25	24	23
Cath	27	27	27	28	30	30	30	32	32	35	34	35	34	35	33	32

Source: CMS dashboard

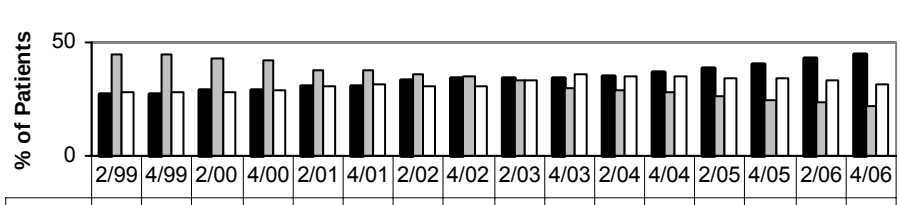
Area-specific Data

New Jersey

A key reason why there has been an increase in the overall rate of fistula use is because New Jersey hemodialysis patients have had more functioning fistulas placed. The fistula rate increased from 27% to 45% between June 1999 and December 2006. Although it is not displayed in the graph above, the number of patients with a maturing fistula (not yet in use) increased by 13%.

The prevalent catheter rate increased from 28% to 36% in the period June 1999 to December 2003 and decreased to 32% by December 2006. The net increase accounts for both catheters alone in use as well as those that have a maturing fistula that is not yet in use.

Vascular Access Type in Use in New Jersey by Percent of Patients, 1999-2006



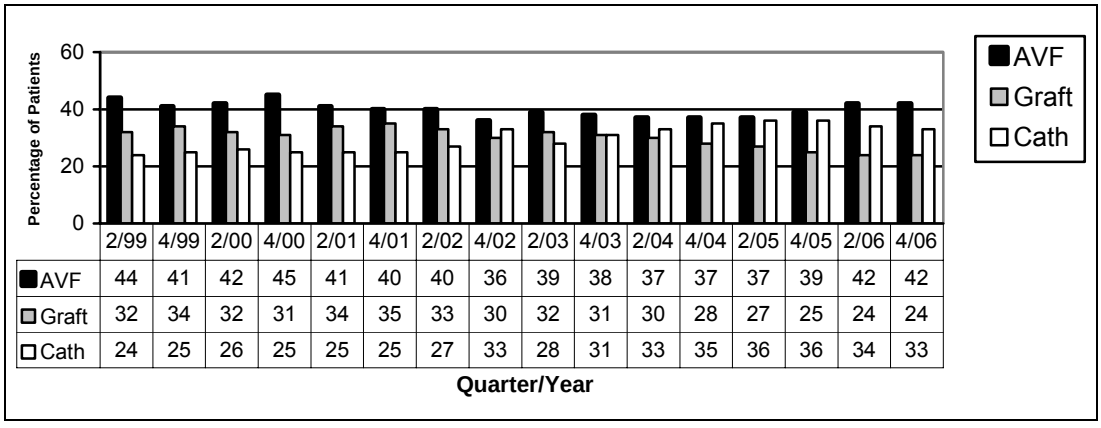
	2/99	4/99	2/00	4/00	2/01	4/01	2/02	4/02	2/03	4/03	2/04	4/04	2/05	4/05	2/06	4/06
AVF	27	27	29	29	31	31	33	34	34	34	35	37	39	40	43	45
Graft	45	45	43	42	38	38	36	35	33	30	29	28	26	25	24	22
Cath	28	28	28	29	31	32	31	31	33	36	35	35	34	34	33	32

Quarter/Year

Puerto Rico

There is regional variation in the distribution of access types in use. Historically, the majority of hemodialysis patients in Puerto Rico had arteriovenous fistulas. Although the majority of these patients still have fistulas, there has been an increased use of catheters in recent years. The prevalent rate of patients using fistulas decreased from 44% to 36% in the June 1999 to December 2002 and increased to 42.07% by December 2006. The catheter rate increased from 24% to 36% by December 2005 and decreased to 33% by December 2006.

Vascular Access Type in Use in Puerto Rico by Percent of Patients, 1999-2006



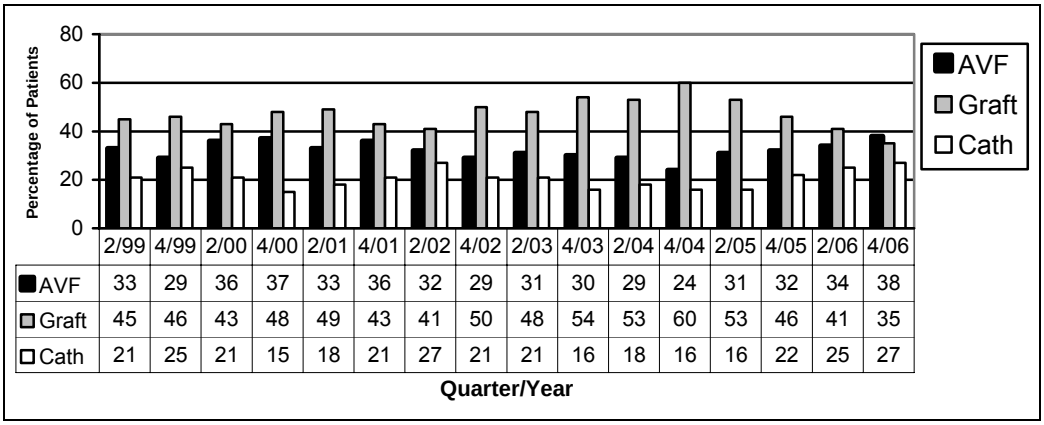
	2/99	4/99	2/00	4/00	2/01	4/01	2/02	4/02	2/03	4/03	2/04	4/04	2/05	4/05	2/06	4/06
AVF	44	41	42	45	41	40	40	36	39	38	37	37	37	39	42	42
Graft	32	34	32	31	34	35	33	30	32	31	30	28	27	25	24	24
Cath	24	25	26	25	25	25	27	33	28	31	33	35	36	36	34	33

Quarter/Year

Virgin Islands

The trend in the Virgin Islands shows an increase in the use of fistulas and a decrease in graft use. Rates fluctuate more widely here because the number of patients is much lower than in other areas. The prevalent fistula rate was highest in 2006 at 37.50%. The catheter rate increased from 21% to 27% during the June 1999 to December 2006 period.

Vascular Access Type in Use in US Virgin Islands by % of Patients, 1999-2006



	2/99	4/99	2/00	4/00	2/01	4/01	2/02	4/02	2/03	4/03	2/04	4/04	2/05	4/05	2/06	4/06
AVF	33	29	36	37	33	36	32	29	31	30	29	24	31	32	34	38
Graft	45	46	43	48	49	43	41	50	48	54	53	60	53	46	41	35
Cath	21	25	21	15	18	21	27	21	21	16	18	16	16	22	25	27

2006 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 in a national set of measures for a random sample of dialysis patients in clinical areas that include dialysis adequacy, anemia management, nutrition and vascular access.

The sample included hemodialysis patients, peritoneal dialysis patients and pediatric patients. Veteran's administration hospitals provided data for 100% of their population while all other facilities extracted data for a $\leq$5% scientifically selected sample of patients.

The 2006 iteration of this project was the thirteenth year of this project conducted in more than 2,000 dialysis facilities nationwide. CMS characterized the project as a 'snap-shot' description of peritoneal and in-center hemodialysis 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 compact disk.

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

Number of Clinical Performance Measures Participants, 2006

Area	Dialysis Facilities	Hemo dialysis patients	Hemo Pediatric Patients	Perit. dialysis Patients	Total Patient forms
New Jersey	118	342	4	36	382
Puerto Rico	36	153	15	28	196
US VI	3	7	0	0	7
Network	157	502	19	64	585

On June 1, 600 hemodialysis forms and 73 peritoneal dialysis forms were sent to dialysis facilities for completion. The veterans' administration facilities received and completed forms for their entire patient population of 88 patients. All forms were received and data entry completed by July 27.

A total of 585 forms were submitted for the ≤5% sample study not including the veterans administration facilities or the reliability forms. Data from 27 of the 585 forms were re-abstracted as part of the reliability testing for the project. The reliability forms for 17 hemodialysis and 10 peritoneal dialysis patients were received and data entry completed by August 30.

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 to compare the results from New Jersey, Puerto Rico, and the US 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 2005 data showed that the goal was met and exceeded. The United States as a whole attained 88% of patients with adequacy ≤65% and TARC reached a similar level of achievement. The chart below shows data from the local discontinued HIP project and the 2006 CPM data collection.

Percent of Hemodialysis Patients with URRs ≥ 65%
for available periods in 2002-2005

Goal: 80 % of patients will have a URR of >/= 65%

Area	4th Qtr 02 HIP	2003 CPM	2004 CPM	2004 Lab	2005 CPM	2005 Lab
New Jersey	87.8			89.2		88.8
Puerto Rico	84.1			89.3		88.9
US Virgin Islands	85.3			80.9		85.4
Network	**87%**	**84%**	**86%**	**89.1**	**88%**	**88.8**

Source HIP 2002, 2003-2005 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 represents network results and cannot be extrapolated to the facility level because the sample size power is insufficient at that level.

In the United States, 83% of adult in-center hemodialysis patients had mean hemoglobin values of ≥11 gm/dL; TARC's percentage was 84%, which is 1% above the national average, and a 2% increase from the previous year.

Iron administration is a necessary adjunct to erythropoietin therapy. National iron-management data showed that 79% of patients had a mean TSAT of ≥20% and 94% of patients had ferritin levels ≥100ng/mL. TARC had 3.74% of patients with a mean TSAT of ≥20% and 95% of patients with ferritin values ≥100ng/mL.

The network percentage of patients with TSAT ≥20% was slightly lower than the national rate despite having a higher than national average administration of intravenous iron. TARC had addressed iron management with facilities during the annual meeting in a presentation by Dr. Steven Fishbane, who has studied the subject extensively.

Nationally, 70% of patients received intravenous iron and in TARC's area, 3.75% of patients received intravenous iron. The Medical Review Board and Board of Trustees discussed these data. As evidenced by the CPM data collection, TARC's results show that iron utilization achieved the improved hemoglobin levels goal.

The anemia management goal was 80% of the hemodialysis patients with a hemoglobin value of ≥11 gm/dL. The chart below shows data from the local HIP project and from CPM data collection in 2006. This goal was met.

Percent of Hemodialysis Patients with Hemoglobin Values ≥11 gm/dL for available periods in 2002-2005

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

Area	4th Qtr '02 HIP	2003 CPM	2004 CPM	2004 Lab Data	2005 CPM	2005 Lab Data
New Jersey	78.1			84.0		83.5
Puerto Rico	72.6			78.5		77.6
Virgin Islands	70.3			63.8		70.8
Network	**76.6%**	**79%**	**82%**	**82.3%**	**84%**	**81.8%**

Source HIP 2002, 2003-2005 CPM data (5% sample), Lab Data Collection (LDC, 100% population)

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),

The goal states that 35% of prevalent patients will have an albumin level of 4.0 gm/dL if the lab uses BCG method, or 3.7 gm/dL if the lab uses BCP method. TARC's CPM results show an albumin mean value of 31%, which decreased from the previous year.

The pattern of higher albumin rates in Puerto Rico patients observed in the lab data collection has been consistently observed and is related to diet. The United States had 36% of patients with the required albumin levels, a decrease of 3% nationally.

Percent of Hemodialysis Patients with Albumin Values >4.0 gm/dL for available periods in 2002-2005

Goal: 35% of prevalent patients will have an albumin of 4.0gm/dL (BCG) or 3.7 gm/dL (BCP) lab method

Area	4th Qtr '02 HIP	2003 CPM	2004 CPM	2005 CPM
New Jersey	34.2%			
Puerto Rico	45.9%			
Virgin Islands	31.1%			
Network	**37.1**%	**33%**	**33%**	**31%**

Source HIP 2002, 2003-2005 CPM data (5% sample)

Vascular Access Reporting

The Centers for Medicare & Medicaid Services (CMS) required data collection for three clinical performance measures derived from the original and revised K/DOQI *Guidelines for Vascular Access*. The National Vascular Access Improvement Breakthrough Initiative, which emphasized a 'fistula first' approach when appropriate, developed from K/DOQI recommendations. Recently, the goal for prevalent fistula use was set at 66% by June 2009.

According to the 2005 CPM report, the percentage of incident and prevalent patients with fistulas was 38% and 39% nationally; TARC had 43% and 34% 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. K/DOQI recommends no more than 10% of patients should have primary vascular access via catheter.

December 2006 data reported 32.47% with catheter access, a decrease of 1.68% from baseline September 2005. The 2005 CPM data reported that 27% of prevalent patients in the United States had a catheter; TARC had 34%, 3% lower than in 2004. 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* data, 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 in 2002-2006

Goal: 43.26% or more of prevalent hemodialysis patients will have a fistula for access

Area	4th Qtr '02 HIP	2003 CPM	2004 CPM	2005 CPM	12/05 FF	12/06 FF
New Jersey	34				39.96	45.06
Puerto Rico	36				38.59	42.07
Virgin Islands	29				32.24	37.50
Network	**34**	**36**	**35**	**34**	**39.51**	**44.16**

Source: HIP/CPM/Fistula First database

Percent of prevalent hemodialysis patients with a catheter access for available periods in 2002-2006

Goal: Decrease catheter usage by 3% annually

Area	4th Qtr '02 HIP	2003 CPM	2004 CPM	2005 CPM	12/05 FF	12/06 FF
New Jersey	31				34.15	32.26
Puerto Rico	33				36.13	33.29
Virgin Islands	21				21.71	27.17
Network	**32**	**32**	**37**	**34**	**34.52**	**32.47**

Source: HIP/CPM/Fistula First database

2006 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 4th quarter 2004 and 1st quarter 2005 period included hemoglobin levels, serum albumin values, blood pressure measurements and calculated dose of delivered dialysis. Data were abstracted from 64 peritoneal dialysis patients' medical records in area facilities; nationwide, 1,337 adult peritoneal dialysis patients >18 years were examined.

In anemia management, 82% of the sampled peritoneal dialysis patients had mean hemoglobin values of ≥11gm/dL, and 84% of the patients had mean transferrin saturation ≥20%. 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. Twenty percent of the sample had a mean serum albumin value of at least 4.0 gm/dL (BCG) or 3.7 (BCP).

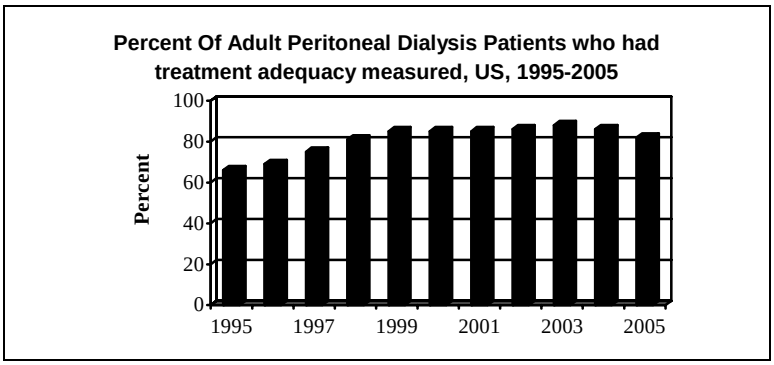
Year	CAPD patients with Kt/V of 2.0 (%)	CCPD patients with Kt/V of 2.1 (%)		Year	CAPD patients with Kt/V of 2.1 (%)	CCPD patients with Kt/V of 2.1 (%)
2005	73%	59%		2001	68%	62%
2004	70%	65%		2000	65%	60%
2003	71%	66%		1999	56%	52%
2002	68%	70%				

CPM data showed that dialysis adequacy measurements were assessed at least once for approximately 82% of the sampled peritoneal dialysis patients compared to 86%, 88%, 86%, 85%, 85% and 85% during the previous six years. It must be noted that this finding did not

demonstrate that adequacy had been achieved in 82% of peritoneal patients, only that some measurement was taken to quantify the dose delivered.

Findings included 73% of CAPD patients had a mean ≥ 2.0 Kt/V adequacy measurement and 59% of cycler patients with a daytime dwell had a mean weekly 2.1 Kt/V while 58% of cycler patients without a daytime dwell had a mean weekly 2.2 Kt/V. Based on the K/DOQI guidelines, 73% of CAPD and 58.5% of CCPD patients had mean adequacy values that met the guidelines, which is a 3% increase from the previous year when 70% met the goal.

The Medical Review Board discussed the report and reviewed selected information with facilities at the annual Council meeting.



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 CCPD patients

National Pediatric Population CPM results

All pediatric patients <18 years who were identified as receiving in-center hemodialysis on December 31, 2004, were included in the study. TARC's total number of pediatric patients was 24 of the national 692 records abstracted.

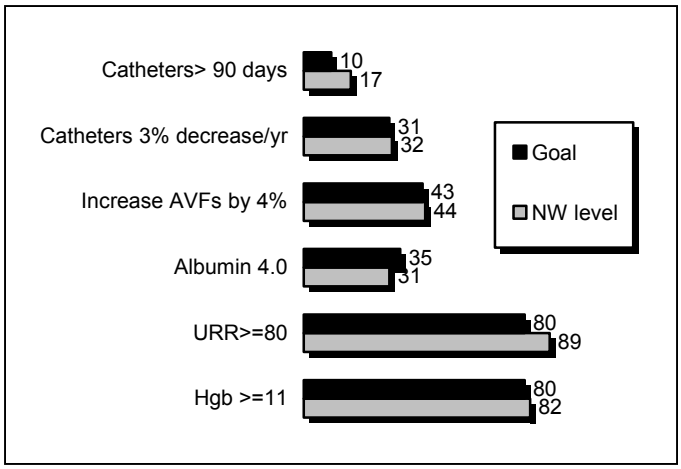
The findings were as follows:

- 89% 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, 11% with a graft, 58% with a chronic catheter;
- 47% of the catheter patients had continuously dialyzed with a catheter for ≥90 days; and
- 48% of patients with a fistula or graft were routinely monitored for the presence of stenosis.

In anemia management, 67% of patients had mean hemoglobin value of ≥11 gm/dL. Nutritionally, 82% of the patients had a mean serum albumin ≥3.5/3.2 gm/dL, 46% had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) during the three-month study.

Effectiveness

Progress towards meeting CMS/TARC Goals



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

- The percentage of patients with a hemoglobin value ≥11gm/dL exceeded the 80% goal;
- TARC exceeded the 80% dialysis adequacy goal at 88.9%;
- The nutrition goal states that 35% will have an albumin level of 4.0 gm/dL. TARC provided through a State grant funding for nutritional supplements to improve this indicator;
- 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%;
- CMS changed the prevalent fistula rate goal to 66%; TARC increased the prevalent fistula rate by 4.9%;
- K/DOQI 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 made progress and continues efforts to meet this recommendation.

Twenty-five facilities were asked to complete a quality improvement plan due to lack of goal attainment for one or more clinical indicators. TARC staff provided technical assistance to those facilities that failed to meet target goals.

Consumer Impact

Delivering safe and effective care provides significant benefits to consumers through better management of the comorbidities that affect consumers. Appropriate clinical management provides consumers with a better quality of life, reduced hospitalization and fewer debilitating conditions.

All efforts were made to provide consumers with the knowledge base to choose the desired treatment modality. Posters were given to each facility and flyers were made available for patient use that described modalities of care and fistula benefits.

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

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

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.
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 & 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 & 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 & Responsibilities* and *Grievance Procedure* are included.

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.

† **Rehabilitation** is defined as *restoring an individual to the maximum level of independence and quality of life that an individual can achieve.*

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 web 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:

- Using a centrally-located bulletin board that featured stories or topics regarding rehabilitation;
- Assessing consumers' physical status, mental health and general well-being on a regular basis;
- Assessing patient, family and staff attitudes toward rehabilitation;
- Screening for employment status or potential;
- Assessing job skills and suitability for vocational rehabilitation;
- Providing information about end-stage renal disease to employers as requested;
- Making information available about the benefits of working;
- Informing consumers annually about treatment modalities to accommodate work and life interests; and
- Utilizing the 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 4 educational programs in addition to the home designee and transplant designee programs. On May 10 the program titled *Emergency Preparedness, Fistula Primero and Patient-Provider Conflict* was held in Puerto Rico. TARC's *Annual Council Meeting* was held in New Jersey on November 1. One hundred percent of the 232 program evaluations received, stated the program objectives were met. One hundred percent of the 323 responses received indicated that the subject matter was relevant to current practice. Two separate but similar meetings were held in Puerto Rico on November 7, a daytime meeting for nurses and an evening meeting for physicians. The topic for both meetings was *Infection Control and Vascular Access.*

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 still others were referred to CMS or the responsible agencies.

Materials were distributed to facility medical directors, head nurses, administrators and quality improvement coordinators during facility visits, mailings or e-mail; several were given as handouts at network-sponsored meetings such as the annual meeting. 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.

Percentage of Home Patients by year in Network 3

Home Dialysis Patients (%)				
2006	6.5%		2000	10%
2005	7%		1999	12%
2004	7%		1998	14%
2003	8%		1997	16%
2002	9%		1996	18%
2001	9%			

Source: SIMS database

Home hemodialysis has not been a popular modality for many years. In 2006, there were thirty-three patients receiving home hemodialysis. One facility offered a daily hemodialysis program but was unable to maintain it for lack of necessary volume; there is great potential for this treatment schedule but reimbursement was not modified to make it financially feasible.

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

TARC recognized two variables that affected the number of home dialysis patients: a lack of patient education and a shortage of qualified nurses available to provide education and training for home dialysis modalities.

To address these issues, TARC continued a home dialysis designee program designed to mirror the transplant designee program. The home designee program was developed to ensure the continued involvement of facility staff in promulgating home treatment and enhancing rehabilitation potential. The program educated staff nurses about home dialysis

options and provided current knowledge and resources for home programs. The result was to have more patients knowledgeable about home dialysis and select home dialysis for their treatment location. The secondary effect for facilities was that they could improve their patient census; if more dialysis patients dialyzed using a home modality, fewer patients would be dialyzed in-center resulting in an improved nurse to patient ratio.

The home designee planning committee met on June 26, 2006. The committee partnered with home dialysis providers to identify barriers to home dialysis and to reorganize the home designee program. The committee knew that dialysis staff should have a current understanding of peritoneal dialysis and of the benefits of home hemodialysis. The planning committee included:

Member	Facility
Laura Suarez	Fresenius Medical Care
Robert Motacki, MA	DCI North Brunswick Dialysis Center
Kathy Searson, RN BS CNN	DCI North Brunswick Dialysis Center
Ann Marie Duffy	Baxter Healthcare Corporation
RoseMarie Acuna, RN, BSN, CNN	Newark Beth Israel Medical Center
Joan Solanchick, Executive Director	Trans Atlantic Renal Council
Patricia Llewelyn, RN, CNN	Trans Atlantic Renal Council
Beverly Hoek, RN, CNN	Trans Atlantic Renal Council

Two designee meetings were held in September, one in northern New Jersey and one in southern New Jersey. Kiosks were placed around the conference room for attendees to become familiar with equipment and ask questions of vendors, home dialysis patients, and home training nurses. In 2006, 185 home dialysis designees completed the program.

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

All consumers must receive information about 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 six transplant facilities had a total of 3,195 people on their kidney transplant waiting list on December 31, 2006,▲ which is only a slight increase from 3,068 people on the waiting list in 2005. 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

▲ Source: SIMS database

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 (88%) of the Medicare-approved and veterans administration dialysis programs in New Jersey 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 21 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 2006, the number of organs available and suitable for use was still lower than those needed or desired by TARC's dialysis patients.

Immunizations

The network distributed to dialysis facilities information to inform their patients about the flu, hepatitis and pneumonia immunizations. This information included the recommended immunization schedule for chronic kidney failure and ESRD patients, CDC pandemic flu information and the network 12 article "*Preparing for the Possibility of a Pandemic – Influenza."*

Volunteerism

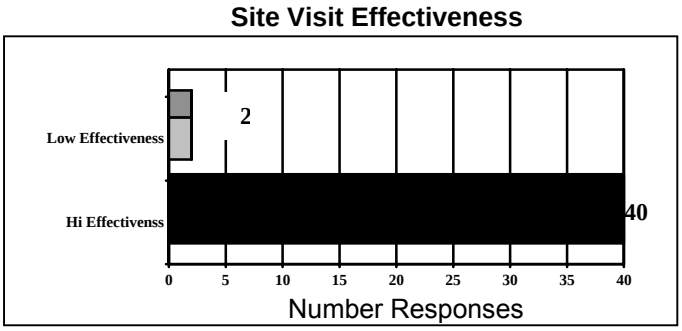
TARC together with dialysis facilities encouraged patients to volunteer at their local food kitchen, American Red Cross and to join the Patient Advisory Committee, all of which would help improve their quality of life and also help others. Psychologically, efforts to help others despite one's own disability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

Effectiveness

Ninety-eight percent of TARC's facilities had a minimum of one home dialysis designee and 94% had a minimum of one transplant designee. Ninety-seven percent of facilities visited had a vascular access coordinator. Home dialysis was chosen by 6.5% of the entire patient caseload. A *Treatment Options* poster was distributed to 100% of TARC's facilities.

During 2006, 41 site visits were made, which was 26% of all area facilities. Treatment options posters, *Consumer Rights & Responsibilities* and *Consumer Grievance Procedures* were posted in clear view at 100% of the facilities visited. TARC had an increase in consumer contacts of 48.9%.

In an effort to evaluate the effectiveness of TARC's site visits, which are labor intensive and time consuming, 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. Forty-two responses were received and most 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 2,983 patients between the ages of 18 to 54. Thirty-seven patients received services from a vocational rehabilitation program and 1,018 were employed (full or part time); 89 patients attended school (full or part time).

In Puerto Rico, there were 1,278 patients between the ages of 18 and 54 years. Sixty-two patients received services from a vocational rehabilitation program, 223 patients were employed (full or part time) and 27 patients attended school (full or part time).

Of the 59 Virgin Islands dialysis patients in the same age range, 5 patients received services from a vocational rehabilitation program, 22 patients were employed (full or part time) and 12 patients attended school (full or part time).

TARC had a total of 4,320 patients in the 18-54 age group; 104 patients received services from a vocational rehabilitation program. Those employed numbered 1,263 and 128 patients attended school (full or part time). TARC had 35% of patients who received services from a vocational rehabilitation program, were employed (full or part time), and/or attended school (full or part time)

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.

I. Each facility will post in prominent place TARC's grievance policy and distribute annually paper copies provided by TARC.

II. 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 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 is approved by CMS as an ESRD provider, a package of materials is sent which contains the *Consumer Grievance Procedure*.

In February, TARC identified the need for a patient education brochure that would describe in basic terms the complaint process and how to contact TARC. A brochure titled *I Am A Kidney Patient What Can I Do If I Have a Complaint* was adapted to meet network needs. The brochure was translated into Spanish and distributed to all facilities in English and Spanish.

Patient Advisory Committee

The Patient Advisory Committee consisted of patients from dialysis facilities in TARC's area and represented all modalities. Members have a genuine concern for quality of care issues. The committee served as a link between patients and TARC, encouraged 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.

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 serous 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. TARC noted an increase in the number of calls concerning abusive and/or disruptive patients. TARC's staff worked with facility leadership to avoid involuntary discharge and recommended the use of the Dialysis Patient Provider Conflict Resolution tool kit. TARC will begin tracking in 2007 the incidence of involuntary discharge to evaluate the extent of the problem.

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

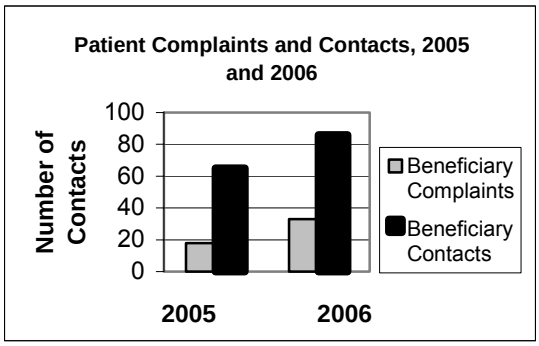
While there were 37 complaints, network staff addressed many more concerns and issues. An aggregate summary of actions follows:

2006	Beneficiary Inquiries	Com-plaints	Data proces-sing	Facility con-cerns	Facility Inquiries	Other Inquiry	Total
Abusive	0	1	0	4	0	0	5
Data Request	0	0	9	0	2	2	13
Disruptive	0	0	0	6	1	0	7
Information	29	0	50	5	58	60	202
Non-Compliant	0	0	0	4	2	0	6
Other	1	5	3	2	0	7	18
Patient Transfer/ Discharge	3	4	8	10	8	5	38
Physical Environment	1	2	0	0	0	0	3
Pre ESRD Inquiry	4	0	0	0	0	1	5
QI Projects	0	0	28	0	18	37	83
Reimburse-ment /Financial	10	1	0	3	7	3	24
Request for Educational Materials	2	0	0	0	8	6	16
Request for Forms	0	0	9	0	2	1	12
Request for Technical Assistance	3	1	26	1	19	21	71
Staff Related	0	2	0	0	0	1	3

2006	Beneficiary Inquiries	Com-plaints	Data proces-sing	Facility con-cerns	Facility Inquiries	Other Inquiry	Total
Transient	2	0	0	0	0	0	2
Treatment/ Quality of Care	0	23	0	0	0	1	24
Vision	0	0	13	0	0	0	13
Total	55	39	146	35	125	145	545

A total of 545 contacts were entered in the SIMS database; of those, beneficiaries initiated 16%. Almost 42% of the beneficiary calls received were information inquiries and requests for educational materials. Beneficiary complaints resolved included lack of staff, appropriate equipment within the unit, and professionalism of staff members. Information requests, either facility or beneficiary-initiated, accounted for 37% of all contacts.

Beneficiary concerns and inquiries were addressed internally by TARC more than 96% of the time. 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.

One of TARC's initiatives in 2006 was to increase beneficiary awareness of TARC's functions and responsibilities as well as to open lines of communication by promoting use of its toll free telephone number. Additionally, TARC assigned a full-time person to the patient service coordinator position. This staff member assumed a proactive role in the facilitation and resolution of patient and/or facility situations and organized the Patient Advisory Committee.

Network staff developed 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. These were distributed to all facilities in English and Spanish. 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. There was a 24%

increase from 2005 to 2006 in the number of calls from beneficiaries since the distribution of the posters and brochures.

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.

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 patient services coordinator, reviewed by the quality improvement administrator 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.

There were a total number of 286 inquiries to the web site, an increase of 48.9% over the prior year. There were 78 questions written in English and 208 in Spanish. Of the total number of questions, some did not pertain to dialysis, transplant or the field of nephrology; those questions were referred to alternate information sources and/or web sites.

The questions originated from anyone with a renal-related issue, not just consumers within TARC's boundaries; subjects included 8 transplant-related, 17 dialysis-related, 53 related to the category 'other renal.' The issues were diverse and included iron management, second transplant, dialysis access, including fistulas and the buttonhole technique, acute renal failure, quality of life and termination of dialysis.

The 208 Spanish questions included 31 transplant-related, 33 dialysis-related, 76 had 'no relation to renal' and 68 were 'other renal.' The topics in each area included living-related and non-related donor, recipient information, donor compatibility and transplant facility location.

Within the dialysis area, peritoneal dialysis, medications, congestive heart failure, vascular access aneurysm, estimated dry weight, creatinine clearance, life expectancy on dialysis and dialysis modalities were examples of issues addressed. The 'other' 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	19,223	19,381	22,444	20,680	81,728
Visits	30,140	31,945	34,111	36,338	132,534
Pages Viewed	156,553	152,926	160,600	159,515	629,594

Provision of Technical Assistance, Educational Material

TARC provided technical assistance, guidance and appropriate referrals to facility staff and consumers. Network staff identified available providers for consumers seeking services, especially transient treatment facilities. Additional aspects of technical assistance included

TARC's role in investigating and resolving patient issues and concerns before they became complaints or grievances.

Bulletins and updated clinical material for professional staff from the Centers for Disease Control and Prevention were faxed and e-mailed to all facilities, including copies of the booklet, *Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients.*

TARC distributed to all dialysis facilities educational resources developed by the national vascular access coalition, other networks, CMS, homeland security, the National Kidney Foundation and the Centers for Disease Control. Topics included: *Mold Prevention Strategies and Possible Health Effects in the Aftermath of Hurricanes and Major Floods, Preparing for the Possibility of a Pandemic – Influenza, Emergency Supply List,* patient emergency cards, articles and posters entitled, *After the Storm, Are You Ready?, Who will you call when disaster strikes in the dialysis facility?*, and the CMS Guide-Emergency Preparedness for Dialysis Patients and Facilities.

TARC updated the web site to include a link to the New Jersey pandemic flu web site and included a new section for patient and providers on disaster preparedness.

Clinical Performance Assistance Provided

TARC recognized that different facilities might identify different root causes for a lack of success as well as pathways 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.

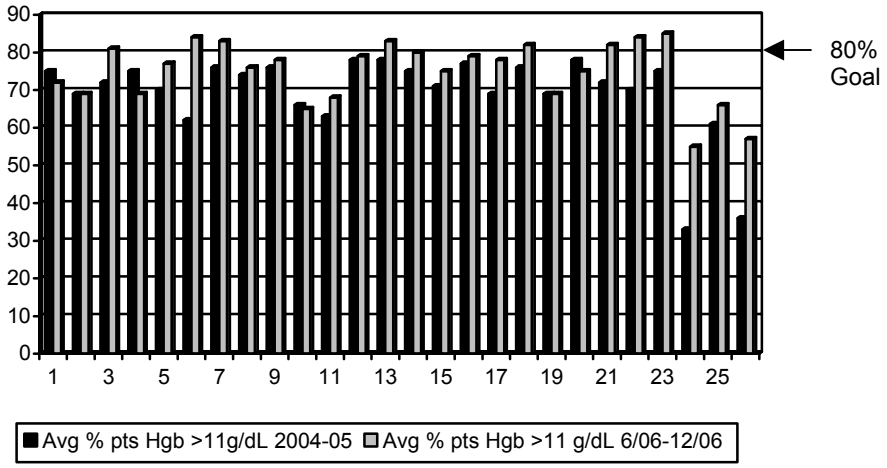
Fistula and Catheter Use

TARC reviewed prior efforts to reduce catheter access use and developed new strategies to address needed improvement. TARC identified for site visits 40 dialysis centers that had >30% catheter rate and had >100 patients. Fistula rates, in these facilities, ranged from 14% to 46%. 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. Nine months after the interventions, data showed an average decrease of 5.75% in catheter rates and an average increase of 8.25%in fistula rates.

Anemia Management

The Medical Review Board analyzed lab data collected in 2004 and 2005 and identified 26 facilities that failed to meet the 80% of patients with a Hgb$\geq$11 gm/dL for 2 consecutive years goal. The facilities were asked to prepare a quality improvement plan, which TARC received in December. Quarterly data will be collected beginning in 2007 and technical assistance provided.

Anemia Quality Assessment Improvement Project (26 facilities)



Non-tunneled and Subclavian Catheters

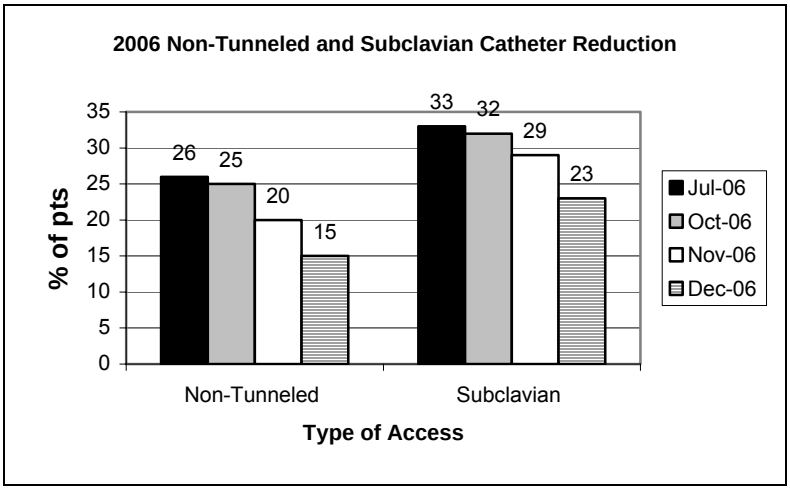
Vascular access with a catheter is required in a small number of cases and is not the preferred method if other alternatives are available. New cases may require short-term use until a permanent access with a fistula or graft is possible. Long-term use of catheters is discouraged because of the high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

In July, 8 Puerto Rico facilities were observed to have non-tunneled catheters in 26% (384) of the patient's 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. In August, TARC did a comparison to New Jersey facilities and found that only 14 patients or 1% of 1,246 catheter population had non-tunneled catheters.

The 8 facilities were asked to prepare a quality improvement plan. TARC developed a comprehensive assistance approach that included site visits, a nursing conference on infection control and vascular access, and an evening meeting with the surgeons and nephrologists.

The physicians developed a six-step improvement plan, which included:

1. Mandatory vessel mapping prior to access placement; tunneled catheters are the method of choice; preferred insertion site for tunneled catheter is the right internal jugular. No further use of subclavian catheters – only in life or death situations;
2. Nephrologists will communicate with surgeons to avoid placement of subclavian catheters;
3. Fistulas shall be placed in all appropriate candidates;
4. Vessel mapping (or other imaging) shall be mandatory before access creation;
5. All newly created fistulas shall be evaluated by doppler (or other imagery) at 4 weeks after surgery; and
6. Increase referrals to peritoneal dialysis and transplantation.



Monthly data were collected and facilities were asked to re-examine each catheter to verify type and placement. Non-tunneled catheters decreased 10% and subclavian catheters decreased 9% by December 2006. TARC will continue oversight until the non-tunneled and subclavian catheters for vascular access are used according to the K/DOQI guidelines.

Technical and Collaborative Assistance Provided

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 break down 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.

TARC worked in collaboration with ANNA national office to increase the number of nurses who attended the winter and fall audio conferences on vascular access. Rather than limit attendance to several host sites, TARC used its local conference call service to gather local nurses wherever located and tie its service into the single ANNA trunk line. TARC had the largest audience participating in the conference.

Videos of the buttonhole technique were copied and distributed to those facilities that inquired about the technique.

Area managers, on the annual meeting evaluation, claimed they did not have the time or staff to search the web for valuable information available. 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.

Effectiveness

Clinical Performance Assistance

Morbidity and mortality data demonstrate that patients with a fistula access have improved quality of life, reduction in 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.

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.

Technical and Collaborative Assistance

The dialysis community discovered they 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 is a major role of networks.

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 piece to reaching TARC's goals is 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.

Patients who participate in their healthcare decisions have 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.

Consumers educated in the grievance procedure know they are not helpless when their care poses 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.

Consumers benefited from their providers becoming informed about and responding to network-specific goals, which aimed for 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 the network and the facilities is to serve renal consumers, all renal-related educational materials enhance patient care delivery.

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, ANNA, 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 Virgin Islands and quality improvement organizations regarding concerns and issues in the dialysis community. 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 monthly in person or by conference call. Periodically, the groups met jointly to discuss projects and progress.

The professional task force distributed quarterly vascular access medical director report cards to all dialysis facilities in New Jersey and started to plan CKD programs for primary care physicians. The task force continued work with the New Jersey Healthcare Quality Strategies organization and ANNA to invite primary care practitioners, cardiologists, endocrinologists and internists. The programs will include discussions about early CKD patient identification and management, and the estimated glomerular filtration rate legislation passed.

The patient education task force started to plan a patient educational meeting for spring 2007. They partnered with the Renal Support Network and the New Jersey Healthcare Quality Strategies organization. The target audience selected for the initial program was central and northern New Jersey; program content will include the Fistula First initiative and titled *What's Your Line?*

Cooperative Activities

Fistula First

The New Jersey Healthcare Quality Strategies organization collaborated with TARC to develop a WebEx presentation about chronic kidney disease and early fistula placement, which is scheduled to air on April 25, 2007. The Patient Advisory Committee reviewed *Fistula First* patient education tools and selected two for immediate distribution to all dialysis facilities. In an effort to promote changes at a system level the *Fistula Gram* newsletter was mailed to all the county medical societies, the chiefs of medicine and the chiefs of surgery at acute-care hospitals.

Transplantation

TARC participated in planning the transplant designee conferences held in two locations in New Jersey. The program was developed in collaboration with the Saint Barnabas Healthcare System. TARC distributed to facility administrators and transplant centers the following documents: Medicare publications, consumer rights and responsibilities, consumer grievance procedure, dialysis facility compare web site information, the *What is TARC?* poster, *I Am a Kidney Patient What Can I Do If I Have a Complaint?* brochure, and a *Treatment Options* poster. 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

The Annual Council meeting in 2005 focused on implementation of a facility disaster plan and provided the clinical and operational information to assist the renal community prepare for emergencies. In 2006, TARC developed 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.

TARC staff participated in the national Kidney Community Emergency Response Coalition and worked collaboratively with the New Jersey Renal Administrators to develop for 2007 the first in a series of educational programs. Planning for the first meeting was initiated with topics identified that will provide renal administrators and infection control nurses with dialysis-specific

plans for the pandemic flu and clarify the role and functions during emergencies of the various organizations involved.

Water Treatment

TARC reviewed water cultures as part of a collaborative effort with a state agency for one dialysis facility in Puerto Rico. TARC developed tracking tools and provided feedback to technical staff and nursing leadership. TARC provided the state agency with current literature and AAMI recommendations for 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.

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, patient safety, care issues and the Fistula First Initiative. The New Jersey and Puerto Rico state agencies added Fistula First inquiries to the survey process.

TARC increased cooperative efforts with the Healthcare Quality Strategies organization in New Jersey and the Quality Improvement Professional Research Organization of Puerto Rico. All worked together on Fistula First activities.

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 Program Operations 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 many new partners. State agencies, insurance carriers, hospital staff, American Nephrology Nurses Association, American Dietetic Association, New Jersey Renal Administrators and the New Jersey Hospital Association 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.

   i. Each facility will monitor forms submission and maintain the required timeliness and accuracy rates of 90%.

   ii. 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
- Chronic Renal Disease Medical Evidence Report (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.

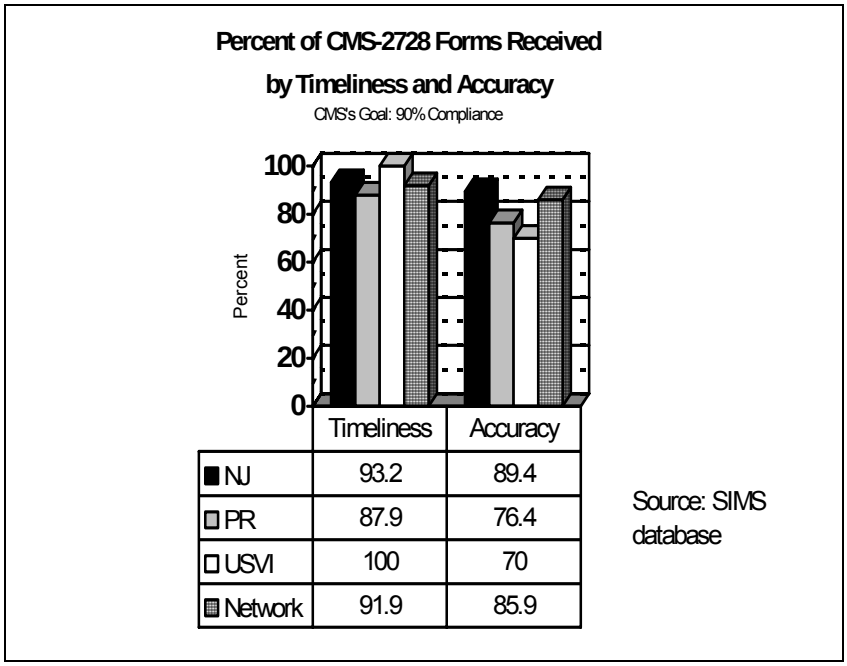
Chronic Renal Disease Medical Evidence Report (CMS-2728)

The Chronic Renal Disease Medical Evidence Report form (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 5,257 initial forms during the year; of these 4,710 (89.6%) were on time and 4,450 (84.6%) were accurate. New Jersey facilities submitted 3,815 forms, of which 3,338 (87.5%) were completed accurately and 3,409 (89.4%) met CMS's timeliness criterion. Facilities in Puerto Rico submitted 1,378 forms of which 1,240 (90%) were on time and 1,053 (76.4%) were completed accurately. Sixty-four forms were received from the Virgin Islands of which 61 (95.3%) were on time and 59 (92.2%) were accurate.



	Timeliness	Accuracy
NJ	93.2	89.4
PR	87.9	76.4
USVI	100	70
Network	91.9	85.9

Source: SIMS database

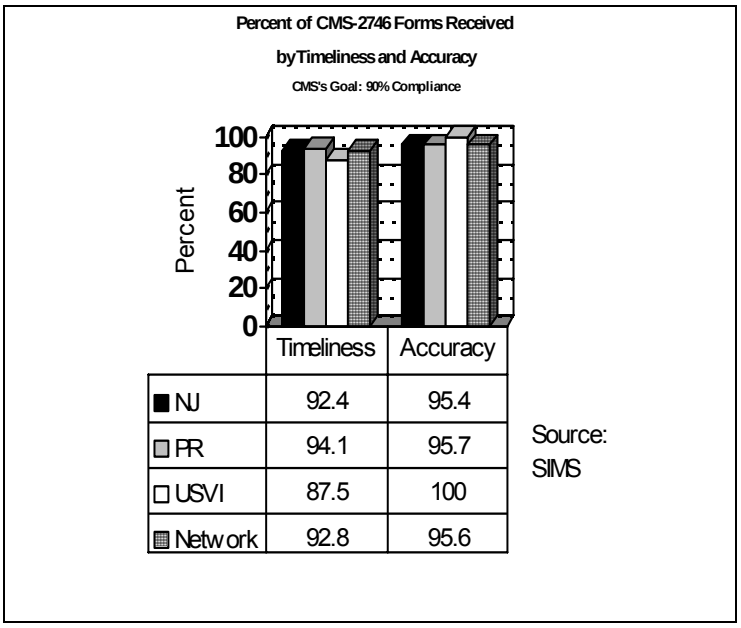
ESRD Death Notification form (CMS-2746)

The ESRD Death Notification form is due within 30 days of a patient's expiration. TARC's facilities submitted 3,958 death notification forms during the year, of which 3,674 (92.8%) were on time and 3,782 (95.6%) were accurate.

New Jersey dialysis units submitted 2,910 death notification forms during the year, of which 2,690 (92.4%) were on time and 2,777 (95.4%) were accurate. New Jersey exceeded both the accuracy and timeliness requirements.

Puerto Rico's dialysis programs submitted 1,008 death notification forms of which 949 (94.1%) were on time, and 965 forms (95.7%) were completed accurately. Puerto Rico exceeded the goal for accuracy and timeliness.

The 3 Virgin Island facilities submitted 40 death forms of which 35 (87.5%) were received on time and 40 forms (100%) were completed accurately. Virgin Islands facilities exceeded the timeliness requirement but fell short in the accuracy requirement.



	Timeliness	Accuracy
NJ	92.4	95.4
PR	94.1	95.7
USVI	87.5	100
Network	92.8	95.6

Source: SIMS

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 2,088 CMS-2728 forms through VISION and thus were required to verify 63 forms; 68 forms were randomly requested and received from 41 facilities, all of which were signed by the physician. Patient signatures were verified on 61 forms, and after investigation, found that the remaining 7 were for patients who had expired.

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.

Twenty facilities (13.7%) of the 116 were found to have blended (timeliness and accuracy) compliance rates lower than the required 80%, despite efforts to help facilities improve.

TARC provided facilities with forms compliance comparative data from 2001 to 2006 and requested improvement plans from 20 facilities not in compliance. TARC required each facility to track forms submitted for timeliness and accuracy and report monthly progress, signed by the administrator. 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.

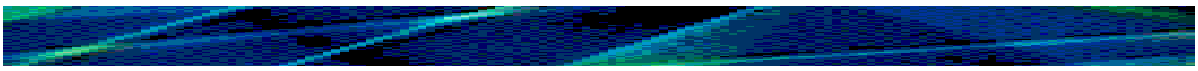
Nine facilities (45%) of the 20 achieved a compliance rate of at least 80%. TARC worked with facilities to improve compliance rates and communicated with those that continued to have problems.

TARC continued to support VISION software by training facility staff in existing facilities when assigned staff changed. No new VISION facilities were trained in 2006.

Consumer Impact

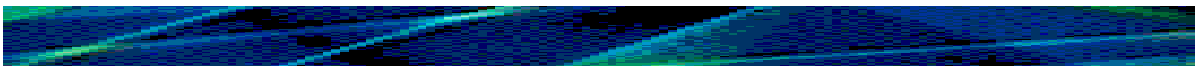
An accurate database is essential for the analysis of clinical indicators. Performance analysis activities utilize current, reliable data to monitor clinical patient outcomes. TARC's efforts to improve data accuracy enhanced data reliability and assured appropriate facility review with improvement plan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

No facility sanction was recommended to federal officials.



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.