3. CMS National Goals And Network Activities

A. Improving The Quality Of Health Care Services And Quality Of Life For ESRD Beneficiaries

TARC staff, Medical Review Board, Board of Trustees and the network Council developed goals and activities for a three year span, 2003 - 2006. The goals are used to focus attention on and promote action in specific areas of nephrology to enhance the delivery of health care services. The goals that were effective as of July 1, 2004 are as follows:

I. Promote consumer education to enable informed decision-making about treatment modalities, participation in care and optimum outcomes.

A. Each facility will educate patients about treatment modalities:
   1. All facilities will have a minimum of one transplant designee.
   2. All facilities will have a minimum of one home dialysis designee.
   3. 10% of the network wide dialysis patient caseload will use home dialysis.

B. Consumer Rights & Responsibilities/ Grievances
   1. Each facility will post in a prominent place, the TARC *Consumer Rights & Responsibilities* and the *Consumer Grievance Procedure*:
   2. Each facility will distribute the *Consumer Grievance Procedure* and the *Consumer Rights & Responsibilities* to the patients as needed.

Supportive Activities

All consumers need to receive information about treatment modality options prior to initiation of renal replacement therapy (RRT) 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 little time between diagnosis and initiation of RRT. All consumers need to be aware that the option to be evaluated for a change in modalities is available at any given time.

To help consumers gain knowledge about treatment options, each unit will have a minimum of one transplant designee. TARC had 278 certified transplant designees in 2004. All 153 facilities within network 3 had at least one transplant designee. The vast majority of transplant designees received their certification from St. Barnabas Medical Center's program or Auxilio Mutuo Hospital's program. Both St. Barnabas Medical Center and Auxilio Mutuo Hospital have longstanding successful transplant designee programs.

Long waiting lists for organ procurement are problematic both in network 3 and throughout the country. The network's six transplant facilities had a total of 2,636 people on their kidney transplant waiting list as of December 31, 2004. This is a decrease from 2,954 people on the waiting list from 2003. This list is not comprised solely of consumers within the network boundaries (information source: SIMS database, May 2004).

Network 3 had six Medicare-certified renal transplantation programs operating during 2004, five in New Jersey and one in Puerto Rico:

- Auxilio Mutuo Hospital
- Hackensack University Medical Center
- Newark Beth Israel Medical Center
- Our Lady of Lourdes Medical Center
- Robert Wood Johnson University Hospital
- Saint Barnabas Medical Center.

Many factors affected the actual number of kidney transplants performed: availability of transplant surgeons, operating rooms, intensive care facilities, specialized nurses and other ancillary staff. A major factor is the number of organs available. Historically, most people on transplant lists waited for cadaveric kidneys.

Interstate transplant referral patterns have been operative for many years. Dialysis consumers sought transplant services not only at one of the six local programs but also at those in neighboring or affiliated states. For example, some New Jersey dialysis consumers received cadaveric organs or transplant work-ups in New York, Maryland, and Pennsylvania during 2004. A number of Puerto Rico consumers received kidney transplants in Texas, Massachusetts and Florida.

While the six transplant programs provide convenient and state-of-the-art transplant services, the ultimate goal is for consumers to have choices among high-quality renal replacement therapies whether or not those services are located within the network's boundaries. The vast majority (89%) 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 in 2004 (facilities had to be in operation for at least nine months and have an ambulatory dialysis caseload to be included in the calculation.) The range in number of dialysis consumers who received a transplant from those dialysis facilities was from one to seventeen consumers.

The transplant designees serve 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 2004, the number of organs available and suitable for use was still fewer than those needed or desired by network dialysis consumers.

There has been an increase in living donors, both related and unrelated donors. According to the ESRD Annual Facility Survey (CMS-2744), 530 dialysis consumers (New Jersey: 444; Puerto Rico: 86) received a kidney transplant during 2004 which was an increase of 82 transplants above 2003 level. This is an increase of 15% over the previous transplant year.

New Jersey

During 2004, New Jersey transplant centers performed 446 kidney transplants. Forty-eight additional New Jersey patients were transplanted outside of the network 3 transplant centers for a total of 494 patients. This is an increase from 364 in 2003 (Source: SIMS database, May 2004). Of the 446 transplants performed in New Jersey, 185 were from living donors and 261 were from cadaveric donors.

Puerto Rico

The dialysis facilities in Puerto Rico were also very active in sending their patients for transplant. Seventy-three percent of their dialysis facilities (facilities had to be in operation for at least nine months and have an ambulatory dialysis caseload to be included in the calculation) had at least one of their dialysis consumers transplanted during the year. The range of recipients was from one to twenty-seven from any single facility.

During 2004, Puerto Rico’s transplant facility performed a total of 86 transplants. Of those 86 transplants, 25 were from living donors and 61 were from cadaveric donors. This is an increase from 84 in 2003. (Source: SIMS database, May 2005).

United States Virgin Islands

Since there is no approved transplant program in the US Virgin Islands transplant referrals are made outside the area.

The number of renal transplants performed yearly may be seen in the following chart:

Transplants Performed by Center by Year, 1995-2004

TRANSPLANT CENTER	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Auxilio Mutuo Hospital	37	25	41	71	56	68	91	68	84	86
PR Subtotal	**37**	**25**	**41**	**71**	**56**	**68**	**91**	**68**	**84**	**86**
Hackensack Univ MC *	0	0	0	0	20	41	52	41	41	48
Newark Beth Israel MC	50	46	51	43	50	47	40	27	52	52
Our Lady of Lourdes Hospital	43	34	43	33	56	63	53	40	41	46
R W Johnson Univ MC*	0	0	0	0	26	57	72	70	72	104
Saint Barnabas MC	106	145	154	167	181	171	169	185	158	194
NJ subtotal	**196**	**225**	**248**	**243**	**333**	**379**	**386**	**363**	**364**	**444**
Network Total	**233**	**250**	**289**	**314**	**389**	**447**	**477**	**431**	**448**	**530**

*Transplant service initiated in 1999 (Source: SIMS database 2005).

Home dialysis as a selected modality showed a continued decline in the number of patients choosing this setting in 2004. In 2004, 984 patients were receiving dialysis in the home. In 2003, there were 1,078 patients receiving dialysis in the home. In 2004, the vast majority of patients, 724 patients, were receiving continuous cycle peritoneal dialysis (CCPD). There has been a steady shift from continuous ambulatory peritoneal dialysis (CAPD) to CCPD over the years.

Percent of Home Patients per Year

Year	% of Patients on Home Dialysis in Network 3
2004	7%
2003	8%
2002	9%
2001	9%
2000	10%
1999	12%
1998	14%
1997	16%
1996	18%
1995	20%

Source: SIMS database, May 2005

Home hemodialysis has not been a popular modality for some years. For both 2003 and 2004, there were 24 patients receiving home hemodialysis. There is great hope for this method but reimbursement has not been modified to make newer daily methods feasible. Twenty of these home hemodialysis patients were represented by 12 providers within the state of New Jersey. Four facilities provided home hemodialysis services within the Puerto Rico area. There were no facilities performing home hemodialysis in 2004 within the United States Virgin Islands.

TARC recognized two variables that affect 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 maintained a home designee program designed to mirror the transplant designee program. The intent of this program was to create a series of events. The program educated staff nurses about home dialysis options. The staff nurses provided current knowledge of home dialysis and resources of home programs to patients. Patients were encouraged to pursue home dialysis as an option. The desired result was to have more patients knowledgeable about home dialysis and select home dialysis as their modality. The secondary gain to the facility was that they could improve their patient census. If more dialysis patients dialyzed using the home modality, fewer patients would be dialyzed in center, resulting in an improved nurse to patient ratio.

The 2004 planning committee reviewed the previous curriculum and modified the program per evaluations obtained from the initial conference in 2003. The committee was composed of the following:

Member	Facility
Joyce Jarvis, MSW	Holy Name Hospital
Robert Motacki, MA	DCI No Brunswick Dialysis Center
Barbara Richilieu, RN MA CNN	Morris Home Dialysis Center
Kathy Searson, RN BS CNN	DCI North Brunswick Dialysis Center
Fran Swire RN, CNN	FMC Englewood Dialysis Center
Michele Inglese, RN BSN CNN	Trans Atlantic Renal Council
Hazel Dennison, RN MSN CNN APN C	Trans Atlantic Renal Council

The 2004 Home Designee program was held on December 9, 2004 at Forsgate Country Club. The program agenda and presenters were as follows:

I. Purpose of the Program and description	Michele Inglese, *Sr QI Coordinator, TARC*
II. Designee Role and Responsibilities	
III. What is Peritoneal Dialysis?	Fran Swire, RN, CNN *Home Dialysis Coordinator, FMC Englewood Dialysis Center*
IV. What are the benefits and disadvantages of PD?	Barbara Richelieu, BSN, MA, CNN *Clinical Manager FMC Morris Home Dialysis*
V. Who are candidates for home PD?	Kathy Searson, RN, BS, CNN *Nurse Manager, Home Dialysis Program DCI North Brunswick*
VI. What is home Hemodialysis?	
VII. What are the benefits/disadvantages of home HD?	
VIII. Who are candidates for home HD?	
IX. Who pays for home dialysis?	Robert Motacki, MS *Renal Administrator*

	DCI North Brunswick
X. What are the psychosocial implications of home dialysis?	Joyce Jarvis, LCSW, MSW *Holy Name Hospital* *FMC Holy Name Home Dialysis*

Participants received written materials for staff and patient education. A list of active home dialysis programs with contact information was provided to all participants. Baxter Healthcare and Fresenius Medical Care provided educational materials.

The 2004 program was well received by the nurses in the audience. Seventy-eight nurses attended the program. The nurses received continuing education units, provided by American Nephrology Nurses Association. The plan is to have a certification/recertification program annually.

TARC believes home dialysis would be beneficial for many of their consumers and continues to develop programs to assist the consumer in making an educated decision for their health care. The development and inception of the home dialysis designee program is to insure the continued discussion and implementation of the goal activities specified above resulting in all the multidisciplinary renal teams to considering all modality choices when orienting newly diagnosed ESRD consumers.

The *Consumer Rights & Responsibilities* along with the *Consumer Grievances* were distributed to all facilities. They are available in English and Spanish. The facilities are asked to display the materials in a prominent place such as the waiting room and distribute paper copies annually and upon request.

In addition to paper copies, TARC *Consumer Rights & Responsibilities* and the *Consumer Grievance Procedure* are 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 materials is sent. In this package are copies of the *Consumer Rights & Responsibilities* and *Grievance Procedure*. Some facilities include TARC's rights as part of the patients' medical records.

The TARC Web site provides a question and answer section for patients. Patients can ask directly for information or have questions answered that relate to their renal disease or dialysis on this Web site. The questions are 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. The Web site is also available for consumers who utilize Spanish as their primary language. A member of the medical review board from Puerto Rico then also reviews the information for clarity of translation.

The total number of inquiries to the Web site for 2004 was 385. There were 188 questions were written in English and 197 were in Spanish. Of the total 385 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 total renal questions answered were 129. A breakdown of the four categories includes transplant, dialysis, unknown and other.

The English version of the questions consisted of a total of 56 responses. These questions were accepted from the Web site and originated from anyone with a renal-related issue, not just from consumers within network 3 boundaries. The true allocation of responses (content of responses was reviewed to categorize information) included 4 transplant-related, 32 dialysis-related, 20 related to the category 'other.' The subjects in each area were diverse and included, creatinine levels, medications, and focal segmental glomerular sclerosis (FSGS) as examples within the

transplant category. Within the dialysis field, traveling with peritoneal dialysis, stopping dialysis and weight gain were examples of issues addressed. The ‘other’ field contained such subjects as, life expectancy, pre-renal disease, financial help as well as a variety of nephrology disease states including horseshoe kidney, Goodpasture’s syndrome and renal parenchymal disease.

The Spanish version of the questions consisted of a total of 73 responses. These questions were accepted from the Web site and originated from anyone with a renal related issue, not just from consumers within network 3 boundaries. The true allocation of responses (content of responses was reviewed to categorize information) included 10 transplant related, 19 dialysis related and 44 related to the category of other. The subjects in each area were diverse and included, laparoscopic transplant, compatibility and creatinine levels as examples within the transplant category. Within the dialysis field, iron administration, dialyzer reactions and dialysis diet were examples of issues addressed. The 'other' field contained such subjects as new diagnosis of kidney disease, polycystic kidney disease and hepatitis B blood results.

Effectiveness
All facilities within network 3 have a minimum of one transplant designee and one home dialysis designee. Seven percent of the network-wide patient caseload have chosen home dialysis as their modality. Additional effort will be directed toward home therapies.

Consumer Impact
All efforts were made to provide consumers with the knowledge base to choose the desired modality. Consumer rights, responsibilities, and grievances were provided to facilities to encourage problem resolution.

II. Encourage facilities to develop continuous quality improvement systems that utilize current theories and promote patient safety.

The facilities will maintain an internal multidisciplinary QI process.

1. Facility management will have CQI meetings that are distinct from other meetings (such as care plan sessions) at least quarterly.
2. Medical directors will participate/lead multidisciplinary CQI teams and institute CQI methodology involving all privileged nephrologists of the facility, as appropriate.

Supportive Activities

The majority of facilities have distinct quality improvement meetings. TARC stresses the importance of multidisciplinary CQI meetings on a regular basis, meeting at least on a quarterly basis.

The consumer Web site was updated to include the following patient safety websites:

- U.S. Department of Health and Human Services Safety and Wellness Information
- Agency for Healthcare Research and Quality (AHRQ) - Preventing Medical Errors

Consumer health and safety information that was sent to facilities included the following:

- A July 30, 2004 CDC notice of medication errors involving patients receiving tetanus vaccine when the order was for PPD testing
- Patient education information, such as posters and flyers, and staff education materials to all facilities regarding flu and pneumonia immunization
- CDC hurricane preparation information
- CDC tuberculosis treatment information

- CDC and CMS ”Assessment of Influenza Vaccine Shortage for Patients in Dialysis Centers 2004-2005 Influenza Season Survey”
- Assessment of Influenza Vaccine Shortage Survey
- Information about consumer safety, along with the consumer safety packet was sent to every new dialysis facility and the facility administrators to promote attention on safety issues on dialysis
- National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Chronic Kidney Disease in Children and Adolescents: Evaluation, Classification and Stratification
- Results of quality improvement projects
- Journal articles and pertinent research information that renal providers may use in their quality improvement programs
- Recommendations for preventing transmission of infections among chronic hemodialysis patients
- Early Referral In Chronic Kidney Disease: An Enormous Opportunity For Prevention

Effectiveness
TARC assisted several facilities to develop and operationalize an internal QI program. TARC supported facilities in QI activities including the Fistula First Program.

TARC sent dialysis facilities information for distribution to consumers about patient safety and quality improvement. Additionally, the consumer Web site was updated with patient safety information about many things such as medications, immunizations/vaccinations, injury and accident prevention and safety and wellness.

Consumer Impact
Delivering safe and effective care provides significant benefits to consumers through better management of the comorbidities that effect ESRD consumers. These improvements mean a better quality of life as well as reduced morbidity.

III. Encourage utilization of the most recent scientific evidence to improve patient care.

A. Facilities will participate in quality improvement projects.
B. Facilities will participate in national and local clinical performance measures projects:
   1. *Adequacy of Dialysis*-facilities will maintain 80% of the hemodialysis patients with mid-week URR values of ≥ 65%.
   2. *Anemia Management*-facilities will maintain 80% of their patients with pre-dialysis hemoglobin values ≥ 11gm/dL
   3. *Vascular access*- all facilities will have a vascular access program that monitors stenosis, promotes AVF’s and decreases catheter use
   4. Encourage catheter rate of ≤ 25% for prevalent patients
   5. *Nutrition*-each facility will have 35% of their patients with an Albumin of ≥ 4.0/3.7 gm/dL (BCG/BCP)

Supportive Activities

In 2003, CMS introduced the National Vascular Improvement Initiative (NVAII), a quality improvement project, to all the networks. This 3-year project was based on the K/DOQI guidelines that indicated that 40% of the prevalent hemodialysis patients should have an arteriovenous fistula (AVF) and 50% of the incident patients should have an arteriovenous fistula

in use. The rationale for this project is hemodialysis patients with AVFs have improved morbidity and mortality outcomes.

This project was given the title *Fistula First*. CMS developed a different approach for this project. Significant differences included: all networks would have the same project. The Institute for Healthcare Improvement (IHI) was hired as a consultant and the large dialysis organizations as well as other stakeholders would be active participants in the decision-making for this national project.

All eighteen networks participated in the same project with the same goals. The *Fistula First* project thus became a national project. In the previous three years, networks had an option to select one of three vascular access-related projects. TARC's previous project was focused on reduction of catheter rates. Three networks had selected increasing AVF rates and all networks gained from their experience during the NVAII project.

IHI was retained by CMS to help guide the networks and the national steering committee for the *Fistula First* project. One of the first activities of the steering committee included creating a charter. The charter is reproduced below:

Project Charter
National Vascular Access Improvement Initiative (NVAII)
Mission Statement

CMS, the ESRD Networks, the renal community, and IHI will work together to increase the likelihood that every eligible patient will receive the most optimal form of vascular access for that patient (in the majority of cases an arterial venous fistula, or AVF), and that vascular access complications will be avoided through appropriate access monitoring and intervention.

The intent is for CMS, the ESRD Networks, and the renal community to reach or surpass the goals set forth in the CMS Clinical Performance Measures project, that is, regional and national AVF rates of 50% or greater for incident patients, and at least 40% for prevalent patients undergoing hemodialysis. CMS has committed to a system-wide improvement project on vascular access over the course of the next three-year ESRD Network contract period, starting July 2003. CMS and the Networks will aim to ensure that every ESRD Network meets or exceeds its specific goal for vascular access improvement over the term of the Network contract.

The project will bring together the best of what is known about improving vascular access. By harnessing the knowledge of the many disciplines whose care influences vascular access choices for patients, we aim to create a new level of cooperation across professional disciplines and care settings.

The project will also support the ESRD Networks in enhancing their own improvement capabilities, and in transferring useful improvement skills to facilities and medical specialists. We envision the Networks using their collective knowledge and experience in new and expanded ways to generate significant national progress around this important issue.

Goals

Goals for the work that are consistent with this mission include:

1. *The United States renal care system as a whole will make significant progress toward attaining CPM and K/DOQI goals for AVF use (50% incidence; 40% prevalence) by the end of the upcoming ESRD Network contract period (2006).*
2. *Several networks will meet or exceed the goal of 50% AVFs for incident patients by the end of the upcoming contractual period.*
3. *Several networks will meet or exceed the goal of 40% AVFs for prevalent patients by the end of the upcoming contractual period.*

4. *Networks that are currently operating at, or close to, the minimum standard for AVF use will establish stretch goals based on assessment of maximum feasible use of AVFs in their patient populations, and will make significant progress in meeting those stretch goals by the end of the upcoming contractual period.*
5. *All networks will reduce to zero the number of patients with catheters or grafts who have not been appropriately assessed for possible AVF placement.*

Problem Statement

Dialysis patients and the medical professionals who care for them recognize that vascular access is the patient's "lifeline." Having a successful access is a major contributor to patient well-being; conversely, access problems are seen as the major cause of illness and disability for those on dialysis.

While substantial progress has been made on key indicators of dialysis quality such as dialysis adequacy (Kt/V), vascular access continues to present significant challenges. It is an important determinant of dialysis adequacy, and has significant implications for morbidity related outcomes such as infection and mortality rates, with higher mortality noted among patients using AV grafts and catheters for long-term dialysis.

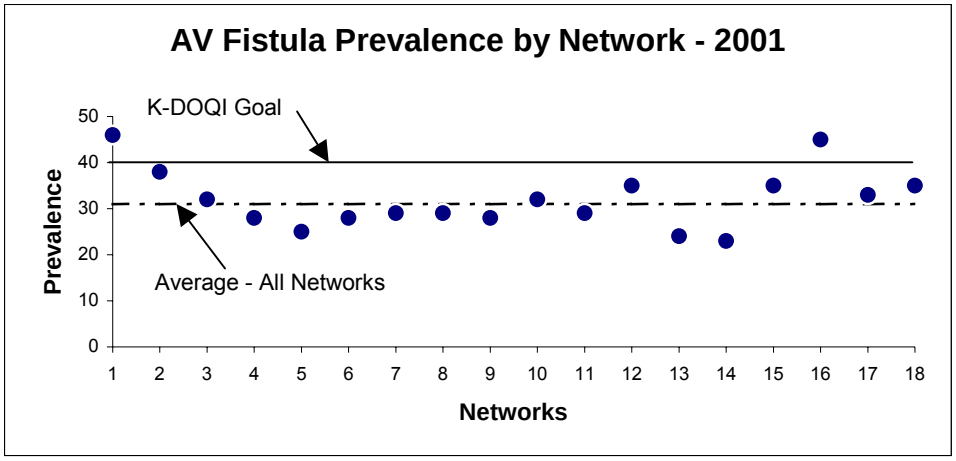
Among those responsible for the care of hemodialysis patients, there is agreement that the preferred type of vascular access is a native arterial venous fistula (AVF). Compared to catheters and arterial venous grafts, native AVFs show significantly lower rates of complication (such as infection and clotting), longer patency, fewer hospitalizations, lower patient morbidity, and significantly lower costs.

The desirability of the AVF is reflected in the CMS ESRD Clinical Performance Measures (CPM) project:

Vascular Access CPM I—A primary arterial venous fistula (AVF) should be the access for at least 50% of all new patients initiating hemodialysis. A native AVF should be the primary access for 40% of all prevalent patients undergoing hemodialysis.

This recommendation echoes that of the K/DOQI (Kidney Disease Outcomes Quality Initiative) practice guidelines for vascular access. K/DOQI is an initiative of the National Kidney Foundation that has led to a comprehensive set of practice guidelines for a wide range of dialysis care processes, including vascular access.

In the United States, rates of AVF use reported in 2001 were 29% for incident patients and 31% for prevalent patients. Among the 18 ESRD Networks, AVF use varies across region and over time. As of 2000, the regions with the highest AVF prevalence had rates of approximately 45%, whereas the region with the lowest rate showed approximately 23% of patients using AVFs for access.



Globally there is strong evidence that significantly higher rates of AVF use can be attained on a system-wide basis. Reported AVF rates for prevalent patients are 90% in Italy, 84% in Germany, 82% in Spain, 77% in France, and 67% in the UK. Even allowing for differences in the patient mix, it would appear that there is a significant gap between actual and potential rates of AVF use in the United States.

Barriers and Opportunities

Certain system problems have been cited to explain low rates of AVF use including:

6. *Inadequate care of pre-ESRD patients, making early placement and maturation of AVF impossible.*
7. *Lack of awareness among nephrologists and vascular surgeons about the current medical criteria for AVF.*
8. *Poor communication between nephrologists and vascular surgeons about nephrologists' specific expectations regarding vascular access.*
9. *Lack of training of vascular surgeons in placing AVFs successfully.*
10. *Financial incentives for surgeons that encourage catheter and graft placement and discourage AVF placement.*
11. *Patients not fully understanding the benefits of AVF and opting for catheters because of the less invasive surgical procedures necessary, and avoidance of needle "sticks."*

Recommendations for improving rates of successful AVF placement have included the following:

12. *Multidisciplinary team approach ensuring coordination and consensus among the interested parties (nephrologists, surgeons, radiologists, dialysis nurses, and patients).*
13. *Establishment of policies emphasizing preferential placement of AVFs*
14. *Early referral of pre-ESRD patients to nephrology care, allowing for early evaluation and placement of AVFs when medically appropriate.*
15. *Patient counseling regarding the advantages of AVFs and specific procedures to protect the vasculature of the arm selected for AVF.*
16. *Good surgical judgment regarding location and technique used to place AVF and to make any needed revisions to ensure successful maturation.*
17. *Referral of vascular access procedures to surgeons with demonstrable interest, skill, and experience.*
18. *Routine preoperative mapping of the patient's arteries and veins.*
19. *Understanding and supporting the maturation period for an AVF.*
20. *Monitoring and documentation to ensure that the AVF is functioning properly and to detect any problems (infection, stenosis) at an early stage so that remedial steps can be taken.*

21. *Timely intervention to correct any emerging problems that might endanger patient well-being or the patency of the access.*
22. *Prospective tracking of outcomes with continuous improvement*

The committee considered the main changes that were required to accomplish the goal of 40% of prevalent hemodialysis patients having AVFs. The key items, called change concepts, were identified as follows:

Routine CQI review of vascular access
- *Designate staff member in dialysis facility (RN if feasible) responsible for vascular access CQI.*
- *Assemble multi-disciplinary vascular access CQI team in facility or hospital.*
  - *Minimally: Medical Director and RN (VA CQI Coordinator).*
  - *Ideally: Representatives of all key disciplines including access surgeons and interventionalists.*
  - *Investigate and track all non-AVF access placements, and AVF failures.*

Timely referral to nephrologist
- *Primary care physicians utilize ESRD/CKD referral criteria to ensure timely referral of patients to nephrologists.*
- *Establish meaningful criteria for PCPs who may not perform GFR or creatinine clearance testing.*
- *Nephrologist documents AVF plan for all patients expected to require renal replacement therapy.*
- *Designated nephrology staff person educates patient and family to protect vessels, when possible using bracelet as reminder.*

Early referral to surgeon for "AVF only" evaluation and timely placement
- *Nephrologist/skilled nurse performs appropriate evaluation and physical exam prior to surgery referral.*
- *Nephrologist refers for vessel mapping where feasible, prior to surgery referral.*
- *Nephrologist refers patients to surgeons for "AVF only" evaluation, no later than Stage 4 CKD (GFR<30). Surgery scheduled with sufficient lead-time for AVF maturation.*
- *Nephrologist defines AVF expectations to surgeon, including vessel mapping (if not already performed).*
- *If timely placement of AVF does not occur, nephrologist ensures that patient receives AVF evaluation and placement at the time of initial hospitalization for temporary access (e.g. catheter).*

Surgeon selection based on best outcomes, willingness, and ability to provide access services
- *Nephrologists communicate standards and expectations to surgeons performing access, e.g., K/DOQI minimal standards for AVF placement, and training in current techniques for AVFs.*
- *Nephrologists refer to surgeons willing and able to meet the standards and expectations.*
- *Surgeons are continuously evaluated on frequency, quality and patency of access placements. Data collection ideally is initiated and reported at the dialysis center as part of ongoing CQI process, and can be aggregated at the Network level.*

Full range of appropriate surgical approaches to AVF evaluation and placement
- *Surgeons utilize current techniques for AVF placement including vein transposition.*
- *Surgeons ensure mapping is performed for any patient not clearly suitable for AVF based only on physical exam.*
- *Surgeons work with nephrologists to plan for and place secondary AVFs in suitable AV graft patients.*

*Secondary AVF placement in patients with **AV grafts***
- *Nephrologists evaluate every AV graft patient for possible secondary AV fistula conversion, including mapping as indicated, and document the plan in the patient's record.*
- *Dialysis facility staff and/or rounding nephrologists examine outflow vein of all graft patients ("sleeves up") during dialysis treatments (minimum frequency, monthly). Identify patients who*

may be suitable for elective secondary AVF conversion in upper arm and inform nephrologist of suitable outflow vein.
- *Nephrologists refer to surgeon for placement of secondary AVF before failure of AVG.*

*AVF placement in patients with **catheters** where indicated*
- *Regardless of prior access (e.g. AV graft), nephrologists and surgeons evaluate all catheter patients as soon as possible for AVF, including mapping as indicated.*
- *Facility implements protocol to track all catheter patients for early removal of catheter.*

Cannulation training for AV fistulas
- *Facility uses best cannulators and best teaching tools (e.g., videos) to teach AVF cannulation to all appropriate dialysis staff.*
- *Dialysis staff use specific protocols for initial dialysis treatments with new AVFs and assign the most skilled staff to such patients.*
- *Facility offers option of self-cannulation to patients who are interested and able.*

Monitoring and surveillance to ensure adequate access function
- *Nephrologists and surgeons conduct post-operative physical evaluation of AVFs in 4 weeks to detect early signs of failure and refer for intervention as indicated.*
- *Facilities adopt standard procedures for monitoring, surveillance, and timely referral for the failing AVF.*
- *Nephrologists, interventional radiologists, and surgeons adopt standard criteria, and a plan for each patient, to determine the appropriate extent of intervention on an existing access before considering placing a new access.*

Education for care-givers and patients
- *Routine facility staff in-servicing and education program in vascular access.*
- *Continuing education for all caregivers to include periodic in-services by nephrologists, surgeons, and interventionalists.*
- *Facilities educate patients to improve quality of care and outcomes (e.g., prepping puncture sites, applying pressure at needle sites, etc.).*

Outcomes feedback to guide practice
- *Networks work with dialysis providers to give specific feedback to all decision-makers on incident and prevalent rates of AVF, AVG, and catheter use.*
- *Review data monthly or quarterly in facility staff meetings. Present and evaluate data trended over time for incident and prevalent rates of AVF, AVG, and catheter use.*

Various network-led subcommittees were formed including tools and resources, data collection tools and reports, marketing and patient education. From the various committees, a standardized data collection tool was developed, standardized reports were developed and a vast amount of resource materials was developed and implemented.

Network staff participated in on-site meetings and conference calls to improve knowledge and provide feedback to activities. In addition, a specific Web site was created for network, IHI and committee use that was continuously updated.

In keeping with the CMS vision of project collaboration, the six large dialysis organizations (LDOs) were included in the planning phase. The participating organizations are: DaVita, Dialysis Clinics Inc., Fresenius Medical Care, Gambro, National Nephrology Associates and Renal Care Group. One of the main purposes was to make the data collection process more efficient by having the corporate offices provide data directly to the designated data coordinating center.

The aforementioned information was provided to both the Medical Review Board and Board of Trustees members of TARC. Directed by the boards, a steering committee was formed and a plan developed which introduced the project, prioritized change concepts and implemented the plan. The committee determined that three areas should be addressed simultaneously to

implement the project. The areas implemented included an introduction of the surgeons to the project, identification of proficient nurse cannulators to train other staff at the unit level and education of the patient by all parties. The plan included initiation of the educational sessions first in New Jersey and then Puerto Rico and the United States Virgin Islands.

The planned educational sessions for the physicians were in small regional sessions. At each session, one nephrologist and one vascular surgeon presented an overview of the project. The audience consisted of nephrologists and vascular surgeons. All presenters were volunteers. Each attendee received a toolkit with numerous articles, samples of tools, communications and patient education materials. The meetings were well received. A total of four meetings of similar structure occurred in different parts of New Jersey in early 2004.

The planned educational sessions for nursing staff consisted of small regional sessions. At each session, the charter, change concepts, reference data, cannulation demonstration videos and sample tools were reviewed. Each participant received a toolkit. In the toolkit, there were reference articles, examples of policies, procedures, cannulation competencies, samples of interdisciplinary communication faxes and letters and patient education materials. Each participant received a self-learning cannulation videotape that provided CEUs. Every facility received two videos for use in training in the unit. There were three nursing educational sessions completed with a total of 154 participants by January of 2004. All facilities completed cannulation competencies on every staff member by early 2004.

Fistula First Data

TARC collected vascular access data from facilities starting in 1997 as part of the local Hemodialysis Improvement Project (HIP). Although the HIP was terminated in 2003, the vascular access data was provided using the *Fistula First* data collection tool for non-LDOs. The LDOs provided vascular access data by facility to a central processor and data was forwarded to the networks. The charts and graphs in the following sections utilize the HIP data as a source from 1997 through June 2003. December 2003 to the present utilizes data that is from the *Fistula First* data collection tool.

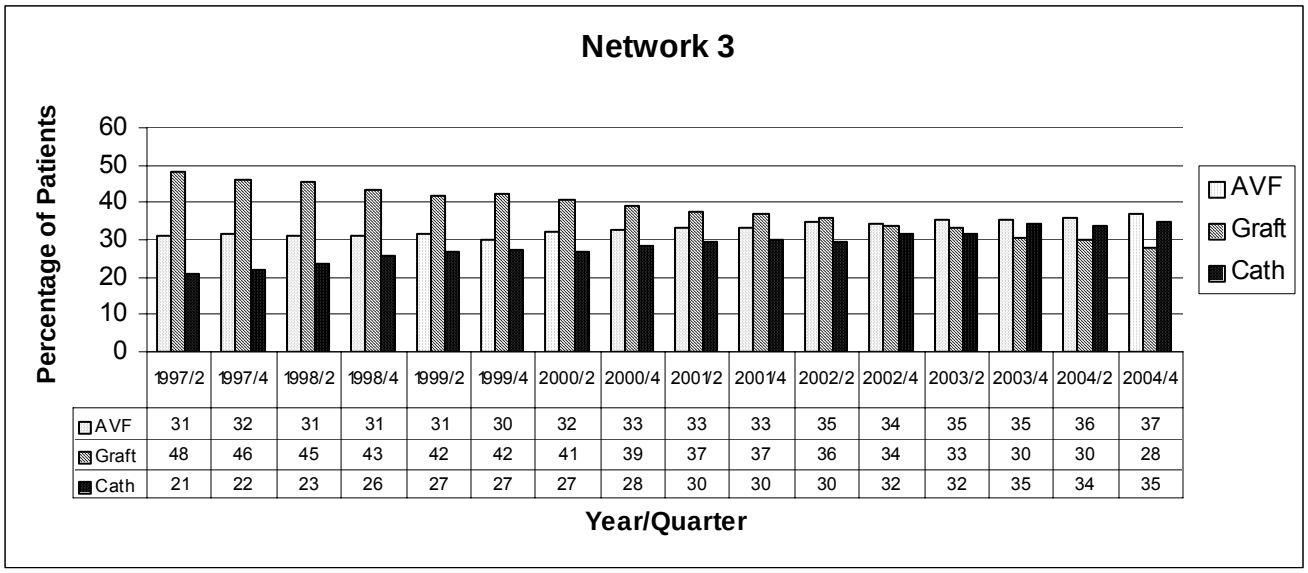
Network Results

Fistula rates within network 3 have increased in small increments since 1997, which was when the DOQI guidelines were published. The goal of the *Fistula First* project is to have 40% of prevalent patients using a fistula by 2006. This goal appears to be the first in several steps of achieving a fistula rate comparable to that of European countries (66%). Note that the vascular access data presented on these pages reflect prevalent patients. Historically, incident patients were not measured separately.

Although AVF rates have increased slowly, catheter rates have also increased. TARC's fistula rate has improved and was 37% as of December 2004.

Many authors have associated catheter rates with increased morbidity and mortality. In June 1997, TARC facilities reported 1,712 patients with catheters. In December 2004, there were 4,325 patients with catheters, which is an increase of 7% over the previous year and an increase since 1997 of 40%. The percentage of patients at risk as of December of 2004 was 34.95%; more than one-third of the hemodialysis population utilizing a catheter for hemodialysis.

Vascular Access Type in Use in Network 3 by Percent of Patients, 1997-2004



	1997/2	1997/4	1998/2	1998/4	1999/2	1999/4	2000/2	2000/4	2001/2	2001/4	2002/2	2002/4	2003/2	2003/4	2004/2	2004/4
AVF	31	32	31	31	31	30	32	33	33	33	35	34	35	35	36	37
Graft	48	46	45	43	42	42	41	39	37	37	36	34	33	30	30	28
Cath	21	22	23	26	27	27	27	28	30	30	30	32	32	35	34	35

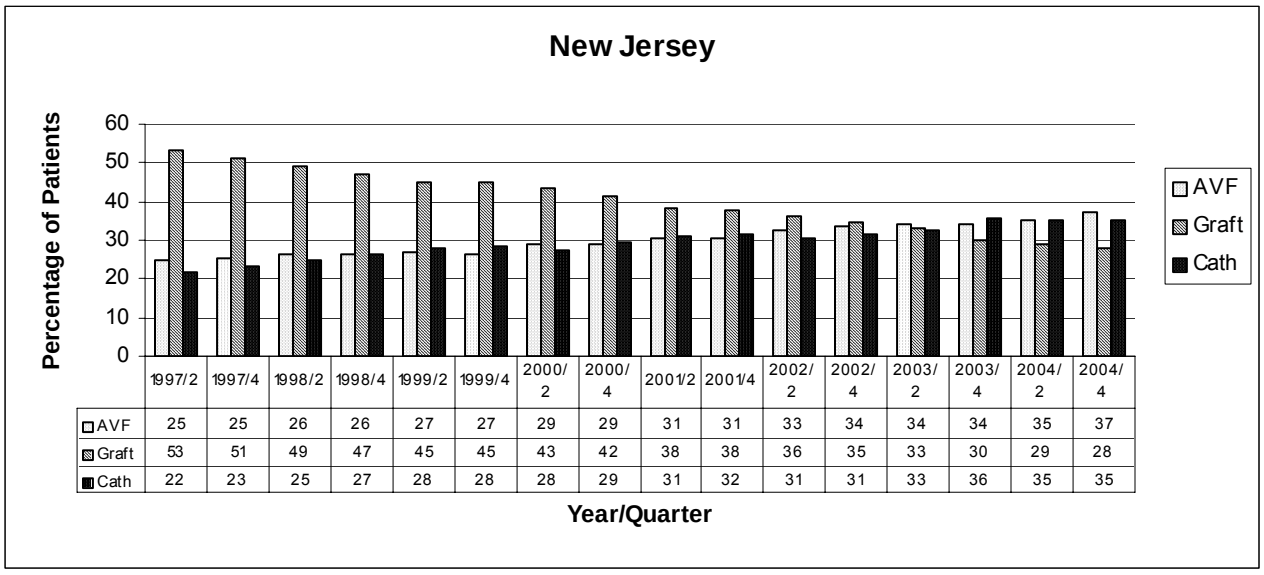
Area Specific Data

New Jersey

A key reason why there has been an increase in the overall rate of fistulae in network 3 is because New Jersey hemodialysis patients have had more functioning fistulae placed. The rate of fistulae increased from 24.7% in June 1997 to 36.7% as of December of 2004. During preparation of data for the *Fistula First* meetings, pockets of high fistulae rates in specific geographic areas were noted within New Jersey. Nephrologists and surgeon partners who championed the project were requested to participate in the annual meeting and Medical Review Board activities.

The rate of catheters will decrease as more fistulae are placed. Decreasing catheter rates has been stressed by TARC.

Vascular Access Type in Use in New Jersey by Percent of Patients, 1997-2004

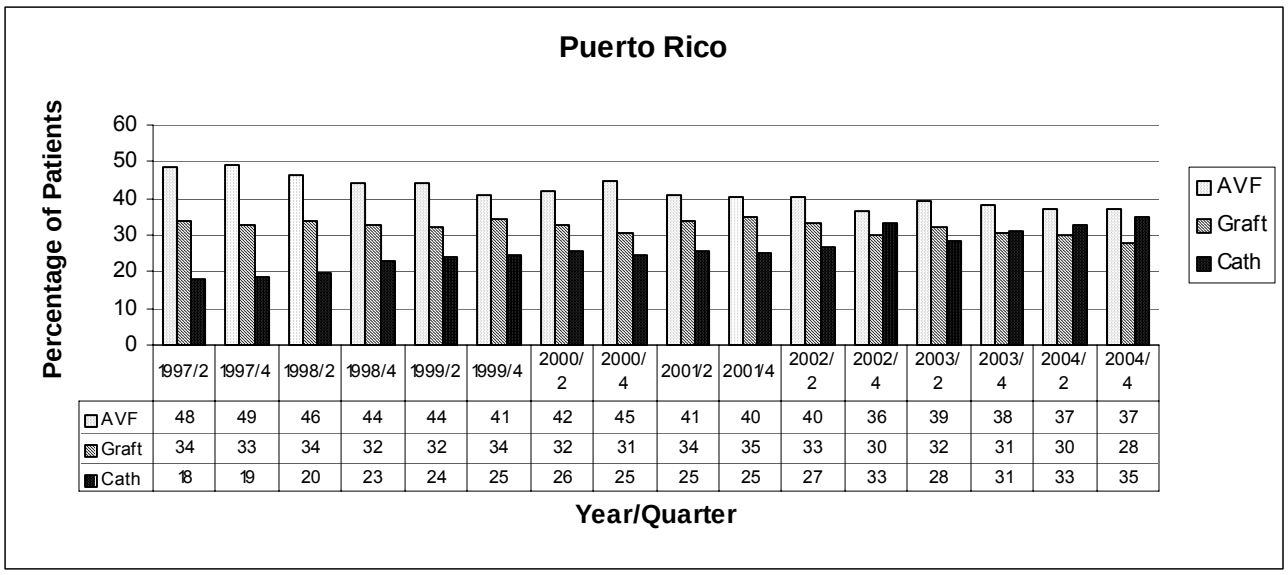


	1997/2	1997/4	1998/2	1998/4	1999/2	1999/4	2000/2	2000/4	2001/2	2001/4	2002/2	2002/4	2003/2	2003/4	2004/2	2004/4
AVF	25	25	26	26	27	27	29	29	31	31	33	34	34	34	35	37
Graft	53	51	49	47	45	45	43	42	38	38	36	35	33	30	29	28
Cath	22	23	25	27	28	28	28	29	31	32	31	31	33	36	35	35

Puerto Rico

There is regional variation in the distribution of access types. Historically, the majority of hemodialysis patients in Puerto Rico had arteriovenous fistulae. Although the majority of hemodialysis patients in Puerto Rico still have AVFs, there is a decline in the trend. The inclination toward catheters in Puerto Rico reflects the increase noted at the network level. The rate of fistulae in prevalent patients within the Puerto Rico area remains unchanged while an increase of 20% catheters was noted from the second quarter of 2003 through the fourth quarter of 2004.

Vascular Access Type in Use in Puerto Rico by Percent of Patients, 1997-2004

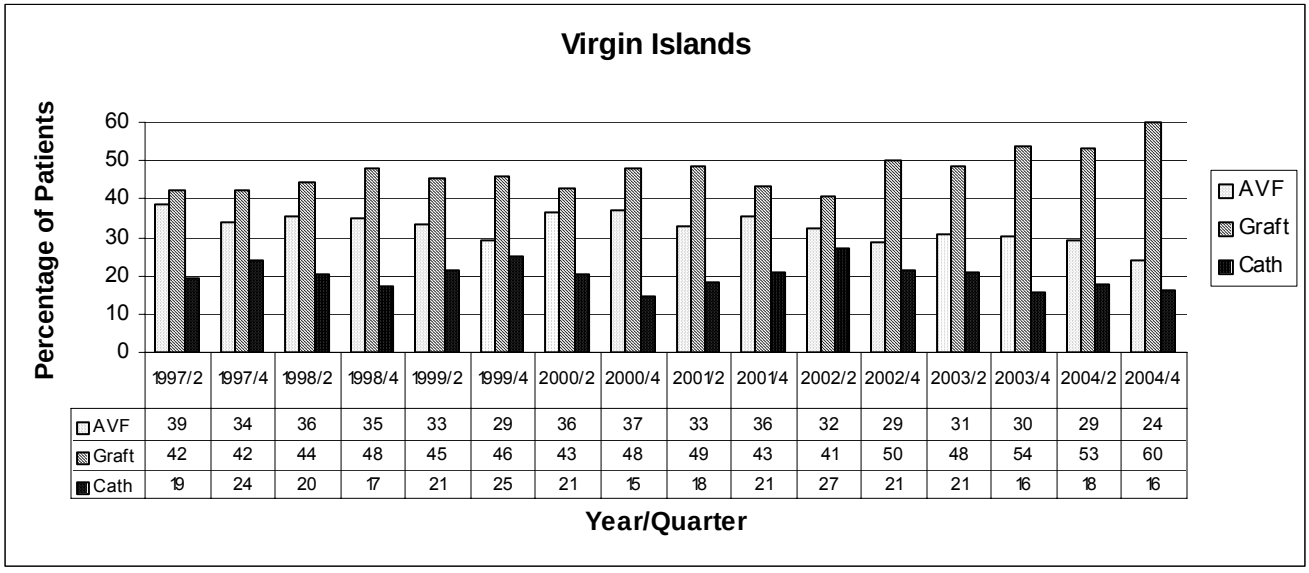


	1997/2	1997/4	1998/2	1998/4	1999/2	1999/4	2000/2	2000/4	2001/2	2001/4	2002/2	2002/4	2003/2	2003/4	2004/2	2004/4
AVF	48	49	46	44	44	41	42	45	41	40	40	36	39	38	37	37
Graft	34	33	34	32	32	34	32	31	34	35	33	30	32	31	30	28
Cath	18	19	20	23	24	25	26	25	25	25	27	33	28	31	33	35

Virgin Islands

The trend in the Virgin Islands also shows a decrease in fistulae and an increase in the graft rate at facilities. The rate of catheters declined over the last 4 quarters of reported data. The 4th quarter 2004 data represents less than 120 patients within the Virgin Islands.

Vascular Access Type in Use in US Virgin Islands by Percent of Patients, 1997-2004



	1997/2	1997/4	1998/2	1998/4	1999/2	1999/4	2000/2	2000/4	2001/2	2001/4	2002/2	2002/4	2003/2	2003/4	2004/2	2004/4
AVF	39	34	36	35	33	29	36	37	33	36	32	29	31	30	29	24
Graft	42	42	44	48	45	46	43	48	49	43	41	50	48	54	53	60
Cath	19	24	20	17	21	25	21	15	18	21	27	21	21	16	18	16

TARC Activities in 2004 to Support the Fistula First Project

Activity	Status
Regional nurses cannulation review meeting	1/06/2004, 06/04/2004, 06/23-25/2004. Completed in New Jersey, PR & VI
Nephrologists & surgeons Meeting	1/20/2004, 2/10/2004, 3/10/2004, 6/22/2004,6/23/2004. Completed in New Jersey, PR & VI
Data collection tool with instructions mailed to non-LDO facilities	04/15/2004. Completed in NJ, PR & VI
Regional LDO administrators and QI meeting	4/08/2004
Non LDO data collection for first quarter 2004	4/15/2004
Mailed FistulaGram newsletter, posters, pens to NJ units	4/26-4/27/2004
Mailed FistulaGram newsletter to all medical directors	04/26/2004
Mailed FistulaGram newsletter to all county medical societies; chief of medicine at all NJ acute care hospitals; chief of surgery at all NJ acute care hospitals	4/29/2004
Regional nurses cannulation review meeting for PR/VI staff.	6/03/2004
Site visits performed on 3 VI facilities to discuss the Fistula First project and individual needs	6/04/2004 and 6/23 –6/24/2004
TARC displayed poster at KUF meeting	6/11/2004
Nephrologist and surgeon meeting in Ponce, Puerto Rico	6/22/2004
Nephrologists & surgeons meeting in San Juan, Puerto Rico	6/23/2004
Meetings with Quality Improvement Professional Research Organization and Virgin Island Medical Institutions (quality improvement organizations) re: *Fistula First* project, other quality improvement topics	6/23-6/24 2004
TARC distributed facility-specific vascular access reports and network comparative data.	8/18/2004, 11/23/2004. Performed quarterly.
TARC analyzed fistula data monthly and identified 3 target groups. These target groups were selected for their low fistula rates. TARC follows each of these groups. Target group needs are identified and strategized.	All three target groups have been evaluated and feedback provided.
TARC sent data collection tool to biostatistician	8/302004; Updates as requested
Fistula First poster mailed to facilities	10/13/2004
TARC presented *Fistula First* data for ANNA Jersey North Chapter.	11/7/2004
Invited surgeons and Interventional radiologists to a separate meeting the evening prior to the Annual meeting to review NVAII project with medical experts.	11/16/2004
The annual meeting topic was NVAII. Dr. Cimino was in attendance. Attendance at Annual meeting for 2004 was largest to date.	11/17/2004
The Annual meeting videotaped to be distributed to all facilities, administrators and Medical Directors in Network 3 for spread in the NVAII project.	11/17/2004; For Distribution 6/2005
Updating surgeon list from all Network 3 facilities in preparation to send out NVAII surgical presentation and potential invitee list to surgical meeting.	Completed.

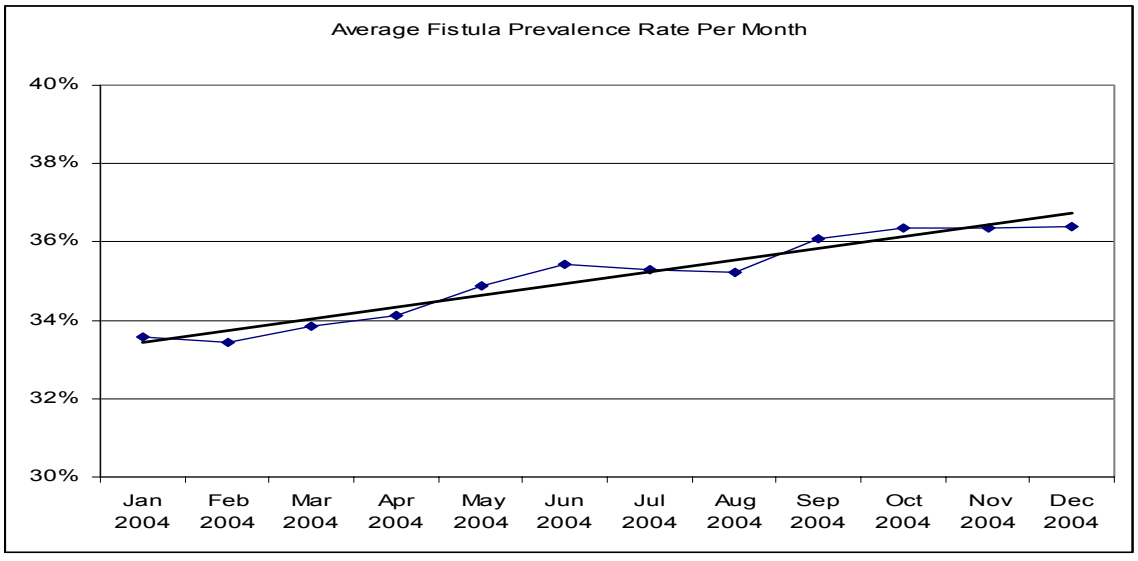
Statistical Analysis for Network 3, New Jersey, Puerto Rico and US Virgin Islands

Improvement in Fistula rates

During calendar year 2004, 61.4% of the reporting facilities with sufficient data for analysis achieved statistically significant linear increases in their fistula prevalence rates ($p < .05$). Due to the inherent sampling error in using only beginning and ending rates, all twelve monthly rates were used for calculations. The rates were weighted to account for the within-facility sampling error and power derived from sample size. Additional interpretative information includes 33.8% showing statistically significant decreases and showing no statistical change. These results suggest that almost 82% more facilities showed statistically significant increases than showed statistically significant decreases. Progress is being made overall for increasing fistula rates for reporting facilities in Network 3. Notably, 61.4% of facilities showed statistically significant increases ($p < .05$), compared with 33.8% showing statistically significant decreases. Nonetheless, the network achieved only the modest increase in actual fistula prevalence rates of approximately 0.3% per month, 3.3% for the year, using the linearized rate of change. Due mainly to the low number of incident patients, 12.8% of facilities showed a statistically significant increase and 11.1% showing a statistically significant decrease. The majority of facilities, 76.1% were statistically unchanged. Yet, a modest increase was seen for the linearized fistula incidence rates overall of approximately 0.2% per month, 2.8% for the year.

Weighted by the average number of prevalence patients across the year for each reporting facility, several statistically significant differences arose by 'State' in the linearized change for the rate of AVF prevalence, catheter prevalence, and catheter with AVF maturing prevalence. Although the magnitudes of change were modest and the differences between 'States' were small, when multiplied by the numbers of patients who were impacted, the changes seen were substantively important for the quality of life and for the outcome of dialysis for many patients in all three 'States'. For AVF prevalence, all three 'States' showed positive change averaged across all of their reporting facilities. The three linearized changes were 2.18%, 2.07%, and 2.20% for New Jersey, Puerto Rico, and US Virgin Islands, respectively. The increase for New Jersey was statistically greater ($p<.05$) than the change for Puerto Rico but was statistically indistinguishable from the change for US Virgin Islands. The change for Puerto Rico was statistically less than for both New Jersey and US Virgin Islands.

Trends in Fistula Rates by Month for Network 3, 2004



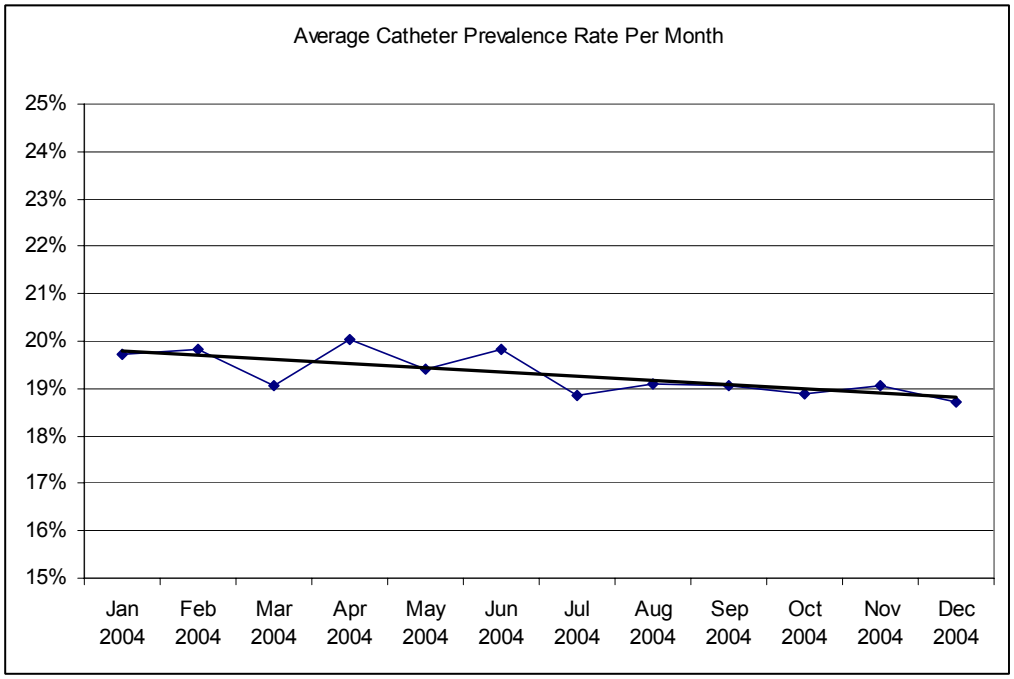
Decrease in Catheter rates

Catheter prevalence rates (greater than 90 days) statistically decreased for 52.8% of facilities while statistically increasing for 43.1% of facilities. The linearized rate decreased by approximately 0.1% per month, 1.0% for the year. The increase in prevalence for catheter rates with fistulae maturing showed modest gains with 52.2% showing statistically significant increases and 42.0 percent showing significant decreases. The average linearized rate of increase was approximately 0.1% per month, 1.1% for the year.

Using the same methodology for comparing the changes in catheter prevalence, New Jersey, Puerto Rico, and US Virgin Islands showed changes of -1.03%, -0.98%, and -1.04%, respectively. All three 'states' showed trends in the direction of improvement. For this quality indicator, negative changes signify improvement for rates of catheter prevalence. The change for New Jersey was statistically greater than for Puerto Rico but indistinguishable from that of US Virgin Islands. The change for Puerto Rico was statistically less than for New Jersey and US Virgin Islands.

For catheters with AVF maturing, all three 'states' showed positive improvement. The changes over the year were 0.74%, 0.71%, and 0.75% for New Jersey, Puerto Rico, and US Virgin Islands, respectively. The change for New Jersey was significantly greater than for Puerto Rico but was statistically indistinguishable from the change for US Virgin Islands. The change for Puerto Rico was statistically less than for both New Jersey and US Virgin Islands.

Trends in Catheter Rates by Month for Network 3, 2004



The above data were abstracted from the *Fistula First* data collection tool. Statistical analysis completed by D. Keller, PhD.

Clinical Indicators From 2004 Annual Report ESRD Performance Measures Project

TARC initiated the Hemodialysis Improvement Project (HIP) in 1996. The HIP was based on the annual Core Indicator Project of CMS. The Core Indicator Project analyzed key clinical indicators as a surrogate for intermediate patient outcomes. The Core Indicator Project developed into the Clinical Performance Measures (CPM) Project.

The clinical indicators of the HIP were adequacy of dialysis as measured by urea reduction ratios (URRs), anemia management as measured by hemoglobin values and nutrition, as measured by serum albumin levels. The HIP evolved over the years to reflect the network practice. Data items that related to one of the clinical indicators were collected and analyzed. Initially, blood flow rates, dialysate flow rates and dialyzer types were collected because all facilities did not have current machines and adequacy was affected. Vascular access data was collected because it related to the adequacy of dialysis. Ultimately, vascular access became its own indicator as more research was reported. Transferrin saturation and ferritin levels were added to the anemia indicator.

In 2003, CMS informed TARC that data collection for the HIP would terminate after the second quarter. TARC would participate in data collection efforts through the lab collection utility. The intent of the lab collection utility was to assist individual facilities to submit data and laboratory results directly from the laboratories. CMS had directed that the lab collection utility results from the last quarter of 2004 (October, November and December) may be collected. LDO data has been provided to the network through the lab collection utility. Those facilities without this capability submit data via compact disc or spreadsheet to TARC. Facility specific statistics will be reviewed to assist in anemia management and URR evaluation as well as evaluating data at the network level against the preliminary CPM data from 2004.

The 2004 ESRD Clinical Performance Measures project was the eleventh year of this data collection in more than 2,000 dialysis programs nationwide. CMS characterized the project as a 'snap-shot' description of peritoneal and in-center hemodialysis patients. The effort focused on the dose of delivered dialysis, anemia management, serum albumin values and vascular access. The samples included: hemodialysis patients, peritoneal dialysis patients, and pediatric patients. The Veteran's Administration hospitals provided data on 100% of their population while all other facilities were subject to a 5% scientifically selected sample number of study patients.

Number of Network 3 Clinical Performance Measures Participants, 2004

Area	No. Dialysis Facilities	No. HD Patients	No. HD Pediatric Patients	No. PD Patients	No. Total Patient forms
New Jersey	102	323	14	30	367
Puerto Rico	41	153	12	31	196
US VI	3	7	1	0	8
Network	146	483	27	61	571

Source: CSC 2004

In May of 2004, TARC received 659 forms for the CPM project data collection and validation study. There were 491 adult (non-VHA) hemodialysis forms, 80 adult hemodialysis forms for VHA, 27 pediatric hemodialysis forms, 52 (non-VHA) peritoneal dialysis forms and 9 VHA peritoneal dialysis forms. Of the 659 forms, data from 28 forms were re-abstracted as part of the

reliability testing of this project. For various reasons, 571 forms were completed. Included in the 571 forms were 89 forms from the VA hospitals.

This was the first year that the LDOs submitted CPM data electronically to CMS. As with any new effort, no problems were expected that would greatly affect conduct of the project. CMS informed the networks that the LDOs discovered problems with specific data fields submitted electronically.

Some of the problems included the following: *weekly* EPO doses for the selected peritoneal dialysis patients (not *monthly* doses); albumin values were rounded and not accurate in the tenths decimal position (i.e. 4.4 became 4.0, etc.); the return to dialysis date (following transplant failure) was interpreted as the date the patient transferred into the facility. Therefore, CMS requested that the LDO dialysis facility staff verify all fields on both the hemodialysis and peritoneal dialysis forms for accuracy and completeness. The 2004 data collection forms for the patient sample were sent. The facilities were instructed to fill in the blank fields if the information was available, to check if the information on the form was correct and to write the information on the form in colored ink or circle the addition/correction so that these can be easily identified. The completed forms were returned to the network office.

The following steps were performed to complete the process of CPM measures collection:

- TARC mailed the hemodialysis CPM forms and peritoneal dialysis CPM forms to the non-LDO and VHA dialysis facilities. After CMS had determined the data set to be accepted from the LDOs, TARC mailed the hemodialysis CPM forms to LDO facilities.
- TARC participated in conference calls with staff of the networks.
- TARC sent the forms to the LDO facilities, as the data could not be provided electronically by the coordinating center.
- TARC participated in conference call referencing CPM data validation issues.
- TARC sent central processor a request regarding forms where data “disappeared”. The pattern seemed to be that these patients left the facility at some point in 2004 following the sample time period.
- TARC sent 304 CPM forms to the LDO facilities for validation of corporate-provided data.
- TARC sent the CPM project data reliability testing forms and instructions to the dialysis facilities.
- TARC sent an email notification that completed CPM validation forms had been verified and entered into SIMS with the exception of one patient. The dialysis facility where the patient had dialyzed during the study period had closed and TARC was unable to retrieve records. The total number of CPM forms in the network 3 sample for 2004 was 659. Of those 659, a total of 349 were received for manual input within the network office. Due to the LDO data issues, a total of 370 calls were made from the network 3 office to clarify information.

The 2003 ESRD Clinical Performance Measures Project Annual Reports were sent to the medical directors, administrators and nursing managers of each facility. Facilities were encouraged to compare nationwide information with their local data and to examine their own patient care practices and processes. The network Medical Review Board and Board of Trustees used the information to identify progress over time and to compare the results of New Jersey, Puerto Rico, and the US Virgin Islands to other areas of the country.

The CMS-designed Clinical Performance Measures report was created to stimulate caregivers in dialysis facilities to ask questions such as: What percent of patients in our facility received the minimum adequate dose of hemodialysis? If results were less than the national average or less than the threshold established by the Medical Review Board, then facility caregivers were to

consider their differing results as an opportunity to improve care. Overall, the goal of the project was that, collectively, providers would achieve the following intermediate outcomes for adult, in-center hemodialysis patients:

- Dialysis Adequacy: Urea reduction ratios of at least 65% (or a Kt/V of 1.2)
- Anemia Management: Hemoglobin values of 11 – 12 gm/dl.
- Albumin Management: Serum albumin values of at least 4.0 gm/dl

Dialysis Adequacy in Network 3

The goal for adequacy of dialysis was that 80% of the hemodialysis patients would have a URR of ≥ 65%. Review of the CPM data for 2004 shows that goal was met and exceeded. Within the United States, 87% of sampled adult, in-center hemodialysis patients achieved a URR of 65% or greater. The chart below represents data from initially the HIP and in 2004 from CPM data collection only. The network level of 86% remains consistent within a similar improvement rate noted throughout the previous year.

The lack of continued improvement may be related to sampling error, however, it may also be related to the failure to improve the fistula rate and the elevation of catheter rates within the network. The 2004 preliminary CPM data only represents a 5% sampling of overall network data and cannot be extrapolated to specific regions within the network.

Percent of Hemodialysis Patients with URRs ≥ 65%
for Available Periods in 2002, 2003, 2004
Goal: 80 % of patients will have a URR of >/= 65%

Area	1st Qtr 02	2nd Qtr 02	3rd Qtr 02	4th Qtr 02	1st Qtr 03	2nd Qtr 03	2004 CPM
New Jersey	86.4%	87.2%	87.4%	87.8	87.6%	90.0%	
Puerto Rico	82.1%	82.0%	82.0%	84.1	83.9%	84.4%	
US Virgin Islands	87.3%	80.9%	82.5%	85.3	83.9%	77.7%	
Network	**85.3%**	**85.8%**	**85.9%**	**87%**	**86.6%**	**87.1%**	**86%**

Source HIP/2004 CPM data

Anemia Management in Network 3

The goal for anemia management was 80% of the hemodialysis patients would have a hemoglobin of ≥ 11 gm/dl. The chart below represents data from initially the HIP and in 2004 from CPM data collection only. This goal was met. It has been acknowledged that anemia has more influencing factors than adequacy. It has also been acknowledged that some of those influencing factors are outside of the control of the nephrology health care team and patient. TARC will continue to encourage facilities to follow anemia management closely, refer patients early when a comorbidity is suspected as causing or influencing the anemia and continue to strive for the goal. The 2004 preliminary CPM data only represents overall network data and was unable to be extrapolated to specific regions within the network.

In the 2004 CPM data, anemia results were analyzed. In the United States 80% of adult in-center hemodialysis patients had mean hemoglobin values of ≥11 gm/dL; in network 3 that percentage was 82%. This was a 3% increase for network 3 from the previous year. The US average for iron management data indicated 81% of patients had a mean TSAT of ≥20% and 92% of patients had ferritin levels ≥ 100ng/mL.nationally. In network 3, 80% of patients had a mean TSAT of ≥20% and 91% of patients had ferritins ≥ 100ng/mL. These percentages are slightly lower than the national rates despite having a higher than national average administration of intravenous (IV)

iron. Nationally, 65% of patients receive IV iron and in this network, 73% of patients received IV iron. The dosage of IV iron is also noted to be at a higher than national average at 245mg per month (national average 233 mg per month). The data were discussed with the Medical Review Board and Board of Trustees. Iron administration is provided to in-center hemodialysis patients as an adjunct to erythropoietin therapy. As evidenced by the 2004 CPM data collection, network 3 results indicate that utilization of iron within the network has achieved the goal of improved hemoglobin levels.

Percent of Hemodialysis Patients with Hemoglobin Values ≥ 11 Grams for Available Periods in 2002, 2003, 2004

Goal: 80% of patients will have a hemoglobin >/= 11 GM/dl

Area	1st Qtr 02	2nd Qtr 02	3rd Qtr 02	4th Qtr 02	1st Qtr 03	2nd Qtr 03	2004 CPM
New Jersey	75.6%	76.4%	76.8%	78.1%	78 %	79.1%	
Puerto Rico	66.8%	72.1%	73.6%	72.6%	74.9%	77.6%	
U.S. Virgin Islands	72.6%	73.8%	69.3%	70.3%	74.4%	79.9%	
Network	**73.5%**	**75.3%**	**75.8%**	**76.6%**	**77.3%**	**78.8%**	**82%**

Source HIP/CPM

Albumin Management in Network 3

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

The goal states that 35% of prevalent patients will have an albumin of 4.0 Gm/dl if the lab uses BCG method or 3.7 if the lab uses BCP method. The previously reported HIP data did not separate the green from purple method results. The 2003 and 2004 CPM results for the network both show an albumin measure of 33%. The pattern ascertained from the previous HIP project of higher rates of albumin in Puerto Rico patients has been consistently observed and is related to diet. The United States had 39% of patients with those albumin levels. The 2004 CPM data only represents overall network data and is unable to be extrapolated to specific regions within the network.

Percent of HD Patients with Albumin Values > 4.0 Gm/dL for Available Periods in 2002, 2003, 2004

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

Area	1st Qtr 02	2nd Qtr 02	3rd Qtr 02	4th Qtr 02	1st Qtr 03	2nd Qtr 03	2004 CPM
New Jersey	35.4%	36.6%	32.6%	34.2%	33.3%	32.7%	
Puerto Rico	45.2%	44.8%	42.1%	45.9%	45.1%	42.1%	
US Virgin Islands	16.6%	39.7%	19.7%	31.1%	40.3%	44.3%	
Network	**37.6%**	**38.6%**	**34.8%**	**37.1%**	**36.3%**	**35.1%**	**33%**

Source: HIP/CPM

Vascular Access Reporting in Network 3

Dialysis Outcomes Quality Initiative (DOQI) states that at least 50% of all new (incident) hemodialysis patients should have a primary arteriovenous fistula (AVF) as the primary access. It further states that 40% of all prevalent hemodialysis patients should have an AVF in use. The NVAII project supports this goal.

There are two specific goals related to vascular access. The first vascular access goal is for network 3 facilities to have a vascular access program to support the *Fistula First* project. As part of the *Fistula First* project, monthly vascular access data is obtained. The types of accesses are documented and the percentages calculated. Quarterly feedback is provided to facilities to review their facility specific goals for fistula placement. The main goal of the *Fistula First* project is to increase AVFs which parallels the network goal of promoting AVF.

According to the 2004 CPM report, the percentage of both incident and prevalent patients with an AVF was 35% nationally; network 3 had 38% and 35% respectively. Seventy-three percent of prevalent patients had their grafts monitored for stenosis. By increasing AVFs, the desired secondary gain is reduction of catheter use.

The second goal related to vascular access is to decrease catheter usage. TARC is working to achieve that goal. DOQI recommends no more than 10% of hemodialysis patients should have a catheter. The MRB and Board of Trustees recognize that a group of patients exist in which a catheter is the only option and directed TARC to develop a goal of 25% of prevalent patients within the network to use a catheter for hemodialysis.

The rate as of December of 2004 was 34.95%. The 2004 CPM data notes that prevalent patients with a catheter within the United State comprise 27%; network 3 had 37%. TARC will continue to encourage facilities to decrease catheter use, provide education and resources to assist in this process and monitor the progress of each facility.

The data supplied in the graphs below is obtained from two sources. The first source is the *Fistula First* data collection tool. This tool requires all facilities within the network provide summary totals monthly to the network that reflect access information on every patient for the month the report is due. The second source of data is derived from the CPM data collection. This is a random sampling of 5% of patients derived by CMS from facilities within the network. This information is supplied to acknowledge the discrepancies noted within the data sets presented below.

Percent of prevalent HD Patients with an AVF for hemodialysis for Available Periods in 2002, 2003, 2004

Goal: 38.4% or more of prevalent hemodialysis patients will have a fistula for access (DOQI goal 40% prevalent)

Area	2nd Qtr 02	4th Qtr 02	2nd Qtr 03	4th Qtr 03	2nd Qtr 04	2nd Qtr 04	2004 CPM
New Jersey	33	34	34	34	35	37	
Puerto Rico	40	36	39	38	37	37	
US Virgin Islands	32	29	31	30	29	24	
Network	**35**	**34**	**35**	**35**	**36**	**37**	**35**

Source: HIP/CPM/Fistula First Data Collection Tool

Percent of prevalent HD Patients with a catheter for hemodialysis for Available Periods in 2002, 2003, 2004

Goal: 25% or less of prevalent hemodialysis patients will have a catheter for access (DOQI goal 10% prevalent)

Area	2nd Qtr 02	4th Qtr 02	2nd Qtr 03	4th Qtr 03	2nd Qtr 04	2nd Qtr 04	2004 CPM
New Jersey	31	31	33	36	35	35	
Puerto Rico	27	33	28	31	33	35	
US Virgin Islands	27	21	21	16	18	16	
Network	**30**	**32**	**32**	**35**	**34**	**35**	**37**

Source: HIP/CPM/Fistula First Data Collection Tool

National CPM results of PD Adequacy

The federal peritoneal dialysis core indicator project is designed to assist providers to improve the care they deliver by highlighting opportunities for positive change. The patient sample resulted in national estimates only (not regional or network-specific). The 2004 Annual Report for the Peritoneal Dialysis ESRD Clinical Performance Measures will be distributed by CMS during the 2005 calendar year.

During this year's project, clinical information was sought for October, November, and December 2003 and January through March 2004 for hemoglobin levels, serum albumin, blood pressure and dose of delivered dialysis for the peritoneal dialysis patients. Data were abstracted from 52 peritoneal dialysis patients medical records in network 3 facilities; nationwide, records for 1,453 adult peritoneal patients over the age of eighteen years were examined.

The Center for Clinical Measurement and Improvement within the Health Standards and Quality Bureau of CMS has not announced federal minimum standards for peritoneal dialysis performance. In anemia management, 39% of the sampled peritoneal patients had a mean hemoglobin values of $\geq$11gm/dL in the 2004 study period, which was the same in the previous year. Sixty three percent of peritoneal patients had a mean serum albumin level of 3.5 gm/dL using the BCG method or 3.2 gm/dL using the BCP method. Twenty percent of the sampled patients had a mean serum albumin measurement of at least 4.0 gm/dL (BCG) or 3.7 (BCP). Although these percentages are low, they represent an improvement from the previous years.

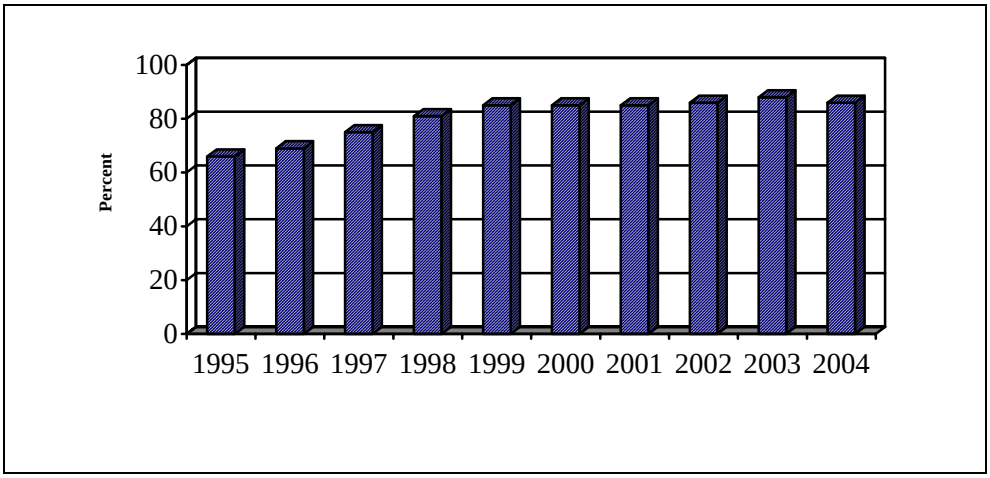
Year	%of CAPD patients achieving Kt/V of 2.0	% of CCPD patients achieving Kt/V of 2.1
2004	70%	65%
2003	71%	66%
2002	68%	70%
2001	68%	62%
2000	65%	60%
1999	56%	52%

CMS found that dialysis adequacy measurements (weekly Kt/V urea or weekly creatinine clearance) were assessed at least once for approximately 86% of the sampled peritoneal patients. This compared to 88%, 86%, 85%, 85%, 85%, and 81% during the previous six years. It must be noted that this finding did not demonstrate that adequacy was achieved in 86% of peritoneal patients, only that some measurement was taken to quantify the dose delivered. The findings were 70% of CAPD patients had a mean Kt/V of ≥ 2.0 and 65% of cycler patients with a daytime dwell had a mean weekly Kt/V of 2.1 while 62% of cycler patients without a daytime dwell

had a mean weekly Kt/V of 2.2. Based on the DOQI guidelines, 70% of CAPD and 65% of CCPD patients had mean adequacy values that met the guidelines. This is a slight decrease from the previous year when 71% of CAPD and 66% patients met the goal. (Network-specific peritoneal adequacy data are not available.)

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

Percent Of Adult Peritoneal Dialysis Patients Who Had Treatment Adequacy Measured, US, 1995-2004



Source: HIP/CPM

The 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 CPM results of Pediatric Populations

All pediatric patients < 18 years who were identified as receiving in-center hemodialysis on December 31, 2004, were included in this project. The total number of pediatric patients included in the data collection was 809, with 27 pediatric patients from network 3. The findings for the entire sample were as follows: 86% of the pediatric in-center patients had a mean delivered calculated, single session Kt/V ≥ 1.2 using the Daugirdas II formula; 27% of patients were dialyzed using an AV fistula, 47% of patients were dialyzed with a chronic catheter continuously for 90 days or longer; 52% of patients with an AVF or a graft were routinely monitored for the presence of stenosis; 48% of patients with an AVF. In anemia management, 67% of patients had a mean hemoglobin of ≥ 11 gm/dL. Another finding was only 27% of the patients had an arteriovenous fistula. Nutritionally speaking, 48% of the pediatric patients had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) during the three month study.

UNITED STATES RENAL DATA SYSTEM

In 2003, the United States Renal Data System (USRDS) initiated the data collection component of the Acute Myocardial Infarction (AMI) Study. Heart disease is one of the leading causes of death in ESRD patients. The purpose of this study was to learn about the cardiovascular care provided to dialysis patients who had myocardial infarctions (MI). This retrospective study

included ESRD dialysis patients who were hospitalized for an acute MI between April 1, 1998 and June 30, 2000. The study was conducted under the direction of the University of Minnesota. All approvals and clearances were obtained prior to the data collection. In network 3, data from 61 patients' records were obtained. Of these 61 patients, 45 patients met inclusion/exclusion criteria and data was collected on those patients. This study involved abstracting data from 23 facilities. Both hemodialysis and peritoneal dialysis patients were included.

The data collection tool had several areas of interest. The initial part clarified demographic information. Several questions involved the patients' medical histories prior to the MI. These questions were organized into past medical history and history 30 days prior to the MI. Clinical data included laboratory values, height, weight, blood pressure, nutritional status, diagnoses and procedures. The dialysis prescription and related variables such as vascular access, were included. One part asked for the medications by type frequency, route, start and stop dates.

The data was submitted to the USRDS in January 2004. The investigators at the USRDS published preliminary data in the USRDS 2004 Annual Report. It consisted of two specific areas of information. It reviewed the rate of cardiovascular events after the initiation of dialysis and the rates of diagnosis and treatment of cardiac disease in dialysis patients.

Preliminary Data

The rates and percentages of cardiovascular disease in both incident peritoneal and hemodialysis patients increased progressively from study initiation through 2002. Overall, the most common condition noted in dialysis patients is congestive heart failure (CHF). In the first six months after dialysis is initiated, the rate of CHF is markedly elevated. The study noted an early hazard (with the first six months) of a cardiac arrest event for hemodialysis patients. For peritoneal dialysis patients, the initial risk was lower, continuing to rise over the course of peritoneal dialysis therapy. It was also noted that the risk of cerebrovascular accidents and transient ischemic attacks was elevated within the first six months of dialysis initiation for both modality choices. In the first six months, there is also a higher risk of mortality evident for hemodialysis patients that was not evident within the peritoneal dialysis group.

The diagnosis and treatment of cardiac disease within the dialysis patient population was also reviewed within the USRDS AMI study. The study noted that within the two years prior to dialysis initiation, there was a trend toward significant procedure utilization. More than 50% of hemodialysis patients received an echocardiogram within the first 36 months after dialysis was initiated. Nearly two-thirds of prevalent dialysis patients that had a MI received an echocardiogram in the two years prior to the MI. In dialysis patients surviving a cardiac arrest, the probability of receiving an implantable defibrillator was only 3%.

PROVISION OF TECHNICAL ASSISTANCE, EDUCATIONAL MATERIAL AND PROBLEM RESOLUTION

Summary Of Technical Assistance Provided To Facilities And Consumers

TARC provided technical assistance, guidance and appropriate referrals for facilities and consumers. The network office identified available providers for consumers seeking ESRD services whether they needed a full-time or transient treatment facility. Additional aspects of technical assistance include the network's role in investigating and resolving patient issues and concerns before they became complaints or grievances.

The network assisted newly approved Medicare ESRD facilities in the development of disaster plans. The plans included provisions for weather-related or other emergencies that would affect the unit's ability to provide renal replacement therapy.

Bulletins and updated medical material for professional staff from the Centers for Disease Control and Prevention were faxed and e-mailed to all New Jersey facilities. In addition, medical articles on anthrax and bio-terrorism were linked to the TARC Web site with updated information.

Clinical Performance Assistance Provided

TARC assisted a facility where federal surveyors had consistently noted poor performance and deficiencies in infection control practices, staff education, continuous quality improvement, care plans and consumer rights and responsibilities. An initial telephone conference was performed to develop a needs assessment with the facility. TARC provided an on-site assistance program which encompassed infection control standards and surveillance, water treatment, initial and on-going staff educational needs, the CQI process, policies and procedures, emergency needs, disaster preparedness, care plans, required forms and governing body.

The assistance provided was an intensive program that consisted of on-site assessment of unit, staff and patient needs, development of a plan to address all of the defined issues, implementation of the plan with the facility partners and evaluation of improvement. TARC provided the facility with tools and educational information to support the assistance provided. On-going monthly telephone and e-mail support was successfully provided to this facility.

Technical and Collaborative Assistance Provided

TARC received a call from a facility indicating there was a water issue that had affected the caller's facility and other local area facilities. There appeared to be an elevated chloramine pattern at an increased frequency. In usual years, the carbon tank would need to be replaced every few months. For the last few months, the tank needed replacement at least monthly.

Patients were transferred temporarily because of the unsafe water. The affected units were all in the northwestern New Jersey area. Units were part of different large dialysis providers and one was an acute facility with a contract for dialysis services. The New Jersey Department Of Health (DOH) sanitarian was contacted. Many calls were made among facilities, New Jersey Department Of Health, Department of Environmental Protection (DEP) and TARC. The State Department Of Health visited facilities and contacted water companies. One water company supplied all of the facilities and was noted to be a constant among the facilities. Manganese had been added to the water source, which may give a false positive on chloramine tests.

The manufacturers of the chloramine water testing kits were notified. TARC sent a letter to all water companies reminding them of dialysis units and the potential issues. The NJ Department of Health contacted TARC on August 9 indicating that the current problem seems to be resolved but could recur if the water companies repeated the same process or did not remove the backwash before the water left the facility. Several facilities continued with this issue and provided TARC with ongoing status reports. Continued and more frequent testing of the RO system was recommended in these facilities. TARC continued to work with the facilities, DOH and the water company source through September.

How Educational And Technical Assistance Affected The ESRD Population

Effects of clinical performance assistance

Morbidity and mortality data suggests that patients with improved anemia management, URRs and a fistula as an access improves the probability of success for a client diagnosed with ESRD. TARC provided a facility noted for poor performance and outcomes with the background, structure, tools and knowledge necessary to improve the level of care delivered to the patients at that facility receiving dialysis.

A collaborative effort between TARC and the interdisciplinary team at the facility proved successful. This facility continues under the guidance of TARC, however the effort placed forth to improve infection control standards and practices, water treatment, staff education, the CQI process, policies and procedures, emergency needs, disaster preparedness, care plans, forms and governing body was significant at the facility level.

Technical and Collaborative Assistance

Water treatment is imperative to the survival of all patients receiving hemodialysis. The American Association of Medical Instrumentation (AAMI) Standards and Recommended Practices 2004 reviews the multiplicity of hazardous situations that can arise from poorly treated water sources as well as neglect of facilities to recognize required interventions to control these situations. The resultant outcome to the consumer of hemodialysis services can include: muscle cramps, hypotension, hemolytic anemia, seizures, dysrhythmias, pyrogenic reactions, angina and cardiac arrest.

The collaboration and effective utilization of knowledge within the DOH, the DEP and TARC were orchestrated in this instance. TARC's ability to facilitate the integration of services between the water distribution facility and the multiple affected dialysis facilities was paramount to protecting the consumer receiving dialysis services at these facilities. TARC also provided knowledge to the affected facilities to proactively react to these situations.

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

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

Whenever possible, TARC provided informational 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. The network strives to be sensitive to local renal community needs and familiarizes others with its role in the CMS contract. This includes coordinating activities and participating with the larger renal community. The Network received requests by letters, faxes, phone calls, the Web site and emails.

TARC staff received numerous telephone calls from both ESRD and non-ESRD consumers with questions about Medicare coverage rules. Some information was provided directly, other consumers were referred to their nephrology social workers and still others were referred to the ESRD Medicare coordinator.

During 2004, the materials were distributed by mailings or email to facility medical directors, head nurses, administrators, quality improvement coordinators and several were also given as handouts at network-sponsored meetings such as the annual Council meeting. In addition to mailings, the network staff responded to individual requests for data and information throughout

the year. The following materials were distributed to the dialysis facilities and in turn to the dialysis patients and consumers.

CONSUMERS:

Complaints/grievances
- Patient Grievance Procedures
- Consumer Rights and Responsibilities
- TARC sent copies of Patients Rights and Responsibilities, and Consumer Grievance Procedure, in both English and Spanish to each new network facility for distribution to all in-center and home patients. The facilities were notified that it is permissible to copy these forms.

Dialysis Access
- Understanding Your Hemodialysis Access Options (English)
- Vascular Access is a Hemodialysis Patient's Lifeline (English)
- *Fistula First* (English)

Dialysis Treatment
- Dialysis: Know Your Number (English and Spanish)
- Treatment options and new ESRD technologies available for consumers

Health Care related
- The public information Web site received numerous questions in English and Spanish. There were queries from family members, patients, and unidentified sources. TARC staff posted responses to questions received on the Web site and by email.
- Medical review board physicians responded to clinical questions posted on the Web site and by email. Questions were about such topics as: results of kidney transplants, nutrition, allergic reactions to dialyzers, polycystic kidney disease, and possibilities of success for renal transplants.
- You have the Power to Prevent Kidney Disease: Learn the Risks (English)
- Help Your Family Prevent Kidney Failure (English)
- Flu and pneumonia immunization information
- CDC hurricane preparation Web site
- CDC tuberculosis treatment information

Medicare Information
- Medicare and You 2004 (English and Spanish)
- Medicare Basics (English)
- Your Medicare Rights and Protections (English and Spanish)
- Your Medicare Benefits (English)
- Medicare Coverage of Kidney Dialysis and Kidney Transplant Services (English and Spanish)
- Medicare Coverage of Diabetes Supplies and Services (English and Spanish)
- Medicare and other Health Benefits your Guide to Who Pays First (English and Spanish)
- Where to get Your Medicare Questions Answered (English)
- The Facts about Upcoming New Benefits in Medicare (English)
- Paying for Outpatient Services: A Guide for People with Medicare (English)
- Pay it Right Protecting Medicare from Fraud (English and Spanish)
- Choosing a Medicare Health Plan (English)
- Choosing a Medigap Policy (English and Spanish)
- Does your doctor or supplier accept "assignment" (English)

- Information on Medicare Approved Drug Discount Cards (English) -New Jersey only
- Medicare.gov-pamphlet (English and Spanish)
- Dialysis Facility Compare- pamphlet (English)

DIALYSIS FACILITIES

TARC annually distributes the following information to each facility in an effort to apprise the renal community of activities within the network area.

- ESRD program goals and the network activities to achieve the goals
- Network 3 Goals 2003 – 2006
- Regional patterns or profiles of care as provided in the Clinical Performance Measures Annual Report
- The network's annual report
- Results of quality improvement projects
- Journal articles and pertinent research information that renal providers may use in their quality improvement programs
- State and regional vocational rehabilitation programs available in the network area
- CMS ESRD Network Requirements
- Alternative Sanctions
- Community Information and Resource Notice
- Annual Notice of Disclosure
- CMS Requirements for ESRD Forms Compliance
- Consumer Grievance Procedure
- Consumer Grievance Procedure-Facility Version
- Consumer Rights and Responsibilities Statement
- Division of Vocational Rehabilitation Services, New Jersey, Puerto Rico/US Virgin Islands
- Release of Data to ESRD Network Organizations, April 7, 2003 letter from CMS

Articles sent to dialysis facilities

- The ESRD Regulatory Landscape
- Improving arteriovenous fistula construction: Fistula First Initiative
- Timing of first cannulation and vascular access failure in hemodialysis: an analysis of practice patterns at dialysis facilities in the DOPPS
- Autogeneous Elbow Fistulas: the Effect of Diabetes Mellitus on Maturation, Patency, and Complication Rates
- Increasing the proportion of diabetics with AV fistulas
- Outcomes of dialysis access-related septicemia among diabetics following optimized AV-fistula placement
- Daily nocturnal home hemodialysis
- ACE Inhibitors in Hemodialysis Patients: Does Survival Improve?
- ACE Inhibitors and Survival of Hemodialysis Patients
- Factors associated with future amputation among patients undergoing Hemodialysis: Results from the Dialysis Morbidity and Mortality Study Waves 3 and 4
- Diabetes education and Care Management Significantly Improve Patient Outcomes in the Dialysis Unit
- Family Members of Patients Treated for ESRD have High Rates of Undetected Kidney Disease
- 19.2 Million U.S. Adults Have Chronic Kidney Disease
- Medical Outcomes Study Short Form-36: A Consistent and Powerful Predictor of Morbidity and Mortality in Dialysis Patients

- National Kidney Foundation's Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Chronic Kidney Disease in Children and Adolescents: Evaluation, Classification and Stratification
- Guidelines by an Ad Hoc European Committee on the Assessment of Growth and Nutritional Status in Children on Chronic Peritoneal Dialysis
- The Person was Inside the Patient, but the Doctors never met Him
- The frequency and significance of the "difficult" patient: The nephrology community's perceptions
- The Implications of Water Quality in Hemodialysis
- New national surveillance system for hemodialysis-associated infections: Initial results
- Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients
- Early Referral in Chronic Kidney Disease: An Enormous Opportunity for Prevention
- Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines
- ATP III Guidelines At-A-Glance Quick Desk Reference

Designee Programs: Home Dialysis and Transplant

- TARC participated in the organizational preparation for the multi-facility Transplant Designee Meeting.
- TARC sent Points of Agreement to the participants of the transplant designees meeting.
- TARC held the Home Dialysis Designee Meeting.

Dialysis Facility Information

- TARC provided all newly approved ESRD facilities with the reference/resource collection of materials that contain the important aspects of the ESRD program and CMS/network requirements.
- New dialysis facilities receive new facility binders with network information, data requirements, patient safety information, and resource material.
- Sent caseload forms and updated instructions to non-VISION facilities.
- Sent the 2003 Annual Facility Survey to all the dialysis facilities in their Network.
- Sent a memo to all facility administrators informing them the TARC Web site public/consumer elements have been updated and are open for use at www.tarcWeb.org.
- Contacted a representative from the Renal Physicians Association in reference to receiving permission to circulate their document addressing the CPT codes for vascular access.
- Announced the opening of the professional area of the TARC Web site including its professional resource content in an electronic memo to facility administrators.
- Sent memo to Quality Improvement Coordinators inviting the submission of abstracts for the Poster session of the Annual Meeting in November 2004.
- Sent new administrator a reference/resource collection of material and information about the important aspects of the ESRD program and CMS/network requirements.
- Sent a medical director of the Veterans Administration Medical Center, their facility-specific report that included tables for comparison of patient population in all VHA dialysis facilities.
- E-mailed ESRD facility administrators confirming the accurate staff categorization for the various standardized functional contact categories for the dialysis facility.
- Sent large mailing to the administrators of the dialysis and transplant facilities. Documents included: 16 consumer oriented Medicare publications, consumer rights and responsibilities, patient grievances, dialysis facility compare (DFC) pamphlet, Know Your Numbers, 2 prevention articles for the families of the ESRD patients, and 2 vascular access documents.
- Sent ESRD facility administrators the caseload/AFS validation packets.

- Sent the facility-specific reports to the administrators and medical directors of the non-veterans administration dialysis facilities.
- Sent the 2003 Annual Report to all network facility administrators, Project Officer, CMS New York Regional Office, Puerto Rico Department of Health, New Jersey Department of Health, New Jersey, Puerto Rico and Pennsylvania Organ Procurement Organizations, six transplant centers.
- Sent the NW 3 Goals, Goal Charts, and attachment to the ESRD facility CEO's, Medical Directors, administrators and quality improvement contacts.
- E-mailed CDC tuberculosis treatment information to all administrators.
- Sent dialysis unit administrators an email requesting Poster Volunteers for the 2004 Annual Meeting in November.
- Sent the New Death Notifications Reports information and instructions to the Nurse Managers and Administrators.
- E-mailed the CDC and CMS "Assessment of Influenza Vaccine Shortage for Patients in Dialysis Centers 2004-2005 Influenza Season Survey" to all clinical managers.
- Sent the Assessment of Influenza Vaccine Shortage Survey to all non-LDO facilities.

Dialysis Treatment Information

- Staff supplied a nephrology group with the Web site address for MDRD calculations to be able calculate their facility's GFR's for MER submission.
- Staff in response to a patient inquiry investigated the status of the production of beef heparin. After speaking with the leading manufacturers learned beef heparin was no longer being produced and what alternatives were available for patients allergic/unable to use pork heparin. TARC notified facilities of this change.
- Responded to a request from a medical director of a PR facility for clarification on which laboratory data to use on 2728 forms. TARC emailed clarification and Web site resources for GFR calculation using MDRD formula.

Patient Health and Safety Information

- E-mailed to administrators and head nurses a July 30, 2004 CDC a notice of medication errors involving patients receiving tetanus vaccine when the order was for PPD testing.
- Mailed patient education information (posters, fliers) and staff education materials to all facilities (dialysis and transplantation) re: flu and pneumonia immunization.
- E-mailed all facility administrators the link to the CDC hurricane preparation site.
- E-mailed CDC tuberculosis treatment information to all administrators.
- E-mailed the CDC and CMS "Assessment of Influenza Vaccine Shortage for Patients in Dialysis Centers 2004-2005 Influenza Season Survey" to all clinical managers.
- Sent the Assessment of Influenza Vaccine Shortage Survey to all non-LDO facilities.
- Sent information about Patient Safety and the Patient Safety Packet to every new dialysis facility and the dialysis administrators to promote attention on safety issues in dialysis.

Vascular Access/ Fistula First

- TARC staff participated in the numerous Vascular Access Quality Improvement Initiative conference calls including; the Vascular Access Data Entry Tool Web sessions, the monthly Implementation Working Group conference calls, the vascular access data collection sessions, the NVAII Marketing and Communications subgroup conference calls. TARC reviews the IHI Web site regularly for any new fistula first postings.
- TARC's ED communicated with RPA's Executive Director to explore the possibility of using the CPT codes for vein mapping, dopplers and other modalities having to do with access placement, maintenance and revision.
- Held a regional cannulation session for nurses.
- Held a NVAII regional medical directors' and surgeons meeting.

- TARC sent a memo to the participants of the Fistula First meeting in response to their requests for patient education materials. Enclosed were a Spanish and English version of the booklet entitled Understanding Your Hemodialysis Access Options produced by the AAKP. In addition the memo informed them these booklets are free of charge and can be ordered using the phone number on the back of the booklet.
- TARC held a NVAII regional medical directors and surgeons meeting.
- TARC distributed facility-specific vascular access reports and network and local area comparative data. Those with catheter rates above 30% were requested to develop improvement plans.
- TARC received a hard copy of the CDC summary report of facility specific vascular access data.
- TARC received their formal NVAII/Fistula First poster display from the Fistula First Marketing and Communications subcommittee for use at network and national meetings.
- TARC sent each non-LDO facility a vascular access data collection disk. The disk contained an Excel workbook with a patient tracking sheet and a facility summary sheet. Each disk was pre-populated with the facility's caseload. Included with the disks were instructions for the use of these tools; recording requirements; and submission timelines.
- Sent a medical director in Puerto Rico two procedures for vein mapping and a useful tool for communication between the facility/nephrologist and the radiologists.
- Sent a packet with the review of Fistula First resources to several medical directors in Puerto Rico.
- Sent an administrator in Puerto Rico the vascular access project and the instructions.
- Sent a local area administrator the Fistula First toolkit given to the nephrologists.
- Sent a quality improvement nurse in Puerto Rico the material that was given to the nurses at the Fistula First meetings for review.
- Received a video on Dr. Twardowski's buttonhole information, and associated articles. The video was reviewed and added to the TARC resource library.
- Sent Puerto Rico area administrator the material that was given to the nurses at the Fistula First meetings for review.
- Mailed the FistulaGram newsletter, posters, and pens to the New Jersey dialysis facilities.
- Mailed the FistulaGram newsletter to all the medical directors.
- Mailed the FistulaGram newsletter to all the county medical societies; chief of medicine at all New Jersey acute care hospitals; and the chief of surgery at all the New Jersey acute care hospitals.
- Sent the medical directors who were unable to attend the NVAII meetings the Fistula First toolkit and the TARC Web site with NVAII information and tools that can be downloaded.
- Held the regional nurses cannulation review meeting for the island facility staff and distributed the vascular access information at the June 3 meeting for nurses in Puerto Rico. Information packet included patient education materials in Spanish and English. For the facility staff in St. Croix who could not attend, the toolkit was brought to one facility and sent to the other.
- Held cannulation meeting for Puerto Rico and Virgin Island nurses in Puerto Rico. Assistant secretary of health and a Medicare surveyor attended.
- Mailed the NVAII toolkit to all medical directors of New Jersey dialysis facilities who did not attend any of the physician meetings.
- Sent copy of buttonhole technique tape to regional quality manager in Puerto Rico.
- Sent copies of the vascular access management and cannulation tapes plus the self-learning module to a Puerto Rico Medicare surveyor.
- Sent the NVAII self- learning module and tapes to dialysis case manager of a Puerto Rico hospital.
- Sent samples of the three surgeons' slide sets to a vascular surgeon and potential presenter at doctor's meeting.

- Received a call from a vascular surgeon in the Caguas area of Puerto Rico. He was unable to attend the meeting in San Juan but was interested in the project. Discussed the project with him and mailed him the NVAII toolkit.
- Mailed the NVAII toolkit, videos and other educational materials to a transplant and vascular surgeon at Auxilio Mutuo in San Juan.
- Sent additional options of vascular access slides to Puerto Rico nephrologists and medical directors.
- Held Fistula First meetings in Ponce with nephrologists and surgeons
- Held Fistula First meetings in San Juan with nephrologists and surgeons.
- Consulted with a medical director looking for vascular access speakers for meeting in northern New Jersey.
- TARC staff member attended a LDO meeting about vascular access.
- TARC received buttonhole technique educational tapes.
- TARC was invited to and attended a vascular access meeting in North Jersey. Approximately 25 people attended including nephrologists, surgeons, nurses, dietitians and an administrator. Goals were presented to decrease catheters and increase fistulae. Local physician presented statistics of access rates for comparison of local, regional and national data. Also presented was a new tracking tool/plan tool that will be implemented in an LDO facility as well as the "twist" lines which allows access monitoring without disconnection of the bloodlines.
- Distributed facility-specific vascular access reports and network comparative data.
- Organized phone calls and sent e-mails to identify and arrange meetings with three local physician (surgeons and nephrologists) groups.
- Requested a vascular surgeon to be part of the Medical Review Board starting in December and he agreed. This surgeon gave two presentations at the nephrology vascular access project meetings and is the champion surgeon of the first panel presenters.
- Contacted physician speakers for feedback and input following the Puerto Rico Society of Nephrology's meeting in August on vascular access.
- Held a conference call with a physician speaker in reference to Puerto Rico. He stated there were 15-20 physicians at the Fistula First section of the Puerto Rico Nephrology Society meeting on August 28-29
- Mailed the Fistula First poster to the dialysis facilities.
- Held the annual meeting which included such prestigious speakers as Dr. William Jennings, Dr. Vo Nguyen and Dr. Gregg Miller. The topic was Fistula First from the perspective of the nephrologist, surgeon and the interventional radiologist. Dr. James Cimino was in attendance. With 324 participants this annual meeting was the network's largest attendance. Other speakers included champion facilities within New Jersey and their achievements in reaching a successful fistula program.
- Received a call from a physician in New Jersey requesting information on utilizing the "buttonhole" technique with his staff. Two video presentations were sent to his facility.
- Distributed facility-specific vascular access reports and network and local area comparative data. Requested facilities to utilize as part of Internal quality review.

Vocational Rehab

- An updated copy of the vocational rehabilitation offices in New Jersey, Puerto Rico and the US Virgin Islands is included in all of the new facility binders.
- Provided individual patients information on exercise and diet.

How provision of educational materials affected the ESRD population

Patients who participate in their health care decisions have many positive benefits. TARC feels an ESRD consumer should be afforded the opportunity to become educated in their disease and

treatment options so they may become participatory in their health care decision processes. A sense of control and empowerment results in a greater sense of well being and positive outcomes. A consumer educated in their rights and responsibilities takes greater ownership in their role. A consumer educated in the grievance procedure knows they are not helpless when their care poses a troublesome situation. A consumer educated in quality indicators is able to track their treatments and know why certain modalities are performed. All of these facets help to make a patient feel they are truly part of a health care team striving to achieve the optimum level of health for that patient. The continuum of care for the ESRD consumers spans a broad spectrum of providers. TARC, through the provision of educational materials, hopes to clarify some of the confusing elements and pave the road of renal replacement therapy.

ESRD consumers indirectly benefited from their providers becoming informed about and responding to both the CMS and the network-specific goals, which strive for quality renal replacement services. Existing or potential providers used network 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 Medicare-certified ESRD facilities is to serve renal consumers, all renal-related educational materials eventually enhance patient care delivery.

Effectiveness
Morbidity and mortality data suggests that patients with improved anemia management, URRs and a fistula as an access improves the probability of success for a client diagnosed with ESRD.

TARC provided informational 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.

Consumer Impact
Consumers should be afforded the opportunity to become educated in their disease and treatment options so they may become participatory in their health care decision processes.

Appropriate clinical management provides consumers with a better quality of life, reduced hospitalizations and less morbidity. TARC continues to contribute toward these outcomes.

IV. Encourage individualized patient care planning that addresses the attainment of the highest quality of life possible with emphasis on vocational rehabilitation, whenever appropriate.

A. The network will make available on loan to both newly approved and existing facilities both text and slides from the Life Options Rehabilitative Advisory Council (LORAC) for use in staff in services and patient education.
B. Assure that facilities periodically evaluate their treatment scheduling practices or other facility policies which may act as disincentives to vocational rehabilitation.
C. Each dialysis facility will compile the number of dialysis patients, ages 18-54, that were referred to the Vocational Rehabilitation Program, and the number of dialysis patients, ages 18-54, employed (full or part time) and attending school (full or part time).
D. The network will encourage the use of the SF-36 assessment form.

Supportive Activities

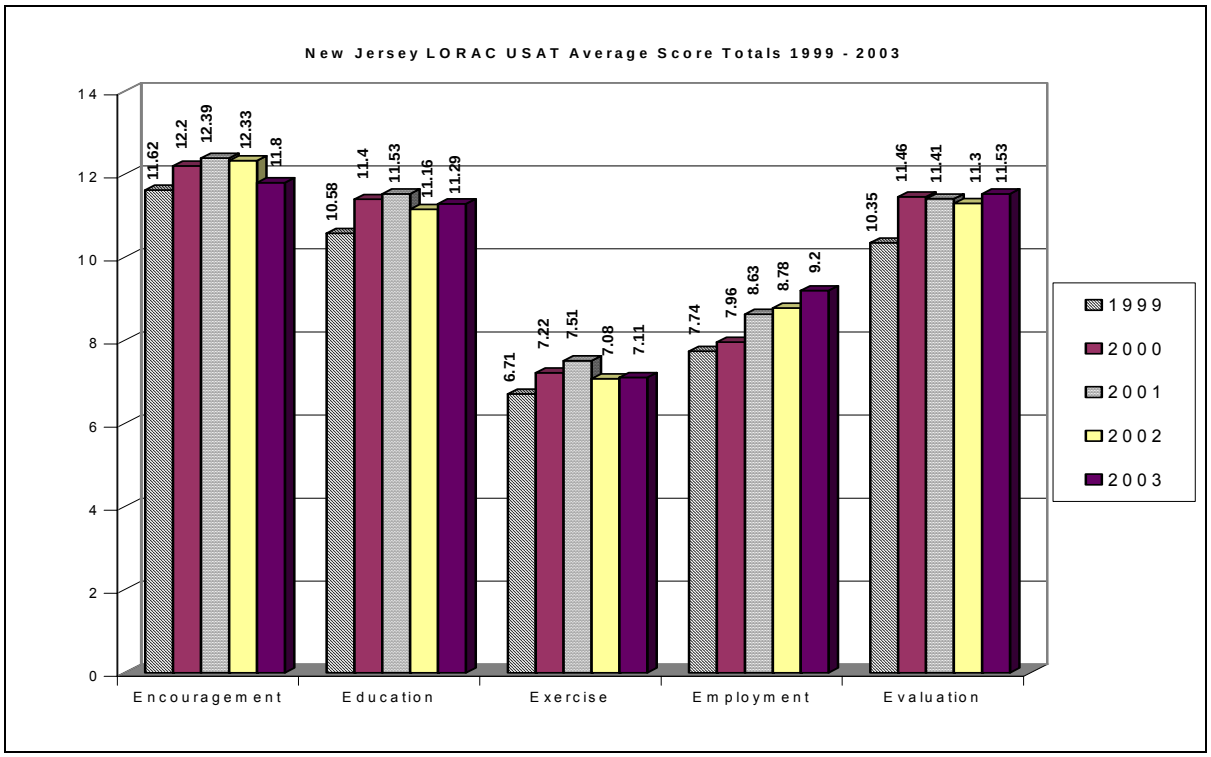
Even though kidney failure is not a curable disease, individuals can live very long and productive lives. Rehabilitating the patient with end-stage renal disease is admittedly difficult in certain

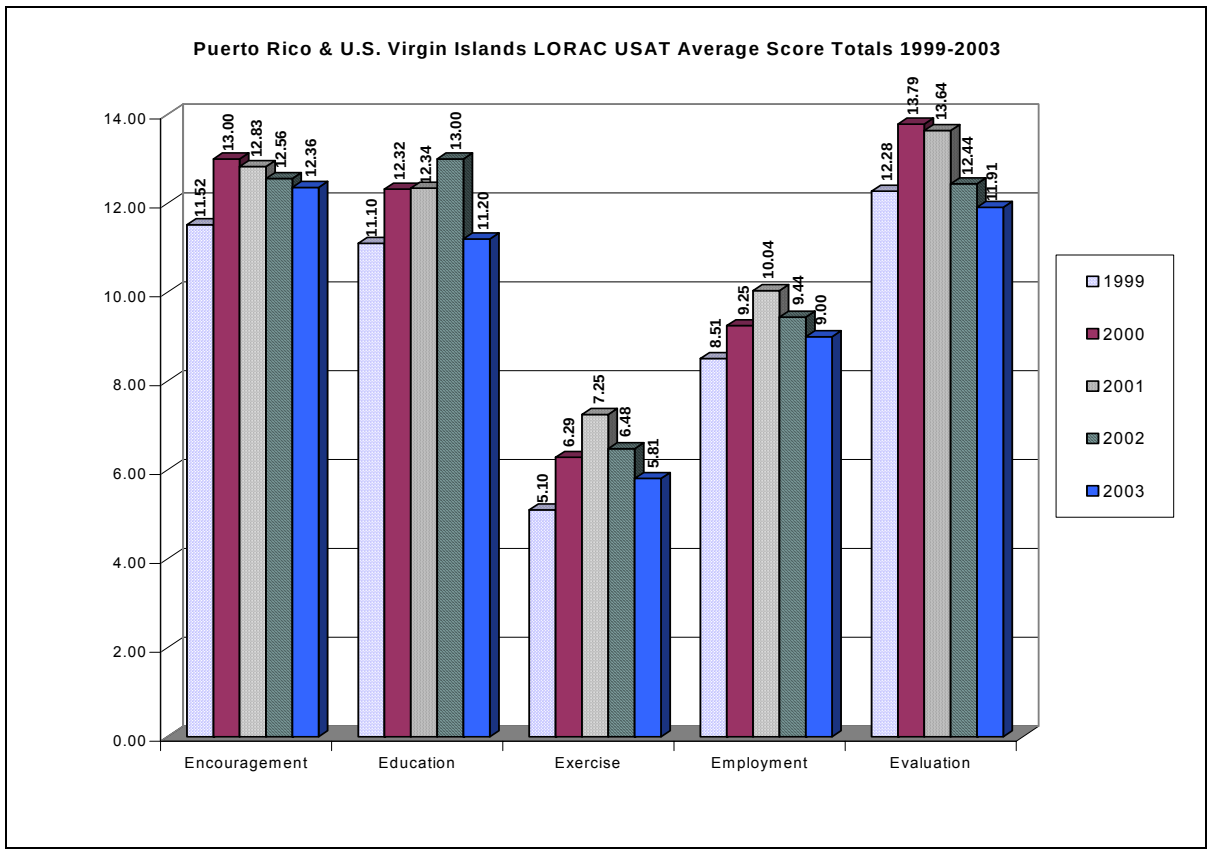
situations. Improving outcomes of kidney disease usually requires that patients learn to manage their illness, report their symptoms accurately and advocate on their own behalf. TARC will continue to encourage patients to become more informed partners in their own care.

The concept of renal 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 (LORAC, 1997). As a way of measuring the progress at the facility level, TARC used resources developed by LORAC to focus unit planning, effort and attention on rehabilitation. Training material and slides were made available for dialysis providers to use for facility in-service programs and program development. The LORAC "Catalog of Materials" is available on the Web site. The list of vocational rehabilitation offices in New Jersey, Puerto Rico and the US Virgin Islands were sent to each facility and are available on the Web site.

As can be seen through the efforts of the network and each facility, many dialysis facilities maintain activities with an active team approach to promote the vocational rehabilitation program by:

- Using a centrally-located bulletin board that features stories or topics regarding rehabilitation;
- Assessing consumers' physical status, mental health and general well-being on a regular basis
- Assessment of patient, family and staff attitudes toward rehabilitation
- Informal screening for employment status or potential
- Determination of ESRD consumers' 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
- Utilizing the redesigned Life Options Web site (www.lifeoptions.org), which offers all Life Options print materials via the Web site allowed users to immediately obtain materials in unlimited quantities
- Non-print materials from Life Options can now be ordered via the Web at no cost to facilities. This includes videos, audios, posters and exercise binders


New Jersey LORAC USAT Average Score Totals 1999 - 2003
14
12
10
8
6
4
2
0
11.62
12.2
12.39
12.33
11.8
10.58
11.4
11.53
11.16
11.29
6.71
7.22
7.51
7.08
7.11
7.74
7.96
8.63
8.78
9.2
10.35
11.46
11.41
11.3
11.53
Encouragement
Education
Exercise
Employment
Evaluation
1999
2000
2001
2002
2003


Puerto Rico & U.S. Virgin Islands LORAC USAT Average Score Totals 1999-2003
14.00
12.00
10.00
8.00
6.00
4.00
2.00
0.00
11.62
13.00
12.83
12.56
12.36
11.10
12.32
12.34
13.00
11.20
5.10
6.29
7.25
6.48
5.81
8.51
9.25
10.04
9.44
9.00
12.28
13.79
13.64
12.44
11.91
Encouragement
Education
Exercise
Employment
Evaluation
1999
2000
2001
2002
2003

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 their disease and its treatment.

Educating consumers is the key to this understanding. To achieve positive outcomes educational goals must be geared to the needs and readiness of the consumer. 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.

After 2003, the ESRD networks could not request the completion of the unit self-assessment tool by Life Options. TARC will continue to encourage the dialysis providers to discuss responses and results within their internal quality improvement programs and to make every effort to initiate at least one new rehabilitation-directed activity for the coming year. TARC promoted the concept that all renal replacement encounters are opportunities to enhance rehabilitative potential.

Patient teaching, communication about medication administration and diet, exercise, improved compliance with treatment schedules, maintaining or restarting employment or school attendance were all favored as means to enhance vocational and other rehabilitation scores. TARC encouraged patient care planning that would address attainment of the highest quality of life possible for each patient. By means of goal statements and correspondence, emphasis was placed on vocational rehabilitation whenever appropriate.

The following information is the analysis of the Annual Facility Survey about vocational rehabilitation related programs, the numbers of employed patients and the number of patients attending school. The dialysis units in New Jersey had 2934 reported dialysis patients between the ages of 18 to 54 years. Seventy-six of the patients, age 18 to 54, were referred to a vocational rehabilitation program. There were 866 New Jersey patients, age 18-54, were employed (full or part time), and 60 patients, age 18-54, had attended school (full or part time). In Puerto Rico there were 1230 reported patients between the ages of 18 to 54 years. Sixty-four patients of the 18-54 age group in their dialysis caseload were referred to a vocational rehabilitation program, and there were 248 patients, age 18-54, were employed (full or part time), and 25 patients, age 18-54, had attended school (full or part time). Of the 47 reported dialysis patients of the 18 to 54 age range in the U.S. Virgin Islands, no patients of the 18-54 age group were referred to a vocational rehabilitation program, 14 patients age 18-54 were employed (full or part time), and one patient, age 18-54, had attended school (full or part time).

Effectiveness
The Network continues to encourage rehabilitation and individualized care planning. Vocational rehabilitation is an ongoing process that continually needs encouragement to continue its development. Material was distributed to facilities for use with consumers and other resources were made available both through mailings and on the Web site.

Consumer Impact
Lifestyle changes are inevitable for 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 both through mailings and on the Web site.

V. **Enable an efficient patient-specific database with quality improvement modules that is consistent with CMS's electronic transmission initiatives.**

A. Each newly approved and existing facility will assure a system is established/maintained that assures knowledgeable facility data reporting personnel.
B. Each facility will ensure timely and accurate submission of 90% of forms generated.
C. Each facility will utilize the federal VISION software to input local patient data.

Supportive Activities

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 ESRD 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., CAPD patient who went home);
- 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;
- Discontinuance of dialysis treatment;
- Patients who became lost to follow-up; and
- Patients who regained native kidney function to the extent that dialysis was stopped.

The Chronic Renal Disease Medical Evidence Report form (CMS-2728) was 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 the TARC office by ESRD Medicare-certified facilities and Veterans Administration Medical Centers according to federal regulations. Submission is expected within forty-five 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. The ESRD Death Notification form is due within thirty days of an ESRD patient's expiration.

TARC staff entered data from the CMS-2728 forms into computer software supported by the federal government. If data required on the form were missing or incompatible with software assumptions, the form was rejected by the software and returned to the facility for correction.

Input forms employed to maintain the network 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

Network staff validated and monitored the accuracy and timeliness of facility data submissions from all dialysis and transplant programs in New Jersey, Puerto Rico and the United States Virgin Islands. During 2004, facility compliance was monitored for each of the federal medical

information system forms mentioned. 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 thirty or forty-five day goal, the number of forms with errors, and the percent compliance by each Medicare-certified dialysis facility. The detail report generated specified the patient-specific information on each form.

Data submission compliance reports were distributed to facility administrators with the expectation that they would positively recognize those employees who achieved the data reporting goal of submitting forms within thirty or forty-five days of events being reported. On the other hand, if the compliance reports reflected forms that were overdue and outstanding, administrators were expected to follow-up with their employees to correct factors contributing to data reporting non-compliance.

To assist VISION facilities in ensuring that all entered data had been received and processed at the network office, monthly feedback reports were distributed. These reports showed the facility's current caseload as well as all events received year-to-date. Facilities reviewed these reports and identified any data that had not been submitted, then entered that data into VISION and submitted it electronically.

A forms meeting is planned for early 2005 in Puerto Rico to address issues with new versions of the CMS-2728 and CMS-2746 forms. The meeting will also address implementation of VISION software in Puerto Rico and the United States Virgin Islands. Forms timeliness and accuracy will be stressed throughout the several day meeting.

Chronic Renal Disease Medical Evidence Report (CMS-2728)

Network 3 dialysis facilities submitted 4,898 CMS-2728 forms during the year. Of these, 4,347 (88.8%) were on time, while 4,260 (87%) were accurate.

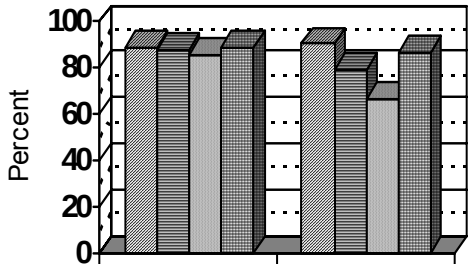
There were 3,502 CMS-2728 forms submitted from New Jersey dialysis programs. Of these, 3,164 (90.3%) were completed accurately; therefore, the accuracy requirement was met in the state for that federal form. Chronic Renal Disease Medical Evidence Report forms were to have been submitted to the network office within forty-five days of the initiation of a regular course of dialysis. Of the forms submitted, 3,118 (89%) met CMS's timeliness criterion.

Facilities in Puerto Rico submitted 1,304 forms of which 1,149 (88.1%) were on time and 1,029 (78.9%) were completed accurately.

42 Medical Evidence Report forms were received in the network office from the US Virgin Islands, 36 (85.7%) were on time and 28 (66.7%) were completed accurately.

Percent of CMS-2728 Forms Received by Timeliness and Accuracy

CMS's Goal: 90% Compliance



	Timeliness	Accuracy
NJ	89	90.3
PR	88.1	78.9
USVI	85.7	66.7
Network	88.8	87

Source: 2004 SIMS Database

ESRD Death Notification form (CMS-2746)

Network 3 dialysis units sent 3,882 death notification forms during the year, of which 3,428 (88.3%) were on time and 3,732 (96.1%) were accurate.

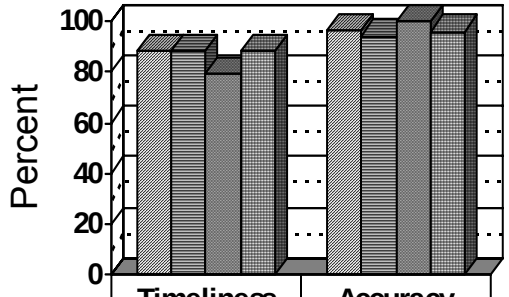
New Jersey dialysis units sent 2,815 death notification forms during the year, of which 2,484 (88.2%) were on time and 2,726 (96.8%) were accurate. New Jersey fell short of the timeliness requirement and exceeded the accuracy requirement.

Puerto Rico's dialysis programs submitted 1,043 death forms of which 925 (88.7%) were on time, and 982 forms (94.2%) were accurately completed. Puerto Rico exceeded the goal for accuracy and has significantly improved in the timeliness requirement.

The two Virgin Island facilities sent 24 death forms; 19 (79.2%) were received on time and 24 forms (100%) were accurately completed.

Percent of CMS-2746 Forms Received by Timeliness and Accuracy

CMS's Goal: 90% Compliance



	Timeliness	Accuracy
NJ	88.2	96.8
PR	88.7	94.2
USVI	79.2	100
Network	88.3	96.1

Source: 2004 SIMS Database

In addition to receiving, processing, and transmitting data reported on the federal medical information system forms the network maintained a patient tracking system (SIMS) that followed 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 federal ESRD Facility Survey, preparation of facility profiles for goal achievement for home dialysis use and referral, and local quality of care improvement efforts.

Network 3 did not train any additional facilities during 2004, but maintained and supported 52 VISION facilities in New Jersey (out of 54 eligible - 96%) and one in Puerto Rico (out of 12 eligible - 8%). No Virgin Islands facilities have yet been trained.

Effectiveness
TARC supported the training, installation and integration of VISION software in eligible facilities. in use of federal software all appropriate facilities. Data reporting personnel were supported through all software updates and form modifications.

Consumer Impact
An accurate database is essential for the analysis of clinical indicators. Performance efforts utilize current and reliable data to monitor the clinical patient outcomes for the benefit of consumers. Accurate and timely reporting of patient data is central to patient Medicare eligibility.

B. Support the Marketing, Deployment and Maintenance of CMS-Approved Software (CROWN)

Consolidated Renal Operations in a Web-enabled Network (CROWN) is made up of 3 software systems:

- VISION (Vital Information System to Improve Outcomes in Nephrology) used by facility staff, and
- SIMS (Standard Information Management System) used by network staff,
- REMIS (Renal Management Information System), a Web based application where data from many different sources, such as the Social Security Administration, UNOS, and CMS can be viewed.

Together, these three components enable electronic exchange and validation of data, facilitating the transformation of data into usable information.

VISION

Network beta testers, including Network 3, participated in testing the April and October releases of the VISION system. The October version introduced the new CMS-2746 format for facilities to begin using and needed to be carefully tested.

Network 3 did not train any additional facilities during 2004, but maintained and supported 52 VISION facilities in New Jersey (out of 54 eligible - 96%) and one in Puerto Rico (out of 12 eligible - 8%). No Virgin Islands facilities have yet been trained.

In October 2004, Network 3 sent a VISION readiness survey to the remaining eligible facilities in Puerto Rico and the Virgin Islands and received positive feedback that all but one facility was able and eager to be trained on the VISION software. Therefore, training is planned for those facilities in Puerto Rico and the Virgin Islands in early 2005.

In 2004, the 53 VISION facilities submitted 2,142 CMS-2728 and 1,435 CMS-2746 forms electronically via the VISION system. Additionally, a total of 4,904 events (Patient Transfers, Recovered Function, etc) were reported through the VISION system.

SIMS

Network beta testers, including Network 3, participated in testing the April and October releases of the SIMS system. As with the VISION system, the October release of the SIMS system introduced the new CMS-2746 format, which needed to be carefully tested.

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 is entered and maintained. That data is replicated to a central database repository on a nightly basis.

SIMS has the capability to produce various reports that are used by facilities to ensure accuracy of facility reporting. In particular, the CMS-2744 form is completed annually, and is 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 is used to reconcile the network database.

SIMS is 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 that which is on file with the Social Security Administration. The network sent these records to the respective facility once per month, whereupon the facility verified the data with the patient and sent the correct information back to the network office.

REMIS

An important component of the CROWN system is the REMIS system. Data entered into SIMS by network staff can be viewed here, as can data sent from sources such as CMS, Social Security Administration, and UNOS. This aggregate data can be used to resolve data discrepancies and complete patient event histories.

In September 2004, an additional component called Alerts was added to REMIS. This component "alerts" network staff to data discrepancies in a manner similar to the notifications processed in SIMS, but allows for additional cleanup of duplicate patient records, invalid claim numbers, and dates being outside an acceptable range. With this utility, network staff is able to maintain a cleaner and more accurate dataset with less processing time than was previously possible.

C. Improving Data Reliability, Validity and Reporting among ESRD Facilities/Providers Networks and CMS (or other appropriate agency).

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

SIMS

Through an automated data transfer application, the SIMS database is replicated to the central repository on a nightly basis. Replication is checked daily to assure that the process has occurred successfully. The replication process is monitored and has performed reliably on a daily basis and is documented on a quarterly basis within the network logs.

All data discrepancies are reviewed for validity and accuracy of data through notifications and discrepancies are resolved within the SIMS database. This process is run on a monthly basis. Data clean-up activities are also run on a monthly basis and utility logs show resolved queries and which need to be addressed.

Data Reconciliation

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

Network staff validated and monitored the accuracy and timeliness of facility data submissions from all dialysis and transplant programs in New Jersey, Puerto Rico and the United States Virgin Islands. During 2004, facility compliance was monitored for each of the federal medical information system forms mentioned. 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 thirty or forty-five day goal, the number of forms with errors and the percent compliance by each Medicare-certified dialysis facility. The detail report generated specified the patient-specific information on each form.

Data submission compliance reports were distributed to facility administrators with the request that they positively recognize those employees who achieved the data reporting goal of submitting forms within thirty or forty-five days of events being reported. Alternately, if the compliance reports reflected forms that were overdue and outstanding, administrators were expected to follow-up with their employees to correct factors contributing to data reporting non-compliance.

CMS Notifications

CMS notifications are requests for patient database validity information. CMS notifications are sent to all facilities within the network on a monthly basis. Facilities then review the element in question and either report the value as correct or provide the corrected data element in question to TARC. This information is then entered in the SIMS database. If there is a discrepancy in data collection (report value from CMS and report value from facility differ), a validation of the element in question is requested from the facility. This ensures valid data is reported to the central database and REMIS.

2728 and 2746 Forms

In 2004, fourteen facilities were found to have blended (timeliness and accuracy) compliance rates of less than 80%. Improvement plans were requested and received from these facilities, and continued monitoring showed that these facilities did begin to show improvement upon implementation of these plans.

The data accuracy and timeliness of forms is also reviewed and documented. Both the 2728 and the 2746 are reviewed against compliance rates biannually. Analysis can be found on pages 65 and 66 of this document. For VISION facilities, a random 3% sample of completed 2728 forms is requested from facilities and signatures of beneficiaries are verified. This is completed on a yearly basis.

A forms meeting is planned for early 2005 in Puerto Rico to address issues with new versions of the CMS-2728 and CMS-2746 forms. The meeting will also address implementation of VISION software in Puerto Rico and the United States Virgin Islands. Forms timeliness and accuracy will be stressed throughout the several day meeting.

Clinical Performance Measures

The 2004 ESRD CPM project was the eleventh year of this data collection in more than 2,000 dialysis programs nationwide. CMS characterized the project as a 'snap-shot' description of peritoneal and in-center hemodialysis patients. The effort focused on the dose of delivered dialysis, anemia management, serum albumin and vascular access. The samples included: hemodialysis patients, peritoneal dialysis patients and pediatric patients. The Veteran’s Administration hospitals provided data on 100% of their

population while all other facilities were subject to a 5% scientifically selected sample number of study patients.

In May of 2004, TARC received 659 forms for the CPM project data collection and validation study. There were 491 adult (non-VHA) hemodialysis forms, 80 adult hemodialysis forms for VHA, 27 pediatric hemodialysis forms, 52 (non-VHA) peritoneal dialysis forms and 9 VHA peritoneal dialysis forms. Of the 659 forms, data from 28 forms were re-abstracted as part of the reliability testing of this project. For various reasons, 571 forms were completed. Included in the 571 forms were 89 forms from the VA hospitals.

UNOS

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

VISION

To assist VISION facilities in ensuring that all entered data had been received and processed at the network office, monthly feedback reports were distributed. These reports showed the facility's current caseload as well as all events received year-to-date. Facilities reviewed these reports and identified any data that had not been submitted, then entered that data into VISION and submitted it electronically.

D. Establish and Improve Partnerships and Cooperative Activities

These activities may include ESRD Networks, QIO's, state survey agencies, and ESRD facilities/providers, Medicare + Choice organizations, ESRD facility owners, professional groups and patient organizations.

Partnerships

CMS regional offices

- Received CMS notice, National Provider ID final rule published
- Provided CMS with assistance in locating source data for Hispanic subset demographics in reference to hemodialysis adequacy.
- Participated in a conference call with the Project Officer.
- Received the Federal Register notice announcement regarding the ESRD CAHPS (Patient Experience of Care Survey) pilot study.
- Presented a new CMS ESRD coding/billing presentation.
- Received revised fact sheets about the upcoming new benefits in Medicare in English and Spanish versions.
- Received an overview of the CMS strategic planning in conference call held.
- TARC served as chair of the 2004 CMS/Forum annual meeting and participated in all conference calls.
- TARC staff attended the 2004 CMS/Forum of ESRD Networks annual meeting in Baltimore.
- TARC staff attended the Human Factors Workshop in Baltimore.
- TARC participated in conference call with CMS RO Boston. Calls will continue on a quarterly basis.
- Participated in a conference call with CMS and AHRQ regarding the CAHHPS pilot study.

- Received an email from CMS stating that 30 facilities will be selected for the CAHPS project.
- Participated in a conference call with Boston regional office and VIMI in reference to a particular Virgin Islands facility.

Data Committee

- Data Committee and TARC staff met to review/revise and make recommend changes and/or additions to the professional Web site.
- Data Committee and TARC staff met to review the approved Web sites for the professional Web site, and to discuss the development of future sections for the consumer Web site.
- Generated the WebTrends Custom Report for the 1st and 2nd quarters of 2004, which gave an overview of the number of visitors the network 3 Web site has had.
    - There were 18,771 visitors to the Web site in this time period, 2,654 of which visited more than once.
    - There were 36,655 visits to the Web site, an average of 199 per day. Visitors stayed on the site an average of over 6 minutes per visit.
    - 271,019 pages were viewed on the Web site, an average of 1,514 per day. This computes to approximately 7.6 pages being viewed per visit.
- Generated the Web Trends Custom Report for the 3rd and 4th quarters of 2004, which gave an overview of the number of visitors the network 3 Web site has had.
    - There were 9,352 visitors to the Web site in this time period, 1,325 of which visited more than once.
    - There were 16,848 visits to the Web site, an average of 183 per day.
    - 132,139 pages were viewed on the Web site, an average of 1,436 per day. This computes to approximately 7.84 pages being viewed per day.

Dialysis Related Organizations

- TARC contacted the 2 local chapters of ANNA in NJ to ask to display the *Fistula First* poster at upcoming meetings.
- Presented *Fistula First* data to the ANNA North Jersey Chapter.
- TARC displayed *Fistula First* poster at Kidney Urology Foundation (KUF) meeting.
- TARC representatives met with the New Jersey Renal Administrators Association.
- TARC attended and participated in the Regional Administrators Meeting
- TARC send the ESRD facility administrators the accurate staff categorization clarification form.

ESRD Networks

- TARC participated in the Patient Services Coordinators conference calls and projects. The committee is developing a non-conforming patient checklist/guidelines and interventions packet, a complaints/grievances question and answer checklist/guidelines, and planning for the March 2004 Forum/CMS meeting.
- The executive director attended summits/meetings with the executive directors from the other networks in January, March and September. The quality improvement staff attended summits/meetings with the executive directors from the other networks in March, July and September. The data staff attended summits/meetings with the data staff from the other networks in March and September. The patient care services staff participated in the ongoing PSC conference calls.
- TARC staff participated in the Executive Director, Quality Improvement Administrator and Patient Services Coordinator (PSC) conference calls.

- TARC staff participated in the many SIMS project Provider and Personnel task group conference calls, SIMS project Patient Events task group conference calls, SIMS User calls, SIMS project Contacts and Grievances task group conference calls, and the scheduled monthly CROWN technical conference calls.
- TARC received and circulated to the other Networks the CMS response to ESRD Network 3's request on behalf of all Networks to collect a modified national surveillance of dialysis-associated diseases data.
- TARC participated in CPM conference calls with QI staff of networks.

Quality Improvement Organizations

- TARC sent to Puerto Rico the Quality Improvement Organization (QIO) information concerning federal nursing assistance program.
- TARC sent the Network 3 Goals, Goal Charts, and attachment to the ESRD facility CEO's, medical directors, administrators and quality improvement contacts.
- TARC participated in a conference call with the Project Officer and New Jersey QIO regarding the medical record review of 6 patients. TARC and the QIO reviewers discussed the cases, reviewed and revised as needed. TARC performed revision of report for QIO and sent the revised addendum to the NJ QIO.
- Sent addendum of medical record review report to NJ QIO
- Notified the Puerto Rico QIO of plans to be in Puerto Rico and would like to meet with them.
- TARC met with QI PRO members. Discussed the stages of CKD and how to communicate this to slow the progression of ESRD.
- TARC met with US VI MI (Medical Institute also known as the PR QIO) members. Discussed the stages of CKD and how to communicate this to slow the progression of ESRD. Also discussed *Fistula First* and requested VI MI's to help as cheerleaders for promoting fistulae.
- Sent to PR QIO information concerning federal nursing assistance program.
- Sent the 2003 Annual Report to all network facility administrators, Project Officer, CMS New York Regional Office, Puerto Rico Department of Health, New Jersey Department of Health, New Jersey, Puerto Rico and Pennsylvania Organ Procurement Organizations, six transplant centers.
- Sent the Network 3 Goals, Goal Charts, and attachment to the ESRD facility CEO's, Medical Directors, administrators and quality improvement contacts.

Social Security Offices

- TARC was contacted by a facility in Puerto Rico requesting assistance with the Social Security office in reference to accepting 2728 forms from the VISION system. TARC contacted the Project Officer who in-turn contacted the appropriate people at the Puerto Rico and Virgin Islands Social Security offices.

State Survey Agencies

- Contacts between TARC and state agencies were made in reference to new facility approval and paperwork submission to the CMS regional offices. TARC staff participated in the planning and development of the quarterly conference calls with the New Jersey Department of Health, and the Puerto Rico Department of Health.
- Members of the New Jersey state agency attended the annual meeting offered by TARC.
- TARC staff contributed to the planning, development of agendas and participation in the quarterly conference calls with the New Jersey Department of Health and the Puerto Rico Department of Health.
- TARC staff spoke with a representative from the New Jersey Department of Health to set up the quarterly conference call schedule.

- TARC participated in their quarterly conference call with the Puerto Rico Department of Health.
- TARC received an email from PR DOH indicating that 3 facilities in PR have/had issues. One facility may be closed due to repeated lack of supplies/drugs, and another facility had drug/supplies shortages and requested a meeting. The third facility was surveyed following a complaint and the surveyors confirmed that there was lack of physician follow up on care plans, etc.
- TARC met with the Assistant Secretary of Health for Puerto Rico and a Medicare surveyor. Two facilities in PR have had repeated problems with conditions and had been threatened with termination.
- TARC performed a site visit to dialysis facility in PR. QI records were reviewed; discussions included transplant referrals, preparation for increased patient population, facility- specific trend data, vascular access status and Fistula First Project.
- TARC held cannulation meeting for Puerto Rico and Virgin Island nurses in PR. Assistant secretary of health and a Medicare surveyor attended.
- TARC and the New Jersey Department of Health interacted in the scheduling of the quarterly conference calls.
- TARC notified Puerto Rico Department of Health of plans to visit, invited them to nurse's meeting and arranged to meet following nurse's meeting.
- Sent the 2003 Annual Report to all network facility administrators, Project Officer, CMS New York Regional Office, Puerto Rico Department of Health, New Jersey Department of Health, New Jersey, Puerto Rico and Pennsylvania Organ Procurement Organizations, six transplant centers.
- Received a call from the NY RO indicating that the closure of 2 Puerto Rico facilities with a tentative closure date of July 4, 2004. TARC placed calls to the Assistant secretary of Health in PR, the regional VP. TARC spoke with the PR DOH to determine what contacts the facility made to prevent duplication of efforts. The dialysis facilities were asked to provide a list of available spaces per shift by facility. Fourteen dialysis facilities were able to accommodate the patients with a total of 481 dialysis openings available on all days and on all shifts in the affected areas. TARC received the transferred patient lists from all but one of the dialysis facilities. The other facility applied for an extension, hired a consultant to write a letter regarding the deficiencies and then provided a list of where the patients were transferred.
- TARC participated in conference call with NJ Department of Health. Topics included chronic dialysis in nursing home settings and pre-ESRD units. TARC was unaware of the first issue and was only marginally aware of the second. Also discussed the situation of the non-ESRD patient, typically CHF patients, who occasionally need dialysis for fluid management. The question was do the outpatient facilities need special licensure. The Fistula First Project was discussed and the surveyors said they have seen the posters in the units and units have demonstrated their attempts to increase fistulae. The provider number changes were discussed.
- TARC performed a site visit to facility in PR for anemia management.
- TARC performed a site visit to facility in PR. The topics of discussion included CPM indicators, educational needs of staff; facility expansion plans and delayed delivery of supplies.
- TARC spoke with the Puerto Rico DOH Medicare Services regarding the closure of 2 facilities in Puerto Rico. One facility has transferred all their dialysis patients and was essentially closed. The other facility had transferred all the Medicare patients but is still dialyzing Reforma (non-Medicare) patients. The management of these facilities had submitted another response that was not acceptable.
- TARC participated in a conference call with PR DOH. The first dialysis facility was not dialyzing any patients but the second unit was still dialyzing 14 Reforma patients. The facility administrator had obtained the forms required for re-application. TARC had received a call from an affiliate of a dialysis provider this week asking questions about re-opening a facility. Discussed temporary transfer of patients from another unit because of an elevator problem. Discussed why the elevator was just not repaired and it appeared to be a cost issue for the hospital. No new facilities are in the works; the earlier frenzy of multiple applications for new dialysis units has fizzled.

Inquired about Puerto Rico staff performing federal surveys on the Virgin Islands. Only initial surveys have been performed. Discussed the Fistula First Project and 2 doctors' meetings. The Puerto Rico DOH stated the surveyors would include Fistula First in their assessment when the new fiscal year starts on October 1st.

- TARC and the NJ Department of Health conducted the quarterly conference call. NJ Department of Health and TARC representatives discussed the voluntary closure of a facility and newly licensed facilities. Additionally, TARC has not received any formal paperwork indicating an acquisition of a facility that will maintain the same provider number. Another facility will be increasing their outpatient stations and changing provider numbers to a freestanding number. TARC mentioned that they received calls from new facilities inquiring about Saint Barnabas Medical Center regarding the transplant designee requirement. The designee role is a substitute for the transplant surgeon. It is not the expectation of TARC that a facility must have a designee before they can be approved. The facility should 1) Send a nurse to the next available meeting and 2). Utilize the transplant surgeon at the very beginning. The NJ Department of Health stated that too often the facilities did not state the selection criteria for transplants when asked during surveys. The New Jersey Renal Administrator Association (NJRAA) suggested that there be quarterly meetings with TARC and NJ Department of Health. This was agreed and the NJ Department of Health/TARC meetings would continue as separate entities.

Vendors

- TARC staff met with Amgen representative regarding the new medication on the market for dialysis patients for calcium and phosphorus control and maintenance.
- TARC participated in a conference call with Amgen regarding the new medication for calcium and phosphorus control and maintenance.
- TARC staff contacted several anemia-related vendors to obtain educational information and arrange for educational sessions on the USVI for the staff.

Cooperative Activities

Fistula First

- TARC staff participated in the numerous Vascular Access Quality Improvement Initiative conference calls including; the Vascular Access Data Entry Tool Web sessions, the monthly Implementation Working Group conference calls, the vascular access data collection sessions, the NVAII Marketing, and Communications subgroup conference calls. TARC reviewed the IHI Web site regularly for any new fistula first postings.
- TARC communicated with RPA's Executive Director to explore the possibility of using the CPT codes for vein mapping, dopplers, and other modalities having to do with access placement, maintenance and revision.
- Held a regional cannulation session for nurses.
- Held a NVAII regional medical directors' and surgeons meeting.
- TARC sent a memo to the participants of the Fistula First meeting in response to requests for patient education materials. Enclosed were Spanish and English versions of the booklet entitled Understanding Your Hemodialysis Access Options produced by the AAKP. In addition the memo informed them these booklets are free of charge and can be ordered.
- TARC held a NVAII regional medical directors' and surgeons meeting.
- TARC distributed facility-specific vascular access reports and network and local area comparative data. Those with catheter rates above 30% were requested to develop improvement plans.
- TARC received a hard copy of the CDC summary report of facility specific vascular access data.

- TARC received formal NVAII/Fistula First poster display from the Fistula First Marketing and Communications subcommittee for use at network and national meetings.
- TARC sent each non-LDO facility a vascular access data collection disk. The disk contained an Excel workbook with a patient tracking sheet and a facility summary sheet. Each disk was pre-populated with the facility's caseload. Included with the disks were instructions for the use of these tools; recording requirements; and submission timelines.
- Sent a medical director in Puerto Rico two procedures for vein mapping and a useful tool for communication between the facility/nephrologists and the radiologists.
- Sent a packet with the review of Fistula First resources to several medical directors in Puerto Rico.
- Sent an administrator in Puerto Rico the vascular access project and the instructions.
- Sent a local area administrator the Fistula First Toolkit given to the nephrologists.
- Sent a quality improvement nurse in Puerto Rico the material that was given to the nurses at the Fistula First meetings for review.
- Received a video on Dr. Twardowski's buttonhole information and associated articles. The video was reviewed and added to the TARC resource library.
- Sent Puerto Rico area administrator the material that was given to the nurses at the Fistula First meetings for review.
- Mailed the FistulaGram newsletter, posters, and pens to the NJ dialysis facilities.
- Mailed the FistulaGram newsletter to all the medical directors.
- Mailed the FistulaGram newsletter to all the county medical societies; chief of medicine at all New Jersey acute care hospitals; and the chief of surgery at all the NJ acute care hospitals.
- Sent the medical directors who were unable to attend the NVAII meetings the Fistula First toolkit and the TARC Web site with NVAII information and tools that can be downloaded.
- Held the regional nurses cannulation review meeting for island staff and distributed the vascular access information at the June 3 meeting for nurses in Puerto Rico. Information packet included patient education materials in Spanish and English. For the facility staff in St. Croix who could not attend, the toolkit was brought to one facility and sent to the other.
- Held cannulation meeting for Puerto Rico and Virgin Island nurses in Puerto Rico. Assistant secretary of health and a Medicare surveyor attended.
- Mailed the NVAII toolkit to all medical directors of New Jersey dialysis facilities who did not attend any of the physician meetings.
- Sent copy of buttonhole technique tape to regional quality manager in PR.
- Sent copies of the vascular access management and cannulation tapes plus the self-learning module to a Puerto Rico Medicare surveyor.
- Sent the NVAII self- learning module and tapes to dialysis case manager of a Puerto Rico hospital.
- Sent samples of the three surgeons' slide sets to a vascular surgeon and potential presenter at doctor's meeting.
- Received a call from a vascular surgeon in the Caguas area of Puerto Rico. He was unable to attend the meeting in San Juan but was interested in the project. Discussed the project with him and mailed him the NVAII toolkit.
- Mailed the NVAII toolkit, videos and other educational materials to a transplant and vascular surgeon at Auxilio Mutuo in San Juan.
- Sent additional options of vascular access slides to Puerto Rico nephrologists and medical directors.
- Held a Fistula First meetings in Ponce with nephrologists and surgeons
- Held Fistula First meetings in San Juan with nephrologists and surgeons.
- Consulted with a medical director looking for vascular access speakers for meeting in northern New Jersey
- TARC staff member attended a LDO meeting about vascular access.

- TARC received buttonhole technique educational tapes from a vendor.
- TARC QIC was invited to and attended a vascular access meeting in North Jersey. Approximately 25 people attended, including nephrologists, surgeons, nurses, dieticians and an administrator. Goals were presented to decrease catheters and increase fistulae. He presented statistics of access rates for comparison of local, regional and national data. Also presented was a new tracking tool/plan tool that will be implemented in an LDO facility as well as the "twist" lines which allows access monitoring without disconnection of the bloodlines.
- Distributed facility-specific vascular access reports and network comparative data.
- Organized phone calls and sent e-mails to identify and arrange meetings with three local physician (surgeons and nephrologists) groups.
- Requested a vascular surgeon to be part of the Medical Review Board starting in December and he agreed. This surgeon gave two presentations at the nephrology vascular access project meetings and is the champion surgeon of the first panel presenters.
- Contacted physician speakers for feedback and input following the Puerto Rico Society of Nephrology's meeting in August on vascular access.
- Held a conference call with a physician speaker in reference to Puerto Rico. He stated there were 15-20 physicians at the Fistula First section of the Puerto Rico Nephrology Society meeting on August 28-29
- Mailed the Fistula First poster to all dialysis facilities.
- Held the Network 3 Meeting for surgeons and radiologists which such prestigious speakers as Dr. William Jennings, Dr. Vo Nguyen and Dr. Gregg Miller. The topic was Fistula First from the perspective of the nephrologist, surgeon and the interventional radiologist. Dr. James Cimino was in attendance. With 324 participants this session was Network #3's largest event. Other speakers included our champion facilities within New Jersey and their achievements in reaching a successful fistula program.
- Received a call from a physician in New Jersey requesting information on utilizing the "buttonhole" technique with his staff. Two video presentations were sent to his facility.
- Distributed facility-specific vascular access reports and network and local area comparative data. Requested facilities to utilize as part of Internal quality review.
- Communicated with a biostatistician who was recommended. The project was reviewed and the data collection tool was sent to him.
- Academy of Pediatrics 3.AJKD

Quality Improvement – Data Collection

- TARC staff had submitted their lab collection utility affiliation data and participated in its revision.
- TARC received a list of the facilities in Network 3 that needed medical director authorization forms completed for the lab collection utility in addition to an authorization form that has been previously used.
- TARC sent medical director authorization for the lab collection utility to the necessary medical directors.
- TARC sent a memo to all facility administrators requesting participation in the collection of lab data for the 4th Quarter 2004 in preparation for the lab collection utility project. TARC sent a pre-populated disk with each facility's caseload for the down loading of data. The memo explained the electronic data utilization should help to reduce the time staff spent on collecting data manually.
- TARC received a GFR national benchmark reminder on April 21, 2004. TARC provided the feedback regarding the data collection tool, reports and other materials to the scientific officer of the Data Collection and Reports Subgroup
- TARC participated in CPM conference call with QI staff of networks.
- Participated in conference call regarding the CPM data validation.
- Participated in the CAHPS Pilot Project conference call.

- Member of data reports Joint Advisory Group and participated in meetings held in Owings Mills, MD.

Transplantation

- TARC was requested to remain on the planning board for the transplant designee conferences held throughout the State of New Jersey. The effort has since evolved into a collaborative one with all transplant facilities in the State requesting participation. The network Quality Improvement Director will be on the planning committee and mediate efforts to insure that representation is fair and an equal effort is made on the behalf of each transplant facility.
- Sent large mailing to the administrators of the dialysis and transplant facilities. Documents included: 16 consumer oriented Medicare publications, patient rights and responsibilities, patient grievances, dialysis facility compare (DFC) pamphlet, Know Your Numbers, 2 prevention articles for the families of the ESRD patients, and 2 vascular access documents.
- Network 3 staff shared the TARC annual report with organ procurement organizations (OPOs) serving the various geographical sections of New Jersey, Puerto Rico and the US Virgin Islands. TARC staff corresponded with the OPOs to request data on organ recovery and transplantation activity in addition to information about kidney recipients, potential organ donors, actual organ donors and the donor consent rate.

Water Treatment

- Parts of New Jersey had significant rainfall, up to 12 inches in one day. Dams broke and flooding occurred in Burlington and Camden Counties. TARC contacted facilities to assess if patient services were affected. One facility had water in 2 offices but not in the patient treatment area. Treatments were started late due to road detours. Only one patient missed treatment due to road problems.
- Received a call from a facility that indicated there was a water issue that had affected the caller's facility and other facilities. The issue was there appeared to be an elevated chloramine pattern at an increased frequency. In usual years, the carbon tank would need to be replaced every few months. For the last few months, the tank needed replacement at least monthly.
- Patients were transferred temporarily because of the unsafe water. The affected units were all in the northwestern NJ area. Units were part of different LDOs and one was an acute facility with a contract for dialysis services. The NJ Department of Health sanitarian was contacted. Many calls were made among facilities, NJ Department of Health, DEPE and TARC. The State NJ Department of Health visited facilities and contacted water companies. A constant among the facilities was they all use a single company as their source. It seems that manganese was added to the water source, which may give a false positive on chloramine tests. The manufacturers of the chloramine water testing kits were notified.
- TARC sent a letter to all water companies reminding them of dialysis units and the potential issues. The NJ Department of Health contacted TARC on August 9 indicating that the current problem seems to be resolved but could recur if the water companies repeated the same process or did not remove the backwash before the water left the facility.
- Received a telephone call from the water company informing TARC that they had resumed their water treatment procedures and had had no adverse reports from dialysis facilities. In mid-afternoon received call from a second facility that they had gotten a faint positive for chloramines at this one unit. An administrator called the water company where she was told the situation would continue as long as rain continued; also learned that a local hospital based unit had called the water company as well.

- TARC called NJ Department of Health and left message for chief sanitarian. Received call back from NJ Department of Health scientist. TARC conveyed facility information. NJ Department of Health advised to continue more frequent testing of the RO.
- TARC called the water company and left a message referencing the two sites. The water company suggested that maintenance procedures are at fault. Suggested manganese test kit be ordered.
- Received a call from the water company asking the advisability of including dialysis facility in their regulatory regular testing sites. Consulted with NJ Department of Health chief, and a facility was suggested that had break-through. This was conveyed to the water company via voice mail.
- Received phone call from a facility regarding a breakthrough of chloramines in their primary and secondary carbon tanks. The carbon tanks were last rebedded in June 2004. The facility discontinued dialysis treatments (no patient reactions noted), called the TARC, NJ Department of Health, the water company, the medical director, and the LDO technical service technician. The technician tested the water with the test reagent and the serum testing for permanganate and determined there was a false positive reaction. After collaboration with the NJ Department of Health, medical director, and the technician, the facility restarted dialyzing patients that day. The chloramines tests consisted of testing with DPD raw data and inhibiting substance, and the serum test prior to every patient shift, and every hour that day.
- The water would be tested from the following sites: incoming water line, post the primary and secondary carbon tanks, post the RO product water, and the first water outlet after the RO. Water would continue to be tested prior to every patient dialysis shift and mid shift in this manner for a week. Facilities in the area were contacted and asked if they had tested their water, when they tested the waters and the results.
- TARC learned that another facility had breakthrough on one tank but continued operations using a second tank. A third facility had breakthrough and had conversations with the water supply company, which confirmed that there was a change in process again that could cause excess permanganate in water. The fourth facility affected was on a Friday night and Saturday morning.
- Subsequently, TARC asked the Department of Health scientist if a journal article would be prepared for public dissemination; a positive response was received.

CMS encourages the networks to establish and enhance partnerships with other health agencies and groups. During 2004, the network collaborated with the CMS regional offices (ROs), state survey agencies (SAs), New Jersey and Puerto Rico Department of Health, other sections of government, quality improvement organizations (QIOs), the New Jersey Renal Administrators, vendors and interested agencies to improve the quality of care provided to consumers within network 3. These activities included sharing information to assist SAs and ROs in conducting their legislative responsibilities. Quality issues were referred as needed. Assistance was also given to other agencies in investigating the quality of renal replacement therapies.

Health and safety problems and complaints were referred to the appropriate state agency for investigation and resolution during 2004. When state investigations were completed, the findings were shared with the network. The network held telephone conferences regarding ongoing concerns within the dialysis facilities with state agency personnel both in New Jersey and on the islands. TARC sent the state agencies copies of the network's annual report and pattern analysis reports. TARC staff attended the CMS sponsored state agency data meeting in Maryland, which was attended by representatives from all of the state agencies.

More specific information concerning facility interaction can be found in a prior section titled, *Provision of Technical Assistance, Educational Material and Problem Resolution*.

The network met its responsibility in 2004 to partner with other governmental agencies and contractors to enhance the safe and therapeutic delivery of dialysis and renal transplantation.

E. Evaluate And Resolve Patient Grievances As Categorized In The Standard Information Management System (SIMS)

TARC may receive a written or oral complaint or grievance from an ESRD 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 complaint will usually be asked 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 are encouraged to use facility internal processes prior to referring a grievance to the network. When a patient does not wish to use the facility process (it is not mandatory that consumers use the facility grievance process) they may contact the network for assistance.

The network's responsibility for complaints/grievances is to review issues raised and determine the required action, i.e., investigation or referral. The network role in resolving grievances varies depending on the situation. Attempts are made to resolve grievances by acting as an investigator, facilitator, referral agent or coordinator between a patient and the provider.

2004 ESRD Patient Grievance

There were no formal grievances filed.

While there were no formal grievances filed during 2004, network staff addressed many concerns, issues, and complaints. An aggregate sample of interactions follows:

Contact Type (Categories of Complaint)	Contact Categories (Areas of Concern)						Totals
	Formal Grievances	Beneficiary Complaints	Beneficiary Inquiries	Facility Concerns	Facility Inquiries	Other Concerns	
Physical Environment	0	2	0	0	0	0	2
Staff Related	0	2	1	0	0	0	3
Treatment Related/ Quality of Care	0	3	2	2	0	0	7
Information	0	2	23	1	26	8	60
Disruptive/Abusive Patient	0	0	0	3	0	0	3
Patient Transfer/ Discharge	0	0	2	5	1	0	8
Professional Ethics	0	0	0	0	0	0	0
Other	0	1	4	6	23	22	56
Total	0	10	32	17	50	30	139

Grievances are requests for a formal investigation of a serious complaint involving a facility, physician or other provider (quality of care issues). **Beneficiary complaints** are requests for assistance on behalf of an ESRD patient regarding concerns about ESRD issues including, but not limited to, care or treatment. **Beneficiary Inquiry** is a request for information, advice, referral, or educational material that does not require problem resolution. **Facility concerns** are requests (from staff) for guidance or advice/assistance in handling difficult issues that are patient related (clinical or behavioral). **Facility inquiry** is a request (from staff) for information, advice, referral, or educational material that doesn't require problem resolution.

A total of 139 contacts were noted in the SIMS database for 2004. Of those, 30% were from beneficiaries. Almost 23% of the beneficiary calls received were informational inquiries and educational materials were discussed and distributed to these beneficiaries as well as verbal resolution of the inquiry. The beneficiary complaints reviewed included lack of appropriate facility equipment, lack of temperature regulation within the unit and a lack of professionalism of staff members. All concerns and inquiries were resolved without formal grievance. Informational contacts, either facility or beneficiary initiated accounted for 43% of all contacts to TARC noted in SIMS for 2004.

Beneficiary concerns and inquiries were handled by TARC more than 93% of the time. Referrals for beneficiary concerns included: New Jersey Department of Health (1), NJPRO (1), Medicare of Puerto Rico (1).

An example of each contact type characterized through SIMS 2004 data includes the following:

- Physical Environment- TARC received a beneficiary complaint from a patient stating it was too cold in his dialysis facility. He requested that the heat be turned up and the staff did not turn up the heat. The patient only wears a tee shirt to dialysis and does not bring a blanket with him. The issue was discussed with the unit administrator with patient consent. The administrator and TARC agreed that the patient should bring a blanket for personal temperature control and that the unit would adjust the temperature as well. A follow-up call to the patient showed this was acceptable.
- Staff related - A beneficiary called TARC to complain about an interaction he had at his facility with a patient care technician. The patient care technician had an argument with the patient while the patient was on dialysis. The patient feels that disciplinary action should have been taken and that nothing was done. TARC explained to the patient that disciplinary actions were confidential. TARC was given permission by the patient to speak to the administrator and review the case. The administrator scheduled a meeting with the patient to review his concerns. A follow-up phone call from TARC to the patient revealed that the meeting went well and the patient was satisfied.
- Treatment Related/Quality of Care - TARC received a call from a facility indicating there was a water issue that had affected the caller's facility and other local area facilities. There appeared to be an elevated chloramine pattern at an increased frequency. In usual years, the carbon tank would need to be replaced every few months. For the last few months, the tank needed replacement at least monthly.
- Patients were transferred temporarily because of the unsafe water. The affected units were all in the northwestern New Jersey area. Units were part of different large dialysis providers and one was an acute facility with a contract for dialysis services. The New Jersey Department of Health sanitarian was contacted. Many calls were made among facilities, New Jersey Department of Health, Department of Environmental Protection and TARC. The state Department Of Health visited facilities and contacted water companies.
- A single water company was noted as the source of supplied water to all of the facilities and was noted to be a constant among the facilities. Manganese had been added to the water source, which may give a false positive on chloramine tests. The manufacturers of the chloramine water testing kits were notified. TARC sent a letter to all water companies reminding them of dialysis

units and the potential issues. The NJ Department of Health contacted TARC on August 9 indicating that the current problem seems to be resolved but could recur if the water companies repeated the same process or did not remove the backwash before the water left the water delivery facility.

- Several facilities continued with this issue and provided TARC with ongoing status reports. Continued and more frequent testing of the RO system was recommended in these facilities. TARC continued to work with the facilities, DOH and the water company source through September when the issue resolved.
- Information - TARC received a phone call from a patient questioning why his physician wanted him to have a URR of 70% and why he needed to have a four-hour dialysis treatment. The benefits of maintaining a URR of 70% were explained to the patient. Follow up with the patient several weeks after the initial contact revealed his appetite was improved, he felt better and that fluid surrounding his heart was now gone.
- Disruptive/Abusive patient - TARC received a call from the administrator of a facility. A patient threatened to bring in a bomb and blow up the facility; police were notified. The patient was transferred for a psychiatric evaluation. The medical director and attending physician were aware. Patient is being transferred to another facility. Patient signed a no tolerance policy. TARC suggested that security be available at facility where patient is transferred and social service as well as other staff alerted.
- Patient transfer/discharge - TARC received phone call from the family of a beneficiary from New York. They would like information on facilities in northern New Jersey where she could transfer to be closer to family. Information provided.
- Professional Ethics - There were no inquiries about professional ethics for the 2004 year.
- Other - TARC received a phone call from a beneficiary who wanted to travel to Puerto Rico. The beneficiary wanted to know if Medicare would still cover his dialysis. TARC explained that Medicare would pay 80% in Puerto Rico, as it does in New Jersey. TARC also explained that Medicaid was specific to New Jersey and would not pay outside of the state.

In addition to the above, TARC staff answered many questions, provided resources, referred to other disciplines, etc.

TARC annually distributes copies of its network grievance procedure to all Medicare-certified facilities within New Jersey, Puerto Rico, and the US Virgin Islands. Facilities, in turn, make these available to their consumers via patient bulletin boards, handouts in dialysis waiting rooms and in orientation packets to all new consumers. During the year, as new facilities opened and became Medicare-certified, a supply of the network grievance procedure was sent with the orientation and resource notebooks.

During 2004, facilities in network 3 met their obligation for distributing the network grievance procedures and for handling and addressing issues of patient concern at the facility level.

4. Sanction Recommendations

No facility sanction was recommended to CMS in 2004.

5. Recommendations For Additional Facilities

In all three geographic areas of Network 3, access to dialysis therapies is within reasonable travel distances from ESRD consumers' homes. At the end of 2004, no new dialysis facilities were recommended for New Jersey, Puerto Rico, or the US Virgin Islands.