2003 Annual Report

ESRD Network Area #3

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1. PREFACE

On behalf of all chronic renal care facilities within Network 3, I am pleased to submit this 2003 annual report of performance and achievements.

All facility staff are to be commended for their efforts to meet goals and participate in the various projects and activities of the network. Progress continues to be made in dialysis adequacy, anemia management and rehabilitation. Data timeliness and accuracy show the results of improvement efforts and provide necessary information for quality improvement project development and federal program management. Such sustained progress serves as a testament to the dedication and commitment of professional staff in the face of facility pressures in staffing, mergers and increased consumer demand for services.

Current efforts directed toward decreasing the number of catheter accesses used in dialysis and an increased number of native fistulas show promise. All recognize the difficulties inherent in such a project but there is little doubt that it will have long-term benefits for consumers.

I want to acknowledge the contribution of all the voluntary board and committee members who worked so assiduously in the development of network activities and the oversight of improvement efforts. Such service is appreciated and brings satisfaction in reviewing results that impact the lives and medical status of renal consumers of care.

Finally I would like to express our appreciation to network staff who coordinate and support all the administrative work we perform.

We look forward to the continuation of this partnership with the Centers for Medicare & Medicaid Services, facility staff, consumers, departments of health and other interested agencies as we begin another phase of health care quality improvement projects.

Jorge Weber, MD
President, Board of Trustees

June 16, 2004

TABLE OF CONTENTS

TABLES AND GRAPHS

2. INTRODUCTION

A. NETWORK DESCRIPTION

NEW JERSEY
GEOGRAPHY AND GENERAL POPULATION CHARACTERISTICS

New Jersey contains 8,215 square miles with 21 counties and 567 municipalities. Its highest elevation is 1,803 feet at High Point and its lowest is sea level at the Atlantic Ocean with an average elevation of 250 feet. Although New Jersey is geographically one of the smallest states in the nation (it ranks 46th), it is the ninth most populous, with approximately 8.6 million residents. There are 1,158 inhabitants per square mile of land area - the most densely populated state in the nation.

The majority of residents reside in metropolitan areas with only 10.6% in rural areas. The U.S. Census Bureau categorized only New Jersey and the District of Columbia as 100% metropolitan areas. The only area to surpass New Jersey in degree of urbanization is California (92.6%) which has the largest resident state population (35.1 million). However, California has a population density of only 225.2/sq. mi.

Approximately 1.1 million (13.1%) of New Jersey's population base is aged 65 and older. The highest concentration of those age 65 or older is found in Ocean and Cape May counties. Nationally, seventeen other states had a higher percentage of those 65 and older.

The population is reported to be 78% white, 15% black, 6% Asian and 1% other. Most of the population growth in New Jersey during the last decade occurred in minority populations; Hispanics sustained the largest increase. Hispanics now constitute approximately 14.2% of the population within New Jersey and Hispanics of Puerto Rican descent comprise more than 33% of all Hispanic residents. The largest increase of New Jersey's Hispanic residents occurred in Hudson and Passaic counties.

New Jersey is surpassed by only 6 other states in the proportion of resident Hispanic or Latino residents. California (34%), Texas (33.6%), Arizona (27.1%), Florida (18.1%), Illinois (13.4%) and New York (16%) surpass New Jersey's 13.3% resident Hispanics and Latinos.

For the year 2000, New Jersey ranked fifth in the number of immigrants admitted from other countries and was surpassed only by the states of California, Florida, New York and Texas. The US Census Bureau reported the admission to New Jersey of 59,920 immigrants from other countries with 9,154 from India, 3,262 from China, 2,905 from the Philippines, 2,316 from El Salvador, 1,788 from Haiti, 1,361from Cuba, 1,098 from Mexico, 500 from Vietnam and fewer from other countries.

Not all age groups are equally constituted. The under 5 age group constitutes 6.6% of the resident population; the 5-17 age group accounts for 18% of the population; the 18-24 group for 8%, the 25-44 age group for 30%; the 45-54 for 14%, the 55 to 64 group for 9.6% and the 65+ age group for 13% of the population. It is important to note that from 1990 - 1998 the 85 and older age group increased by 38%. This growth in the aged population among the residents of New Jersey contributes to the increase in the mean age of consumers presenting for renal therapy due to end-stage disease.

Eighty-three per cent of New Jersey residents were born in the United States. New Jersey's birth rate of 14.0 is lower than the national rate of 14.5/1,000 estimated population as is its fertility rate (per 1,000 women aged 15-44 years estimated) of 66.3 vs. 66.9. Death rates by cause show the leading cause to be heart disease followed by cancer, cerebrovascular diseases, chronic obstructive pulmonary diseases, diabetes mellitus, accidents, and HIV. The death rate was 8.8 (per 1,000) in 2001 while the national rate was 8.5.

The marriage rate (per 1,000 population) in 2001 was 6.6, higher than the 1998 rate of 5.9, but still lower than the national rate of 8.4; divorce rates were reported to be 3.5 in New Jersey and 4.0 nationally for 2001.

In 1998, the latest available data showed New Jersey per capita personal health care expenditures ($2,900/resident) were exceeded only by the states of Connecticut ($3,298), New York ($3,255), Pennsylvania ($2,941) and Rhode Island ($2,937). The major portion was expended on hospital services followed by physician services, drugs and non-durables, nursing home care, other professional services, dental services, home health care, other personal health care and medical durables.

Health insurance coverage did not extend to 13.1% in 2001 of the New Jersey population which was an increase above the 12.6% in 2000. The national average in 2001 was 14.6% and 14.0% in 2000. Children not covered in New Jersey in 2001was 11.5%, 9.3% in 2000; the national average was 11.7% in 2001 and 11.6% in 2000.

Excluding doctors of osteopathy and federal employees, New Jersey in 2001 had 303 physicians per 100,000 population, a slight increase over the 2000 rate of 298, which in both years was exceeded only by the states of Connecticut, Massachusetts, New York, Maryland, Vermont, and Rhode Island. The 2000 national rate was 251 and in 2001 was 253.

Twenty states surpassed New Jersey with its rate of 856 nurses per 100,000 population (805 in 2000); the national rate was 797. Six states surpassed New Jersey's rate of 303 physicians per 100,000 population; the national rate was 253.

The percentage of New Jersey residents with advanced educational degrees (8.8%) exceeds the national average of 7.2%. Eight states exceeded the New Jersey rate. In 2000, 87.3% were high school graduates and 30.1% had bachelor's degrees or higher levels of attainment.

In 2001, the average elementary and secondary school teacher's salary in New Jersey was $53,300. New Jersey was surpassed by only two other states for secondary salaries: California and Connecticut ($54.8 and $54.0). The national average was $43,300 in 2001. Only Alaska ($2,129), Connecticut ($1,864), Minnesota ($1,673), and New York ($1,749) exceeded New Jersey's average 2000 per capita student expenditure ($1,579).

The New Jersey unemployment rate for 2003 was recorded to be 5.9%. Variations among the 21 counties ranged from 4.3% to 9.9%.

New Jersey Unemployment Rate

COUNTY	1990 (%)	1995 (%)	1999 (%)	2000 (%)	2002 (%)	2003 (%)
Atlantic	6.2	8.6	7.2	5.7	6.6	6.9
Bergen	3.9	5.8	3.7	3.1	5.0	4.9
Burlington	4.6	5.0	3.3	2.9	4.6	4.6
Camden	5.9	6.4	4.6	3.9	5.8	6.1
Cape May	7.7	12.1	10.1	8.6	9.6	9.9
Cumberland	7.5	9.8	8.6	7.2	8.5	8.6
Essex	6.3	7.7	5.7	4.7	7.3	7.3
Gloucester	5.6	6.5	4.5	3.8	5.2	5.5
Hudson	7.3	9.3	7.2	5.7	8.1	8.0
Hunterdon	2.7	3.2	2.1	1.7	3.6	3.9
Mercer	4.4	5.4	4.0	3.0	5.1	4.8
Middlesex	4.5	5.5	3.8	3.1	5.4	5.4

COUNTY	1990 (%)	1995 (%)	1999 (%)	2000 (%)	2002 (%)	2003 (%)
Monmouth	4.1	5.4	4.0	3.2	5.3	5.3
Morris	3.2	4.3	2.8	2.3	4.4	4.4
Ocean	5.1	6.2	4.6	3.9	5.4	5.7
Passaic	6.4	8.6	6.2	5.0	7.5	7.7
Salem	5.3	6.5	4.7	4.4	6.4	6.9
Somerset	2.9	3.8	2.5	2.1	4.4	4.3
Sussex	4.2	5.7	3.5	2.9	5.1	5.5
Union	5.4	6.5	4.8	4.0	6.4	6.3
Warren	4.3	5.7	4.2	3.1	5.3	5.7
All	*5.1*	*4.6*	*4.6*	*3.8*	*5.8*	*5.9*

The average annual wage in New Jersey (2000) was $43,691. Disposable personal income rankings showed New Jersey higher than all states except Connecticut and Massachusetts. New Jersey's median household income in 2000 ($51,739) was third highest in the country.

The 2002 New Jersey per capita personal income ($39,453) was slightly higher than the previous year as reported by the Census Bureau ($38,153). New Jersey maintained second place in 2002-2003, surpassed only by Connecticut, and has been in the top ten states since 1983.The Bureau of Economic Analysis at the US Department of Commerce showed variation among counties:

New Jersey Per Capita Personal Income ($)

COUNTY	1996	1997	1999	2000	2001
Atlantic	29,415	30,187	32,086	31,618	31,550
Bergen	40,676	43,123	48,017	50,435	51,900
Burlington	26,669	27,849	30,747	33,910	34,683
Camden	25,518	26,500	28,035	29,312	30,496
Cape May	25,759	26,419	29,455	30,611	31,412
Cumberland	20,662	21,663	22,894	22,675	23,616
Essex	31,411	32,581	34,824	35,919	37,134
Gloucester	23,374	24,340	27,077	28,296	29,243
Hudson	24,233	24,943	27,662	28,100	28,584
Hunterdon	37,675	39,830	44,833	52,107	53,815
Mercer	33,893	36,598	39,626	40,911	42,317
Middlesex	29,544	30,881	34,267	36,196	36,691
Monmouth	32,401	33,952	37,267	40,639	42,028
Morris	41,018	42,913	49,957	56,047	58,151
Ocean	25,113	25,725	27,694	29,694	30,023
Passaic	24,426	25,560	27,559	29,023	29,355
Salem	24,374	25,162	27,178	28,949	29,149
Somerset	44,089	46,392	52,078	56,613	55,580
Sussex	27,134	28,162	30,270	34,563	34,628
Union	33,090	35,157	38,487	40,016	41,149
Warren	25,466	26,687	29,079	31,026	31,323
US	*24,164*	*25,288*	*35,612*	*30,271*	*29,770*

The 1999-2001 average of the New Jersey population estimated to be below the poverty level was 7.7% while the national rate was 11.6%. Four states had lower rates than New Jersey. In 1980, 9.0% of New Jersey's population was reported to be below the poverty level; the national rate was 13.0%.

Average retired workers monthly benefit dollars in New Jersey were the highest of any state in 2002 at $989/mo.followed by Michigan ($964). The average weekly unemployment benefit in New Jersey was second highest of all states at $331, exceeded by Massachusetts ($360).

The state continues to have one of the highest AIDS caseloads following New York, California, Florida, Pennsylvania, Maryland and Texas. In 2001 New Jersey had 1,756 reported cases.

NJ Adult/Adolescent AIDS Cases Reported 7-01 to 6-02 and Cumulative Totals A/O 6-02

Age Group	7/01 – 6/02		Cumulative Total	
(at diagnosis)	No.	%	No.	%
13-19	13	1	201	0
20-29	141	9	5,996	14
30-39	541	35	19,768	46
40-49	570	37	12,413	29
49+	276	18	4,673	11
Total	1,930	100	43,051	100

In 2002 the Centers for Disease Control reported the lowest national tuberculosis rate (5.2) in the United States since reporting began in 1953. New Jersey's case rate in 2002 was 6.2 (530 cases). Five other states had higher case rates than New Jersey: Hawaii (11.5), California (9.0), New York (7.5), Texas (7.1), and Florida (6.5). New Jersey's case rate in 1998 (640 cases) and 1999 (571 cases) was 7.9 and 7.0, respectively; nationally, the rates were 6.8 and 6.4.

Currently, two sub-population groups account for approximately 75% of tuberculosis cases: foreign-born persons and US-born non-Hispanic black population. The most frequent birth countries are Mexico, Philippines, Vietnam, India, China, Haiti and South Korea.

Although mergers and acquisitions have increased in recent years, in 2001 New Jersey had 78 acute care hospitals compared to 95 in 1990. The number of organizational affiliations has increased so that the institutional count will vary depending on the selection criterion utilized.

INCIDENCE OF RENAL DISEASE IN NEW JERSEY

In 2001, all but one state had an adjusted end-stage renal disease incidence rate that exceeded 200 per million population. The *2003 Annual Data Report* of the United States Renal Data System (USRDS) listed ten state areas with higher age, race, sex-adjusted incidence rates than New Jersey compared to three states in 1999. The New Jersey adjusted incidence rate in 2001 was reported to be 346/million. (Annual incidence rates do not have the stability that averages for a three or five-year period would exhibit.)

The USRDS published adjusted annual incidence rates from 1990-2001. Each year New Jersey showed an increase demonstrating a steady trend: 224, 245, 259, 272, 300, 310, 307, 330, 341, 366, 345, 346.

The average age of consumers starting therapy in 1999 was 61compared with the average age in 1990 of 58. Nationally, the median age was reported in the *2003 Annual Data Report* of the United States Renal Data System to be 65 in 2001.

According to the ESRD Facility Survey in 2003, 3,325 consumers initiated therapy in New Jersey facilities compared to the 2002 count of 3,155. Older people, in particular those over 65 years of age, continued to represent the largest and fastest growing age group of ESRD beneficiaries. Of the total new starts in 2002, 57% were 65 years or older and 47% were 70 years or older. Twenty percent were eighty years or older. These percentages varied little from the prior year and all showed increases.

Other characteristics of the New Jersey incident population closely mirror national new case renal statistics: 56% were male and 44% female; 31% black and 61% white.

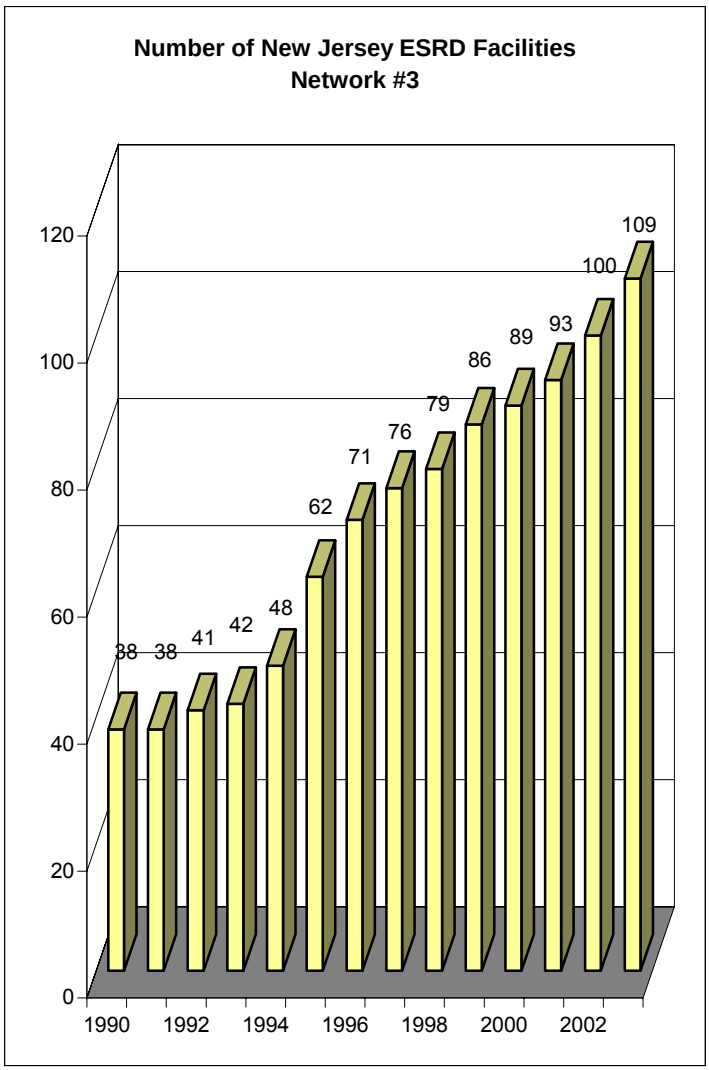
Among incident cases the most frequently reported primary diagnoses were diabetes (41%) and hypertension (33%). Collectively, these two diagnoses represented the largest proportion of new cases in 2003.

RENAL THERAPY IN NEW JERSEY

The New Jersey Department of Health regulated the approval of all new ESRD providers and expansion of services through the certificate of need process until January 1992. Since that time, chronic ambulatory dialysis is no longer subject to certificate of need requirements. The number of facilities increased from 38 in 1991 to 103 (not including a non-Medicare certified ESRD veterans hospital) in 2003. This is a 271% increase.

In 2003, the total approved station count rose to 1,871. During 2003, the number of Medicare-certified facilities rose from 100 to 109. Most facilities are no longer hospital-based since 68 free-standing clinics and 9 hospital satellite facilities provide service. There were 26 hospital-based facilities and one veterans administration hospital, which is not a participant in the Medicare program.

Almost all facilities were approved to provide staff-assisted hemodialysis except for a few peritoneal-only units; 63% (n=109) offered CAPD/CCPD training; 17% (n=109) offered hemodialysis home training. These services reflect the choices among patient and physician preferences for therapy and were available throughout the state.



Source: CMS approval letters

Staff-assisted hemodialysis, favored by 93% of ESRD consumers (83% in 1996), remained the dominant therapy in the state. Continuous cycling peritoneal dialysis (CCPD) became the dominant home therapy (n=417) with continuous ambulatory peritoneal dialysis (CAPD) the second most prevalent (n=209). Home hemodialysis accounted for only 21 cases statewide.

The national distribution of modalities reported for 2001 was the following: facility hemodialysis, 65%; home hemodialysis, 0.3%; CAPD/CCPD, 6%; other and uncertain, 0.7%; transplant 28% (Source: USRDS *2003 Annual Data Report*)

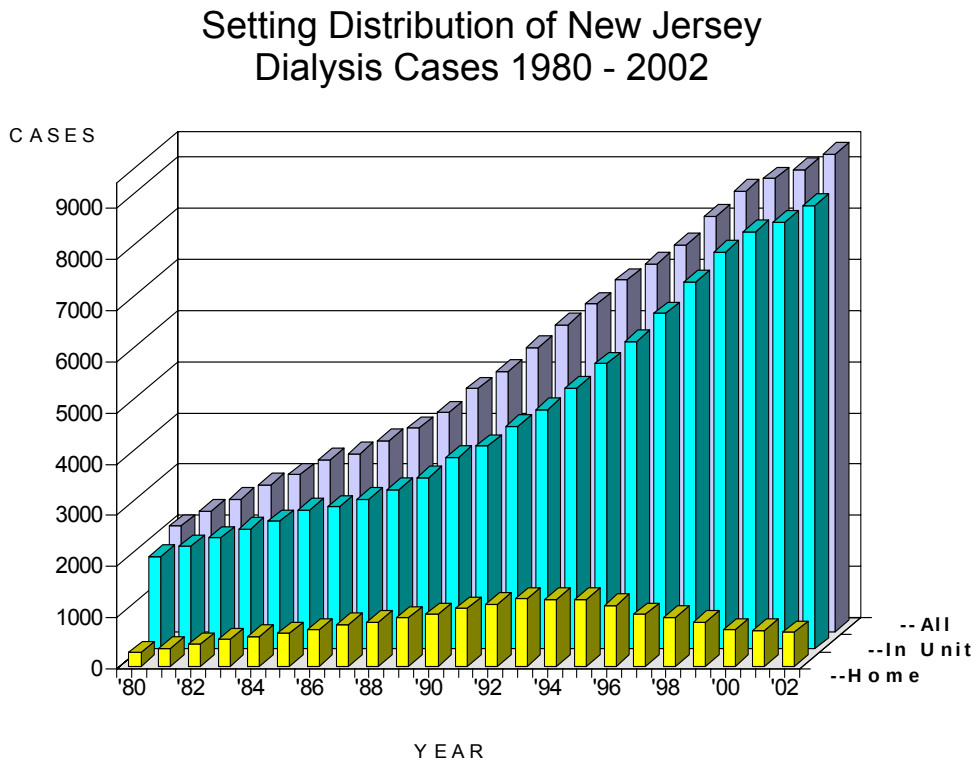
PREVALENCE

The USRDS published adjusted annual point prevalence rates/million population for 1990-2001 by state. New Jersey results were 812, 893, 960, 1018, 1100, 1163, 1216, 1278, 1344, 1418, 1447 and 1476.

The prevalent caseload increased 2.7% over the prior year. Of the approximately 9,597 prevalent consumers receiving dialysis in New Jersey, 56% were male and 44% female. Forty-one percent of the population on dialysis was black, 50% white, with other racial groups constituting the remainder.

Thirty-seven percent of the consumers receiving chronic dialysis were 70 years or older, and 23% were within the 60-69 age group. Fifty-nine percent of the prevalent consumers receiving dialytic therapy in New Jersey during 2003 were aged sixty years or older. The aged population continues to be the fastest growing segment both receiving long-term chronic care and initiating treatment.

Diabetes was the most frequently reported primary disease of all prevalent consumers on dialysis at 39%. Hypertension followed at 30% of the caseload and glomerulonephritis ranked third at 14%. The majority of consumers (69%) in treatment were diagnosed with either diabetic nephropathy or hypertensive disease - the two leading national risk factors for ESRD.



Source: Network #3 database, CMS-2744
Trans-Atlantic Renal Council

MORTALITY DATA

Death notification reports for New Jersey ESRD consumers were analyzed by sex, race, and cause of death. The primary cause of death reported in 2003 continued to be cardiac (45%) which again reflected national data. Infection was reported in 20% of the 2,588 death records received. Of all deaths reported in 2003, 63% were white, 31% black; 54% were male, 46% female. Primary diagnoses among deaths reported were diabetes (44%), hypertension (31%), glomerulonephritis (8%), polycystic disease (1%), and other/unknown.

TRANSPLANTATION

Five renal transplant centers serviced the New Jersey ESRD population with referrals also being made to neighboring New York, Philadelphia, and Maryland. Recent years have seen an inflow for transplantation to New Jersey of neighboring state residents as well. Organ procurement activities were the responsibility of two federally-approved agencies, the New Jersey Organ and Tissue Sharing Network (The Sharing Network) and the Gift of Life Donor Program.

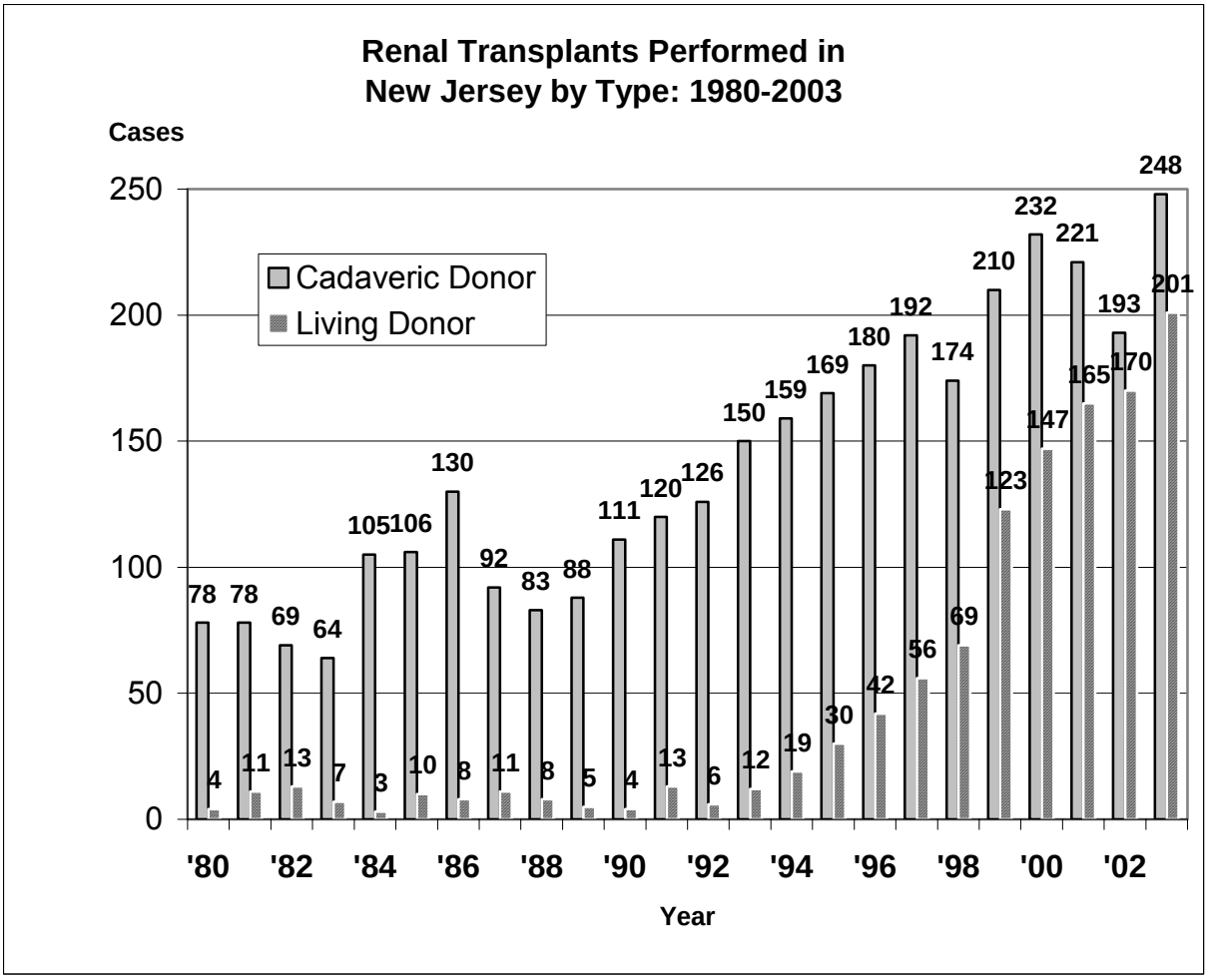
In 2003, 448 transplants were performed in New Jersey at federally-certified ESRD renal transplant centers, an increase of 4% over 2002 performance. Of the 448 transplant procedures performed within New Jersey, 248 had cadaveric donors and 201 had living donors.

The number of consumers on a waiting list in New Jersey continued to increase to a total of 2,566, 21% apparently higher than the previous year; the extent to which the counts contain duplicate and triplicate counts is not known. Unless the donor pool is enlarged, transplantation will not be available to the majority of consumers on the list except, perhaps, after a lengthy waiting period. Alternatively, living donor transplantation may be able to provide some candidates with more timely access to this modality.

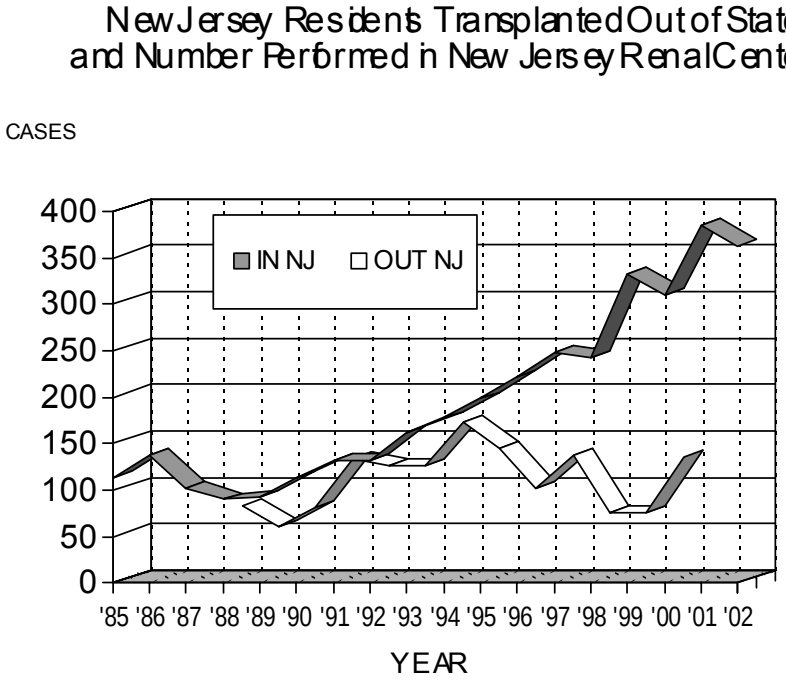
Nationally, transplantation among minority groups occurred at a slower rate reportedly due to cultural factors and problems encountered in genetic matching protocols. New Jersey transplant centers transplanted minority consumers at a rate higher than the national average.

Although kidney donors parallel national data in regard to race categorization (predominantly white females, followed by white males, and ranking last, blacks-male and female), the minority population transplanted appears to be comparatively better served within New Jersey.

As stated above, two federally-approved organ procurement organizations serve New Jersey: The Sharing Network and the Gift of Life Donor Program.



Source: Network 3 Database, CMS-2744 , UNOS
Trans-Atlantic Renal Council



PUERTO RICO AND THE VIRGIN ISLANDS

GEOGRAPHY AND GENERAL POPULATION CHARACTERISTICS

Similar to New Jersey, Puerto Rico is densely populated (1,124/sq. mi.) with land area covering nearly 3,427 square miles and a population of 3.859 million. There were 1,027.9 inhabitants per square mile according to the 2000 census. Between 1990 and 2000, the population increased 8%.

Puerto Rico Population by Age, 2000

Age Group	Population
0-24	1,520,995
25-54	1,513,031
55-64	349,447
65-74	240,951
75-84	136,480
85+	47,706
All	3,808,610

Droughts are one of the naturally occurring hazards to the local population. Sediment buildup (60% storage reduction over the last 50 years) in reservoirs reduced the holding capacity of several major water supplies. Reclamation efforts are underway and should reduce the periodic threat to potable water supplies. The U.S. Geological Survey works with 15 local agencies to operate a real-time hazard alert network concerned with rainfall, stream flow, lake levels and beach erosion from catastrophic events.

In recent years Puerto Rico has experienced major expansion in the construction and tourism sectors. Construction of housing, commercial buildings and infrastructure (super aqueduct, urban train, highways) contributed to economic development. Some manufacturing plants did expand but the effect of favorable tax benefit elimination is uncertain for the future; Section 936 will be completely phased out in 2005.

The 2000 Census Bureau report showed that the labor force (1.303 million) was distributed among several types of work: 2% were engaged in agriculture, 12% in manufacturing, 18% in trade and 19% in government positions. Approximately 14% were unemployed in 1998, 13.7% in 1999, 11% in 2000.

One in every four Hispanic families lives at the federal poverty level with average earnings well below the U.S. national average. Forty percent of all households rely on some form of public assistance. The average monthly benefit paid to retired workers is $527. The average annual employee compensation reported by the most recent Bureau of the Census publication (2000) was $20,064; the average family income was $33,559.

In 1999 there were 525,000 Medicare enrollees; Medicaid had 1,055,000 enrollees in 1998. The local Health Reform Program covers 1.8 million indigent residents.

The birth rate reported by the U.S. Bureau of the Census in 2000 was 15.2/1,000 population; the death rate (2000) was 7.2/1,000 population. The median age is still 32.1 years. Of the residents, 509,856 (23%) were high school graduates; 418,253 (19%) had a bachelor's degree or higher. The average employee compensation in 2000 was $21,123; the average family income was $36,776.

Population characteristics describe basic life choices, such as early acquisition of medical care and the existence of discretionary income to provide adequate housing and nutritional support. Many communities are isolated and lack treated water supplies. The Environmental Protection Agency (EPA) has been working with the local health department's environmental division to provide special water filters, chlorine if needed, and basic education on suitable potable water for drinking.

Health system reform was undertaken to provide universal coverage and eliminate governmental ownership of facilities.

The death rate for HIV (17.6) was second (in ranking) only to Washington, DC. Similarly, the rate for diabetes mellitus (61.5) was the highest among all states and the District of Columbia.

THE U.S. VIRGIN ISLANDS

The territory of the Virgin Islands consists of 3 islands - St. Thomas, St. Croix and St. John - and about 50 islets, most of which are uninhabited. These islands are located 60 miles southeast of Puerto Rico between the Caribbean Sea and the Atlantic Ocean in the Lesser Antilles chain of the West Indies. It is an unincorporated territory of the United States administered by the Office of Insular Affairs, U.S. Department of the Interior. The governor and lieutenant governor are elected for four-year terms.

The land area covers 134 square miles with an overall population estimated to be 108,000. There were 761 residents/sq. mi. in 1990.

Residents are comprised of people from the West Indies (45% native to Virgin Islands, 29% born elsewhere in West Indies), Puerto Rico (5%), U.S. mainland (13%), and other (8%). Racial composition in the Virgin Islands is estimated to be 80% black, 15% white and 5% other. Spanish and Creole are spoken in addition to English.

US Virgin Islands Population by Age, 2000

Age Group	Population
0-24	52,542
25-54	45,948
55-64	12,174
65-74	6,468
75-79	1,903
80+	1,882
All	120,917

Source: US Bureau of the Census, International Database.

Approximately 37% of the territory's population resides in urban areas, while 63% is located in rural or suburban developing communities. Forty-six percent of the population resides on the island of St. Thomas. Charlotte Amalie remains the urban center of St. Thomas. Christiansted and Frederiksted are the major towns on St. Croix.

Population density fluctuates among the individual islands. St. Thomas has the highest density with 1,579 persons per sq. mi.; St. Croix has 583/sq. mi. and St. John only 118/sq. mi.

There are two international airports in the Virgin Islands; one is on St. Thomas and the other on St. Croix. Transport to St. John is via scheduled ferry from St. Thomas or St. Croix. Cars on the islands use 856 km of paved highways.

The birth rate reported by the U.S. Census Bureau has been declining since the 1970s and is estimated to be 13.7/1,000 population (2001). Similarly, the death rate follows the declining trend and is reported to be 5.6/1,000 population. The median age is reported to be 33.4 years which is slightly higher than Puerto Rico's 32.1.

Of the 65,603 residents 25 years and older, 17,044 (26%) were high school graduates and 10,989 (17%) held a bachelor's degree or higher. The median income was $28,553 in 2000. In 2000 the average monthly benefit paid to retired workers was $640.

The primary economic engine of the islands is tourism. It accounts for more than 70% of gross domestic product. Approximately 32% of the employed were in retail sales or the services provided for recreation, motels, hotels and restaurants. Manufacturing includes textile, electronics, pharmaceutics and watch assembly.

The total labor force is estimated to be 48,000 distributed among services (62%), industry (20%), agriculture (1%), and other (17%). The unemployment rate was estimated to be 6.2% in 1994.

In 1989 hurricane Hugo caused $500 million damage from which residents have not yet completely recovered and which extended to the tourism industry. Local business owners continue to lament the drop in available advertising money that is funded through hotel taxes since many hotels had to close because of hurricane damage. In 1997 it was anticipated that only $8.5 million would be raised through the hotel tax which was considered to be insufficient. The inventory of hotel rooms before the hurricane

was estimated to be 1,400 while in 1997 was approximately 850. Governmental fiscal administration was hampered by an imbalance in funds received compared to funds to be disbursed to vendors, tax refunds, and overdue wages.

One of the world's largest petroleum refineries is on St. Croix. Little agriculture is present and most foodstuffs are imported.

The Virgin Islands have a strategic importance located along the Anegada Passage which is a key shipping lane for the Panama Canal. Saint Thomas has one of the best natural deepwater harbors in the Caribbean.

The Islands have unique waste disposal problems. The U.S. Army Corps of Engineers conducted an environmental assessment at a St. Thomas landfill in 1996 and found that mercury vapors and phosphogenes were present which, after long-term exposure, can produce illness and certain forms of cancer. Alternative solutions are being explored.

(Puerto Rico and the Virgin Islands are not included in all tables of the various reports utilized to describe these areas, which limits some comparisons to national published data.)

RENAL DISEASE: PUERTO RICO AND U.S. VIRGIN ISLANDS

The number of newly diagnosed ESRD cases, inclusive of those who started treatment in out-of-area facilities, was 1,310 a 3% increase from 2002. Sixty-five percent of the newly diagnosed were reported to have a primary diagnosis of diabetic nephropathy. This continued to parallel the national trend of the growing number of diabetics starting dialytic therapy and represents a marked increase from 1990 when diabetes as the primary cause in new cases was only 45%. Hypertension was the second highest reported diagnosis at 15% and 9% of the newly diagnosed caseload was reported with a diagnosis of glomerulonephritis.

These rates vary when analyzing the data received on all prevalent consumers alive at year-end 2003 on the islands. Of the 3,550 consumers receiving treatment at year-end - a 1% increase from 2002 - 55% reported diabetes as primary cause of renal failure, 16% glomerulonephritis and 17% hypertensive disease. The majority of consumers were reported as racially mixed (65%), male (62%).
Age grouping is similar for both new cases and the prevalent dialysis patient population on the islands. Consumers in the 50-69 age group are the dominant population; 50% and 54%, respectively, in the incident and prevalent figures. Thirty-one percent of prevalent cases are between the ages of 30 and 54. Twenty-nine percent of the incident cases are age 70 or more. Twenty-nine percent of the prevalent cases are age seventy or older.

The primary cause of death for ESRD consumers treated in Puerto Rico and the Virgin Islands at year-end was cardiac (36%); infection ranked second (33%).

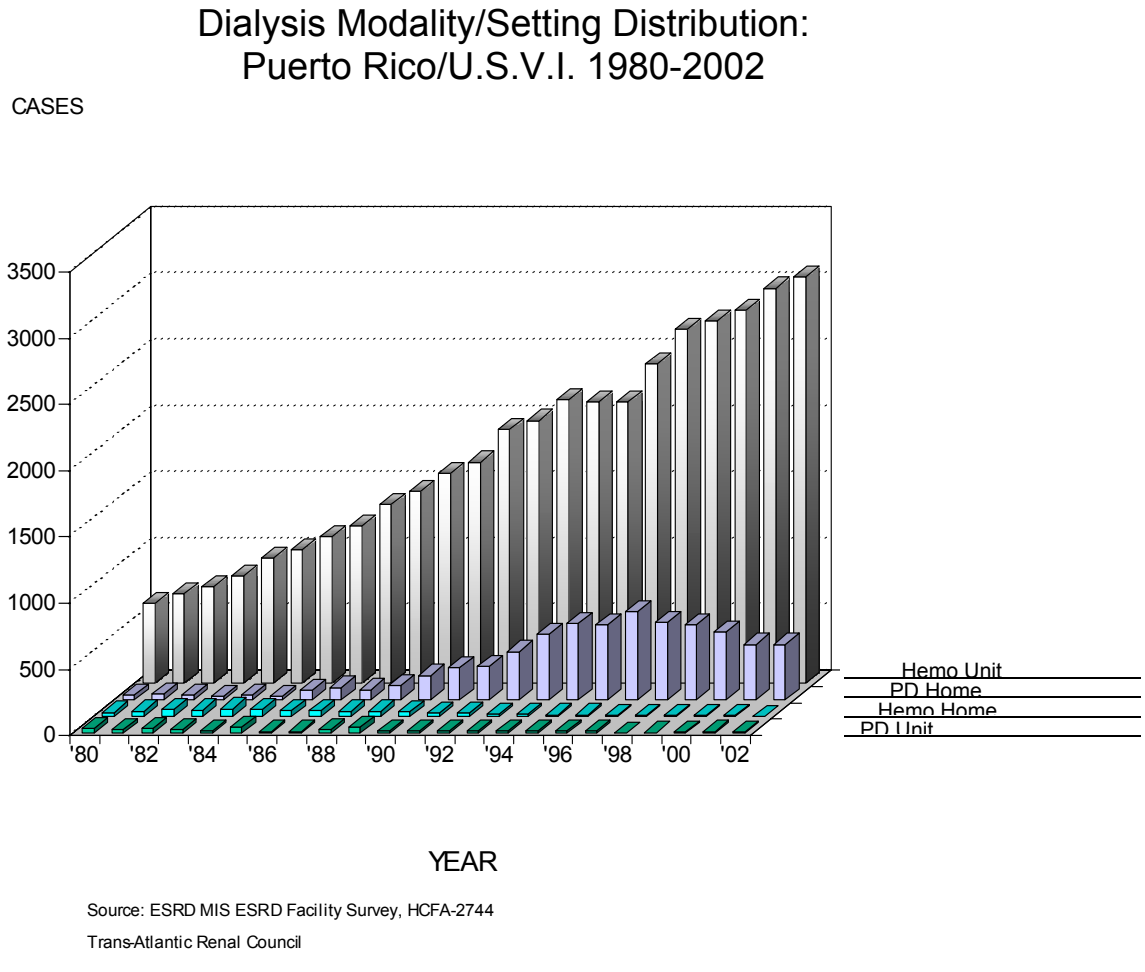
TREATMENT MODALITIES

Forty-one facilities were approved on the island of Puerto Rico to provide ESRD services and three facilities within the U.S. Virgin Islands (one hospital-based unit on the island of St. Thomas, one hospital-based unit on St. Croix and one free-standing facility on St. Croix.) Thirty-two facilities on Puerto Rico are freestanding clinics. There is one veterans administration hospital and 8 hospital-based units on Puerto Rico. The station count increased to 776 from 717 in 2002 (inclusive of Puerto Rico and the Virgin Islands). The two facilities on the Virgin Islands had a total of 20 stations and a total of 135 cases at year-end.

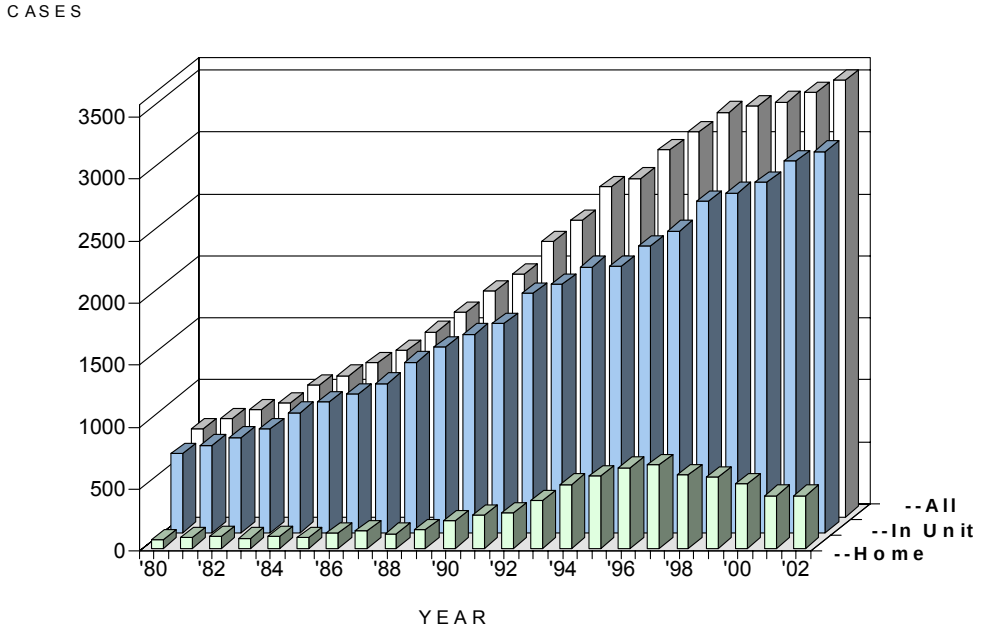
Treatment choice continued to favor staff-assisted hemodialysis—3,186 (88%) consumers in Puerto Rico and all consumers on St. Thomas and St. Croix. Self-care training in CAPD, CCPD and home hemodialysis were provided in Puerto Rico in spite of limited housing conditions. Eighty-five percent of the home population was on home CCPD. In 2003, 363 consumers were on CCPD and 61 consumers were on CAPD. No consumers used home hemodialysis. The combined total of consumers on various forms of home dialysis in Puerto Rico equaled 424 in 2002, 426 in 2002, 521 in 2000, 574 in 1999 and 679 in 1998. Four home consumers were reported on St. Croix.

Eighty-four transplants were performed in 2003 at the one Medicare-approved transplant center. This was an increase of 31% above 2002 performance (64 and 91 in 2001). Of these procedures, 56 were from cadaveric donors. There were 388 consumers are on an active waiting list.

Formerly, the organ procurement agency was located at the transplant hospital and was part of that organization. In 1996 a separate agency was established, Life Link of Puerto Rico, which is affiliated with Life Link of Florida.

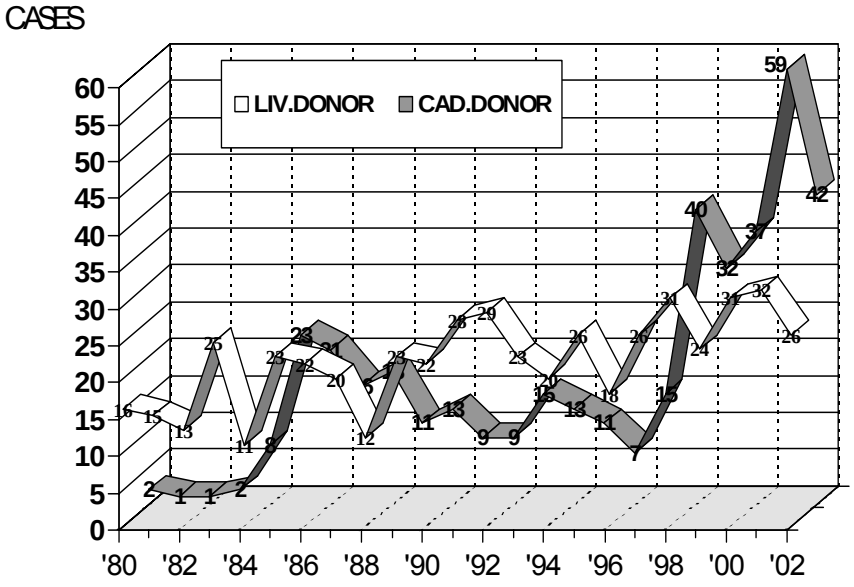


Setting Distribution of Dialysis Cases
Puerto Rico/U.S.V.I. 1980-2002



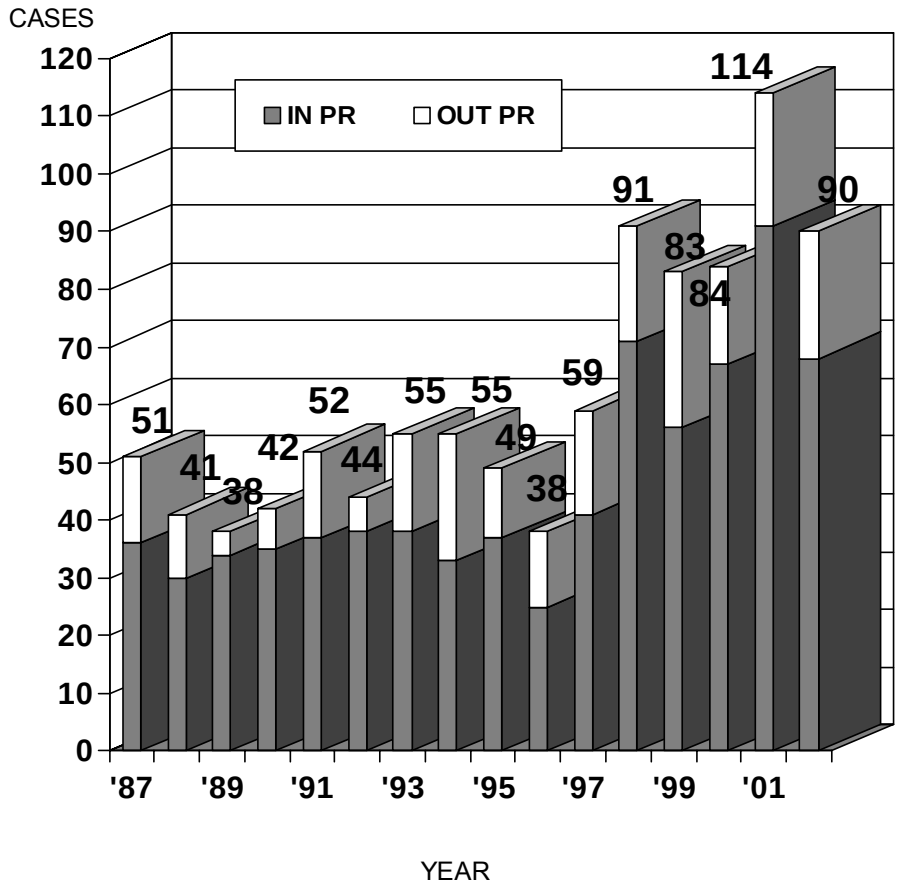
Source: Network #3 database, HCFA-2744
Trans-Atlantic Renal Council

Renal Transplants Performed in
Puerto Rico/U.S.V.I. by Type: 1980-2002



Source: Network #3 database, HCFA-2744
Trans-Atlantic Renal Council

Total Puerto Rico/U.S.V.I. Residents Transplanted
and Number Done in and out of Puerto Rico



Source: Network database; UNOS data 1994 forward;
ESRD MIS ESRD Facility Survey

Trans-Atlantic Renal Council

B. NETWORK STRUCTURE

1) STAFFING

Professional and clerical staff conducted daily activities of the network organization under the direction of the Board of Trustees and in accordance with federal guidance.

2) NAMES AND TITLES OF STAFF

Cheryl Brown Data Clerk	Michele Inglese Senior QI Coordinator	Tricia Phulchand Administrative Assistant
June Chronic Huhn QI Coordinator	Jeanne Lavin QI Administrator	Joan Solanchick Executive Director
Patricia Dorsa Bookkeeper		

3) KEY RESPONSIBILITIES

The project director was Joan Solanchick, who administered the contract, maintained external relations through ongoing communication with other agencies, state programs and the general public, and supervised daily operations.

Jeanne Lavin, RN, is quality improvement administrator with a hospital background and many years of experience in ESRD patient care. She monitors all quality improvement efforts, plans future project implementation and works with individual facilities.

Michele Inglese, RN, continued as senior quality improvement coordinator with quality improvement coordinator June Chronic-Huhn, RN. In these positions they assisted with the conduct of improvement activities, monitored facilities, performed on-site visits, clinical data review and responded to consumer problems.

Chris Brown and Mitch Parker, Diginexus LLC, developed data analysis and statistical reports. They assured computer support operations, validation, testing and design of special programs that implemented federal directives. Additionally, they trained facilities in the use of new federal *Vision* software use and implementation.

Accurate data analysis is based on careful processing, manual review and data entry. Cheryl Brown performed data entry, resolved discrepant reporting, monitored the accuracy and completeness of the database.

Tricia Phulchand monitored all project submissions as well as assisted in the implementation of facility transmission of *VISION* data, monitored complete and timely data submission.

These individuals provided the clinical and administrative expertise to assure reliability of statistical data and oversight of quality improvement activities.

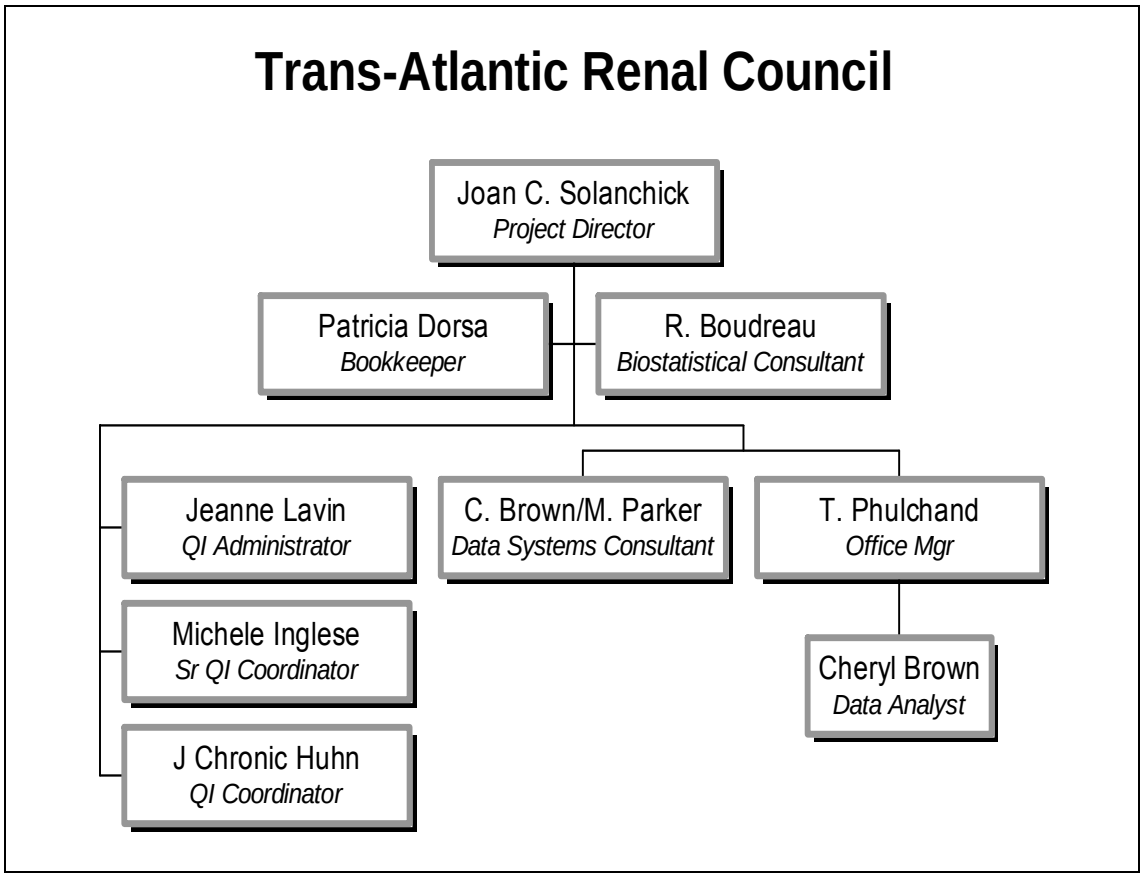
OPERATIONS

There are two major functions within the operation of the network: quality improvement and data management. It could be maintained that quality improvement is the sole function of the network and data analysis serves only to focus and measure the quality improvement function.

Quality improvement personnel were responsible for staffing the Medical Review Board and all related activities, the federal clinical performance measures project, local quality improvement activities and educational programming. Staff prepared draft material for review by the Medical Review Board, monitored developments in the field, reviewed reports submitted by each facility and analyzed comparative results. Facility site visits were conducted when appropriate.

Data management personnel were responsible for all data input, report production, generation of diskettes and transmission of data to CMS. They subjected data to tests of statistical significance and interpreted results for clinical personnel as well as assisted in designing studies and producing reports.

Clerical personnel prepared documents, correspondence and general mailings as well as maintained files in a manner consistent with usual office practice.



Network staff conducted the ongoing collection and processing of data, review of compliance with federal requirements as well as network goals and objectives, and distribution of pertinent information to all ESRD facilities within the defined geographic region.

The Council of member facilities provided the direction for monitoring performance outcomes and measuring the quality and appropriateness of care. The Medical Review Board and the Board of Trustees provided invaluable advice and expertise to achieve improvements in patient care. In addition, a resource pool of knowledgeable ESRD consumers and other highly skilled clinical nephrology professionals (physicians, registered nurses, social workers and dietitians) was developed to act in a consulting role for periodic review of educational materials, special studies, core indicators and speakers at educational meetings.

This "resource pool" has been valuable in assisting staff to "test" new data requirements and changes in quality improvement activities, and to analyze the impact of advancing technology or areas of interest. All board and committee members serve voluntarily with no compensation.

4) COMMITTEES

The basic committee structure includes the Board of Trustees and the Medical Review Board. Other committees and subcommittees are established when the need arises. Currently, the Data Systems Implementation Committee is providing direction and oversight for Web site contents.

5) FUNCTIONAL DESCRIPTION

NETWORK COUNCIL

The Council provided broad direction and guidance in the development of goals for self-care, transplant referrals and criteria selection for monitoring performance of providers and plans for improvement. Representation on the Council was multidisciplinary, culled from professionals with demonstrated expertise in their specific field and representative of the geographic characteristics of the network.

The Trans-Atlantic Renal Council ('Council') was composed of thirty-three (33) regular members: twenty-three (23) from New Jersey, seven (7) from Puerto Rico/Virgin Islands, and three (3) consumers. The formal Council representatives reflect the geographic area encompassed by the network as well as the various disciplines and types of facilities contained within the network stipulated by federal regulations. All Council members were selected from volunteers and approved by the Board of Trustees. Liaison members from governmental and voluntary agencies affiliated with the care of ESRD consumers were invited. To the extent possible, Council membership was restricted to not more than one person from a facility or affiliated group of facilities. Council meetings are open and a significant number of the renal community attends the annual meeting.

The geographic representation by discipline is illustrated below:

North NJ	**Central NJ**	**South NJ**	**Puerto Rico**
1 consumer	2 consumers		
5 physicians	3 physicians	2 physicians	2 physicians
3 registered nurses	1 registered nurse	2 registered nurses	2 registered nurses
1 social worker			
2 administrator registered nurses	1 administrator		
1 transplant physician			
		1 dietitian	

Council formal representation by type of facility follows:

	New Jersey	**Puerto Rico**
Hospital-based	12	1
Non-profit satellite	2	
Corporate provider	8	7

The Council met one time as allowed under contract. This meeting was used to present comparative data on local and national goals and provide educational programming on new technology and areas of interest. The meeting was held on October 15, 2003 at the Sheraton Woodbridge Place, in Iselin, New Jersey. Lecture topics and speakers were:

Network Activities	Jorge Weber, MD, *President, Board of Trustees* Toros Kapoian, MD*, BOT member*
End of Life and Palliative Care for the ESRD Patient	Alvin H. Moss, MD *Professor of Medicine, Director of Health Ethics and Law* *Robert C. Byrd Health Sciences Center* *West Virginia University*
BREAK	Exhibits & Poster Presentations
End of Life Ethical Issues In ESRD	Margaret Mahon, RN, PhD *Clinical Specialist, Palliative Care and Ethics* *Hospital of University of Pennsylvania*
Legal Issues in End of Life Care	Myra Sanderson, JD *Dialysis Clinics Incorporated*

An annual meeting highlight was the presentation by Barbara Ahmet Simon, BSN, of the Ahmet B. Ahmet Award to one consumers selected from the many inspirational nominations submitted by facility staff.

Eight posters prepared by New Jersey facilities were displayed at the annual meeting.

BMA-Hillside	Ready, Set, Green Light...Know Your Number Today!!! Patricia Mascia, RN; Patricia Kennedy, RN, CNN
FMC-Irvington/Englewood	Breaking the Catheter Trend Caroline Wilson, RN, CNN; Saramma Mathew, RN, BSN, CNN
DCA Vineland	An evaluation of Icodextran Product Use in Peritoneal Dialysis Dr. Elis Priori; Patricia Hannum, RN; Hazel Dennison, RN, MSN, APN, C.; Dr. David Blecker
DCI North Brunswick	Access Care and Repair Lisa Bross Gajary, LPN; Mary Lou Clancy, RN, CNN
DCI North Brunswick	Patient Evaluation -The Flu Shot and You Neeta Bahal O'Mara, PharmD, BCPS; Kathy Bivens, RN, CNN
DCI North Brunswick	Epogen Dosing for Home Patient Administration Kathy Searson, RN, BS, CNN; Barbara Calvanelli, RN, CNN

Hackensack University Medical Center	Use of Unit Council Structure to Implement Hepatitis B Surveillance and Prevention Program Marie Reid, RN, BSN; Sharon Mancini, RN, BSN; Claudia Douglas, RN, MA, APN, C; Kathleen Herron, RN; Ghia Jackson, PCT; Christopher Parisi
Robert Wood Johnson University Hospital	Medication Use Evaluation of IV Ascorbic Acid in Epogen Resistant Chronic Renal Failure Patients Sarah Tomasello, PharmD, BCPS; Garletha Allen, RN, BSN, CNN; Caroline Steward, RN, MSN, CNN; Robin Roberts, RN, CNN; Joanne Coderre, RN, CNN; Colleen Gallery

MEDICAL REVIEW BOARD

The Medical Review Board (MRB) evaluates the appropriateness of ESRD care, treatment procedures, and services delivered to ESRD consumers. The prescribed composition of the MRB is: (11) members and a chairperson from the following categories: a minimum of one physician board-certified in nephrology, an experienced nephrology registered nurse responsible for nursing services, a licensed renal social worker, a registered renal dietitian and a patient representative. All of the members are engaged in ESRD treatment.

The 2003 Medical Review Board was composed of one consumer, one registered dietitian, one social worker, three registered nurses, one administrator and five physicians. Three members were from Puerto Rico and the remainder were from New Jersey. The following chart illustrates the MRB's composition:

Type of Facility	**North NJ**	**Central NJ**	**South NJ**	**Puerto Rico**
Hospital-based	1 nurse		1 dietitian	
Non-profit satellite	1 social worker	1 physician 1 administrator		1 nurse (transplant agency)
Corporate provider	1 physician		2 physicians	1 physician 1 nurse
Patient	1 patient			

The Board of Trustees accepted nominees for election to the Medical Review Board from the active organizational members. An individual must possess the qualifications and have demonstrated their ability to evaluate the quality and appropriateness of care delivered to ESRD to serve on the Medical Review Board.

The MRB has the responsibility for the development of criteria and standards for evaluation of care; review of facility protocols for patient modality selection; review of patient grievances as necessary according to standard procedures adopted by the Board; development of protocols for individual case review; evaluation of existing available services and recommendations for the addition of alternative services as needed; the analysis of facilities' compliance with network goals and recommendations for improvement.

No person serving on the MRB may have responsibility for review of any case in which he/she has, or had, any professional involvement, received reimbursement or supplied goods. No person serving on the MRB with a financial interest, direct or indirect, in a facility furnishing ESRD services may review the

ESRD services of that facility. Confidentiality assurances are utilized by the MRB to protect the rights of consumers, providers, and facilities.

The activities of 2003 included reviewing facility-specific data for four indicators of hemodialysis via the Hemodialysis Improvement Project (HIP), reports of the Clinical Performance Measures Project, the National Vascular Access Improvement Initiative, and other data from CMS. There were no patient grievances to review.

The MRB meeting dates and locations were:

March 5, 2003	Forsgate (Jamesburg, NJ)
June 4, 2003	telephone conference call
September 3, 2003	Forsgate (Jamesburg, NJ)
December 3, 2003	telephone conference call

BOARD OF TRUSTEES

The Board of Trustees ('Board') consisted of eleven (11) members. Upon resignation of a member, inability to complete a term of office, or non-attendance at two (2) consecutive board meetings, the position would be deemed vacant and would be filled by a new member selected by the president of the board. The new member then would serve for the unexpired term held by the member whose position he/she filled.

The board elected from among its membership the following officers: president, vice president, secretary, and treasurer. The president served as the president of the board and chairman of the Council, and monitored all network operations with the project director. The vice president presided or acted in the absence of the president. The secretary was responsible for keeping minutes of all board meetings and assured proper maintenance of all records and reports (except financial) for the Council. The treasurer was responsible for reporting the financial status and budget preparation of the Council.

The 2003 Board of Trustees was composed of one consumer, one social worker, two nurses and five physicians. One member was from Puerto Rico and the remainder was from New Jersey. The chart below illustrates the Board's composition:

Type of Facility	North NJ	Central NJ	South NJ	Puerto Rico
Hospital-based	1 physician 1 social worker 1 nurse	2 physicians		
Non-profit satellite				
Corporate provider	1 nurse	1 physician 1 dietitian	1 nurse	1 physician
Patient		1 patient		

The election of officers took place at a regularly scheduled meeting of the Board. Election of officers was by simple majority of those members present and voting.

The board monitored and directed the daily operation of the network organization.

The board has the authority to:

- Employ and terminate any personnel required for the business of the network;
- Prepare a plan which defines network goals, objectives and implementation of objectives;
- Prepare an evaluation methodology to measure progress;
- Develop network operating and governing policies and procedures;
- Suggest alternative approaches to meeting goals and objectives for the network's consideration;
- Review and update the network plan on a regular basis;
- Review all fiscal matters of the network and review records on such matters which include, but are not limited to, the collection and disbursement of all funds;
- Certify the representatives for appointment to the Council, and keep up-to-date records of the membership of the Council;
- Appoint members and designated alternates to the Medical Review Board
- Review the By-Laws, amending them when necessary.

To further assure a broad perspective on appropriateness of care and outcome measurements, a transplant surgeon and board certified pediatric nephrologist may serve on the board or as a consultant to the board. These members are selected based on their expertise to further promote the goals and objectives of the network.

The Board of Trustees meeting dates and locations were
March 19, 2003 - Forsgate (Jamesburg, NJ)
June 18, 2003 - telephone conference call
September 10, 2003 - Forsgate (Jamesburg, NJ)
December 10, 2003 - telephone conference call

DATA SYSTEM IMPLEMENTATION COMMITTEE

This committee was formed in order to discharge the network's responsibility to assist facilities provide efficient care by utilizing current technology. The TARC web site was developed and maintained to educate consumers and the public, and translated into Spanish for the Hispanic communities of New Jersey and Puerto Rico.

The Data Implementation Committee is comprised of dietitians, nurses, dialysis technicians, an information technology coordinator and a social worker that helped to plan, organize, develop and evaluate the necessary components of the web site’s professional section. The format was further developed and expanded to include but is not limited to the following categories: TARC information, reports, data, quality improvement, nephrology team and resources.

In 2003, the Data Committee recommendations for the development of the professionals web sites were reviewed, the quality improvement and web quality tools were refined, links and resources were researched for additions or deletions, the clinical and technical issues section was modified, emergency management and the disaster manual links were added to resources and links, and the nephrology team section was restructured. The Data Committee will meet in 2004 when the professional web site is on line to review and make recommendations to the professional web site.

During 2003, the English and Spanish Consumer web sites were periodically reassessed, revised, and maintained. The dialysis facilities locations and services were reviewed, revised and updated as new facilities emerged or if facilities were purchased by other dialysis corporations. The web links were reviewed and revised as needed for both the English and Spanish web sites.

The question and answer portion of the site allowed visitors to post ESRD related questions. A wide variety of questions in both English and Spanish were answered by Medical Review Board members. The

breadth of question topics spanned from the life span of an ESRD patient to assistance with locating a transplant unit.

The Data System Implementation Committee was composed of five nurses, one social worker, two dietitians, and three technicians. The chart below illustrates the Board's composition:

Type of Facility	**North NJ**	**Central NJ**	**South NJ**
Hospital-based	2 nurses 2 technicians		1 nurse
Non-profit satellite		1 technician	
Corporate provider	1 dietitian	1 dietitian 2 nurses	1 social worker

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, 2003 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. Patient Rights & Responsibilities/ Grievances
   1. Each facility will post in a prominent place, the TARC *Patient Rights & Responsibilities* and the *Patient Grievance Procedure*:
   2. Each facility will distribute the *Patient Grievance Procedure* and the *Patient Rights & Responsibilities* to the patients as needed.

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.

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 $\geq$ 65%.
   2. *Anemia Management*-facilities will maintain 80% of their patients with pre-dialysis hemoglobin values $\geq$ 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 $\leq$ 25% for prevalent patients
   5. *Nutrition*-each facility will have 35% of their patients with an Albumin of $\geq$ 4.0/3.7 gm/dL (BCG/BCP)

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. **Activity**: 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. **Activity**: Each dialysis facility will complete at least annually the LORAC self-assessment tool to identify efforts in the five rehabilitative 'E's: encouragement, education, exercise, employment, and evaluation.
C. **Activity**: Assure that facilities periodically evaluate their treatment scheduling practices or other facility policies which may act as disincentives to vocational rehabilitation.
D. **Activity**: 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).
E. **Activity**: The network will encourage the use of the SF-36 assessment form.

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.

Modality Goal

Transplantation

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.

All consumers need to receive information about treatment modality options prior to initiation of renal replacement therapy (RRT) and at regular intervals following initiation. 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 266 transplant designees in 2003. All but 4 facilities had transplant designees. 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 have longstanding successful transplant designee programs.

Long waiting lists for organ procurement are problematic both in network 3 and throughout the country. This long wait is further exacerbated for consumers with certain tissue matching needs. The network's six transplant facilities had 2,954 people on their kidney transplant waiting list as of December 31, 2003. This list is not comprised solely of consumers within the network boundaries.

Network 3 had six Medicare-certified renal transplantation programs operating during 2003, five in New Jersey and one in Puerto Rico:

- Auxilio Mutuo Hospital
- Hackensack 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. There has been an increase in living donors, both related and unrelated donors. During 2003, these centers performed 448 kidney transplants. Of those 448 transplants, 201 were from living donors and 247 were from cadaveric donors.

According to the ESRD Annual Facility Survey (CMS-2744), 486 dialysis consumers (New Jersey: 376; Puerto Rico:108; US Virgin Islands:2) received a kidney transplant during 2003, which is an increase of 68 transplants from 2002. 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 2003.

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 (81%) of the Medicare-approved and Veterans Administration dialysis programs in New Jersey at year's end had a minimum of one patient receiving a kidney transplant in 2003 (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 2003, the number of organs available and suitable for use was still fewer than those needed or desired by network dialysis consumers.

The dialysis facilities in Puerto Rico and the US Virgin Islands, we also very active in sending their patients for transplant. 79% 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.

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

TRANSPLANT CENTER	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Auxilio Mutuo Hospital	33	37	25	41	71	56	68	91	68	84
PR Subtotal	**33**	**37**	**25**	**41**	**71**	**56**	**68**	**91**	**68**	**84**
Hackensack Univ MC *	0	0	0	0	0	20	41	52	41	41
Newark Beth Israel MC	49	50	46	51	43	50	47	40	27	52
Our Lady of Lourdes Hospital	21	43	34	43	33	56	63	53	40	41
R W Johnson Univ. MC*	0	0	0	0	0	26	57	72	70	72
Saint Barnabas MC	108	106	145	154	167	181	171	169	185	158
NJ subtotal	**178**	**196**	**225**	**248**	**243**	**333**	**379**	**386**	**363**	**364**
Network Total	**211**	**233**	**250**	**289**	**314**	**389**	**447**	**477**	**431**	**448**

*Transplant service initiated in 1999

Home Dialysis

Home dialysis as a selected modality showed little change in the number of patients in 2003. In 2002, there were 1,089 patients receiving any type of home dialysis while in 2003, there were 1,079 patients receiving dialysis in the home. The vast majority of patients, 781 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.

Home hemodialysis has not been a popular modality for some years. In 2003, there were 21 patients receiving home hemodialysis. This year TARC had a facility introduce daily hemodialysis. DCI North Brunswick researched the modality and performed intense preparation to initiate the program. As this modality is relatively new in the US and certainly new in network 3, many hours were required to learn the system, write policies and procedures, educate the affected parties not just the patient, and implement a program. In addition, the facility needed to identify what to monitor, at what frequency, set targets and identify problem areas. There is great hope for this method but one problem is reimbursement has not caught up with technology. Currently, it is cost prohibitive to have a large scale program due to reimbursement. However, we look to this pioneer facility to continue to blaze the trail in this venue.

TARC recognized two facts: there has been a decrease in the number of home dialysis patients over the years in network 3 and there is a nursing shortage which is predicted to get worse. In addition, there are predictions of a rapid growth in the number of patients. To address these issues, TARC initiated a home designee program. The intent of this program was to create a series of events. The program would educate staff nurses about home dialysis options. The staff nurses would be able to provide current knowledge of home dialysis and resources of home programs to patients. Patients could pursue home dialysis as an option. The desired result is to have more patients knowledgeable about home dialysis and select home dialysis as their modality. The secondary gain to the facility is they could maintain their patient census. If more dialysis patients were dialyzed using the home modality, fewer patients would have to be dialyzed in center, resulting in a smaller number of nurses being needed for a lower in-center population.

A planning committee was formed to create this home designee educational program. Invitations to participate were sent to the nurses of the active home-training facilities. The committee met in early 2003 to review the concept, develop the initial educational program and design the continuation of the program. The committee was composed of the following registered nurses:

Member	Facility
Liz Kilken	Morris Home Dialysis
Diana O'Keefe	FMC Englewood Dialysis Center
Barbara Richilieu	Morris Home Dialysis
Daphne Scott	FMC Pinebrook
Kathy Searson	DCI North Brunswick
Fran Swire	FMC Englewood Dialysis Center

Two additional members were asked to participate: Robert Motacki, MS of DCI to represent the administrative view and Joyce Jarvis, MSW of Holy Name Hospital to represent the psychosocial view.

In early, November, the first Home Dialysis Designee educational day was held at Robert Wood Johnson University Hospital. The program agenda and presenters were as follows:

I. Purpose of the Program and description	Michele Inglese QI Coordinator, TARC
II. Designee Role and Responsibilities	
III. What is Peritoneal Dialysis	Diana O'Keefe, RN,CNN Fran Swire, RN, CNN Home Dialysis Coordinator, FMC Englewood Dialysis Center
IV. What are the benefits and disadvantages of PD	Elizabeth Kilker, RN, CNN Barbara Richelieu, BSN, MA, CNN Clinical Managers 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 and supported lunch.

The program was well received by the nurses in the audience. About 100 nurses attended the program. The nurses received continuing education units, provided via Robert Johnson University Hospital. The plan is to have a certification program and recertification program annually.

As this program was offered in November, TARC did not expect to see any change in numbers or percentage of patients receiving home dialysis in 2003. There may not be any significant change in 2004

as this is a new program and is only one part of successful plan. Only 9% of the dialysis population in network 3 was receiving home dialysis in 2003. The rate of home dialysis has been very steady.

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

TARC truly 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.

PATIENT PARTICIPATION GOAL

Patient Rights & Responsibilities/ Grievances

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

The Patient Rights & Responsibilities along with the 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 like the waiting room. In addition to paper copies, both are posted on the web in English and Spanish. Paper copies are distributed annually and on request. When a new facility is approved as an ESRD provider by CMS, a package of materials is sent. In this package are the copies of the Rights & Responsibilities and Grievance Procedures. Some facilities include TARC's rights as part of the patients' medical records.

CQI/ SAFETY GOAL

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.

The majority of facilities have distinct quality improvement meetings. All but 3 facilities in NJ and 1 in PR have multidisciplinary CQI meetings on a regular basis, meeting at least on a quarterly basis. All facilities indicated that the medical director participates in the CQI process.

On June 11, 2003, a safety meeting was held in San Juan, PR for the staff of the dialysis units in Puerto Rico and the US Virgin Islands. Dr. Jorge Weber was the key speaker. Approximately 80 people attended. The presentation included the current state of medical errors in the US, the systems needed to prevent errors, examples specific to dialysis and the culture of safety. Participants volunteered "misses and near misses" from their professional experience.

QUALITY IMPROVEMENT PROJECT/CLINICAL INDICATORS GOALS

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)

QIP Assessment and Reduction of Catheters in Hemodialysis QIP (ARCHQIP)

CMS offered 3 quality improvement project options to networks during the 2000-2003 period. All projects involved vascular access for hemodialysis. TARC selected catheter reduction as the improvement project and this project was initiated in 2002. TARC utilized the DOQI Guidelines recommendation that a facility's catheter population should not exceed 10%. The project contained 2 process indicators: actual referral for an alternate access and assessment of each catheter patient using a root-cause analysis. There were 3 outcome indicators: the total number of catheter patients in the hemodialysis population, the patients with catheters greater than 90 days and the patients inappropriately on catheters greater than 90 days. Twenty-six facilities were assigned to the intervention group and seventy-nine facilities were assigned to the non-intervention group. The 26 intervention facilities had the highest catheter rates in 2001. The intervention facilities received education by meetings, materials and toolkits. Data was collected from the control facilities at two specified times. Data was collected from the intervention facilities at four specified times. Due to various circumstances, the intervention group was reduced to 21 facilities.

The results were the intervention facilities had a statistically significant improvement in all three outcome indicators and the control group showed an increase in one outcome indicator. Both groups showed improvement in the assessment process indicator. Neither group showed improvement in the process indicator of actual referral to the surgeon for an alternate access.

QIP/ Fistula First Project

In 2003, CMS introduced a quality improvement project, called National Vascular Improvement Initiative (NVAII), to all networks. This 3-year project was based on the K/DOQI guidelines that indicated that 40% of the hemodialysis patients should have an arteriovenous fistula (AVF) and 50% of the new patients should have an AVF. The rationale for this project is hemodialysis patients with AVF have improved morbidity and mortality outcomes. This project was soon renamed the Fistula First Project. CMS approached this project in a slightly different manner. Some significant differences were: all networks

would have the same project, the Institute for Healthcare Improvement (IHI) was hired as a consultant and the large dialysis organizations would be active participants in some of the decision-making.

By making all networks participate in the same project with the same goals, this project then became a national project. In the 3 prior 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 selected increasing AVF rates and all networks gained from their experience during this project.

IHI was retained by CMS to help guide the networks and the national steering committee that was formed. One of the first activities of the steering committee included creating a charter.

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:

- *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).*
- *Several networks will meet or exceed the goal of 50% AVFs for incident patients by the end of the upcoming contractual period.*
- *Several networks will meet or exceed the goal of 40% AVFs for prevalent patients by the end of the upcoming contractual period.*
- *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.*
- *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.

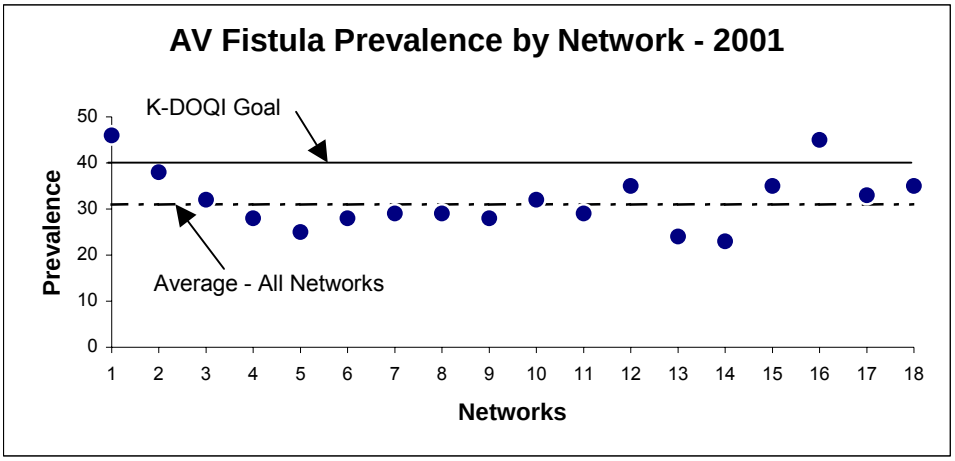
Among those responsible for the care of hemodialysis patients, there is agreement that the preferred type of vascular access is a native arterial venous fistula (AVF). Compared to catheters and arterial venous grafts, native AVFs show significantly lower rates of complication (such as infection and clotting),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

Patient Scenarios

To illustrate some of the ways in which patients receive suboptimal vascular access consider the following scenarios:

> ***Patient A:*** *A 55-year old African-American male was appropriately referred to a nephrologist when his primary care physician assessed his kidney disease as Stage 4 (20). The nephrologist was frank about the probable need for kidney dialysis, and recommended having an AVF placed in advance of the need for dialysis. The patient agreed to this plan. However, before the AVF could be placed, the patient's condition worsened unexpectedly, leading to hospitalization and immediate need for hemodialysis. The patient received a catheter, and was referred to a vascular surgeon for permanent access. In the interest of transitioning the patient from the catheter as quickly as possible, the surgeon recommended placing a graft, even though there was no doubt about the patient's suitability for an AVF.*

Patient B: *A 68-year-old diabetic Caucasian female was referred to a nephrologist and was informed that she would need dialysis in the near future. The nephrologist referred the patient to a vascular surgeon who recommended placing a graft because of doubts about whether her vasculature would support an AVF. No ultrasound or other venous mapping was performed. The nephrologist did not question the surgeon's recommendation, request mapping, or seek a second opinion. The patient received a graft.*

Patient C: *A 48-year old uninsured Hispanic male arrived in the emergency room of a large urban hospital. He was severely uremic and the medical team recognized that he must receive hemodialysis immediately. A catheter was placed, he was dialyzed, his condition stabilized, and he was released to outpatient dialysis care. No specific plans were made to establish permanent access.*

Patient D: *A 62 year-old diabetic Asian female received an AV forearm graft, which was initially successful. However, over a period of 18 months she experienced recurrent clotting problems requiring radiologic intervention and hospitalization. When her first forearm graft failed and could not be successfully revised, she was referred on an emergency basis to the surgeon who placed a second graft in the other arm. No one on her care team considered the possibility of placing an AVF in the upper arm nor did they prepare a specific access plan in anticipation of the eventual failure of her first graft.*

Barriers and Opportunities

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

1. *Inadequate care of pre-ESRD patients, making early placement and maturation of AVF impossible.*
2. *Lack of awareness among nephrologists and vascular surgeons about the current medical criteria for AVF.*
3. *Poor communication between nephrologists and vascular surgeons about nephrologists' specific expectations regarding vascular access.*
4. *Lack of training of vascular surgeons in placing AVFs successfully.*
5. *Financial incentives for surgeons that encourage catheter and graft placement and discourage AVF placement.*
6. *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:

7. *Multidisciplinary team approach ensuring coordination and consensus among the interested parties (nephrologists, surgeons, radiologists, dialysis nurses, and patients).*
8. *Establishment of policies emphasizing preferential placement of AVFs*
9. *Early referral of pre-ESRD patients to nephrology care, allowing for early evaluation and placement of AVFs when medically appropriate.*
10. *Patient counseling regarding the advantages of AVFs and specific procedures to protect the vasculature of the arm selected for AVF.*
11. *Good surgical judgment regarding location and technique used to place AVF and to make any needed revisions to ensure successful maturation.*
12. *Referral of vascular access procedures to surgeons with demonstrable interest, skill, and experience.*
13. *Routine preoperative mapping of the patient's arteries and veins.*
14. *Understanding and supporting the maturation period for an AVF.*
15. *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.*
16. *Timely intervention to correct any emerging problems that might endanger patient well-being or the patency of the access.*
17. *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:

1. *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 subcommittees were formed including tools and resources, data collection tool and reports, marketing and advertisement, etc. From the various committees, a standardized data collection tool was developed, standardized reports were developed, a vast amount of resource materials were/are available, an official logo was created, etc.

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

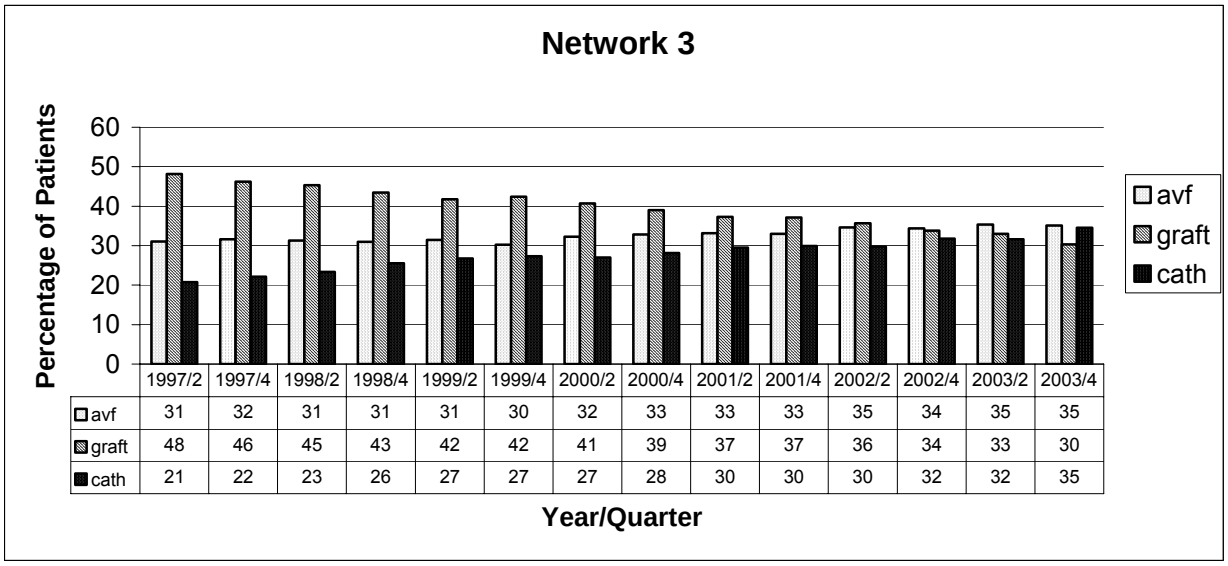
In keeping with the CMS vision of project collaboration the six large dialysis organizations were included in the planning phase. The 6 participating organizations are: DaVita, Dialysis Clinics Inc., Fresenius Medical Care, Gambro, National Nephrology Associates and Renal Care Group. One of the main intents was to make the data collection process more efficient by having the corporate offices provide data directly to the designated data-coordinating center. That data center is called eSource and is physically located in Network 6 in North Carolina.

All the aforementioned information was given to both the Medical Review Board and Board of Trustees members. From the boards, a steering committee was formed to determine a plan to introduce the project, prioritize the change concepts and implement a plan. The steering committee met in the summer of 2003. The committee determined that there were three areas that should be addressed simultaneously to start the project. The areas identified were: introducing the surgeons to the project and including them in the project, identifying proficient nurse cannulaters to train other staff at the unit level and education of the patient by all parties. The plan included initiating the educational sessions first in NJ and then PR/USVI.
The planned educational sessions for the physicians would be small regional sessions. At each session, one nephrologist and one vascular surgeon would present. The audience would consist of nephrologists and vascular surgeons. All presenters would be volunteers. The first regional physician meeting was held in Cherry Hill, NJ in December. The nephrologist presenter was Ron Zanger, MD, medical director

of Gambro Cherry Hill and chairman of TARC's MRB. The vascular surgeon was Yousef Ibrahim, MD, vascular surgeon form Our Lady of Lourdes Medical Center, Camden, NJ. Approximately 15 physicians attended. Each attendee received a toolkit with numerous articles, samples of tools, communications and patient education materials. The meeting was well received. Three future meetings were planned for other areas of NJ to occur in early 2004.

The planned educational sessions for nursing staff would be 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 module produced by Medisystems that could provide CEUs. Every facility received a copy of 2 videos for use in training in the unit. All facilities were to complete cannulation competencies on every staff member by early 2004. Two meetings were held in NJ in December. The first was held in Jersey Shore Medical Center and the second was held in Holy Name Hospital. Approximately 110 people attended the 2 meetings. The third, and final meeting in NJ, is planned for January at Shore Memorial Hospital.

TARC had collected vascular access data from facilities starting in 1997 as part of the Hemodialysis Improvement Project (HIP). Although the HIP was terminated in 2003, the vascular access data was provided using a different method. The LDOs provided vascular access data by facility to eSource and that data was then forwarded to the networks. Non-LDO facilities completed a new data collection tool and submitted that to TARC. The charts and graphs in the following sections utilize the HIP data as a source from 1997 through June 2003. The December data is from the Fistula First data.



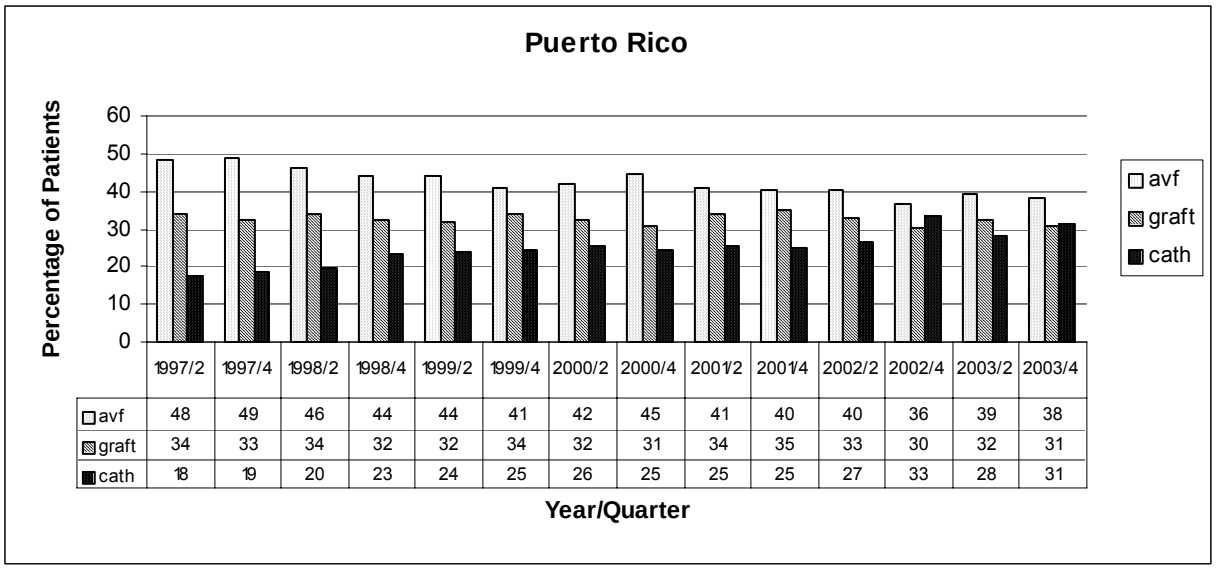
	1997/2	1997/4	1998/2	1998/4	1999/2	1999/4	2000/2	2000/4	2001/2	2001/4	2002/2	2002/4	2003/2	2003/4
avf	31	32	31	31	31	30	32	33	33	33	35	34	35	35
graft	48	46	45	43	42	42	41	39	37	37	36	34	33	30
cath	21	22	23	26	27	27	27	28	30	30	30	32	32	35

Fistula rates have slowly been increasing 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. That appears to be a reachable goal. Note the vascular data presented on these pages only reflect prevalent patients. Historically, the incident patients were not measured separately.

What cannot be omitted in looking at the above graph is the disappointing increase in catheters. Although AVF rates have increased slowly, the catheter rate has increased rapidly. So many authors have associated catheter rates with increased morbidity and mortality. Research indicates that catheter placement as a temporary measure increases morbidity and mortality. This pattern is not understandable

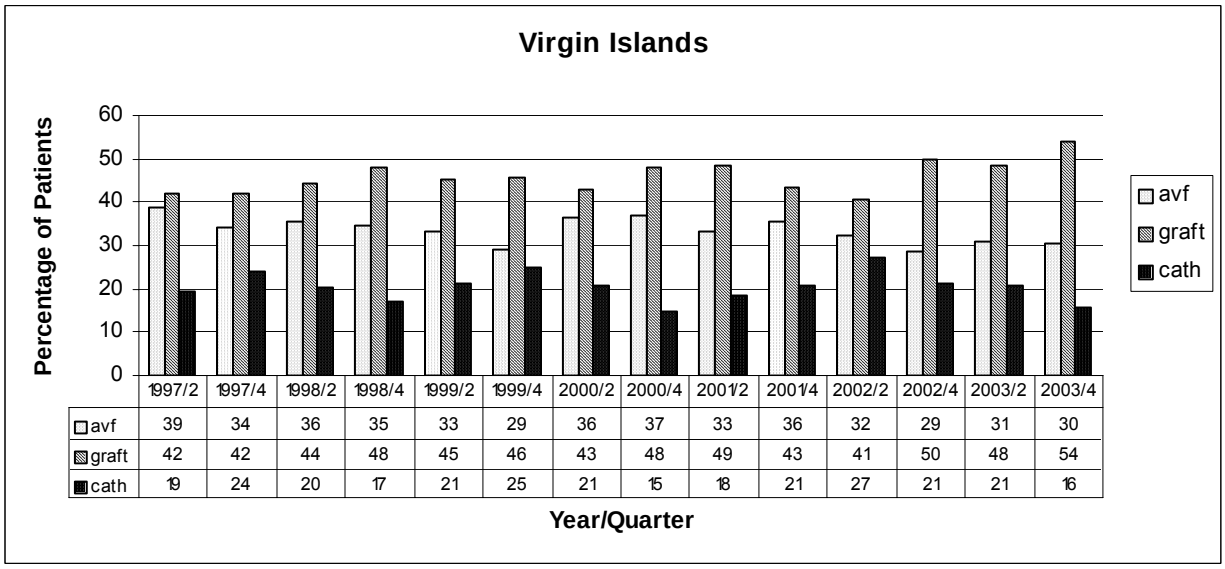
considering the amount of information available. In June 1997, the facilities reported 1,712 patients with catheters. In December 2003, there were 4,041 patients with catheters. The number of patients at risk more than doubled and over one third of the hemodialysis population are at risk related to catheters.

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, the declining trend in AVF is worrisome. The increasing trend in catheters is quite worrisome.



	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
avf	48	49	46	44	44	41	42	45	41	40	40	36	39	38
graft	34	33	34	32	32	34	32	31	34	35	33	30	32	31
cath	18	19	20	23	24	25	26	25	25	25	27	33	28	31

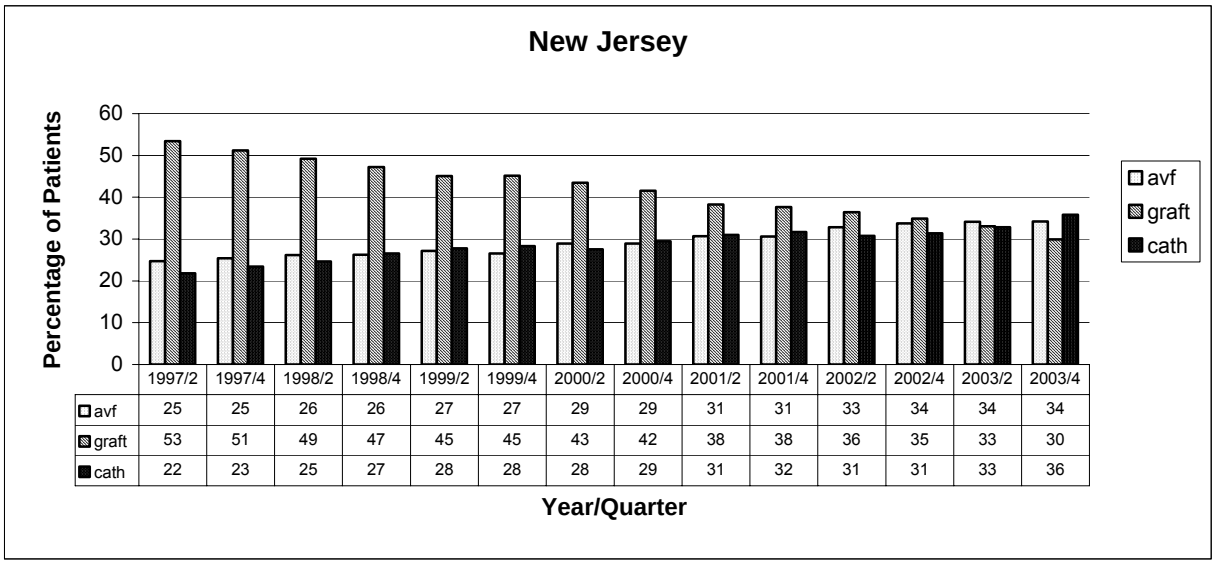
The trend in the Virgin Islands also shows a decrease in fistulae. However, the rate of catheters decreased over the last 4 quarters. Hopefully, that trend can continue. This information needs to be kept in perspective. The 4th quarter 2003 data represents less than 120 patients.



	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
avf	39	34	36	35	33	29	36	37	33	36	32	29	31	30
graft	42	42	44	48	45	46	43	48	49	43	41	50	48	54
cath	19	24	20	17	21	25	21	15	18	21	27	21	21	16

The main reason why there has been an increase in the overall rate of fistulae in network 3 is because NJ hemodialysis patients have had more functioning fistulae placed. The rate of fistulae increased from

24.7% in June, 1997 to 34.2% in December 2003. This is commendable. During the preparation for the Fistula First meetings, the distribution of AVFs in NJ indicated pockets of high fistulae rates in specific geographical areas. This needs to spread. The rate of catheters may decrease as more fistulae are placed. NJ has the same disappointing trend of increased catheter rates as Puerto Rico.



	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
avf	25	25	26	26	27	27	29	29	31	31	33	34	34	34
graft	53	51	49	47	45	45	43	42	38	38	36	35	33	30
cath	22	23	25	27	28	28	28	29	31	32	31	31	33	36

Clinical Indicators

TARC initiated the HIP in 1996. The HIP was based on the annual Core Indicator Project of CMS (formerly HCFA). The Core Indicator Project analyzed key clinical indicators as a surrogate for intermediate patient outcomes. The Core Indicator Project became the Clinical Performance Measures Project (see CPM section). The clinical indicators of the HIP were adequacy of dialysis as measured by urea reduction ratios (URRs), anemia as measured by hemoglobins (Hgb) 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, bloodflow 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 must cease. In its place, TARC would initiate participation in Elab. This project was initiated by Network 11 a few years earlier. Instead of individual facilities submitting data, laboratory results would be collected directly from the laboratories. Arrangements were made, agreements and releases signed and starting with data from the end of 2003, Elab was launched in network 2. Not all facilities use a major outside labs. Those facilities submit data via disc to TARC. Standard reports are issued. At this time, the reports are not ready.

The goal for adequacy of dialysis was 80% of the hemodialysis patients would have a URR of $\geq$ 65%. This goal was met and exceeded. The chart below represents data from the HIP. This is excellent for the hemodialysis patients of the network. The facilities should be commended for an outstanding job.

Percent of Hemodialysis Patients with URRs ≥ 65% in 2002 and 2003

Area	1st Qtr 02	2nd Qtr 02	3rd Qtr 02	4th Qtr 02	1st Qtr 03	2nd Qtr 03
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%**

Source HIP

The goal for anemia was 80% of the hemodialysis patients would have a hemoglobin of ≥ 11 Gm/dl. This goal was not 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 the culprit of the anemia and continue to strive for the goal.

Percent of HD Patients with Hemoglobin Values ≥ 11 Grams in 2002 and 2003

Area	1st Qtr 02	2nd Qtr 02	3rd Qtr 02	4th Qtr 02	1st Qtr 03	2nd Qtr 03
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%**

Source HIP

There are 2 specific goals related to vascular access. Although the goals are articulated, they are entwined in the Fistula First Project. The first vascular access goal states all facilities will have a vascular access program. As part of the Fistula First Project, monthly vascular access data is obtained. The types of accesses are documented and the percentages calculated. The main goal of the Fistula First project is to increase AVFs. Which parallels the network goal of promoting AVF. By increasing AVFs, the desired secondary gain is reduction of catheter use. The second specific goal related to vascular access is to encourage catheter use of < 25%. We have a long way to go to achieve that goal. This goal is quite generous. K/DOQI recommends no more than 10% of hemodialysis patients should have a catheter. The boards of TARC recognize that a group of patients exist in which catheter is the only option. However, the current rate of 34.5% is unacceptable. According to the CPM report, 46% of prevalent patients had their grafts monitored for stenosis. 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 final clinical indicator goal concerns nutrition. 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. Although the HIP did not separate the green from purple method results, the goal was met. As a network, 35.1% of the prevalent patients had an albumin of at least 4.0 Gm/dl. This pattern of higher rates of albumin in Puerto Rico patients has been consistently observed and is related to diet.

Nutritional Status: Percent of HD Patients with Albumin Values > 4.0 Gm/dL in 2002 and 2003

Area	1st Qtr 02	2nd Qtr 02	3rd Qtr 02	4th Qtr 02	1st Qtr 03	2nd Qtr 03
NJ	35.4%	36.6%	32.6%	34.2%	33.3%	32.7%
PR	45.2%	44.8%	42.1%	45.9%	45.1%	42.1%
USVI	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%**

Involuntary Patient Discharge Survey

Network 11 initiated, developed and coordinated an involuntary patient discharge survey. Twelve networks volunteered to participate, others declined to participate. Throughout the nation, networks had an increase in calls from patients and facilities concerning involuntary patient discharge. Some networks had been collecting and tracking data on this topic for some time prior to the survey. TARC did not experience large volumes of calls about this topic but did have a consistent few calls each year. TARC decided to participate in the survey to determine the scope of this issue in the network 3 area. TARC received the survey from the coordinating network and distributed the survey to the social workers in the facilities in December 2002. The vast majority of facilities in network 3 participated and returned the completed surveys in January 2003. Seven patients were discharged involuntarily in the network 3 region in 2002.

The survey asked for the number of patients discharged involuntarily, demographic data, time on dialysis, reason for the discharge, who performed the discharge, notice time and outcome. The survey was voluntary for the facilities. In March, the coordinating network presented the findings to all networks at the annual meeting in Baltimore. Included in the presentation was a handout with network-specific results. In network 3, the majority of patients were given a 30-day notice and the discharge was performed as a joint effort by the nephrologist, medical director and facility. The majority of patients were placed in other units. In all but 1 case, there was no sudden event that triggered the event. In almost all cases, the issue was behavioral such as threats, abuse or noncompliance. This was consistent with the cumulative findings of the 12 participating networks except that the discharge was generally performed by the facility or the facility plus director/nephrologist where in TARC, all 3 roles performed the discharge. In TARC, no facility identified payment as a reason for discharge but that was a reason in other networks. In TARC, 4 males and 3 females were discharged. The patients' ages were evenly distributed from 18-64 years old. The race and ethnicity in the TARC discharged patients were also evenly distributed. TARC had the lowest rate of involuntary discharge reported on this survey compared to the other networks that had completed surveys.

The Clinical Performance Measures Project

The 2003 ESRD Clinical Performance Measures project was the tenth year of such data collection in more than 2,000 dialysis programs nationwide. CMS characterized the project as a 'snap-shot' description of adult peritoneal and in-center hemodialysis patients. The effort focused on dose of delivered dialysis, anemia management, serum albumin values and vascular access. The samples included: 8,487 hemodialysis patients, 1,354 peritoneal dialysis patients, and 663 pediatric patients. The Veteran's Administration hospitals provided data on 100% of their population while all other facilities were subject to a scientifically selected sample number of study patients.

During the spring of 2003, the network office received project data collection forms and patient form labels. Network staff mailed 120 abstraction facility packages; 675 patients were involved. Instructions asked that clinical performance measures forms be submitted for only those in-center hemodialysis patients who received thrice-weekly treatment. For various reasons, 571 forms were completed. Included in the 571 forms were 96 forms from the VA hospitals.

Number of Network 3 Clinical Performance Measures Participants, 2003

	Dialysis Facilities	HD Patients	Pediatric Patients	PD Patients	Total Patient forms
New Jersey	90	369	13	30	412
Puerto Rico/VI	30	122	11	26	159
Network	120	491	24	56	571

Upon receipt in the network office, the 571 data abstraction forms were checked for accuracy and reasonableness of information provided. All forms were entered and completed records were transmitted electronically to CMS.

CMS selected a 5% peritoneal dialysis sample for network validation and the network selected a 5% hemodialysis validation sample. Facility staff sent documents from 28 selected records to the TARC office for review. TARC staff identified any discrepancies, input changes and transmitted those records to CMS.

The 2002 ESRD Clinical Performance Measures Project Annual Report was sent to 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 Medical Review Board discussed CMS's preliminary report and reviewed selected information with facilities at the annual Council meeting. For the country as a whole, eighty-nine percent of the sampled adult, in-center hemodialysis patients received a dose of dialysis equivalent to a delivered calculated, single session Kt/V ≥ 1.2. The percentage is unchanged from the previous year. In network 3, eighty-seven percent of the sampled population received a dose of dialysis equivalent to a delivered calculated, single session Kt/V ≥ 1.2.

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:

- Urea reduction ratios of at least 65% (or a Kt/V of 1.2);
- Serum albumin values of at least 4.0 gm/dl; and
- Hemoglobin values of 11 – 12 gm/dl.

Anemia data were also analyzed. In the United States 79% of adult in-center hemodialysis patients had mean hemoglobin values of ≥11 gm/dL; in network 3 that percentage was 79%. This was a 1 % increase for network 3 from the previous year. Iron management data indicated 80% of patients had a mean TSAT of ≥20% and 92% of patients had ferritins ≥ 100ng/mL. nationally. The patients in network 3 had 79% of patients had a mean TSAT of ≥20% and 90% of patients had ferritins ≥ 100ng/mL. These percentages are slightly lower than the national rates despite having a higher than national average administration of IV iron. Nationally, 64% of patients receive IV iron and in this network, 67% of patients received IV iron. This discrepancy is puzzling. The data were discussed with the Medical Review Board and Board of Trustees. .

Nutritional status, measured by albumin levels, of hemodialysis patients was again assessed. There are 2 commonly used methods of albumin measurement, bromcresol green (BCG) and bromcresol purple (BCP), which have slightly different results. The network data showed 33% of patients had an albumin of ≥ 3.7gm/dL by BCP or 4.0 gm/dL by BCG, which was unchanged from the previous year. The United States had 35% of patients with those albumin levels.

Initially vascular access data were included as a variable associated with adequacy of hemodialysis. As more information came to light, vascular access data became a distinct indicator. Questions regarding type and monitoring processes were added.

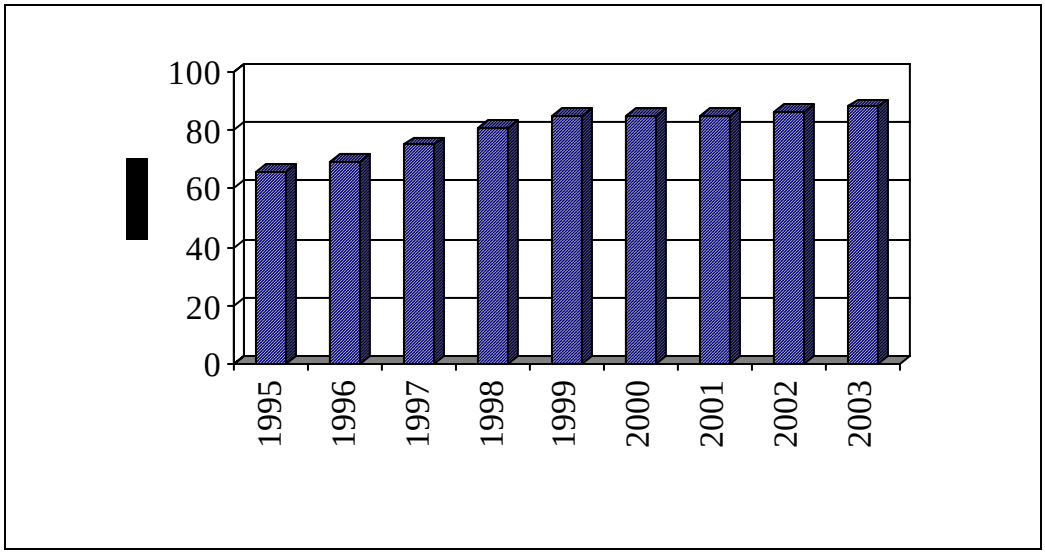
Vascular access CPM I states at least 50% of all new hemodialysis patients should have a primary arteriovenous fistula (AVF) as the primary access. It further states that 40% of all prevalent hemodialysis patients should have an AVF. According to the results of this project 36% of all hemodialysis patients in network 3 had an AVF, while, nationally, 33% of patients had AVFs. Both network 3 and the nation saw an increase in the percentage of patients with AVFs. The goal is achievable and may be too low. There were 3 networks that had over 40% fistula rate in prevalent patients, according to the report.

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).

During this year's project, clinical information was sought for October and December 2002 and January through April 2003 for hemoglobin levels, serum albumin, blood pressure and dose of delivered dialysis for peritoneal dialysis patients. Data were abstracted from 56 peritoneal dialysis patients medical records in network 3 facilities; nationwide, records for 1,354 adult peritoneal patients over the age of eighteen years were examined.

CMS found that dialysis adequacy measurements (weekly Kt/V urea or weekly creatinine clearance) were assessed at least once for approximately 88% of the sampled peritoneal patients. This compared to 86%, 85%, 85%, 85%, 81% and 75% during the previous six years. It must be noted that this finding did not demonstrate that adequacy was achieved in 88% of peritoneal patients, only that some measurement was taken to quantify the dose delivered. The findings were 71% of CAPD patients had a mean Kt/V of ≥ 2.0 and 66% of cycler patients with a daytime dwell had a mean weekly Kt/V of 2.1 while 67% of cycler patients without a daytime dwell had a mean weekly Kt/V of 2.2

Percent Of Adult Peritoneal Dialysis Patients Who Had Treatment Adequacy Measured, US, 1995-2003



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

Based on the DOQI guidelines, 71% of CAPD and 66% of CCPD patients had mean adequacy values that met the guidelines. This is an improvement from the previous year when 68% of CAPD patients met the goal, although there was a decline in the CCPD populations' adequacy of dialysis. (Network-specific peritoneal adequacy data are not available.)

National 2003 CPM results of PD Adequacy

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

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 ≥11gm/dL in the 2003 study period, which is 3% higher than the previous year. Sixty percent of PD patients had a mean serum albumin level of 3.5 gm/dL using the bromcresol green method or 3.2 gm/dL using the bromcresol purple method. Finally, 18% of the sampled patients had a mean serum albumin measurements 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.

All pediatric patients < 18 years identified as receiving in-center hemodialysis on December 31, 2002 were included in this project. The total number of included pediatric patients was 663. There were 24 pediatric patients from network 3 included in the data collection. The findings for the entire sample were 90% of patients had a mean delivered calculated, single session Kt/V ≥ 1.2. In anemia management, 60% of patients had a mean hemoglobin of ≥ 11 gm/dL. A disturbing finding was only 28% of patients had an arteriovenous fistula. Nutritionally speaking, the pediatric patients had a mean serum albumin ≥ 3.9/3.7 gm/dL (BCG/BCP).

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 MIs. 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 Dr. Charles Herzog 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, 16 patients were alive. The remaining 45 patients had expired before the data collection 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, like 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 USDRS will analyze the data and the findings will be published at a future date.

PROVISION OF TECHNICAL ASSISTANCE, EDUCATIONAL MATERIAL AND PROBLEM RESOLUTION

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. These requests are received by letters, faxes, phone calls, the website and emails. Below are some examples of how TARC assisted to assure that ESRD consumers received the care they needed and providers had necessary information:

- 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.

- 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 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 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 provided all the newly approved ESRD facilities with the reference/resource collection of materials that contain the important aspects of the ESRD program and CMS/network requirements.

- 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.

- January 8, 2003, TARC sent the 2003 Hemodialysis Improvement Project forms and instructions to all the facilities in New Jersey, Puerto Rico and the Virgin Islands.

- January 9, 2003, TARC provided Debbie Smith, CMS, with information about renal-related specialty groups for a proposed ESRD meeting.

- January 9, 2003, TARC sent supplies of the 2003 monthly caseloads and permanent change of name/address forms to all the facilities in New Jersey, Puerto Rico and the US Virgin Islands.

- January 10, 2003, TARC sent the 2002 Annual Facility Survey to their one hundred and forty one facilities.

- January 17, 2003, Network staff spoke with Stephanie Senior, Director, CMS in reference to the nursing contingency plan provided to the St. Croix Hospital's CEO in preparation for an anticipated nursing strike proposed to start on January 20, 2003.

- January 21, 2003, TARC provided the CEO of Juan Luis Hospital, St. Croix, with a list of the corporate offices for the six major corporate providers of dialysis.

- January 21, 2003, TARC staff attended Patient Services Coordinators conference call regarding non-conforming patient checklist/guidelines and interventions.

- January 28, 2003, TARC staff attended the New Jersey Renal Administrator Association meeting. The guest speaker was Debbie Smith, the ESRD Coordinator from the Region 2 CMS office.

- January 29, 2003, TARC held the second meeting of the Home Designee program. A core group of nurses focused on content development. The meeting was held at the Morris Home facility.

- February 3, 2003, TARC staff notified all dialysis facilities supplied by the Elizabeth Town Water Company, of the company's employee strike. TARC advised the facilities to check their water prior to each shift of patients and notify the water company, their medical director and TARC of any untoward results.

- February 5, 2003, TARC received a request for an impact letter from the Life Options Rehabilitation Program. A letter stating the numerous benefits of their program was sent to all dialysis facilities on February 10, 2003.

- February 5, 2003, TARC received a sample of K/DOQI Notebook Articles.

- February 7, 2003, a letter was sent to the Executive Director of the Medical Education Institute thanking them for providing the survey tool for vocational rehabilitation. Many facilities have expressed how beneficial the tool was in:1) identifying specific patient needs, 2)establishing goals and objectives to meet those needs and 3) benchmarking with previous years.

- February 10, 2003, TARC staff sent the article, *Why Patients With ESRD Do Not Select Self-Care Dialysis as a Treatment Option*, from the American Journal of Kidney Diseases, to all of the member on the Home Dialysis Designee program development task force.

- February 11, 2003, TARC sent a copy of, *Preparing for Emergencies: A guide for People on Dialysis,* to a question beneficiary stating his facility was unable to provide him with a copy. TARC called the facility in and provided them with additional copies.

- February 13, 2003, TARC notified all facility administrators of TARC's new email notification process.

- February 21, 2003, TARC staff attended the Core Data Set Task Group meeting in San Antonio, Texas. The meeting hosted by the FORUM was to perform a review of current data collection tools and methods in an effort to define a core data set and collection methods that shall both

meet CMS requirements and provide the networks with the tools needed to meet contract requirements.

- March 4, 2003, TARC's ED sent a second request to the New Jersey Office of Emergency Management for a list of local emergency management coordinators.

- March 14, 2003, TARC staff participated in a conference call with CMS and Puerto Rico's DOH to review the status of two facilities, BMA San Juan and Bayamon Renal Center. The meeting was a collaborative exchange of information to assist inspectors with future inspections.

- March 31, 2003, TARC scheduled their annual council meeting for Wednesday October 15, 2003 at the Sheraton Woodbridge Place Hotel, Iselin, New Jersey. End of life care will be the main focus of the meeting. Contracts are being reviewed.

- 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.

- April 3, 2003, TARC shared information with CMS in reference to the application of the transient rule for home peritoneal dialysis patients.

- April 4, 2003, TARC sent a PowerPoint vascular access presentation and vascular access toolkit to the Institute for Healthcare Improvement.

- April 7, 2003, TARC received notification from CMS of the potential hazard to peritoneal dialysis patients using Icodextrin for their peritoneal dialysis treatments. All of the facilities in New Jersey, Puerto Rico and the Virgin Islands that provide peritoneal dialysis services for network three were called and notified of this hazard. None of the network three facilities were using this product.

- April 8, 2003, TARC's ED sent all of the network's renal dialysis and transplant providers Doctor Jencks' letter of April 7th in reference to the release of data to ESRD Network Organizations.

- April 8, 2003, TARC sent dialysis facilities information regarding HIPAA.

- April 16, 2003, TARC sent information about Patient Safety and invited every dialysis facility and administrators to come and participate in the Patient Safety Meeting Educational program designed to focus the attention on safety issues in dialysis.

- April 17, 2003, TARC's ED attended the National Renal Administrators' meeting.

- April 24, 2003,TARC sent information to the dialysis unit professional staff and the form for the Nomination of a Patient for the Annual A. Ahmet Rehabilitation Award.

- April 28, 2003, TARC sent a flyer to dialysis facilities, administrators, and Medical Directors to SAVE THE DATE for the Trans-Atlantic Renal Council Annual Meeting and Educational Program on Wednesday, October 15, 2003

- April 30, 2003, TARC staff contacted the New Jersey Hospital Association upon notification of the active role the N.J.H.A. was taking in SARS recognition and prevention. The N.J.H.A. provided TARC with eight official publications ranging from triage guidance to exposure management. Also the NJHA agreed to send TARC current updates on the status of patients in New Jersey.

- May 1, 2003, TARC collaborated with the New Jersey Department of Health in the for the May 8th meeting.

- May 5, 2003, TARC participated in a call to the Puerto Rico Department of Health in reference to the upcoming meetings in Puerto Rico, i.e., TARC Safety meeting, DOH meeting. An overview of DOH visits to BMA San Juan and Bayamon Renal Center were discussed.

- May 5, 2003, TARC received a warning notification from the Baxter Corporation in reference to their product Extraneal, a peritoneal dialysis solution. TARC notified all of the facilities providing peritoneal dialysis in New Jersey, Puerto Rico and the Virgin Islands of the warning.

- May 6, 2003, TARC sent a compilation of the issues and concerns written by attendees at the TARC safety meetings to all of the network's facility medical directors and administrators, in an effort to increase awareness and prevent potential medical errors.

- May 8, 2003, TARC's ED and staff went to Trenton to meet with the NJDOH surveyors. Lines of communication and collaboration were redefined and a quarterly conference call schedule was established. TARC presented a purposed collaborative agreement for the DOH's review and comments.

- May 8, 2003, TARC sent three copies of the 2001 Annual Report and the 2003 hemodialysis and peritoneal dialysis CPM forms, as requested, to the New Jersey Department of Health.

- May, 8, 2003, the 2001 Annual Report for Clinical Performance Measures was sent to the New Jersey Department of Health along with a copy of the hemodialysis and peritoneal dialysis forms utilized for the study.

- May 15, 2003, TARC sent a memo reminding facility administrators about the Patient Safety Meeting in San Juan on Wednesday June 11, 2003 at the Ritz Carlton in Puerto Rico.

- May 15, 2003, TARC sent a notice to all facility administrator and Department of Health in Puerto Rico and the Virgin Islands informing them of the network Patient Safety meeting to be held on June 11th in San Juan.

- May 16, 2003, TARC's ED and staff participated in the ranking and submission of CORE DATA SET measurement indicators, and in the group activities and presentations at the Core Data Set meeting in Las Vegas on June 11 &12, 2003.

- May 22, 2003, TARC sent information to vendors regarding the Trans Atlantic Renal Council Annual Meeting and Education Program on October 15, 2003.

- June 5, 2003, TARC and the New Jersey Department of Health interacted in the scheduling of the quarterly conference calls.

- June 10, 2003, TARC staff sent information to New Jersey water companies asking them to contact us as well as the Administrator of the dialysis facilities in the event of any changes in the water composition due to a water main being flushed, addition or deletion of chemicals, or contamination of any kind that may affect the water supply.

- June 11, 2003, TARC, in accordance with federal priorities, developed patient safety presentations for their facilities. Toolkits and materials provided by the FORUM had been reviewed, consolidated and the content defined for a meeting in Puerto Rico. The patient safety meeting was held in the Ritz Carlton Hotel in San Juan. The content replicated the content of the

previous safety meetings held in New Jersey. Dr. Weber, the presenting physician, stressed the need for facilities to increase their awareness and promotion of patient safety. The meeting was well attended. The excellent evaluation scores were reflective of the need for this informative and timely program. Evaluation scores were determined using a 1 to 5 (5 being the highest) Likert scale with an averaging score of 4.56.

- June 17, 2003, TARC sent all of the network's medical directors the new algorithm for the determination of ESRD using data on the Medical Evidence Report/CMS form 2728. Included in this mailing was the provider education article, *National Participating Physician Directory*.

- June 17, 2003, TARC collaborated with CMS in the resolution of a discrepancy for the termination date of facility 31-2526.

- June 18, 2003, TARC discussed the NVAII during the Board of Trustees' conference call. The Board agreed the first step should be the formation of a multidisciplinary task group. Four Board members volunteered to serve on the task group.

- June 18, 2003, TARC staff participated in the Patient Services Coordinators conference call regarding complaints/grievances definitions discussion and committee planning for the march 2004 forum/cms meeting.

- June 26, 2003, TARC participated in a conference call with the Puerto Rico Department of Health. Puerto Rico currently has thirty-six facilities and fifteen C.O.N. applications have been approved with an estimated opening date of one year. The DOH anticipates another ten C.O.N. applications in the near future. Areas of concern in relation to the opening of many new facilities were discussed and TARC stated their recommendations.

- June 30, 2003, TARC sent the NVAII project's introductory mailing to the network's dialysis facility medical directors. The mailing included the Project Charter and an invitation for active participation by all interested physicians.

- July 3, 2003, TARC mailed the Dialysis Facility Compare (DFC) – 2003 Quality Measures Reports for each facility to their medical director, administrator and quality improvement nurse.

- July 7, 2003, in response to the KDOQI request for participants for the review of, *Clinical Practice Guidelines for Blood Pressure Management and the use of Antihypertensive Agents in Chronic Kidney Disease,* TARC submitted the names of their two candidates.

- July 15, 2003, TARC staff interacted with the New Jersey Department of Health to establish quarterly conference call dates.

- July 17, 2003, TARC provided assistance to colleagues in attaining an algorithm for evaluating vascular accesses.

- July 24, 2003, TARC staff attended the National Renal Administrators' meeting.

- July 24, 2003, TARC provided the demographic data, minus all patient identifying data, requested by the Puerto Rico Department of Health.

- August 5, 2003, the New York Regional Office sent TARC the URL for ESRD National Provider Listing. Upon reviewing the list for New Jersey, TARC found many errors in the data posted.

TARC contacted CMS and in response to their request TARC provided an in-depth listing of the data discrepancies.

- August 5, 2003, TARC sent a memorandum to all network dialysis/transplant facility administrator in reference to Medicare beneficiary terminations. The memo informed them of the criteria for termination and included an enclosure titled: *Termination of Medicare Coverage for Beneficiaries With End Stage Renal Disease Questions and Answers.*

- August 6, 2003, TARC conferred with the New Jersey Department of Health in reference to the change of the provider numbers for a hospital system that has just entered into a management contract and acquisition agreement with a corporate provider.

- August 27, 2003, TARC received notice Toros Kapoian, MD, FACP, a TARC Board of Trustees member and former Medical Review Board Chairman, had been chosen as the ESRD Forum representative on the NVAII National Leadership Group.

- September 4, 2003, TARC received notice: Life Options Wins Gold Award in 2003 National Health Information Awards Program.

- September 9, 2003, TARC staff participated in their quarterly conference call with the New Jersey Department of Health.

- September 18, 2003, TARC staff participated in the IHI *Setting the Context for Change and Spread* conference call, and the IHI *Framework, Leadership, and Set-up for Spread* on September 25, 2003, and

- September 29, 2003, TARC staff participated in the editing of the questions from the previous CDC surveys noted to be problematic in preparation for the 2003 CDC survey.

- September 29, 2003, TARC sent a request to all dialysis facility administrators for submission of all their facility's lab affiliations. This information shall be used to investigate the feasibility of electronic data collection.

- The network dialysis facilities were provided with historical data specific to each facility's anemia management and adequacy of dialysis outcomes. Based on historical performance, and upon the recommendation of the boards, the facilities not meeting TARC goals were asked to submit an improvement plan for these two areas of care. Network staff provided the facilities with the tools to assist in the development of the improvement plan.

- October 15, 2003, the network held their annual council meeting and educational program at the Sheraton Woodbridge Place Hotel, Iselin, New Jersey. The main theme of the meeting was, End of Life Care. Three notable speakers addressed the topic from different perspectives, end of life and palliative care for the ESRD patient, end of life ethical issues and legal issues in end of life care. All three speaks were well received based on the program evaluations. Doctors Weber and Kapoian presented network activities. An announcement was made identifying Doctor Kapoian, a current Board of Trustee member and former Medical Review Board Chairman, as the ESRD Forum representative on the National Vascular Access Improvement Initiative Leadership Group. The program also featured the presentation of the Ahmet B. Ahmet Rehabilitation Award to a very deserving young lady with ESRD who had overcome many barriers to become nurse and educator. Twelve facilities had poster presentation and eighteen vendors participated with displays. The American Nephrology Nurses Association and the Commission on Dietetic Registration granted approval of six contact hours for program attendees.

- November 6, 2003, TARC staff participated in a quarterly conference call with the Puerto Rico Department of Health. Agenda topics included: status on the moratorium on granting licensure for new dialysis facilities, revision of the Certificate of Need process, inpatient facilities with provider numbers but no chronic caseloads, facility updates and Virgin Islands update.

- November 11, 2003, TARC staff participated in the WebEx demonstration for the vascular access data entry tool.

- December 3, 2003, TARC provided clarification for ELAB in reference to facilities needing to use more than one laboratory for their blood work.

- December 3, 2003, TARC reported the preliminary data of the 2003 Hemodialysis CPM data (Appendix 8 from the 2003 CPM Annual Report) to their Medical Review Board.

- December 10, 2003, TARC reported the preliminary data of the 2003 Hemodialysis CPM data (Appendix 8 from the 2003 CPM Annual Report) to their Board of Trustees.

- December 15, 2003, TARC staff participated in the choice of the five most important questions from the National Surveillance of Dialysis-Associated Diseases, 2002.

- December 22, 2003, in response to the Centers for Medicare and Medicaid Services (CMS) July 1, 2003, change in the patient eligibility algorithm for the ESRD program recorded on the CMS 2728 form, TARC sent a memo to all nephrologists who submitted MERs with GFRs above the prescribed ranges, [GFR > 25 ml/min (adults) or >35 ml/min (pediatrics)]. Forty-five nephrologists received the memo which included a request for a written justification of the submission of an MER with values over the stipulated thresholds.

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;
- 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;
- Other materials such as journal articles and pertinent research information that renal providers may use in their quality improvement programs;
- Treatment options and new ESRD technologies available for consumers;
- State and regional vocational rehabilitation programs available in the network area.

During 2003, these materials were distributed by mailings 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. A sample list of materials distributed follows:

- Network 3 Goals 2003 – 2006;
- Medicare and You 2002 (Spanish and English)
- Your Medicare Rights and Protections (English)
- Your Medicare Benefits (Spanish)
- Medicare Coverage of Kidney Dialysis and Kidney Transplant Services (Spanish)
- Choosing a Medigap Policy
- Preparing for Emergencies

- Dialysis Facility Compare: Guide to Medicare Certified Dialysis Facilities
- Patient Grievance Procedures
- Patient Rights and Responsibilities
- CMS 2746 forms (Death Notices)
- Dialysis Facility Compare Reports
- Dialysis Facility Reports, which includes standardized mortality rates, hospitalization rates, etc.
- Flu posters and flyers
- Goals charts
- Release of Data to ESRD Network Organizations, April 7, 2003 letter from CMS
- The ESRD Regulatory Landscape, Robers, S., NNI, December 2002
- Aspirin, beta-blocker, and angiotensin-converting enzyme inhibitor therapy in patients with end-stage renal disease and an acute myocardial infarction, Berger, et al., Journal of American College of Cardiology
- Cardiac Troponin T and C-Reactive Protein for Predicting Prognosis, Coronary Atherosclerosis, and Cardiomyopathy in Patients Undergoing Long-term Hemodialysis, de Filippi, C., et al., JAMA
- The New PD DOQI Guidelines, John Burkart, ASN Renal Week, 2002
- Depression and its association with peritonitis in long-term peritoneal dialysis patients, Troidle, L., et al., AJKD, August, 2003
- Discrepancies between Adequacy Goals in Peritoneal Dialysis: Role of Gender, Castillo, A. et al., AJKD, December 2002
- Albumin at the Start of Peritoneal Dialysis Predicts the Development of Peritonitis, Wang, Q., et al., AJKD, March 2003
- Oral Nutritional Supplementation Increases Caloric and Protein Intake in Peritoneal Dialysis Patients, Boudville, N., et al., AJKD, March 2003
- Cardiovascular disease in pediatric chronic dialysis patients, Chavers, BM, et al., Kidney International, August, 2002
- Unexpectedly High Prevalence of Posttransplant Anemia in Pediatric and Young Adult Renal Transplant Recipients, Yorgin, P., et al., AJKD, December 2002
- The Patients and Staff who Try Our Patience, Sukolsky, A., NNI, May 2003
- Dealing with the Noncompliant Patient: 10 Steps to achieving compliance, Valdez, PhD. R, NNI, April 2003
- Is ‘an Ounce of Prevention’ the Key to Working With the Aggressive Dialysis Patient, Valdez PhD, R, iKidney, com
- Medical Outcomes Study Short Form 36: A Consistent and Powerful Predictor of Morbidity and Mortality in Dialysis Patients, Lowrie, E., et al., AJKD, June 2003
- Keeping Your Water System Safe, Curtis, J., NKF 2003 Clinical Meeting, April 2003
- Infection Control
- Guidelines for Environmental Infection Control in Health-Care Facilities, MMWR, June 6, 2003
- Investigation and Control of Vancomycin Intermediate and Resistant Staphylococcus aureus (VISA/VRSA), CDC, March 11, 2003
- Excellent outcome of Lamivudine treatment in patients with chronic renal failure and hepatitis B virus infection, Schmilovitz-Weiss H, et al., Journal of Clinical Gastroenterology, July 2003
- Pre-ESRD
- R.hu-Erythropoeitin (EPO) treatment of pre-ESRD patients slow the rate of progression of renal decline, Tapolyai, M., et al., BMC Nephrology, 2003

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 preformed. 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 simplify 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 hopeful 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. Overall, since the ultimate purpose of both the network and the Medicare-certified ESRD facilities operating within the network area, is to serve renal consumers, all renal-related educational materials eventually enhance patient care delivery.

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 need 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 to web sites with current medical information on anthrax.

How educational and technical assistance affected the ESRD population

TARC assisted the consumers in the facilitation of travel arrangements by providing the names, addresses, telephone numbers and names of key dialysis unit personnel in dialysis units for transient treatments.

TARC provides assistance to facility managers and medical directors in the recognition of unsafe practices through follow-up correspondence of patient safety issues from the patient safety meetings, and patient education materials.

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.

Vocational Rehabilitation

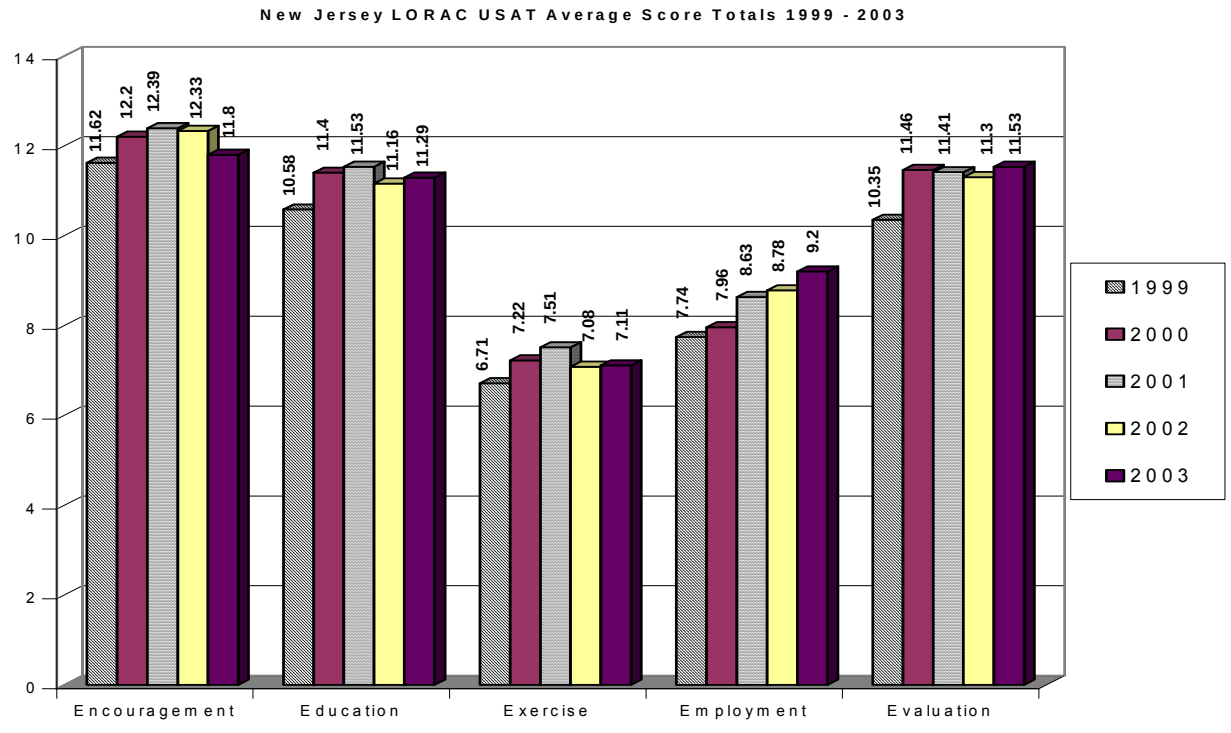
Even though kidney failure is not a curable disease, individuals can live very long and productive lives. Rehabilitating the patient with end-stage renal disease is admittedly difficult in certain situations. Improving outcomes of kidney disease usually requires that patients learn to manage their illness, 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.

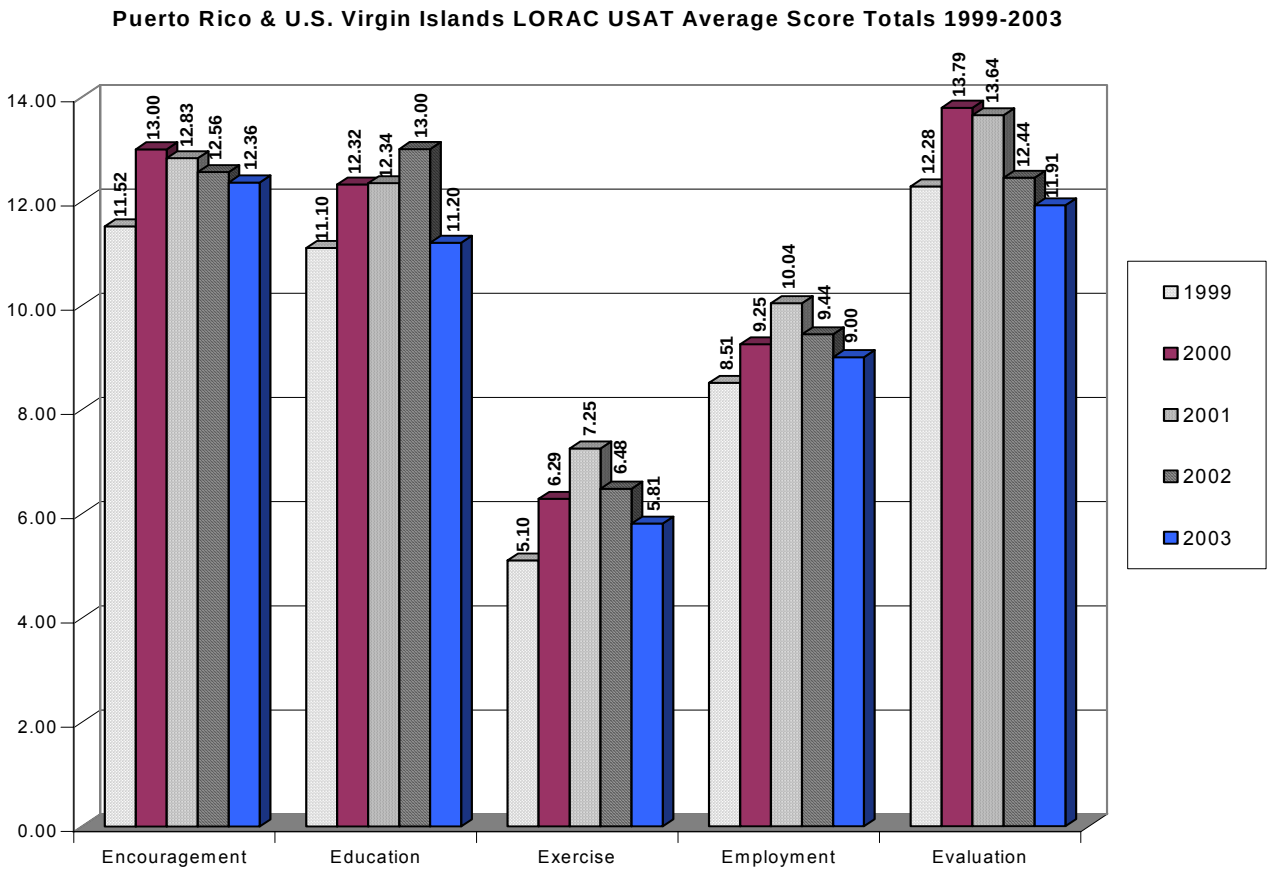
The concept of renal rehabilitation involves more than working to improve the clinical and functional status of dialysis patients. It is a comprehensive approach to care with the goal of helping patients resume productive activities and independent living (LORAC, 1997). As a way of measuring the progress 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" as well as listings of the vocational rehabilitation office in New Jersey, Puerto Rico and the US Virgin Islands were sent to each facility.

In the year 2003, even with the advent of several new dialysis facilities in New Jersey and Puerto Rico, there was a 94% response rate for the network facilities completion of the Unit Self-Assessment Tool (USAT). It is important for all facilities to remember that each year the USAT results build on the ones from the year before and contribute to establishing a continuous process of care with attention to improved outcomes for those with chronic kidney disease.

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 website (www.lifeoptions.org), which offers all Life Options print materials via the website 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.





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.

TARC encouraged 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.

Analysis of the vocational rehabilitation goal and its impact on the ESRD population

The following information is the analysis of the Facility Survey Addendum question which requested information about vocational rehabilitation related programs, the numbers of employed patients and the number of patients attending school. The dialysis units in New Jersey reported that 115 patients of the 18-54 age group in their dialysis caseload were referred to a vocational rehabilitation program. There were 990 New Jersey patients, age 18-54, employed (full or part time), and 92 patients, age 18-54, attended school (full or part time). In Puerto Rico, 115 patients of the 18-54 age group in their dialysis caseload were referred to a vocational rehabilitation program, and there were 216 patients, age 18-54, employed (full or part time), and 30 patients, age 18-54, attended school (full or part time). There were 15 patients in the U.S. Virgin Islands of the 18-54 age group referred to a vocational rehabilitation program, 15 patients age 18-54 employed (full or part time), and two patients, age 18-54, who attended school (full or part time).

One of the network's goal activities encouraged facilities to evaluate their treatment schedules as well as other facility policies that could be disincentives for working consumers or students. In the past, consumers at staff-assisted hemodialysis facilities had expressed problems with their dialysis schedules when they returned to work or school. Facilities reported that 51 of the New Jersey facilities, 23 of the Puerto Rico facilities and one of the facilities in the US Virgin Islands offered a staff assisted hemodialysis shift after 5:00 p.m.

The goal to emphasize rehabilitation and individualized care planning was achieved in 2002. Vocational rehabilitation is an ongoing process that continually needs encouragement to continue its development. There are still several areas that need improvement, and information along with expectations will be communicated to the dialysis facilities.

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: the SIMS software system used by network staff, the VISION software system used by facility staff, and the REMIS system, a web based application where data from many different sources, such as the Social Security Administration and CMS can be viewed.

In 2003, Network 3 conducted VISION training for 4 facilities in Puerto Rico. VISION training was also performed for 37 facilities in New Jersey, bringing the total number of facilities now using the VISION system to 53, the largest total of any network in the country.

During 2003, facilities in Puerto Rico and New Jersey submitted 1,366 CMS-2728 and 816 CMS-2746 forms electronically via the VISION system. Additionally, a total of 2,827 events (Patient Transfers, Recovered Function, etc) were reported through the VISION system.

Two new versions of the CROWN system were released in 2003. Network 3 participated in the beta testing of the November release, providing valuable feedback on both the SIMS and VISION software systems.

C. 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

CMS encourages the networks to establish and enhance partnerships with other health agencies and groups. During 2003, 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 2003. When the state investigation was completed the findings were shared with the network. The network had telephone conversations about ongoing concerns 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.

Network 3 staff shared the TARC annual report with organ procurement agencies (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.

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 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 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 representatives met with the New Jersey Renal Administrators Association.

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

The network met its responsibility in 2003 to partner with other governmental agencies and contractors to enhance the safe and therapeutic delivery of dialysis and renal transplantation.

D. 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.

2003 ESRD Patient Grievance

There were no formal grievances filed.

While there were no formal grievances filed during 2003, network staff addressed many concerns, issues, and complaints. A sample of interactions follows:

- TARC received a Beneficiary Complaint Review Category PR-QIO Referral Form stating the complainant's dialysis facility has water supply issues. When the water supply is low the facility shortens his treatment time from the prescribed four and one half hours to three hours. He states the facility is not providing full services but is charging Medicare for a full treatment. TARC, not serving as the oversight body for regulatory requirements, referred this to the Department of Health.

- TARC received a call from a beneficiary with questions about a change in his dialyzer. He stated he had not been notified prior to the change and was ill after his treatment as a result of the change. TARC reviewed the chain of events with the beneficiary and discovered neither the treating nephrologist or dialysis staff had been notified of these symptoms after the dialysis treatment. TARC called the facility and spoke with their leadership who stated all of the patients

had been notified of the prescribed change by letter and given the rationale of increasing their URRs as the reason for the change. A copy of this letter and a copy of the patient's treatment record were sent to TARC for review. TARC placed a follow up call to the beneficiary to inquire about his state of health and advised him to speak with his nephrologist and dialysis staff. TARC placed a follow up call to the dialysis facility to check both the beneficiary in question's status and the status of all their patients after this change. TARC was informed the facility sent a second copy to the change letter to all beneficiaries and changed the patient in question's dialyzer back the original prescription.

- TARC received an anonymous message on voice mail in reference to a patient being dialyzed at this provider. The caller said the patient was currently hospitalized (with the hospitals name provided) due to paralysis from a stroke caused by the poisons from a clotted hemodialysis access (graft). He stated the dialysis facility staff failed to recognize the problem, which had existed for the prior six weeks, and appropriate measures were not taken to prevent the current hospitalization. He stated the patient and her family needed help from this negligence. Due to the inpatient status of the patient, TARC notified their Project Officer and was advised to notify the QIO. The case was referred to the QIO.

- TARC received a complaint. The complaint stated numerous regulatory issues, i.e., lack of medication supply, inappropriate placement of pipe on floor of facility, water cooler placement. TARC spoke with the Department of Heath and sent them a copy of the complaint.

- TARC received a complaint forwarded by the NJ QIO. The letter was anonymously written and contained a variety of complaints targeting two nephrologists. The complaints ranged from treatment related to professional behavior. TARC staff made unannounced visits to both facilities. Patients were interviewed; charts, laboratory results, education records and staffing patterns were reviewed. Staff was observed during treatment turnover. Upon completion of the visit, TARC staff could find no evidence to substantiate the claims made in the letter.

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 2003, 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.

Medical Information System Goal

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

Activity: Each newly approved and existing facility will assure a system is established/maintained that assures knowledgeable facility data reporting personnel.
Activity: Ensure timely and accurate submission of 90% of forms generated.
Activity: Each facility will enable internal data processing systems that will support CQI activities, efficient electronic data transmission and the use by professional staff of internet resources.

Activity: TARC will provide periodic data processing instruction for facilities.
Each facility will track and report progress in various indicators via web site data entry.

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. There has been a steady improvement in reporting accuracy, network-wide.

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;
- Edit Reports from CMS;
- Federal REMIS on-line system.

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. Staff used a computer-based facility timeline system designed for this purpose. During 2003, 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.

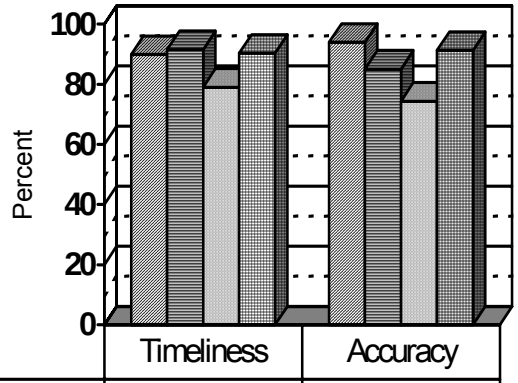
Data submission compliance reports were distributed to facility administrators with the expectation that they would positively recognize those employees who achieved the data reporting goal of submitting forms within thirty or forty-five days of events being reported. On the other hand, if the compliance 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. Trend data that showed persistent non-compliance identified specific facilities that were asked to prepare formal improvement plans.

Chronic Renal Disease Medical Evidence Report (CMS-2728):

There were 3,222 CMS-2728 forms submitted from New Jersey dialysis programs. Of these, 3,028 (94%) 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, 2,904 (90.1%) met CMS's timeliness criterion.

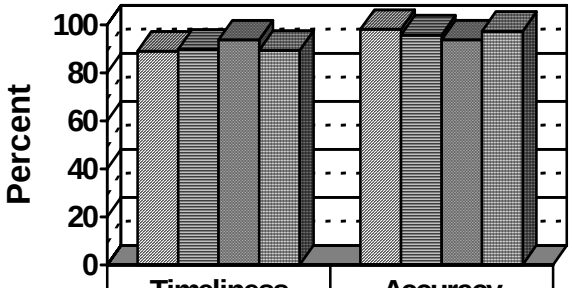
Facilities in Puerto Rico submitted 1,281 forms of which 1,173 (91.6%) were on time and 1,090 (85.1%) were completed accurately. 43 Medical Evidence Report forms were received in the network office from the US Virgin Islands, 34 (79.1%) were on time and 32 (74.4%) were completed accurately.

Percent of CMS-2728 Forms Received by Timeliness and Accuracy
CMS's Goal: 90% Compliance.



	Timeliness	Accuracy
NJ	90	94
PR	91.6	85.1
USVI	79.1	74.4
Network	90.4	91.3

Percent of CMS-2746 Forms Received by Timeliness and Accuracy
CMS's Goal: 90% Compliance



	Timeliness	Accuracy
NJ	89.1	98.2
PR	89.9	95.8
USVI	93.8	93.8
Network	89.4	97.4

ESRD Death Notification form (CMS-2746)

New Jersey dialysis units sent 2,385 death notification forms during the year, of which 2,126 (89.1%) were on time and 2,343 (98.2%) were accurate. New Jersey fell short of the timeliness requirement and exceeded the accuracy requirement. Puerto Rico's dialysis programs submitted 1,076 death forms of which 967 (89.9%) were on time, and 1,031 forms (95.8%) were accurately completed. Puerto Rico exceeded the goal for accuracy and has significantly improved in the timeliness requirement. The two Virgin Island facilities sent 32 death forms; 30 (93.8%) were received on time and 30 forms (93.8%) were accurately completed.

In 2003, the annual mailing included facility performance goal charts and the CMS requirements for ESRD forms compliance.

Reminders of what patients should be reported as "new" versus graft failures, transfers, and modality changes were included in the notice. The facilities were provided with the new change of name and address form that must be completed and sent with the monthly census report.

Patient Tracking System Reporting Goal

In addition to receiving, processing, and transmitting data reported on the federal medical information system forms the network maintained a patient tracking system 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.

To accomplish patient tracking, all facilities notified TARC of all patient status changes on a monthly basis. Any change in the dialysis caseload was 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.

4. SANCTION RECOMMENDATIONS

No facility sanction was recommended to CMS in 2003.

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 2003, no new dialysis facilities were recommended for New Jersey, Puerto Rico, or the US Virgin Islands.