

**Final Catheter Reduction Project Report**  
**ESRD Network 11**  
**March 31, 2003**

**Assessment and Reduction of Catheters in Hemodialysis**

Alicia Hare, Jan Deane, Diane Carlson, ESRD Network 11, St. Paul, MN, Bruce Lindgren, Biostatistics Consulting Lab, University of Minnesota, Minneapolis, MN.

**Abstract**

**Background**

K/DOQI Vascular Access Guideline # 30 states that less than 10% of patients on hemodialysis should use a catheter for chronic dialysis (i.e., longer than three months). The 2001 CPM Project showed that in Network 11, 19% of patients were dialyzed with a catheter for three months or longer. This indicates a significant opportunity to reduce catheter use.

**Goals**

The goal of this project is to use two interventions in an effort to decrease catheter rates and to create system change within Network 11 dialysis facilities that will be sustainable following the completion of the project. Improvement was measured based on the Reduction in Failure Rate (RFR) in the three-month to six-month catheter rates between the comparison group (Jan-June 2001) and the intervention group (Jan-June 2002).

**Methods**

The project sample included all adult patients beginning in-center hemodialysis during Jan-June 2002. All catheter patients were identified at incidence and assessed at three months for catheter status. Patients who were still dialyzing with a catheter as sole access were identified for intervention. The intervention consisted of a protocol and model algorithm, developed by the Network 11 Medical Review Committee. The patients were then assessed at six months for catheter status. Patients who died, transferred to peritoneal dialysis (PD), or underwent transplantation within the first 3 months of treatment were excluded.

**Results**

The three-month to six-month catheter rates decreased significantly ( $p=0.011$ ) from 52.7% in 2001 to 44.8% in 2002, and the RFR was 15%. The vascular access surgeon referral rates also improved significantly from 43.4% in 2001 to 51.3% in 2002 ( $p=0.01$ ), and the RFR was 15%. In addition, 44.4% of facilities stated that the model protocol was useful in overcoming barriers to referral and placement of permanent access, 34.4% of facilities stated that practice changed as a result of the project, and 31.3% of facilities established a vascular access management procedure as a result of the project.

**Conclusion**

Project objectives were met. Further work and analyses are planned.

## **Introduction and Objectives**

In 1997, the National Kidney Foundation published the Dialysis Outcome Quality Initiative (NKF-DOQI) Clinical Practice Guidelines for Vascular Access. These guidelines, now known as the Kidney Disease Outcomes Quality Initiative (K/DOQI), were updated in 2001. These guidelines recommend that less than 10% of chronic maintenance hemodialysis (HD) patients should be maintained on catheters as their permanent chronic dialysis access. In this context, chronic catheter access is defined as the use of a dialysis catheter for more than three months in the absence of a maturing permanent access.

Several sources were used by Network 11 to identify opportunities to reduce catheter rates. Data from the annual CDC National Surveillance of Dialysis Associated Diseases show that for the years 1998 – 2001, prevalent catheter rates in December of each year have remained relatively constant.

<u>Year</u>	<u>% of Network 11 patients dialyzing with a catheter</u>
1998	26%
1999	24%
2000	27%
2001	28%

The National CPM Project conducted annually by CMS also collects catheter information on prevalent patients, differentiated by catheter use and catheter use for greater than three months. The 4<sup>th</sup> quarter 2001 data showed that 27% of prevalent patients in Network 11 dialyzed with a catheter, and 19% of patients used a catheter for greater than three months.

The objective of this project is to reduce the percent of patients in Network 11 dialyzing with a catheter as sole access six months after initiation of dialysis by (1) improving the process by which patients are referred for permanent access placement during the first six months of dialysis, and (2) assisting the facilities to overcome barriers to timely placement of permanent access.

## **Methods**

There are three processes involved in the placement of permanent access for HD. They are assessment of catheter appropriateness, referral for access placement, and surgical placement of permanent access. Patients with appropriate catheters (e.g., pre-transplant, transfer to PD, death) were excluded from the project, and therefore, all three-month catheter patients were assessed as having an inappropriate catheter (dialysis using a catheter as sole access for three months or longer).

The following process measures were used to evaluate the effectiveness of those processes.

1. Numerator: Number of three-month catheter patients assessed with inappropriate catheters and continuing to dialyze with a catheter six months after the start of dialysis  
Denominator: Number of three-month catheter patients
2. Numerator: Number of three-month catheter patients referred to a surgeon for permanent access placement by six months after the start of dialysis  
Denominator: Number of three-month catheter patients
3. Numerator: Number of three-month catheter patients having a permanent access placed six months after the start of dialysis  
Denominator: Number of three-month catheter patients

For the purposes of this project, improvement is measured as the Network 11 six-month catheter rate as compared with the same measurement in vascular access data collections in 1999 and 2001. The outcome indicator is the percent of patients with an inappropriate catheter three months after starting dialysis (three month catheter patients) who continue to have an inappropriate catheter six months after starting dialysis (six month catheter patients). Because the appropriate catheter patients were excluded (explained previously) all remaining three-month catheter patients were presumed to have inappropriate catheters. Accordingly, the following outcome measure is the same as process measure #1.

Numerator: Number of three-month catheter patients continuing to dialyze with a catheter six months after the start of dialysis.

Denominator: Number of three-month catheter patients

**Note:** For the purposes of the study, patients who have transferred to PD, been transplanted, or died within the first three months of treatment are excluded from the project.

#### Data Collection

Data was collected on a patient-specific basis from the dialysis units from 1/1/2002 – 12/31/2002.

- Initial Data Collection Form (1/1/2002 – 6/30/2002): Upon identification of a new patient starting dialysis from the CMS Form 2728 received in the Network 11 office, the Initial Data Collection Form (attachment A) was FAXed to the dialysis unit for completion and return to the Network 11 office. There were 2,860 Initial Data Collection Forms completed and returned to the Network 11 office.
- Three-Month Follow-up Form (4/1/2002 – 9/30/2002): Dialysis facilities were asked to complete a Three-month Follow-up Form (attachment B) on all patients who were dialyzing with a catheter as sole access per the Initial Data Collection Form. Those 487 three-month patients identified as

dialyzing with a catheter as sole access were included in the intervention group (three-month catheter patients).

- Six-Month Follow-up Form (6/1/2002 – 12/31/2002): Dialysis facilities were asked to complete a Six-month Follow-up Form (attachment C) on those patients who had been dialyzing with a catheter as sole access per the Three-Month Data Collection Form (intervention group).

Figures 1 and 2 show the timeline of this data collection with related activities.

Figure 1 – 2002 Data Collection Process

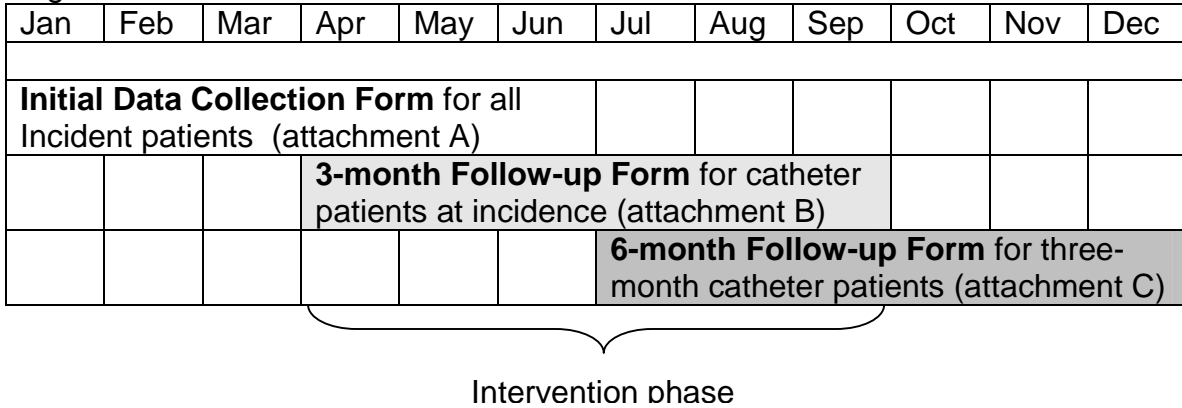
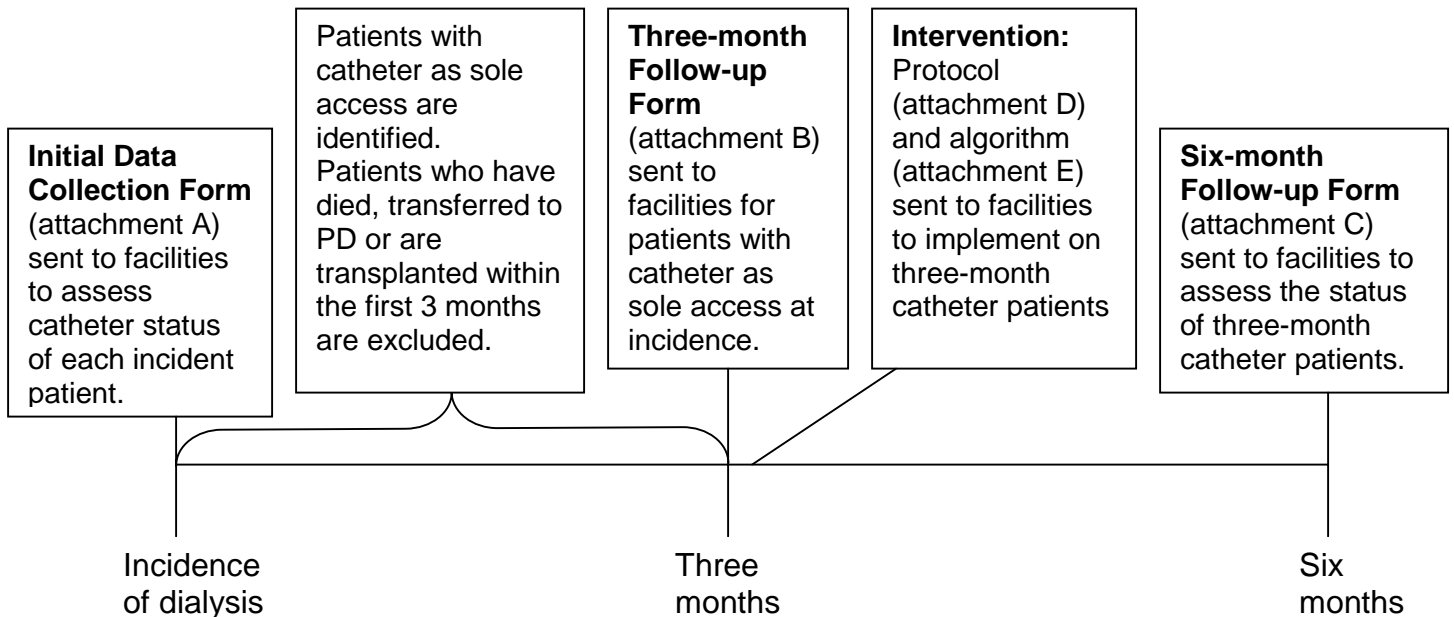


Figure 2 – 2002 Intervention Process



## Intervention

The intervention phase began when a patient was identified as having a catheter as sole access at the end of their first three months of dialysis. The Three-month Follow-up Form (attachment B) was used to collect this information. If this data collection showed that the patient was still using a catheter as sole access and had not been referred to a surgeon, that patient's facility was sent a copy of the Network 11 Medical Review Committee model protocol (attachment D) and algorithm (attachment E) for implementation. The model protocol and algorithm were developed to assist facilities to identify and overcome barriers for placement of permanent access. The Six-month Follow-up Form (attachment C) was sent to facilities to assess and identify the catheter status of those patients who were in the intervention group. It was also used to measure both the effectiveness of the intervention and the usefulness of the protocol and algorithm in changing practice patterns.

## Data Analysis

As the data was received, it was entered into an ACCESS database. The database was managed and analyzed using SAS v. 8 (SAS, Inc.) software to determine the statistical difference between the six-month catheter rate in the intervention group (2002) and the six-month catheter rate in the comparison group (2001). The overall statistical comparison was the Chi-square test of equal proportions among the three groups. Additionally, the intervention group was compared to the comparison group using a 2-sample test of proportions including Yate's continuity correction. A p-value of < 0.05 was considered statistically significant for the above tests. The Reduction in Failure Rate (RFR) was calculated to measure the percent of change that did occur, based on the amount of change from baseline that could have occurred.

## Results

### Primary Process Measures for 2002

1. The percent of three-month catheter patients who were still dialyzing with a catheter as sole access at six months.  
There were 487 three-month catheter patients. Of those patients, 218 (44.8%) continued to dialyze solely with a catheter at the six-month follow-up.
2. The percent of three-month catheter patients who were referred to a surgeon for permanent access placement by the six-month follow-up.  
250 of the 487 three-month catheter patients (51.3%) were referred to a surgeon between three and six months.

It is important to note that within these results are as many as 99 patients who were referred to a vascular access surgeon and were either awaiting surgical placement or had a permanent access created but it was not being used yet. These patients are a subset of #2 (above) and as they

have a permanent access placed and used, the number and percent of patients in #3 (below) will increase.

3. The percent of three-month catheter patients who were dialyzing with a permanent access at six months  
Of the 487 three-month catheter patients, 151 (31%) were dialyzing with a permanent access by six months.

#### Outcome Measure for 2002

The outcome measure for this project is the same as process measure #1, that is, the percent of three-month catheter patients still dialyzing with a catheter as sole access at six months.

Of the 487 patients dialyzing with a catheter as sole access at three months, 218 (44.8%) were still dialyzing with a catheter as sole access at six months.

#### Measurement of Improvement

Measurement of improvement was based on the Reduction in Failure Rate (RFR) between the remeasurement (2002) and the baseline (2001) data. A statistical analysis was also performed on the data from 2001 and 2002. When we planned this project, it was anticipated that there would be a second comparison group based on a similar data collection in 1999. Upon further analysis, we found that the 1999 project measured catheter rates at incidence of dialysis and six months after incidence, with no three-month collection. Therefore, change in three to six month catheter rates could not be compared for 1999, and so those fields are indicated as not available or N/A. Table 1 shows the changes and Reduction in Failure Rate (RFR) between 2002 and 2001 for the three process measures.

Table 1 – Process Measure Results

Process Measure	1999	2001	2002	RFR
1. Percent of three-month catheter patients who continued to have catheter as sole access at 6 months	N/A	52.7% (322/611)	44.8% (218/487)	15%
2. Percent of three-month catheter patients who were referred to a vascular access surgeon by six months	N/A	43.4% (265/611)	51.3% (250/487)	14%
3. Percent of three-month catheter patients with a permanent access in use at 6 months	N/A	32.4% (198/611)	31% (151/487)	(-2%)

Table 2 demonstrates the statistical comparison of the outcome measure between 2001 and 2002. This shows the statistically significant reduction in

three to six-month catheter rates that was demonstrated between 2001 and 2002.

Table 2 – Outcome Measure Results

Outcome Measure	2001	2002	p-value*
Percent of three-month catheter patients with catheter as sole access at 6 months following initiation	52.7% (322/611)	44.8% (218/487)	0.011

\*statistical significance = p-value < 0.05

The Reduction in Failure Rate (RFR) for the outcome indicator was calculated based on the three-month to six-month catheter rate for the 2001 (baseline) and 2002 (remeasurement) data collections. Prior to tabulating the results from 2001, it was known that there were 611 patients in the three-month catheter group for the 2001 data. It was anticipated that the six-month catheter rate would be at least 60%. A sample size calculation revealed that at least 500 patients would be required in the 2002 three-month data to identify a 10% reduction in catheter rate as a statistically significant improvement. If the six-month catheter rate in 2002 were reduced to 50%, it would result in a RFR of 17%, based on the following calculation.

$$(50\% - 60\%)/60\% = 17\% \text{ reduction}$$

Table 3 shows the actual results from the 2001 and 2002 data. There were slightly less than 500 three-month catheter patients in the 2002 sample.

Table 3 – Outcome Measure Results

	2001	2002	RFR
Percent of three-month catheter patients with catheter as sole access at six months	52.7% (322/611)	44.8% (218/487)	15%

The RFR was calculated as follows:

$$(44.8\% - 52.7\%)/52.7\% = 15\% \text{ reduction}$$

#### Intervention

Two interventions were used to create change.

1. Patient-specific follow-up data forms at three and six months were collected on each patient who was dialyzing with a catheter as sole access.
2. An algorithm and model protocol were sent to the facility following identification of patients dialyzing with a catheter as sole access three months after initiating dialysis. The facility was encouraged to implement the protocol for that specific patient.

These interventions were intended to assist the facility to identify those patients dialyzing with an inappropriate catheter (i.e., longer than three months) and to provide a process by which the patient can be moved to permanent access in a timely and efficient manner. As part of the data collection process, facilities were asked to identify why the patient was not referred for permanent access placement. Although there did not appear to be one root cause as to why a patient was not referred, the two top reasons were “medical condition contraindications” (12%) and “no referral plan” (12%). Both of these issues are addressed in the protocol so that periodic follow-up continues. It is interesting to note that “emergency start,” the explanation most often given for catheter presence was only identified as a root cause in six patients (0.4%).

As part of the process of evaluating the effectiveness of the interventions, it was important to identify whether or not the facility’s practice changed as a result of the interventions. Facilities were asked three additional questions on the six-month data collection form.

1. Did you find the protocol helpful?
2. Did you change practice as a result of the protocol?
3. Did you develop a procedure based on the protocol?

The data showed that 44.4% of facilities with patients in the three-month sample (71/160) said that the protocol was helpful in overcoming barriers to referral and placement of permanent access. When asked if practice had changed due to the use of the protocol, 34.4% (55/160) said that their facility had changed its practice. In addition, 31.3% (50/160) of facilities indicated that they had established a vascular access management procedure as a result of the project.

### **Conclusion**

The goal of this project was to reduce catheter rates, and this goal was met. The three-month to six-month catheter rates were statistically significantly reduced. The vascular access surgeon referral rate was also significantly improved. The results are clinically and statistically significant.

In planning for the calculation of the Reduction in Failure Rate (RFR), it was estimated that the number of 2002 three-month catheter patients would be approximately 600, but probably not less than 500. This was based on past data collections. An unexpected result of applying the intervention on a patient-specific basis was that many facilities received the model protocol several times, so that it was already in use as additional patients initiated dialysis. This created a Hawthorne effect that resulted in a lower than expected number of three-month catheter patients (487), which in turn may have affected the magnitude of the RFR. In spite of this, the actual RFR of 15% is remarkably close to the estimated RFR of 17%.

This project looked at vascular access placement in the incident patient population rather than the usual prevalent patient population. This was done for two reasons.

1. Provide an awareness of access issues before the patient “falls through the cracks” and remains on a catheter for an extended period of time.
2. Catch the patient during the early time frame, before they develop a “catheter bias” that would encourage them to refuse permanent access placement.

The interventions used in this quality improvement project were intended to achieve improvement in three areas.

1. Assist in timely referral for permanent access placement
2. Identify the barriers to placement of permanent access
3. Provide interventions to overcome the identified barriers

The data show that statistically significant improvement has been shown in timely referral for access placement. The data also show that almost half of facilities found the protocol helpful. Also, one-third of the facilities changed their practices and established vascular access management procedures as a result of this project.

It is anticipated that with collection of vascular access data in 2003 (CPM and CDC data sets), this reduction in incident catheter rates will translate into a small reduction in prevalent rates. More importantly, as practice is changed and patients continue to move towards permanent access in the early months of dialysis, the prevalent catheter rates will continue to decrease in future years.

The data show that statistically significant improvement has been shown in timely referral for access placement. The data also show that almost half of facilities found the protocol helpful. Also, one-third of the facilities changed their practices and established vascular access management procedures as a result of this project.

In the original QIP Narrative Project Plan, we proposed that two root causes for catheters in Network 11 might be inattention by staff and lack of a vascular access tracking system. Although the root causes identified by this project were unique to individual patients and facilities, it is interesting to note that, following interventions that called attention to catheter patients and provided a protocol for vascular access referral, statistically significant improvement was shown in both the increased percent of patients referred for permanent access placement and the decreased percent of six-month catheter patients.

An area for further study involves those facilities that appear to demonstrate best practices with regards to moving patients to permanent access in a timely and efficient manner. Of the facilities participating in the initial data collection, 13%

(36/276) had > 75% of new patients starting dialysis with a permanent access already in place. Further, of those facilities in the three-month data collection, 24% (55/231) had 100% of incident patients with permanent accesses placed. It will be important to communicate with these facilities to determine:

1. How and when are patients referred for permanent access in the pre-ESRD period?
2. What protocols and procedures do those facilities use for movement of patients towards permanent access placement after dialysis has been initiated?

Answers to these questions and dissemination of that information to other facilities in Network 11 will further improve the status of vascular access and further improve the quality of care received by hemodialysis patients in Network 11. Methods of spreading the improvement may include such things as Annual Meeting presentations by best practices facilities and regional workshops specifically addressing these issues.