A Randomized Evaluation of Two Health Care Quality Improvement Program (HCQIP) Interventions to Improve the Adequacy of Hemodialysis Care of ESRD Patients: Feedback Alone *versus* Intensive Intervention

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Abstract. End-stage renal disease (ESRD) Networks are quality improvement organizations that collect, analyze, and report information to clinicians and allied health providers about discrepancies between observed patterns of care of ESRD patients and what has been recommended by clinical practice guidelines. The Networks facilitate response to this information by assisting ESRD treatment centers to develop quality improvement programs to redress inadequate care. The authors evaluated this process of quality improvement by selecting 42 treatment centers in a single ESRD Network with the lowest facility-specific mean urea reduction ratio (URR). The treatment centers were randomly assigned to two intervention strategies: (*1*) feedback alone; (*2*) an intensive intervention that included feedback, workshops, distribution of educational materials and clinical practice guidelines, technical assistance with the development of quality improvement plans, and continued monitoring. The intensive intervention had greater improvement in the increased proportions of patients dialyzed with prescribed blood flow ($P = 0.02$) and documented review of prescription ($P = 0.01$). Furthermore, the mean center URR increased nearly 3% among intensive intervention centers (from 68.1 to 70.9) but only 0.09% among the feedback centers (68.2 to 69.1) ($P = 0.002$). Similarly, time on dialysis increased 7.5 min on average among patients in intervention centers but decreased 2 min for patients in comparison centers ($P = 0.03$). These results demonstrate that Network feedback, coupled with the intensive intervention, resulted in improvement in care that would otherwise not have occurred.

The adequacy of hemodialysis care in the United States has substantially improved during the last decade. This improvement has been documented by and is coincident with a quality improvement program called the Health Care Quality Improvement Program (HCQIP) conducted by the Centers for Medicare & Medicaid Services (CMS) end-stage renal disease (ESRD) Network system (1,2). The HCQIP has been an ongoing component of in the ESRD program since 1994 (2). HCQIP uses clinical practice guidelines to define processes of care associated with better patient outcomes. Networks annually survey a random sample of ESRD patients to collect, analyze, and report information about variations in these processes of care to ESRD treatment centers (3). The Networks then assist centers in conducting quality improvement interventions targeted at correcting less than optimal care (3).

Since the inception of the HCQIP, adequacy of hemodialysis, measured by the urea reduction ratio (URR), has been a quality improvement target (2,3). The URR is a proportionate measure of blood clearance during the dialysis treatment, and values of 65% and higher are associated with decreased mortality (4–7). URR have steadily improved since the inception of the HCQIP, and evaluations have found that these improvements are associated with quality improvement activities conducted by the Networks (8,9). However, in the absence of a controlled evaluation, there is continuing uncertainty as to the benefit of the ESRD HCQIP for improving URR (10). This report describes the results of one HCQIP intervention to

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improve URR conducted in treatment centers in a single ESRD Network. Limited resources restricted the number of treatment centers that could be included in this quality improvement activity, allowing us to base our evaluation on a random allocation of eligible centers to intensive intervention and feedback alone as quality improvement strategies.

Materials and Methods

The clinical setting for this activity was outpatient ESRD treatment centers in ESRD Network 6. The Network comprises all treatment centers serving three southeastern states, and it is the largest by prevalent patient population of the 18 geographically comprehensive networks, serving over 22,000 patients treated in 369 treatment centers at the time of the intervention. All centers actively dialyzing patients within the three-state region on January 1, 2001, were eligible for selection for the quality improvement intervention.

Resources limited the intervention to no more than 21 centers. Therefore, a sample of 42 centers was drawn and assigned randomly in equal numbers to either an intervention group or a comparison group to evaluate the quality improvement intervention. On the basis of this sample size, we estimated that the study had 90% power to detect a 7% difference and 80% power to detect as small as a 5% difference in improvement in the proportion of adequately dialyzed patients between the intervention and comparison groups.

Selection of Treatment Centers for Quality Improvement

The Network conducts an annual survey that collects detailed treatment data on a random sample of each center's patients (Dialysis Outcomes Data Collection). These data are used to monitor dialysis adequacy and treatment outcomes for all centers in the Network. Nursing staff use a standard form to provide data on 30 adult hemodialysis patients randomly selected by the Network staff or on all patients in centers with fewer than 30 patients.

Data are collected retrospectively from the most recent monthly dialysis session during which dialysis adequacy measures were obtained and include the predialysis and postdialysis blood urea nitrogen (BUN), delivered blood flow rate, delivered dialysate flow rate, dialysis access type, and delivered treatment time.

Data from the Dialysis Outcomes Data Collection survey conducted during January 2001 were used to calculate center-specific proportions of patients meeting a target URR of 65% or more. The 42 centers with the lowest proportion of patients meeting this target were selected for quality improvement intervention.

Random Allocation

A random number list was generated and used to assign the selected treatment centers to the intervention group or the comparison group. A separate Network staff member contacted each center and notified them of their selection. One of the eligible centers closed before the beginning of the project; therefore, a total of 41 centers were randomized; 21 centers were assigned to the intervention group, and 20 were assigned to the comparison group.

Intervention Activities

Centers in both the intensive intervention and feedback groups received center-specific quality of care feedback reports that summarized the findings from the January 2001 Dialysis Outcomes Data Collection. These reports provided comparative data that enabled center staff to compare dialysis adequacy among their patients relative to that among patients treated in other treatment centers within the Network.

The centers in the feedback group received no further intervention. In contrast, centers allocated to the intensive intervention group received a multifaceted intervention that, in addition to the treatment center-specific feedback reports, included educational workshops and materials, technical assistance from Network staff, and intensive monitoring of dialysis adequacy (11–13).

Educational Workshops

Educational workshops were held in two locations convenient to the intervention centers. Attendance was requested for the Medical Director, Center Administrator, and Director of Nursing, with attendance rates of 74%, 81%, and 95% for the three groups. During the workshops, participants were presented with an overview of the project followed by a review of potential barriers to providing adequate hemodialysis. Workshop participants were then shown how continuous quality improvement (CQI) methods could be used to identify interventions to overcome these barriers (14).

Educational Materials

Educational materials for both staff and their patients were distributed to participants following the workshops. The materials for center staff included information taken from the NKF-DOQI adequacy of hemodialysis guidelines as well as resources to assist facility staff in conducting a CQI project to improve hemodialysis adequacy (6–7). The materials for patients included videos, booklets, and brochures related to the NKF-DOQI Guidelines and the importance of receiving adequate dialysis.

Quarterly Monitoring

Each intervention center completed a dialysis adequacy survey quarterly on a random sample of patients and provided information about processes of care such as the dialysis prescription for each patient included in the survey. In addition, staff provided documentation of any physician and/or clinical staff review of URR values on a monthly basis. Network staff verified the data reported on the data collection form by abstracting medical records from 25% of the selected centers at baseline and from 45% of centers at remeasurement.

Center-specific information about adequacy of dialysis and dialysis prescriptions were tabulated for each intervention center and reviewed by the Network Medical Review Board (MRB). This board consists of physicians, allied health professionals, and patients who are elected by treatment center representatives in the Network and who serve on a voluntary, non-reimbursed basis. The MRB provided feedback to each center on a quarterly basis about progress toward attaining goals for adequacy of hemodialysis. The MRB also closely monitored the process of care measures including the proportion of patients whose dialysis time, dialyzer type, blood flow, and dialysate flow met the prescription. In some instances, designated members of the MRB provided phone consultation to treatment centers that were having difficulty demonstrating improvement in hemodialysis adequacy.

Technical Assistance

Participants from intervention centers were offered assistance by Network staff in developing a center-specific improvement plan based on the process and outcome indicators for their treatment center. Network staff identified a quality improvement coordinator within each intervention center and maintained phone contact with that person during the remainder of the intervention period.

Duration of Intervention

The centers were notified of their selection for the quality improvement project in April 2001. Baseline dialysis adequacy and process of care indicator data were collected at that time for the months of February 2001 to April 2001. The workshops were held in May 2001, and the intervention centers were asked to submit monthly data to the Network from May 2001 to January 2002. The remeasurement data were collected in May 2002 for the months of February 2002 to April 2002. Therefore, the total intervention period lasted 12 mo.

Statistical Analyses

All data analyses used center-specific values that were based on simple averages of data collected either on all patients in the center (patient demographic and clinical characteristics) or on random samples of dialysis patients within the center (dialysis adequacy and process measures). Because we used simple random selection to select patients for inclusion in the adequacy surveys and facility level data as our unit of analysis, no complex sample design or patient weighting scheme was required for the analyses.

The URR for each patient was calculated as the difference between the predialysis and postdialysis BUN divided by the predialysis BUN multiplied by 100. For each center, we calculated the proportion of patients whose URR was 65% or greater to serve as the primary center-specific measure of dialysis adequacy. We took the average of this value from three monthly dialysis adequacy surveys conducted from February 2001 to April 2001 as the baseline measure for adequacy. The corresponding value from adequacy surveys repeated after the intervention from February 2002 to April 2002 was used as the post-intervention measure for adequacy. The change from baseline in the proportion of patients with a URR of 65% or greater was calculated for each center as the difference between the post-intervention and baseline values. We compared the effect of intensive intervention to that of feedback alone on changes in processes and intermediate outcomes of care (mean URR, delivered time of dialysis, and blood flow rate) between the two groups. Because the differences among centers in the intervention and comparison groups were approximately normally distributed, the average differences were compared between groups using a *t* test. All significance testing was evaluated using a two-sided *P*-value of 0.05, and all analyses were performed with SAS Version 8 statistical software (SAS Institute, Inc., Cary, NC).

Results

There were 369 treatment centers in Network 6 on January 1, 2001. The distribution among these centers of the center-specific proportion of patients with a URR of 65% or greater is shown in Figure 1. Treatment centers selected for the intensive intervention and feedback alone are in the left-hand of the distribution in Figure 1. The average proportion of patients within treatment centers in Network 6 with a URR of 65% or greater was 87.1%, and 81% of the centers had 80% or more of their patients above this URR threshold. In contrast, the 42 centers selected for the intervention averaged 68.5% of patients with a URR of 65%.

The baseline characteristics of the selected centers are shown by group in Table 1. None of the average values for either the patient demographic and clinical characteristics or for the adequacy and dialysis process measures were significantly different between the two groups.

All 21 centers in the intensive intervention group participated in an educational workshop, were provided with educational materials, accepted Network assistance in the development of an improvement plan, and provided data quarterly for monitoring. The progress of the center-specific improvements was discussed at four quarterly meetings of the Network MRB, and phone consultation by the MRB Chair was provided to three intervention centers during the course of the project.

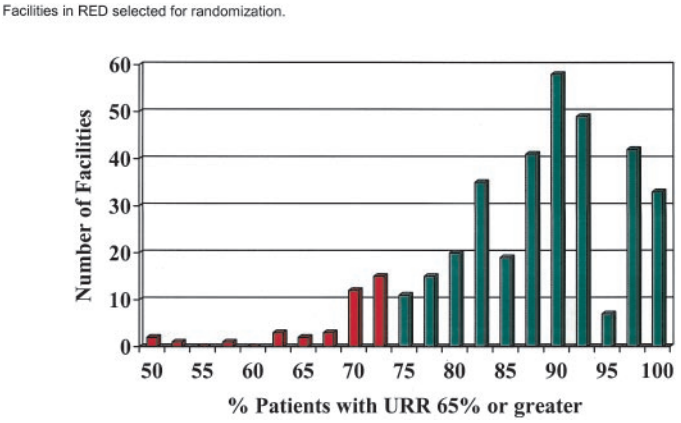

Figure 1. Distribution of treatment centers according to the proportion of patients with a urea reduction ration (URR) of 65% or greater, Network 6, January 2001.

Improvement in Documentation of Care

During the course of the study, the proportion of patients with medical record documentation of dialysis prescription review by a member of the healthcare team increased 30.9% in intensive intervention centers but declined 17.5% in feedback only centers ($P = 0.01$) (Table 2). In contrast, documented changes in the dialysis prescription among patients whose adequacy measures were suboptimal declined more than 8% during the study period for both intensive intervention and feedback alone centers.

Improvement in Intermediate Processes of Care Related to URR

The proportion of patients who underwent dialysis with the prescribed blood flow rate increased 12.9% from baseline to remeasurement among intensive intervention centers but decreased 4.1% in feedback alone centers ($P = 0.02$) (Table 2). Similar increases in the proportion of patients dialyzed for the prescribed treatment time were seen in both groups (Table 2).

The average time on dialysis for centers in the intensive intervention group increased more than 7 min, and the average treatment time for patients in feedback centers decreased 2 min ($P = 0.03$) (Table 3). In contrast, the mean blood flow for all dialyzes performed in the centers increased to a similar extent in both groups (Table 3).

Improvement in Adequacy of Dialysis

Over the course of the quality improvement project, the proportion of patients with a URR $\geq$ 65% increased about 10% in both the intensive intervention and feedback alone centers (*P*

Table 1. Distribution of baseline patient and treatment characteristics by intervention status in 41 ESRD Network 6 dialysis treatment centers enrolled in a hemodialysis adequacy quality improvement project, 2001–2002[a]

Characteristic	Intervention ($n = 21$)	Comparison ($n = 20$)	P
Mean number of patients	106.5	102.2	0.8
Mean patient age (yr)	58.6	59.1	0.6
Male (%)	53.1	52.3	0.7
White race (%)	29.9	30.5	0.9
Diabetic ESRD (%)	38.9	36.8	0.4
Myocardial infarction (%)	5.8	5.1	0.6
Congestive heart failure (%)	25.0	24.9	0.9
Angina (%)	18.8	17.7	0.7
Catheter for access (%)	25.3	30.2	0.3
Mean URR	68.1	68.2	0.9
Mean blood flow (cc/min)	398.7	384.4	0.2
Mean dialysis time (min)	211.4	215.0	0.5

[a] ESRD, end-stage renal disease; URR, urea reduction ratio.

Table 2. Average pre- and post-intervention values for the studied outcome and process measures by intervention status among 41 treatment centers in ESRD Network 6 enrolled in a hemodialysis adequacy quality improvement project, 2001–2002

Outcome/Process Measure	Intervention			Comparison		
	Pre	Post	Difference[a]	Pre	Post	Difference[a]
URR ≥65	75.0	85.4	10.3	70.7	80.4	9.6
Dialyzed prescribed time	61.4	69.3	7.9	60.1	70.3	9.0
Dialyzed with prescribed dialyzer	97.0	99.3	2.2	99.5	98.6	−1.0
Dialyzed at prescribed blood flow	47.6	60.4	12.9	58.2	54.2	−4.1[b]
Dialyzed at prescribed dialysate flow rate	87.6	89.7	2.1	94.3	92.7	−1.8
Review of adequacy documented in chart	36.0	66.9	30.9	44.4	25.4	−17.5[b]
Prescription change based on adequacy	29.0	20.4	−8.6	31.8	22.2	−8.4

[a] The average of each center's post-minus pre-intervention values.
[b] $P < 0.05$. Test of the hypothesis that the average pre minus post differences between intervention and comparison centers are not equal.

= 0.8) (Table 2). In contrast, the increase in mean URR of nearly 3% from baseline to remeasurement among intensive intervention centers was significantly greater than the 1% increase that occurred among feedback alone centers. (Table 3).

Discussion

This report demonstrates first that, despite continued improvement in the adequacy of hemodialysis provided to ESRD patients during the last decade, many treatment centers continue to provide less than adequate dialysis to substantial proportions of their patients. Second, our evaluation demonstrates that Network activities result in changes that would otherwise not occur in the documentation, prescription, and delivery of adequate hemodialysis in these treatment centers. Taken together, these results provide further support for a substantive role for Network HCQIP interventions in the improvement of ESRD care that has been observed since the inception of the program in 1994.

The CPM Project report is a summary of a national survey of the quality of care of randomly sampled ESRD patients from each Network, and it is the starting point for Network quality improvement activity (15). The first CPM report in 1994 found that 43% of all hemodialysis patients nationally and 32% of patients in Network 6 were adequately dialyzed (16). These inadequately dialyzed patients were not randomly distributed

Table 3. Average pre- and post-intervention values for the dialysis adequacy and process measures by intervention status among 41 treatment centers in ESRD Network 6 enrolled in a hemodialysis adequacy quality improvement project, 2001–2002

Outcome/Process Measure	Intervention			Comparison			P^b
	Pre	Post	Difference[a]	Pre	Post	Difference[a]	
Mean URR	68.1	70.9	2.85	68.2	69.1	0.96*	0.002
Mean blood flow (cc/min)	398.7	413.7	14.9	384.4	401.8	19.4	0.5
Mean treatment time (min)	211.4	218.8	7.4	215.1	213.3	−2.0	0.03

[a] The average of each center's post-minus pre-intervention values.
[b] Test of the hypothesis that the average pre minus post differences between intervention and comparison centers are not equal.

among treatment centers in the Network, and nearly 43% of the 213 treatment centers in ESRD Network 6 at the inception of the HCQIP in 1994 had a facility-specific mean URR less than 65% (17).

We have previously reported that an individual patient's URR, measured in the same manner as described in our current quality improvement intervention, was associated with subsequent risk of death; each 10% increase in URR was associated with a 17% reduction in risk of death (18). Furthermore, we used the same data to demonstrate that, after controlling for patient characteristics associated with increased risk of death and other facility organizational, technological, and management characteristics, a lower treatment center mean URR was independently associated with increased mortality (18). Thus, the selection of intervention centers was based on measures that have been previously shown to identify populations who are at higher risk of death.

Our ongoing evaluations of Network 6 quality improvement activities have shown that these center-to-center variations in URR were amenable to change (17). Furthermore, the 2001 CPM report found that nationally 86% of the hemodialysis patients were adequately dialyzed, while the corresponding rate for ESRD Network 6 was 85% of patients, a distinct improvement over the Network's baseline adequacy of dialysis relative to the rest of the nation (17,19). Thus, treatment centers with low mean URR and higher proportions of inadequately dialyzed patients are an appropriate group with which a Network should seek to help improve care.

There is some evidence that Network quality improvement interventions contributed to the improvement in hemodialysis adequacy within treatment centers and among Networks. For example, we have previously reported the effectiveness of HCQIP-based interventions in assisting treatment centers to improve adequacy of hemodialysis (17). The first HCQIP quality improvement intervention conducted by Network 6 during 1994 and 1995 targeted 22 centers with the highest proportion of patients with URR values less than 50% (17). These centers were selected for an intensive, targeted intervention similar in design to the current intervention and which included center-specific feedback reports, educational materials, a mandatory workshop, and monitoring until improvement was attained. After 1 yr, the mean URR in the intervention centers had increased an average of 7% compared with 1.4% in the remainder of the dialysis centers in the Network. The average reduction in the proportion of patients with a URR less than 65% in the intervention centers was 17.2% compared with 4.8% in the other centers. Comparable reductions in the proportion of patients with a mean URR less than 60% were 16.2% in intervention centers and 2.0% in comparison centers.

Facility-specific intervention increases the level of mean URR and reduces the variability of URR values among individual patients within centers undergoing intensive intervention (20). Fink *et al.* (20) examined the adequacy of care delivered patients in the treatment centers selected for the 1994 Network 6 intervention to patients in nonselected treatment centers. They compared the correlation of patient-specific URR within intervention centers to that of patients in nonintervention centers. The Network intervention reduced facility-to-facility patient differences in URR values, raising the mean URR within a center and changing the distribution of URR values within the facility toward that observed in nonintervention, better-performing facilities.

On the basis of this experience, ESRD Network 6 continued using the intensive intervention strategy for HCQIP quality improvement efforts. Despite this improvement in ESRD Network 6 hemodialysis adequacy, the Network's 2000 facility survey found that 11% of centers ($n = 42$) had 30% or more of patients who had failed to achieve a minimum URR of 65%. The large number of treatment centers in Network 6 with twice the national rate of inadequately dialyzed patients despite continuing Network efforts to improve dialysis adequacy provides the context for our current evaluation. We used our standard intensive intervention strategy as described previously (17) and compared the results with those within comparable treatment centers who were sent a facility-specific quality of care report. We noted greater improvements in documentation, processes of care associated with delivery of adequate dialysis, and the facility mean adequacy of dialysis in the intensive intervention centers than in those that received feedback alone.

There are many different factors that may have contributed to the failure of intervention centers to deliver an adequate hemodialysis dose, including inadequate blood flow, inadequate dialysate flow, shortened treatments, and insufficient prescription (21–25). The variety of factors that may influence the occurrence of inadequate dialysis for a particular patient underscores the necessity of an approach like that adopted for

the HCQIP. HCQIP begins by providing information about variations in quality of care to treatment centers as performance feedback reports (1). Physicians and allied healthcare providers are expected to use this information to help identify deficiencies in processes of care and to conduct quality improvement programs to redress these problems. The process of quality improvement is intended to allow the treatment center to identify and correct problems that are unique to the treatment center (1,14). Our results show that HCQIP, when coupled with assistance and supervision, results in greater quality of care improvements than might have occurred otherwise.

It is clear from our evaluation that feedback alone was associated with an increase in the proportion of patients receiving adequate dialysis, an increase in adequate dialysis similar to that seen among the intensive intervention centers. In the absence of a non-intervention group, however, we cannot conclude that the change was due to the HCQIP process. Our inclusion of the feedback group in our evaluation did, however, allow us to determine the impact of the intensive intervention on care, underscoring the need for appropriate comparison groups when conducting program evaluation. These intervention-specific improvements included increased proportions of patients dialyzed with prescribed blood flow and documented review of prescription. Furthermore, the mean center URR increased nearly 3% among intensive intervention centers (from 68.1 to 70.9) but only 0.09% among the feedback centers (68.2 to 69.1). Similarly, time on dialysis increased 7.5 min on average among patients in intervention centers but decreased 2 min for patients in comparison centers.

There are a number of limitations to our study that must be noted. First is the undoubted influence of non-Network factors that also promote the improvement of dialysis adequacy. Although we did not document the role of these factors, quality improvement activities conducted by national dialysis chains, CME programs, and journal articles on the importance of hemodialysis adequacy were prevalent during the intervention period. The effect of these external factors, however, is accounted for, in part, by the design of our evaluation.

Furthermore, our evaluation was not conducted at the onset of the Network's efforts to improve hemodialysis adequacy, but after a long period of quality improvement activities directed at reducing inadequate dialysis. The improvements we observed, however, were comparable to those noted in our earlier, non–randomly controlled evaluations (17); it is therefore unlikely that the intensive interventions is limited in effectiveness by prevailing levels of care in the population of treatment centers

Our intervention was most successful in increasing the difference in mean URR between intervention and comparison treatment centers. The survival benefit of URR diminishes above the threshold of 65%, and it should be noted that the comparable increases were observed in the proportion of adequately treated patients by this criterion in the intervention and comparison groups. We have previously shown in comparisons between intervention facilities with all other treatment centers that both mean URR and the proportion of adequately dialyzed patients are clinically and statistically significantly increased by this quality improvement intervention (9). Our current report now provides evidence that these improvements in adequacy of dialysis were, in part, a response to our quality improvement intervention that would not otherwise have occurred.

Our intervention was conducted in a single Network, and there is some concern that the intensive intervention might not be generalizable to other regions of the country. With respect to this, we have previously examined those characteristics of Network interventions that were associated with the greatest improvement in dialysis adequacy (9). The same factors that we incorporated into our intensive intervention were associated with improved dialysis adequacy when employed by other ESRD Networks.

In conclusion, we have shown that a HCQIP intervention conducted by a single ESRD Network resulted in greater improvement in dialysis adequacy than occurred in response to feedback alone. Our results provide further support for the role of Network directed HCQIP activities in monitoring and improving ESRD care. Clearly, further study is needed to clarify fully the role of the individual components of our intensive intervention in changes in care. In particular, the ESRD Networks should be encouraged at the beginning of any national QI activity to conduct appropriately designed and powered randomized evaluations of the intervention to develop the evidence that Network facilitated quality improvement activities such as we have described, conducted in a non-punitive manner, can result in improved patient care.

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