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Continuous Quality Improvement in Dialysis Units

The goal of outpatient hemodialysis is to deliver an adequate treatment asymptomatically, with a minimum expenditure of time, effort and money. Continuous quality improvement methods were applied to our outpatient dialysis units, which had previously performed case-oriented review. As a result of these efforts, we are now able to deliver an adequate dialysis, defined as a urea kinetic constant (Kt/V) of at least 1.0, 90% of the time and without significant symptoms 90% of the time, while using conventional cuprophane dialyzer membranes. We had previously been able to deliver an adequate dialysis only 67% of the time, without symptoms during 85% of treatments. Further improvements will require redesign of our treatment systems, but the effect of each change can be assessed compared to a well-defined baseline. Dialysis providers must develop this kind of quantitative analysis if they are to meet the demands of the public to document quality care.

Physicians often resist standard case-based methods of quality assurance, which has been termed quality by inspection, because almost every patient's care can be criticized retrospectively. Recently, many have advocated a different approach, termed quality assurance by design.[1] A central notion is that most quality problems are inherent in the design of systems of work. We believe that a quantitative systems approach to quality assurance is particularly useful in dialysis units, and we share our experience using this approach as we went about the business of caring for dialysis patients.

Our units are freestanding, nonprofit clinics located in rural west Tennessee. The average in-patient census during these studies was 100. The median age was 64 years; approximately 60% were men and 55% were white. Diabetes was the cause of end-stage renal disease in 30%, while the distribution for the remainder was typical of that reported in the United States.[2]

The goal of hemodialysis therapy is to deliver an adequate asymptomatic treatment, with the minimal expenditure of time, effort and money. We initially chose to focus on delivery of asymptomatic treatment, since we were able to define our goals with precision, and numerical analysis was simple. We then focused on delivering adequate therapy. This was a more complex goal, because adequate therapy is an interplay of the dialyzer, the treatment delivery system, the nurse, the vascular access and the patient. This is very much a work in progress, for we are continually reassessing elements of our system.

DELIVERING ASYMPTOMATIC DIALYSIS

This study concentrated on a single unit with an average of 18 patients and three nurses. All complications were tabulated for 1 month, and the five most common events were selected for monitoring (see *Table 1*). These symptoms developed as a result of efforts to reestablish dry weight. Since the staff might respond by avoiding symptoms at the expense of attaining dry weight, we also monitored the number of times each patient left the unit at above his or her estimated dry weight. Chosen parameters were followed with feedback to the staff, who then designed strategies to prevent complications in individual patients.

Intensive education resulted in improvement during the first two periods. In the third period, two new nurses began training, and the complication rate increased 5%. During the fourth interval, the new nurses gained experience, and the complication rate began to approach the baseline, but at the cost of letting patients go home above dry weight. In the fifth period, the head nurse went on maternity leave, and the nephrologist complained about the number of patients being seen in the emergency room with fluid overload, resulting in a prompt decline in the number of patients leaving above dry weight, but at the expense of an increase in complications. During the final period, the head nurse returned to work, the trainees moved on to their assigned unit, and the three experienced nurses began to attain their previous level of performance.

Patient compliance, the number with significant cardiovascular instability, and changes in the number or mix of patients in each period were not considered. Both compliance and cardiovascular stability

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have a major impact on a patient's response to dialysis, but the question is not how well the patient behaves, but how well we achieve our objectives. Complications will occur at some rate, no matter how deft the nurse, and this rate reflects the cumulative effect of the limitations of current methods of providing hemodialysis. As a result of these studies, we set a goal of a complication rate below 10% while reestablishing dry weight 99% of the time. Subsequent experience shows that these goals are attainable with our current low patient:staff ratio and our experienced cadre of nurses.

ADEQUACY OF DIALYSIS

Delivery of adequate dialysis depends upon the patient arriving for his scheduled treatment with a functional vascular access, having the nurse cannulate the vascular access properly, then operating the equipment using an effective dialyzer for the prescribed time to obtain the desired treatment. In recent years, discussions of adequate dialysis have focused on quantitative analysis of the kinetics of urea removal (Kt/V). Analysis of the only controlled trial of dialysis prescription, the National Cooperative Dialysis Study (NCDS), indicates that a prescribed Kt/V of less than 0.8 is inadequate.[3] Recently, Gotch and associates have suggested that a great deal of dialysis in the United States is inadequate judged by this standard.[4] On the other hand, the optimum amount of dialysis that should be delivered is unknown. Many assume that a delivered Kt/V of 1.0 is adequate, but some suggest that the goal should be a Kt/V of 1.2, 1.3 or even higher.[5]

We introduced kinetic modeling as a quality assurance monitor, rather than as a guide to individual prescription dialysis. Delivered Kt/V and protein catabolic rate (PCR) were measured using a three-point measurement method with a computer programmed with a single pool, variable volume model.[6] Because timing of the postdialysis blood sample is the most critical technical step, it was drawn after the patient's blood was rinsed back with normal saline and 3 minutes had elapsed with the line clamped. Thus, the samples were drawn from 10 to 15 minutes following dialysis completion. All values were pooled and analyzed for statistical significance.

All patients dialyzed using a Drake-Willock UF 480 with bicarbonate-buffered dialysate, and one of two conventional Cuprophan hollow-fiber dialyzers (Travenol CF 1211 or CF 1511). Blood-flow rate was 225 ml/min and dialysate flow was 600 ml/min. All treatments were performed by licensed nurses (RN or LPN) and patient:staff ratios were usually 3:1, and never more than 4:1. The median nurse had 5 years' experience. Dietary intake was estimated by history and diary methods, and midweek predialysis urea concentrations were monitored. Ninety percent were prescribed a 4-hour treatment. Patients with a predialysis hematocrit less than 30% received erythropoietin injections.

We made a clinical prediction of inadequate dialysis, defined as a Kt/V of less than 0.8, and then determined the delivered Kt/V. The results are shown in *Table II*. The traditional empiric measures of adequacy were reasonably specific (85%), but only modestly sensitive (43%) compared with kinetic modeling.

Table I: Delivering asymptomatic dialysis treatments.

	Control	Period 1	2	3	4	5	6
Number of dialysis treatments	172	196	328	328	707	415	596
Hypotension (%)	12.2	10.2	8.8	13.4	12.0	13.0	10.7
Fluid replacement (%)	18.6	11.2	10.1	18.5	14.6	16.8	13.0
Cramping (%)	5.2	4.1	3.0	6.7	3.3	2.8	2.2
Vomiting (%)	1.7	1.0	0.3	2.7	2.3	1.2	1.5
Left above dry weight (%)	1.2	1.0	0.3	0.6	1.6	0.7	0.5

Table II: Clinical prediction of dialysis adequacy.

		Predicted Adequate	Predicted Inadequate
Actual	Adequate	50	9
	Inadequate	17	13

Sensitivity 13/30=0.43
Specificity 50/59=0.85
The actual "inadequate dialysis" was defined as a Kt/V of less than 0.8. See text for further discussion.

We then began intensive staff inservice, with particular attention directed to accurate timing of the dialysis treatment. A second survey in September 1990 showed the mean dose of dialysis delivered had increased to 1.01, but that 19% of the patients still did not receive a minimally adequate dialysis on that day (see *Table III*). Blood-flow rates were then increased from 225 ml/min to 300 ml/min. The mean dose of dialysis increased to 1.05, and the number of inadequate treatments decreased to 10%. After 1 year of quarterly surveys, the mean dose of dialysis de-

Table III: Use of kinetic modeling as a quality assurance indicator.

	N	Mean Kt/V	Median Kt/V	S.D.	SEM	N<0.8 (%)
Study 1	89	0.90	0.86	0.21	0.02	30 (33.7%)
Study 2	95	1.01	1.02	0.25	0.03	18 (18.9%)
Study 3	96	1.00	0.97	0.23	0.02	18 (18.9%)
Study 4	104	1.05	1.04	0.24	0.02	10 (9.6%)
Study 5	84	1.25	1.23	0.21	0.02	0*

* 6 (7%) were less than or equal to 0.95

livered had increased to 1.24, no patient received less than 0.8, and only 7% had a Kt/V less than 1.0. Mean PCR is currently 1.11.

Our reprocessed dialyzers were tested in every patient at 6-month intervals for the past 5 years. When the dialyzer did not perform at 80% of the manufacturer's in vitro clearance value, reuse was limited. In no case was a dialyzer reused more than 12 times. The dialyzers were manually reprocessed with bleach and sterilized with 4% formaldehyde. Fiber bundle volume testing was measured every time. With this system, our average number of reuses has declined from eight to four. One of our units does not reuse dialyzers, and we cannot find any statistically significant differences in delivered Kt/V in this unit, compared with the others. We have concluded that reuse does not significantly reduce our delivered Kt/V.

Table IV: Thrombosis of vascular access (number per 100 patient-months).

	Total	Unit A	Unit B	Unit C	Unit D
1989	4.3	4.6	7.8	0.8	–
1990	6.0	2.7	17.0	3.0	3.9
1991*	6.0	4.6	12.0	4.0	4.4

* Data complete through 8/31/91.

ADEQUACY OF VASCULAR ACCESS

Increasing the blood-flow rate to 300 ml/min also increases recirculation, so the effect of this change on dialysis delivery is influenced significantly by the state of the patient's vascular access. Schwab, et al[7] suggested that the pressure in the venous limb of the dialysis circuit could be used as a marker of vascular stenosis, which could then be treated by angioplasty. We began routine fistula pressure monitoring studies in late 1989. As shown in *Table IV*, the monitoring program was associated with a slight increase in fistula thrombosis, 6.0 episodes per 100 patient-months. Subgroup analysis showed that one unit's rate of fistula thrombosis was much higher than the others both last year and this year. Analysis of water pH, content, and a review of technic and anticoagulation practice has not explained these findings.

Why has the rate of thrombosis apparently increased following more frequent fistulagrams and angioplasty procedures? One explanation may be that more thrombectomies are performed before the graft is abandoned. In previous years, the access surgeon decided whether to revise or abandon the graft. We now routinely do a postthrombectomy fistulagram when the cause of thrombosis is not readily apparent. Since lesions are often found that can be "improved" by angioplasty, we may persevere longer than previously in our attempt to salvage a graft. There are no quantitative data to indicate how many times salvage should be attempted. We are currently exploring with our surgeons

and radiologists ways to apply the methods of continuous quality improvement to improve our data base and hopefully achieve a goal of better vascular accesses that last longer.

COMMENTS

Several questions may be raised about the studies described here.

• *How do these results compare to those obtained by others?* Data on the morbidity of dialysis treatment are not reported regularly, but our ability to deliver asymptomatic dialysis 85% to 90% of the time appears to exceed that found by others.[8]

It was not our intention to prove or disprove the value of Kt/V as a measure of dialysis adequacy. Instead, we used the number as a measure of our success. As long as we use the same method, we can monitor our process and can demonstrate the effect of changes in other variables, such as the dialyzer reprocessing program, staffing ratios, etc. We had previously used a standard quality assurance program to monitor our units, and our baseline results, though disappointing, are similar to those found by the USRDS study.[9] Our mortality experience prior to instituting the program was also similar to that reported by the USRDS.[2] These studies do show, however, that calculation of Kt/V is superior to clinical impression in monitoring the quality of dialysis delivered.

• *What does it mean to physicians and nurses to measure quality this way?* Nurses must first be educated and trained in how to deliver safe, effective, asymptomatic dialysis. They must then be empowered by physicians to act on this information. We believe that a nurse, who spends 12 hours weekly with a patient, is in a much better position to adjust the treatment than is a physician. The nurse will know whether the patient feels well or ill, has abided by the fluid restrictions, and what problems have been encountered previously with the individual patient's dialysis. The physician's role is to set operational limits for the system and to attend to the patient's medical problems that are unrelated to dialysis.

The physician needs to understand the extent to which attaining the goal of asymptomatic, adequate dialysis is a function of the nurse's expertise, which, in turn, is a function of previous education, training and on-the-job experience. Dialysis patients are often sick, and at least 25% of them can be expected to die in any year. How are the nurse or physician to judge the effect of dialysis separately from the effects of other health problems? Here, the feedback provided by a quantitative approach to quality assessment becomes crucial. If you know you are delivering asymptomatic, adequate dialysis 90% of the time, and that this is the limit of your operational system, you can take pride in maintaining this standard of performance, even though the patient dies. At the same time, when you know how well you are achieving your desired goal, you are then free to experiment with changes to see if, in fact, you can do even better. Quantitative feedback then becomes an important factor in the empowerment process.

Throughout this paper, we have de-

scribed the processes we have used to try to improve the quality of our dialysis delivery systems. At this point, though, we wish to emphasize that the nurse is the single most important "dialysis delivery system." No method of quantitative quality improvement will yield results if it does not lead to improved skills on the part of the staff. We are therefore concerned about the trend to using more people with less formal training to deliver dialysis treatments. Not only is it difficult to educate and train these individuals to the point where they can exercise informed clinical nursing judgment, the dilution of trained persons markedly increases pressure on the remaining nurses. We believe successful implementation of quantitative quality assurance requires a commitment of the physician, administrators and head nurses to developing a sense of craftsmanship in the individual dialysis nurse. While we are using an industrial model of analysis, we remain convinced that there is no substitute for individual pride and judgment. Empowerment is a feedback loop, where those who demonstrate skills are given additional opportunities to grow and develop and to exercise judgment. Hence, empowerment should not be confused with either abandonment of responsibilities by those in charge or abdication of ultimate responsibility by the physician.

• *Can quantitative quality assurance help dialysis providers in dealing with the federal government?* We believe the answer is yes. We have shown that we can expect to deliver a Kt/V of 1.0 without symptoms 90% of the time using conventional membranes and a patient to staff ratio of 3:1. We can also show that we are not making a profit doing this. Thus, if studies prove that synthetic membranes or a higher Kt/V are associated with a significant survival benefit, we know that conversion will impact staff ratios. If we can show a negative impact of reduced staff ratios on symptoms and adequacy of delivered dialysis, our argument for an increase in reimbursement to cover the added cost of the dialyzer will be more persuasive. Perhaps more importantly, it provides a firmer base for analyzing the impact of further passive reductions in reimbursement that are created by inflationary pressures on wages and prices at a time when the screen has remained frozen.

Like the little boy who cried wolf, we have complained about reimbursement to the point where we are not heard. The question has been, and continues to be, "Where are the data?"[10] We need to know what can really be expected from dialysis using conventional membranes in "average" units. We need to know if using synthetic membranes is better, worse or about the same in terms of actual experience in average units. We need to know how many people, and of what skill mix, we must have to deliver optimum dialysis. Finally, as dialysis professionals, we must begin to develop solid data on the morbidity of our treatments in the frail individual suffering from multisystem diseases. Does the patient with diabetes and extensive vascular disease really benefit from being dialyzed? As part of the national debate on health-care costs, we

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must begin to deal with the utility of our treatments on a quantitative basis if we are to provide appropriate care of the highest quality at a reasonable price. We offer our results in the hopes that others will join us in the search.

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