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Effect of Linking Practice Data to Published Evidence

A Randomized Controlled Trial of Clinical Direct Reports

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OBJECTIVES. The purpose of this study was to evaluate the effect of clinical direct reports (practice data with pertinent evidence from the literature) on dialysis modality selection for patients with end-stage renal disease.

METHODS. A randomized controlled clinical trial was conducted at five dialysis centers. Five of the 10 physician participants were assigned through centralized computerized randomization to the intervention group (who received 12 center-specific clinical direct reports encouraging the consideration of peritoneal dialysis), and five were assigned to the control group, who received usual information but no similar report. One hundred fifty-two patients were eligible for monitoring.

RESULTS. The number of patients allocated to peritoneal dialysis was significantly higher in the intervention group than in the control group (15.3% versus 2.4%; $P = 0.044$). Due to a need for transient initial hemodialysis by some patients, the percentage of patients receiving peritoneal dialysis further increased through the end of the 3-month follow-up (18.0% versus 4.9%, $P = 0.041$).

CONCLUSIONS. There were no significant differences between the intervention and control groups in meeting patient preferences, metabolic status, and complication rates. The results of this study show that linking pertinent published evidence to actual practice data can support the implementation of practice recommendations and influence the selection of dialysis treatment for new patients.

Key words: randomized controlled clinical trial; computerized feedback; utilization; dialysis. (Med Care 1998;36:79–87)

The average annual per patient cost for the end-stage renal disease (ESRD) program is nine times higher than the per patient cost for Medicare as a whole. The ESRD program is the only federally funded program under Medicare to cover people of all ages on the basis of their diagnosis and 93% of all patients with ESRD qualify. When the ESRD program was created in 1972, it was estimated that enrollment would level off at 90,000. Currently, enrollment is up to 165,000 with no end in sight.[1] With a view to reducing Medicare costs, much attention has been given to comparing the cost-effectiveness of the various treatments for ESRD. Although transplantation generally is accepted as the most cost effective and medically preferable treatment choice for most patients, transplants have been limited to approximately 10,000 per year due to the lack of available organs.[2,3]

Several studies have shown that continuous ambulatory peritoneal dialysis (CAPD) is more cost-effective than hemodialysis for many patients.[3–5] The mortality rate is high among ESRD patients treated with dialysis.[6] There is controversy regarding whether the mortality rate is affected by modality choice. There also is a diversity in opinions regarding modality selection. However, at the time of this trial there was a consensus that peritoneal dialysis rates needed to be improved in Missouri.

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A valuable resource for monitoring ESRD trends was created when the United States Renal Data System was established in May 1988 to collect and analyze information about ESRD in the United States. The United States Renal Data System Annual Report contains data on the incidence and prevalence of treated ESRD, treatment modalities, and outcomes on morbidity and mortality report.[7] Similar databases have been established by some states (eg, Michigan[8] and Missouri[9]) and in Europe (European Dialysis and Transplant Association Registry).[10] The informational impact of these databases on physician practice patterns, however, has never been studied adequately.

Recommendations for health care quality improvement are scrutinized increasingly on the basis of controlled clinical evidence. Correspondingly, the Columbia Registry of Medical Management Trials was established to support practitioners and researchers with the best available evidence on the practical value of interventions changing the delivery of health services.[11–15] The registry uses the following eligibility criteria to select trials for inclusion: (1) prospective, concurrently controlled trial with a random assignment of intervention; (2) a utilization or information management intervention in the study group without similar assistance in the control group; (3) evaluation of the intervention measures change in the process and/or outcome of care. The registration process includes extensive searches, checking of eligibility criteria by two reviewers, assignment of key words for retrieval, and entry into a bibliographic database. The registered reports are collected through database searches, manual searches, and informal contacts. Currently, the Registry contains approximately 1400 reports on randomized controlled clinical trials in the area of health services research and the number of registered trials is continuously increasing. The Columbia Registry contains reports from approximately 380 journals. Some journals appear more frequently in the registry than other journals (Table 1). The number of randomized controlled trials published in 1995 compared with the number published in 1985 has quadrupled.

Based on the trials of the Columbia Registry, interventions influencing clinical practices can be classified into three delivery categories: computerized, information service, and process management interventions. In terms of the actual content of information intervention, the following three categories have been analyzed extensively: (i) reminder messages, apparently powerful interventions, recommend specific clinical actions to physicians at the time of decision making (eg, health maintenance prompt, alert for an urgent action); (ii) education, a frequently applied but not particularly effective method of disseminating clinical practice recommendations; and (iii) feedback, report on past activities to influence future decisions, a much needed bridge between reminders and education but the results with currently used peer-comparison (profiling) approaches are dismal.[16] Despite these unsuccessful attempts with

TABLE 1. Randomized Clinical Studies of Organizational Interventions

Category (Top Five Sources)	Number of Trials
Computer Systems	228
Med Care, 21; Proc Annu Symp Comput Appl Med Care, 21; JAMA, 10; J Gen Intern Med, 8; Arch Intern Med, 7; Diabetes Care, 7	
Information Services	593
Med Care, 28; BMJ, 25; Am J Public Health, 24; Ann Intern Med, 16; JAMA, 15	
Process Management	516
N Engl J Med, 25; BMJ, 23; J Am Geriatr Soc, 23; JAMA, 20; Med Care, 20	
Total	1337
Med Care, 69; BMJ, 53; Am J Public Health, 45; JAMA, 45; N Engl J Med, 38	

profiling, there is an obvious need for effective on-the-job performance improvement and a better way to link actual clinical activities to evidence from the literature.

The purpose of this study was to examine the effects of clinical direct reports, augmented with pertinent scientific evidence, on dialysis modality selection. The hypothesis was that clinical direct reports (practice data and pertinent evidence from the literature) would influence the number of patients allocated to the peritoneal dialysis modality (CAPD/continuous cyclical peritoneal dialysis [CCPD]) versus hemodialysis.

Methods

Five dialysis centers participated in this randomized controlled clinical trial. All centers provided both hemodialysis and peritoneal dialysis outpatient services. Some centers also provided inpatient care, but acute care dialysis inpatients were not included in the study. The following centers participated in the study:

Quality Care Dialysis Center, an investor-owned, freestanding dialysis clinic in Bridgeton;

Quality Care Dialysis Center North County, an investor-owned, freestanding dialysis clinic in Florissant;

Missouri Delta Medical Center, a tax-exempt hospital-based center in Sikeston;

Jewish Hospital of St. Louis, a tax-exempt hospital-based center; and

The University of Kansas Medical Center, a tax-exempt, university-based hospital center in Kansas City, Kansas.

Sample

All physicians caring for patients at the study centers were asked to participate. Many centers use a team approach to make treatment decisions and, therefore, the number of physicians was limited to those who make the ultimate decision as to treatment modality. Of those participating physicians, half were assigned through centralized computerized randomization to the intervention group (who received the monthly database report) and half were assigned to the control group (who received no report). A stratified randomization method was applied to ensure that physicians of each center had an equal chance to be assigned to either group. A pretrial power calculation targeted the detection of 10% difference in treatment allocation assuming 70% power and 0.05 type I error.

Patients meeting specific inclusion criteria were eligible for monitoring the effect of intervention in the study. The inclusion criteria were: (a) treatment by one of the participating physicians, (b) chronic renal failure, (c) new dialysis patient, and (d) older than 17 years of age. A patient was considered new on dialysis if he or she had not been dialyzed for at least 1 month prior to entering the study (eg, renal function deteriorated recently, waited for a transplant, had a failed transplant, or was dialyzed previously and restored to normal renal function but now required chronic dialysis).

Intervention

Twelve monthly clinical direct reports were generated from existing data, such as the Missouri Kidney Program database and the United States Renal Data System annual reports (Appendix A). The clinical direct reports combine center specific information or practice patterns with the latest published evidence on the efficacy and cost of various dialysis modalities. The reports contained, in various months, information in the form of quotes and tables covering the following areas:

- A center-based comparison for each trial center in the study compared with other centers throughout Missouri;
- Current survival rates for patients, nationally and in Missouri, by treatment modality;
- Current age, gender, and race distributions for all patients, nationally and in Missouri, by treatment modality;
- Opportunities for cost saving, as illustrated through current studies in the literature;
- Quality of life comparisons for patients on hemodialysis versus peritoneal dialysis;
- Complication and hospitalization rates for patients in Missouri by treatment modality; and
- Information gathered from the trial database pertaining to the physician's patient population.

Reports were mailed to the intervention group with an explanatory cover letter and a stamped, self-addressed postcard to be sent back upon re-

ceipt of the report. The control group received no similar information.

Variables

The following variables were used to describe the participating physicians: average age, gender, average number of years in practice, specialty (board certification), and the average number of hemodialysis and peritoneal dialysis patients during the year preceding the study.

As patients began dialysis, their baseline data were encoded on the baseline data form. The baseline data form included demographic data and information on the medical condition of the patient prior to dialysis. At the end of 3 months, the follow-up form, which recorded the patient's health status and any treatment changes or complications that occurred in the 3-month period, was completed.

Data Collection

During the 15-month trial period, background data on all new patients of the participating physicians were gathered by nurses trained as trial assistants from each center. The trial assistants were trained in the proper procedures for completing all forms. Trial assistants did not know which physicians received the intervention and, therefore, all monitoring of patients was independent and masked to the intervention. The physicians were masked to the cumulative results of the trial.

A computer program, with checks for range and consistency, was used to store and analyze all data. All answers were given a code number and entered into a spreadsheet program using the appropriate code. In addition, periodic telephone conferences were held to discuss potential problems and to help ensure completeness and accuracy of the data. All patients were assigned an identification number as they entered the study. All logs were filled out in ink and any changes or corrections were crossed out but still readable. The confidentiality of the patient and physician identifiers was protected fully and the identifiers were discarded as the data for this study were obtained.

Analysis

Pretreatment characteristics of study patients were analyzed by using the baseline patient data form. Averages were calculated for age and health status. Percentages were analyzed for the number of patients employed prior to treatment, number in hemodialysis, number in peritoneal dialysis, number previously dialyzed, and number previously transplanted. The total number of patients within a given primary diagnosis and patients with other comorbidity also was calculated. The effects of the intervention were evaluated by calculating the percentage of patients within a given treatment modality, hemodialysis or peritoneal dialysis, at the end of the trial period for both the control and intervention groups.

The secondary effects were analyzed by calculating the percentage of patients who changed treatment during the monitoring period due to patient preference, inadequate renal function, exit site infection, or peritonitis. The number of complications was calculated as the percentage of those patients with an exit site infection, peritonitis, vascular access site infection, or thrombosis. The ending health status was expressed as averages of the blood urea nitrogen and hematocrit (HCT) values for all patients.

For statistical comparison of the physician sample, the two-sample Student's t test was used. In the comparison of baseline characteristics and in testing the hypothesis that clinical direct reports influence peritoneal dialysis use, the two-sided Fisher exact test was used.

Results

The total number of new dialysis patients eligible for monitoring was 152 (17 from Quality Care Dialysis Center, 23 from Missouri Delta Medical Center, 41 from Jewish Hospital of St. Louis, and 35 from Quality Care Dialysis Center North County, and 36 from University of Kansas Medical Center). There were no significant differences between the patients in the intervention and the control groups on any of the baseline variables (Table 2). However, if acute dialysis was counted as being previously dialyzed, then there was a significant difference ($P = 0.003$) between four intervention patients (3.6%) and 8 control patients (19.5%).

The majority of the patients in the trial had a primary diagnosis of either diabetes with renal manifestations (36.8%) or hypertensive renal disease (36.8%). Other primary diagnoses of patients in the trial included chronic membranous glomerulonephritis, polycystic kidney disease, unspeci-

TABLE 2. Baseline Characteristics of Patients

Characteristics	Patients Groups		
	Intervention	Control	*P*
Average age	59.0 (19.4)	61.9 (15.4)	NS
Gender (M/F)	56/55	21/20	NS
Number employed prior to treatment	29 (26.1%)	9 (22.0%)	NS
Number previously dialyzed	4 (3.6%)	4 (9.8%)	NS
Number previously transplanted	2 (1.8%)	1 (2.4%)	NS
Primary diagnosis			
Diabetes with renal manifestations	39 (35.1%)	17 (41.4%)	NS
Hypertensive renal disease	41 (37.0%)	15 (36.6%)	
Other	31 (27.9%)	9 (22.0%)	
Health status			
BUN	63.8 (33.5)	67.9 (28.2)	NS
HCT	26.8 (8.8)	29.9 (4.2)	0.005

NS, not significant; BUN, blood urea nitrogen; HCT, hematocrit.

fied nephritis or nephropathy, obstructive nephropathy, interstitial nephritis, focal glomerulosclerosis, nephrotic syndrome with membranoproliferative glomerulonephritis, and unspecified renal failure. In the study, 90.1% of the intervention patients and 85.4% of the control patients had at least one disease of the circulatory system. Congestive heart failure (30.3%) and hypertension (73.7%) were the two most prevalent diseases of the circulatory system. There was no significant difference between the intervention and control groups for these diseases. There also was no significant difference between the intervention and the control group for pneumonia or arthritis.

The analysis of baseline physician data, including age, gender, average years in practice, board certification, and the ratio of patients on peritoneal dialysis, showed no significant differences between control and intervention groups. There were five physicians in the intervention group and five physicians in the control group. One control group physician dropped out of the trial at 6 months. One intervention physician dropped out of the trial at 8 months. The average number of new hemodialysis patients was 23 and the average number of new CAPD/CCPD patients annually was four at the centers prior to the intervention.

TABLE 3. Treatment Allocation

	Patient Groups		
	Intervention	Control	*P*
Treatment allocation (start)			
Hemodialysis	94 (84.7%)	40 (97.6%)	0.044
CAPD/CCPD	17 (15.3%)	1 (2.4%)	
Reason(s) for treatment allocation			
Patient preference	93 (83.8%)	41 (100.0%)	0.004
Other specific reason	11 (9.9%)	0 (0.0%)	0.036
Reason not provided	7 (6.3%)	0 (0.0%)	NS

CAPD, continuous ambulatory peritoneal dialysis; CCPD, continuous cyclical peritoneal dialysis.

Table 3 presents the allocated treatments and reasons for the allocated treatments. A significantly greater number of intervention patients than control patients received the treatment of CAPD/CCPD. Patient preference was the most common reason provided for the allocated treatment (88.2%). Ninety-three patients (95% confidence interval [CI]: 79.5–104.3) in the intervention group and 41 patients (95% CI: 29.1–53.8) in the control group indicated patient preference as the reason for the allocated treatment. Other specific reasons for the allocated treatment included family preference, residual renal function, medical need, and catheter failure. A significantly greater number of control group patients indicated patient preference as the reason for their treatment allocation ($P = 0.004$). A significantly greater number of intervention group patients provided other specific reasons for their treatment allocation ($P = 0.036$).

Table 4 presents the secondary effects of the intervention. After 3 months of follow-up on each patient, there was a significantly greater number of patients in the intervention group who were on peritoneal dialysis ($P = 0.041$). Twenty patients (95% CI: 14.3–21.8) in the intervention group and 2 patients (95% CI: 0.1–6.9) in the control group were on the CAPD/CCPD modality at the 3-month follow-up. A total of 9 patients (8.1%) changed from hemodialysis to peritoneal dialysis and 1 patient (0.9%) switched from peritoneal dialysis to hemodialysis. Ten patients expired before they could be followed for 3 months (9.0%). One patient (0.9%) stopped dialysis, 1 patient (0.9%) transferred to another dialysis center, and 1 patient (0.9%) was transplanted. Ten patients were lost to follow-up (9.0%). There was no significant difference in health status as measured by blood urea nitrogen and hematocrit at the 3-month follow-up between intervention and control groups. However, there was a significantly greater number of patients in the intervention group who experienced a vascular access site infection or thrombosis ($P = 0.009$).

There was no significant difference between the intervention and control groups for the discrepancy between initial patient preference and actual treatment received at the three month follow-up. At the end of the 3-month follow-up, three patients from the intervention group who initially preferenced hemodialysis were receiving peritoneal dialysis and two patients (one each from the intervention and control groups), who initially preferred peritoneal dialysis, were receiv-

TABLE 4. Secondary Effects of Intervention

Effects	Patient Groups				P
	Intervention		Control		
Treatment allocation (3-month follow-up)					
Hemodialysis	76	(68.5%)	31	(75.6%)	NS
CAPD/CCPD	20	(18.0%)	2	(4.9%)	0.041
Reason for treatment change					
Peritonitis	1	(0.9%)	0	(0.0%)	NS
Patient preference	8	(7.2%)	1	(0.9%)	NS
Patient stopped, transferred, or transplanted	3	(2.7%)	0	(0%)	NS
Health status					
BUN	53.9	(19.5)	59.3	(18.9)	NS
HCT	31.1	(6.7)	32.5	(4.6)	NS
Complications					
Patient expired	6	(5.4%)	4	(9.8%)	NS
Vascular access site infection or thrombosis	22	(19.8%)	1	(0.9%)	0.009
Exit site infection	3	(2.7%)	0	(0.0%)	NS
Peritonitis	1	(0.9%)	0	(0.0%)	NS
Other	11	(9.9%)	0	(0.0%)	0.036

CAPD, continuous ambulatory peritoneal dialysis; CCPD, continuous cyclical peritoneal dialysis; NS, not significant; BUN, blood urea nitrogen; HCT, hematocrit.

ing hemodialysis. Three intervention group physicians substantially increased their use of peritoneal dialysis. In comparison, only one of the physicians in the control group increased the use of peritoneal dialysis and other control group physicians did not change.

Discussion

The results of this study show that communicating clinical practice statistics with appropriate comparisons and pertinent recommendations from the literature can be effective in changing dialysis practices. The homogeneity of intervention and control groups resulted from the randomization and was confirmed by the baseline comparison. Consequently, the only detected difference at endpoint, a difference in the use of peritoneal dialysis, should be attributed to the clinical direct reports applied in the intervention group. Interestingly, although the rate of peritoneal dialysis decreased in the control group, the rate of peritoneal dialysis increased in the intervention group making the difference practically and statistically significant. In more general terms, it is interesting to observe the significant effect of the nonintrusive, nonjudgmental, and simple information intervention of this study on clinical practice patterns. The documented effect is in sharp contrast with the aggressive approach of many utilization management techniques that have never been tested in controlled experiments or showed questionable value in controlling rising health care costs.

Based on several cost calculations, the simple intervention of this study can result in substantial cost savings. As the data in Table 5 indicate, a number of studies have been conducted showing that peritoneal dialysis is more cost effective than hemodialysis. According to these studies, the average annual savings (calculated by subtracting the reported costs of peritoneal dialysis from the costs of hemodialysis) range from $5,944 in the Dor et al[17] study to $7,592 in the Balas et al[18] study, to $8,091 for males in the Garner et al[19] study; the Prowant et al[20] study is substantially higher ($19,133) because it includes all medical costs associated with chronic renal failure, not just the direct costs associated with dialysis. Assuming that the intervention group would have had the same percentage using CAPD/CCPD as the control group had no intervention occurred, then 6 individuals ($111 \times 4.9\% = 5.4$) would have been on CAPD/CCPD rather than the 20 identified. Because of the intervention, an additional 14 individuals are using CAPD/CCPD rather than hemodialysis. To calculate the potential cost savings associated with the intervention applied in this study, if the total cost data of $19,133[20] were applied to these individuals, the cost savings were $267,862.

Apparently, there is a need for better understanding of the channels of communication within the medical profession, and the impact of information on medical practice.[21] Scientific journals, currently the dominant communication channels in medicine, represent the mass media type approach to the dissemination of clinical research results. To overcome the limitations of mass media communication, direct mail frequently is recommended alternative. Unlike mass media, direct mail enables the sender to get the attention of recipients through timely mailing. Through improved targeting, direct mail does seem to generate a higher response rate.[22] Experts recommend that the most important benefits, endorsed by substantiating evidence, should

TABLE 5. Comparison of Annual Costs for Hemodialysis and Peritoneal Dialysis

Study	Measure Used for Comparison	HD–PD Per Year
Prowant et al (1980)	Medicare allowable charges—total	$19,133
Garner et al (1986)	Net social costs—male	8,901
	Net social costs—female	7,062
Dor et al (1992)	Regressed modality specific costs	5,944
Balas et al (1995)	Activity-based accounting direct costs	7,592

HD, hemodialysis; PD, peritoneal dialysis.

be emphasized.[23] A national study indicated that direct mailing is the preferred source of health care information.[24] The concept of direct mail could be further investigated in the area of patient participation in selecting the dialysis modality.

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Appendix A.

(Confidential Information-Do not forward to other physicians)

Clinical Direct Report
(XXX Center, XXX, Missouri)

The following are tables depicting the distribution of patients by treatment modality in Missouri and nationally as compared to the patients in your center:

	Center based OHD	CAPD and CCPD	OTHER
National[a]	80%	12%	8%
Missouri[b]	72%	21%	7%
Your Center[c]	63%	13%	24%

[a]Improvements in Data Quality in the USRDS Database: Determining Treatment Modalities. Excerpts from the United States Renal Data System 1992 Annual Report. Am J Kidney Dis 1992;20(2 suppl):89.
[b]Missouri Kidney Program Annual Report, 1993.
[c]Database of the Missouri Kidney Program, 1993.

- Your center ranks 27th among all 61 dialysis centers within the state for percentage of patients on CAPD. The average for all dialysis centers in the state is 17%.[c]
- Most recent findings of the latest study on comorbidity for in-center hemodialysis versus peritoneal dialysis found no significant difference in comorbidity for a randomly selected sample of patients."

  (Improvements in data quality in the USRDS Database: Determining treatment modalities. Excerpts from the United States Renal Data System 1992 Annual Report. Am J Kidney Dis 1992;20(2 suppl:89).

- "In the United States the current success rate of CPD, the improvement in peritonitis rates, the appropriate methods of prescribing CPD, the use of automated PD techniques and the profitability of this modality may not be well understood."
  "Physician bias is transmitted either directly or indirectly to the patient when modality selection is being made. Physicians are often asked by patients to make the best decision for them since many new ESRD patients feel incompletely informed and overwhelmed by such choices."
  "Available scientific literature suggest that no important medical outcome differences are seen when comparing hemodialysis (HD) to CPD for the majority of patients. Why then does CPD continue to be utilized by so few patients worldwide?"

  (Nissenson AR, Prichard SS, Cheng IKP, Gokal R, Kubota M, Maiorca R, et al. Non-medical factors that impact on ESRD modality selection. Kidney Int 1993;43(40 suppl):S120).

Source: Renal Database Trial, University of Missouri, Health Services Management, 324 Clark Hall, Columbia, MO 65211.
OHD, outpatient hemodialysis; CAPD, continuous ambulatory peritoneal dialysis; CCPD, continuous cyclical peritoneal dialysis.