

# Early Intervention Improves Mortality and Hospitalization Rates in Incident Hemodialysis Patients: RightStart Program

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**Background and objectives:** Annualized mortality rates of chronic hemodialysis (CHD) patients in their first 90 d of treatment range from 24 to 50%. Limited studies also show high hospitalization rates. It was hypothesized that a structured quality improvement program (RightStart), focused on medical needs and patient education and support, would improve outcomes for incident CHD patients.

**Design, setting, participants, & measurements:** A total of 918 CHD incident patients were prospectively enrolled in a multicenter RightStart Program, and compared with a time-concurrent group of 1020 control patients from non-RightStart clinics. RightStart patients received 3 mo of intervention in management of anemia, dosage of dialysis, nutrition, and dialysis access and a comprehensive educational program. Outcomes were tracked for up to 12 mo.

**Results:** At 3 mo, RightStart patients had higher albumin and hematocrit values. Dose of dialysis and permanent access placement were not statistically significantly different from control subjects. Compared with baseline, Mental Composite Score for RightStart patients improved significantly. Mean hospitalization days per patient year were reduced with RightStart *versus* control subjects. Mortality rates at 3, 6, and 12 mo were 20, 18, and 17 for RightStart patients *versus* 39, 33, and 30 deaths per 100 patient-years for control subjects, respectively.

**Conclusions:** A structured program of prompt medical and educational strategies in incident CHD patients results in improved morbidity and mortality that last up to 1 yr.

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The mortality rate of treated patients with ESRD was 23 deaths per 100 patient-years at risk in 2003, as reported by the US Renal Data System (USRDS) (1). This high mortality rate, as compared with other countries (2), persists despite recent advances in our understanding of the uremic state and improvements in the science and technology of renal replacement therapy. In addition, in 2003, patients with ESRD spent an average of 14 d/yr in the hospital, which comprises more than one third (38%; \$6 billion dollars) of the \$16 billion dollars spent annually to care for patients with ESRD (1).

Although patients with ESRD qualify for Medicare benefits, regardless of age, those who are younger than 65 yr must undergo 90 d of therapy before qualifying for these benefits. To present uniform outcomes data, the USRDS analyzes all data for all patients after 90 d of therapy, regardless of age at initiation of therapy; therefore, the high mortality rate noted may represent an underestimation of the mortality risk for all incident patients, because it does not include mortality data of the first 90 d of dialysis therapy.

A limited number of studies have examined the outcomes of patients in the first 90 d. The earliest data reported were by Held *et al.* in 1990 (3), citing a 12% mortality rate in the initial 90 d of dialysis treatment. This represents an annualized rate of 48 deaths/100 patient-years in patients who start dialysis. These data are confirmed by Khan *et al.* (4), who reported a similar annualized rate of 50 deaths/100 patient-years. Soucie and McClellan (5), using voluntary facility reports, measured a mortality rate of 24 deaths/100 patient-years at risk. Finally, mortality data from Renal Care Group (unpublished data) as tracked for all patients from 1996 until 2006, ranged from 40 to 45 deaths/100 patient-years of annualized mortality ( $N > 10,000$  incident patients). No study has systematically examined this issue, especially in terms of interventions to improve this unacceptably high death rate.

The goal of this particular quality improvement program was to implement an intervention strategy focused on improving the clinical outcomes during the initial 90 d of maintenance hemodialysis. We hypothesized that application of a broad and systematic program in the first 90 d may improve the mortality and morbidity rates of this incident CHD population. Specifically, we developed a program that comprises intensive patient education, encouragement, and support coupled with an intervention strategy to implement in a timely manner “best practices” and National Kidney Foundation Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines, which have

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been shown to improve patient outcomes in prevalent CHD patients (6,7). To test this hypothesis, we initiated a multicenter trial of the RightStart (RS) Program in 39 outpatient clinics selected on the basis of high new patient influx, high first 90-d mortality, and clustered proximity of clinic location. The study patients received intervention for 3 mo and were followed for a period of 12 mo after initiation of maintenance dialysis; the clinical outcomes of this intervention group were compared with a concurrent control cohort of a comparable number of incident patients who received usual care in geographic proximity.

## Concise Methods

### *Patient Population*

In 39 participating clinics, a total of 918 patients who were new to hemodialysis were prospectively enrolled in the RS program by an RS case manager within 2 wk of initiation of outpatient dialysis. The enrollment period spanned from May 2002 to November 2005. Exclusion criteria were seasonal and transient patients, as well as patients with poor cognitive function resulting in an inability to learn as judged by the staff administering the RS program. The majority of these patients were in nursing home residences. During the subsequent 3 mo, participating patients received focused interventions and education according to a defined program. Patients received intervention for 3 mo and were followed intensively during that time. In addition, outcomes data were collected for up to 9 mo thereafter, for a total of 1 yr of follow-up. A concurrent control group was composed of 1020 randomly selected patients who were from a total of 31 outpatient dialysis units and initiated maintenance hemodialysis therapy from May 2002 until March 2005 (concurrent with the RS program in dialysis facilities in the same dialysis chain and geographic area and often with the same physician practices), but who were not in facilities that participated in the RS program. Case managers, generally nurses, were trained in ongoing data collection and data entry into the database for the RS patients. Data for the control group were electronically retrieved from the computerized medical chart that was used for the RS group as well, and they received no study-related intervention.

### *RS Program Interventions*

The program was approved by the medical director of each facility as a standard of care for all incident patients. During the 3-mo intervention period, the case manager followed each patient with an intensive patient education program coupled with interventions focused on several specific areas of clinical care, namely anemia management, adequate dialysis dose, nutrition, reduction of catheter use, review of medications, logistical support, and psychosocial assessment with appropriate referral to social services, as well as encouragement to participate in self-care and rehabilitation services. The case manager collaborated with the facility staff and the medical director to ensure prompt and overall optimal care in these five areas. On average, the case manager met with the patient one to two times per week during the first month and every 1 to 2 wk thereafter for the remaining 2 mo.

All laboratory parameters were drawn on the first outpatient treatment, and a focus on prompt and complete care was implemented. For the control group, the laboratory variables were available within the initial 4 wk of initiation of maintenance hemodialysis. Anemia was managed by initiating new patients at a dosage of 150 U/kg Epogen when the hemoglobin was <10 g/dl. Initially, the education of dietary interventions emphasized restrictions of fluid and nutrient intake, but approximately 8 mo after the start of the program, these educational

materials were revised to encourage a liberal intake of protein and calories for all new patients to reverse the typical decline in nutritional status that is seen in patients with stages 4 and 5 chronic kidney disease (8). Appropriate dietary instructions were added later as clinically indicated. A focus on vascular access included patient education and facilitation of appointments for permanent access placement. Throughout the 3-mo intervention period, an individualized, comprehensive patient education program was implemented using individual and verbal teaching and dissemination of written and audiovisual materials (compact disks and videotapes) that were designed for patients who were new to hemodialysis therapy. The patient education program was focused on health self-management and rehabilitation as appropriate for the patient.

Outcomes measured in the RS group were demographics, laboratory parameters, vascular access type, hospitalization, mortality tracked for 1 yr, and quality of life using the Kidney Disease Quality of Life Short Form (KDQOL-SF) standardized assessment tool (9,10) administered during the first 3 (baseline) and 6 mo only. In addition, a 23-question Dialysis Knowledge Test designed specifically for the RS program was administered at baseline, 3 mo, and 6 mo. These tests were not administered to the control group.

### *Statistical Analyses*

Initial data analyses consisted of demographic, laboratory, hospitalization, and mortality comparisons at the end of the intervention period (90 d) and at 180 and 365 d, comparing the two groups: RS and concurrent control. Patient baseline characteristics were compared by using the  $\chi^2$  test for categorical variables and by using the Mann-Whitney *U* test for continuous variables. Data are presented as means  $\pm$  SD. Laboratory values of hematocrit, serum albumin, and urea reduction ratio (URR) levels between RS and control groups were compared at 3, 6, and 12 mo separately by using Mann-Whitney *U* tests. The overall difference of the laboratory values during the 12-mo period was assessed using general linear models with bootstrap covariance accounting for correlated measures within a patient. Two separate analyses were performed as outcome variable using (1) actual values and (2) change from baseline. Both models contain main effect terms of treatment arm and time (categorical) as fixed effects. Analysis of change was performed by including baseline value as a model covariate. Residuals were assessed graphically for normality. For analysis of mortality, patients were censored at time last verified as being alive by study personnel or at 365 d after the initiation of the intervention. Time to death between the two study groups was compared by using the Kaplan-Meier survival plots and the log-rank test. Cox proportional hazard regression was used to compute hazard ratio (HR) and 95% confidence interval (CI) quantifying the effect of the RS compared with the control group. Frailty method was used in the Cox regression model to account for variability between facilities as random effects (11). Rate of death in incident patients was computed by dividing total number of deaths by total follow-up years (days at risk divided by 365.25). Cox proportional hazard regression models were used to identify factors that modify the effect of the intervention simultaneously, including study arm, age (continuous), race (white *versus* other), gender, and presence or absence of diabetes and all two-way interaction terms of the study arm and the other variables. The effect of the intervention was analyzed using similar Cox regression model separately among patients by level of the identified variable modifying the effect of the intervention (*e.g.*, diabetes). Patients with missing data points were excluded from the multivariable analysis, resulting in 1280 patients available for multivariate analysis.

## Results

### Demographics and Baseline Laboratory Parameters

Analysis of patient demographic characteristics by study arm for the RS and control patients showed that mean ( $\pm$  SD) age was  $62 \pm 16$  for RS and  $62 \pm 17$  for control group ( $P = 0.94$ ). The proportion of men and women in each group was not different, with 46% men in the RS group and 46% men in the control group ( $P = 0.85$ ). With regard to race, information was available only for a total of 1362 patients. Of these, 59% in the RS group and 55% in the control group were white, and 37% in the RS group were black or Hispanic compared with 36% in the control group ( $P = 0.09$ ). A total of 54% of patients had diabetes (type 1 and type 2 combined) in the RS group and 53% in the control group ( $P = 0.81$ ). At entry into the facility, laboratory parameters including hematocrit, serum albumin, and URR were not significantly different between the two groups (Table 1).

### Time Trends in Anemia, Hemodialysis Adequacy, and Nutrition

We initially compared the differences in time trends as an absolute value and as a change from baseline values for anemia (as measured by hematocrit), hemodialysis dosage adequacy (as measured by URR), and nutrition (as measured by serum albumin) between study arms. Table 1 depicts the results for these variables at days 90, 180, and 365. Compared with baseline values, there were statistically significant increases in hematocrit and serum albumin level across time points for both RS and control groups ( $P < 0.001$  for hematocrit,  $P = 0.09$  for albumin by general linear models). In addition, mean serum albumin concentrations were statistically significantly higher at 90, 180, and 365 d in the RS group compared with the control group, although the absolute difference was relatively small. Hematocrit was statistically significantly higher at 90 d in the RS group compared with the control group. No significant differences were observed for hemodialysis adequacy (URR) between the two groups.

### KDQOL-SF and Dialysis Knowledge Tests

The KDQOL-SF average scores were analyzed separately for the Mental Composite Score (MCS) and Physical Composite

Score (PCS). Scores that were collected during the initial 3 mo were combined as a baseline measurement and were compared with measurements at 6 mo for the same patients. Average MCS scores were  $48.6 \pm 11.5$  in the initial 3 mo ( $n = 389$ ) and  $51.4 \pm 11.1$  at 6 mo ( $n = 159$ ;  $P < 0.05$  by Mann-Whitney  $U$  test; Table 2). Both baseline and 6-mo scores were higher than the reference score of  $46.5 \pm 11.8$  as determined by the Dialysis Outcomes and Practice Patterns Study (DOPPS) (10). Average PCS scores were  $38.0 \pm 10.2$  in the first 3 mo ( $n = 389$ ) and  $36.5 \pm 9.7$  at 6 mo ( $n = 162$ ; NS by Mann-Whitney  $U$  test). These were also greater than the reference score of  $32.7 \pm 10.6$  (10).

The Dialysis Knowledge Test was scored on the basis of the percentage of correct answers for each time the test was administered. The average scores (percentage correct) at baseline, 3 mo, and 6 mo were  $62.1 \pm 18.9$ ,  $68.8 \pm 19.4$ , and  $79.3 \pm 14.9$ , respectively. These scores represented significant improvement at all testing points, as compared with baseline ( $P < 0.001$ ).

### Impact of Program on Mortality

Figure 1 shows incidence rate of deaths observed at 90, 180, and 365 d after the initiation of the study. Of the 1965 patients who were followed during the study period, a total of 218 deaths occurred in a period of 1 yr, among which 95 deaths occurred in the RS group and 123 deaths occurred in the control group. Rates of death were 20 *versus* 39 at 90 d, 18 *versus* 33 at 180 d, and 17 *versus* 30 per 100 patient-years at 365 d for RS *versus* control, respectively. There were significantly lower death rates for patients who participated in the RS program when data were examined on the basis of per 100 patient-years (Figure 1), which are congruent with the comparisons of cumulative probabilities of survival provided on Kaplan-Meier curves in Figure 2 ( $P < 0.001$  for all comparisons). After adjustment for the random effects of facility difference, the decrease in HR of death for the RS *versus* the control group at 365 day remained significant (HR 0.59; 95% CI 0.45 to 0.79;  $P < 0.001$ ). There was a 41% reduction in 365-d risk for death in patients who participated in the RS program.

Data were also analyzed according to different subgroups:

Table 1. Hematocrit, URR, serum albumin, and catheters at 90, 180, and 365 d<sup>a</sup>

Parameter	Baseline		90 D		180 D		365 D	
	RS	Control	RS	Control	RS	Control	RS	Control
Hematocrit (%; mean $\pm$ SD)	$31.6 \pm 4.4$	$31.4 \pm 4.6$	$37.9 \pm 4.7^b$	$36.7 \pm 5.1$	$36.2 \pm 4.5$	$36.2 \pm 4.5$	$36.0 \pm 4.0$	$36.0 \pm 4.0$
URR (%; mean $\pm$ SD)	$69.0 \pm 11.0$	$69.0 \pm 11.0$	$70.7 \pm 8.3$	$70.7 \pm 9.0$	$72.6 \pm 7.2$	$72.5 \pm 7.8$	$73.5 \pm 7.1$	$73.8 \pm 7.9$
Albumin (g/dl; mean $\pm$ SD)	$3.50 \pm 0.61$	$3.44 \pm 0.54$	$3.70 \pm 0.46^c$	$3.66 \pm 0.46$	$3.77 \pm 0.44^c$	$3.74 \pm 0.42$	$3.86 \pm 0.46^c$	$3.80 \pm 0.41$
Hemodialysis catheters (%)	69 <sup>b</sup>	56	47 <sup>b</sup>	38	28 <sup>c</sup>	24	15	13

<sup>a</sup>RS, RightStart; URR, urea reduction ratio.

<sup>b</sup> $P < 0.001$  *versus* control.

<sup>c</sup> $P < 0.05$  *versus* control.

Table 2. KDQOL-SF survey and Dialysis Knowledge Test scores for RS patients<sup>a</sup>

Parameter	Baseline	3 Mo	6 Mo
KDQOL-SF MCS (mean ± SD)	48.6 ± 11.5 (n=389)	NA	51.4 ± 11.1 (n=159) <sup>b</sup>
KDQOL-SF PCS (mean ± SD)	38.0 ± 10.2 (n=389)	NA	36.5 ± 9.7 (n = 162)
Dialysis Knowledge Test (mean % correct ± SD)	62.1 ± 18.9 (n=561)	68.8 ± 19.4 (n = 362) <sup>c</sup>	79.3 ± 14.9 (n=231) <sup>c</sup>

<sup>a</sup>KDQOL-SF, Kidney Disease Quality of Life; MCS, Mental Component Score; NA, not applicable; PCS, Physical Component Score.

<sup>b</sup>P < 0.05 versus baseline.

<sup>c</sup>P < 0.001 versus baseline.

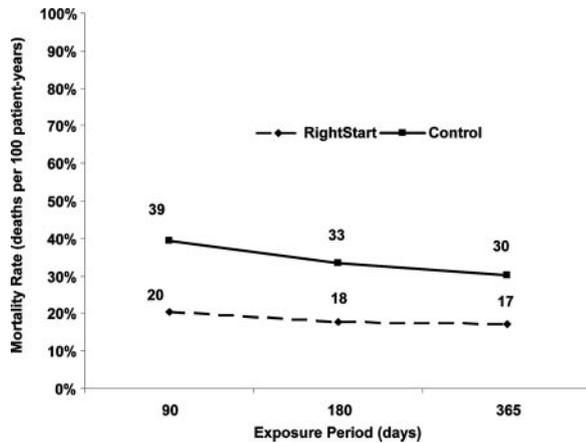


Figure 1. Incidence rates of death per 100 patient-years at 90, 180, and 365 d for both study groups. P < 0.001 versus control at all 3 time points.

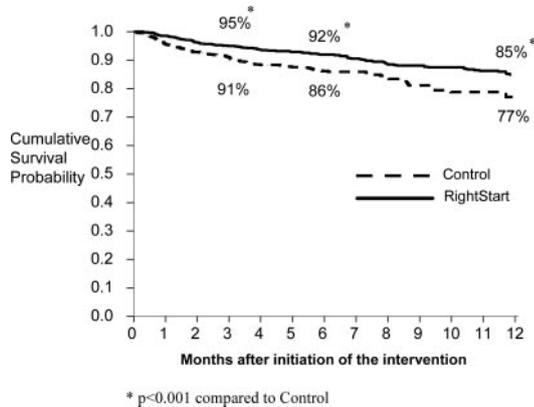


Figure 2. Kaplan-Meier estimates of cumulative survival probability for both study groups.

Diabetes (presence or absence of), age (younger or older than 65), gender, and race (white and nonwhite). There was a 45% reduction in the risk for death among patients without diabetes in the RS group (HR 0.55; 95% CI 0.34 to 0.90; P = 0.016); however, in patients with diabetes, the reduction in the risk for death comparing RS with control was less and not statistically significant (HR 0.88; 95% CI 0.54 to 1.40; P = 0.60). No significant differences in mortality rates were observed for the other subgroup analysis (age and gender) between study groups.

Impact of Program on Hospitalization

We analyzed hospitalization in cumulative hospitalization days for each group according to the different exposure times. As shown in Figure 3, we observed a significant reduction in cumulative hospitalization days for RS patients compared with control patients. Specifically, mean hospitalization days per patient year were reduced in RS versus control patients (2.1 versus 3.1 d at 3 mo, 4.5 versus 6.3 d at 6 mo, and 7.2 versus 10.5 d at 12 mo; P < 0.001 for all time points by Mann-Whitney U test). After adjustment for varying follow-up times by using within-patient average day of hospitalization, the difference remained significant (P < 0.0001).

Discussion

This focused intervention in approximately 1000 patients who initiated maintenance hemodialysis was successful at the end of 1 yr of follow-up in reducing death rate by approximately 40% as compared with a control group of long-term hemodialysis patients. This was evident particularly in the differences in mortality within the first 90 d (20 versus 39% per 100 patient-years at risk for RS versus control). To our knowledge, this is the first report of an

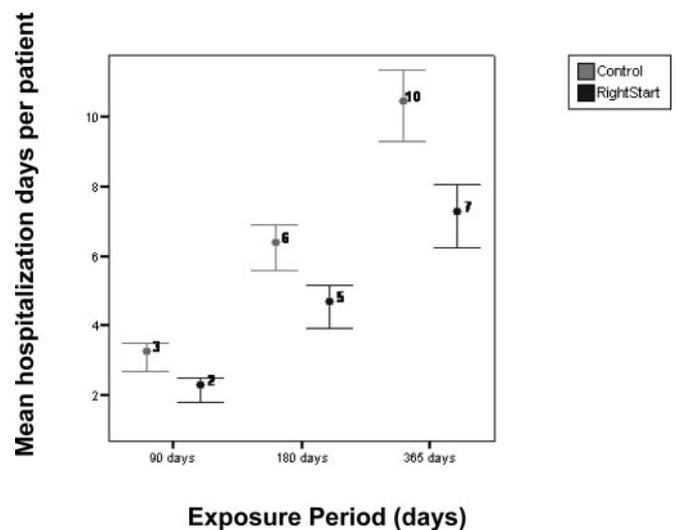


Figure 3. Cumulative hospitalization days at the three exposure times. P < 0.001 versus control for all time points. Error bars show 95% confidence interval of the mean.

intervention that has successfully improved death rate within the first 90 d of initiation of maintenance dialysis.

In addition to these improvements in mortality, patients in the RS program experienced significantly lower hospitalization rates. The improvement in both mortality and hospitalization rates was evident for up to 1 yr of follow-up, considerably longer than the period of active intervention of approximately 90 d after initiation. This improvement in patient outcome in the RS group was associated with a higher proportion of patients who achieved treatment guidelines by K/DOQI and best practice patterns from DOPPS and other studies; although this improvement in process outcomes (URR, hematocrit, and albumin) was statistically significant in some cases (albumin and hematocrit), it was modest and may not entirely explain the significant reduction in mortality.

One of the areas in which significant improvement has been observed is anemia management. Specifically, whereas hematocrit statistically significantly increased in both groups during the initial 6 mo of follow-up, the RS group had a statistically significantly higher increase as compared with the control group. This is not a surprising finding, because multiple studies have shown that anemia of ESRD is a treatable condition (12,13). A number of studies have also shown that improving anemia in patients with ESRD, at least to the recommended target hemoglobin value of 11 to 12 g/dl, is associated with better mortality and hospitalization rates (14,15). Notably, the RS group was able to reach the threshold of hematocrit  $>33\%$  (hemoglobin of 11 g/dl) earlier and maintain it at that level for longer, suggesting that the more aggressive anemia management might have benefited survival in this study.

An important component of the intervention for the RS group included intensive nutritional counseling. For enhancing nutritional outcomes, a liberal intake of protein and calories for all new patients to reverse the typical decline in nutritional status that is seen in stage 4–5 chronic kidney disease was encouraged once the patient was initiated on dialysis (16). Our results indicate that although both groups showed an improvement in serum albumin over time, the extent of increase was statistically significantly higher in the RS group compared with the control group when analysis was performed comparing each follow-up time point. Although these data may indicate that aggressive nutritional supplementation might be an additional factor in the observed beneficial effects of the RS program on mortality and morbidity, the relatively small difference between the two groups should be taken into account when interpreting these results.

A critically important area that requires attention in the care of the long-term hemodialysis patients is the increasing prevalence of permanent catheter use. Recent data indicate that approximately 72% of long-term hemodialysis patients initiate dialysis with a catheter (17). Increased use of catheters has been associated with increased death and hospitalization rates as well as inability to achieve optimal dialysis dosage (18,19). Accordingly, one of the components of the RS intervention was to decrease the prevalence of permanent catheters during the initial 90 d of maintenance hemodialysis. Unfortunately, our data indicate that we were not able to have an impact on this outcome significantly, and both the RS and control groups had

similarly high catheter rates, suggesting that catheter prevalence is outside the control of the case manager (20).

We also did not observe a statistically significant difference in dialysis adequacy between the RS and control groups; however, it is notable that URR increased in both groups within the first month and reached a mean value  $>70\%$  in the second month of observation. Given the results of the Hemodialysis (HEMO) Study (21), one can speculate that the maximum benefit from increased dialysis dose has been accomplished by both groups, and no further significant improvement in mortality can be obtained even if the URR levels are further increased in the RS group. It is also likely that the lack of statistically significant differences in dialysis dose between the RS and control groups was due to the complex vascular access issues mentioned.

Another factor that may help explain the improvements in patient outcome is the impact of individualized patient education with an emphasis on self-empowerment and rehabilitation on depression scores that is often observed in patients who undergo life-changing events, such as initiation of dialysis. Although we did not compare psychosocial adjustments between the RS and the control groups because these data were not available in the control group, the improved performance of the intervention group in the MCS of the KDQOL-SF may have also contributed to the improvement in mortality. In that respect, the DOPPS (10) indicated that a worsening of 10 points in MCS score is associated with a 13% increased risk of mortality at 12 mo. Our data showed that RS intervention was able to improve the MCS by an average of two points after 6 mo, from 49 in the first 3 mo to 51 at 6 mo. Similarly, the PCS was better than the DOPPS average PCS of 33, although there was a slight numeric drop over the intervention period (10).

A Dialysis Knowledge Test was administered at baseline, 3 mo, and 6 mo. The average score (percentage correct) was 62.1, 68.8, and 79.3%, respectively. It is noteworthy that scores that were achieved at the end of the intervention period (3 mo) were maintained up to 6 mo. Our results show that patients are capable of learning and retaining information with use of written and audiovisual tools. Although change in behavior as a result of learning was not specifically measured, it is likely that these more knowledgeable patients were better equipped for self-management, including such things as better medication and dietary compliance, participation in the plan of care, and motivation to ask questions.

The results of this study should be interpreted with some caution. First, this was not a randomized, controlled study, and it used a concurrent study cohort for comparison. There were also certain selection biases that we were unable to prevent, such as exclusion of patients with cognitive impairment in the RS group, which might have affected our results (22). Although the process of excluding patients with cognitive dysfunction was not formalized, it was not merely the decision of the case manager, and there was a detailed discussion with the project leader. Obviously, there was intent to work with as many patients who can respond to the educational and supportive intervention. That baseline characteristics are similar in RS and control groups indicates that exclusion of patients with cognitive impairment had a relatively small effect on the cohort. Nevertheless, the overall mortality rate of the control group could be influenced by inclusion of this high-risk pop-

ulation. There may also be potential variability in each individual dialysis unit participating in the study. We also had a number of missing demographic and clinical data, primarily for the control group, which might have influenced our baseline analyses. Finally, although labor costs of the program were an additional financial burden on the participating facilities, these were mitigated by the reduced hospitalization and mortality of the patients in the RS program.

## Conclusions

A targeted program of medical and teaching intervention to meet the specific needs of incident long-term hemodialysis patients results in improved morbidity and mortality. Notably, the most impressive mortality difference occurs in the first 90 d, and this beneficial effect lasts up to 12 mo, indicating the critical importance of early intensive intervention in this patient population.

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## Disclosures

L.B.P. is currently an employee of NovoNordisk, Inc. (Princeton, NJ) and M.K. is an employee of Amgen Inc.

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See related editorial, “Value of Quality Improvement Reporting,” on pages 1104–1105.

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