Relationship among Length of Facility Ownership, Clinical Performance, and Mortality

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Background and objectives: The association between level of performance in achieving guideline-recommended clinical indicators and relative reduction in patient mortality is inconsistent among large dialysis organizations (LDOs). Because growth rates among providers differ, we reasoned that clinical performance and mortality rates in dialysis facilities may be related to length of facility ownership.

Design, setting, participants, & measurements: We examined achievement of clinical performance indicators among prevalent long-term hemodialysis patients who were enrolled in cohorts of DaVita facilities between December 2005 and December 2007. We compared results in 606 facilities owned before December 1, 2004 (existing), with those seen in 504 facilities that were acquired in October 2005 (newly acquired).

Results: At baseline, existing compared with newly acquired DaVita facilities showed higher levels of clinical performance and lower patient mortality. These differences persisted up to 2 years for selected outcomes, including dialysis adequacy and anemia management. Substantial improvement was seen in both cohorts for mineral bone disease outcomes; however, 2 years after acquisition, between-cohort differences in relative risk for death were no longer discernible.

Conclusions: These findings confirm that intervention to improve quality outcomes in dialysis facilities produces direct benefits that are tangible to patients. Our results also provide new evidence that length of ownership may be a significant factor in determining facility performance within a large dialysis organization.

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Use of clinical indicators to gauge dialysis facility performance has contributed substantially to improving outcomes of patients who undergo dialysis in the United States and elsewhere. Patients who achieve end points that are recommended by nationally accepted guidelines, regardless of the strength of evidence underpinning the guidelines (1), show lower associated mortality and hospitalization than those who do not (2–4). Moreover, patients in facilities with high levels of facility performance show lower mortality and hospitalization benefits, even when results are adjusted for patient comorbidity and demographic risk factors (5). Finally, when facility performance improves, patient survival also improves (6,7).

The reported relationship among clinical performance, patient outcomes, and ownership of facilities is not straightforward, however. Before 1996, for-profit ownership was reported to be associated with higher mortality compared with not-for-profit status (8,9). More recently, type of ownership has been reported to have little effect on associated mortality (3). The observation that recent growth of for-profit facilities has outstripped that of not-for-profit facilities in the United States (10) suggests the hypothesis that length of ownership may positively affect both direct and indirect patient outcomes. The acquisition in October 2005 of a large cohort of dialysis facilities by DaVita afforded the unique opportunity to test this hypothesis by comparing clinical performance in acquired and existing DaVita facilities before and at intervals after the acquisition.

Materials and Methods

Study Design

We examined achievement of clinical performance indicators and mortality among prevalent long-term hemodialysis patients who were enrolled in cohorts of DaVita facilities between December 2005, the month that DaVita initiated quality assessment and process improvement in acquired facilities, and December 2007 (Figure 1). Each facility is identified as "newly acquired" or "existing". Facilities that were merged, closed, sold, or opened subsequent to and during the three sampled months for the laboratory values and for the entire calendar year for mortality were not included in the analysis. We compared results in 606 facilities that were owned before December 1, 2004 (existing), with those seen in 504 facilities that were acquired in October 2005 (newly acquired).

Clinical and Laboratory Measures and Analysis

Facility-level metrics for laboratory values were collected in December 2005, December 2006, and December 2007. Clinical outcomes are based on the last laboratory value collected in each respective month. We assessed facility performance using percentage of facility patients who achieved the following key clinical indicators (KCI): Albumin ($\geq$3.5 g/dl), calculated hemoglobin (Hb; $\geq$11.0 g/dl), corrected calcium-phosphorus product ($Ca \times PO_4$; <55 mg ^{2}/dl)^2), corrected calcium ($\leq$9.5 mg/dl), ferritin ($<$100 ng/dl), iron saturation ($<$20% saturation),

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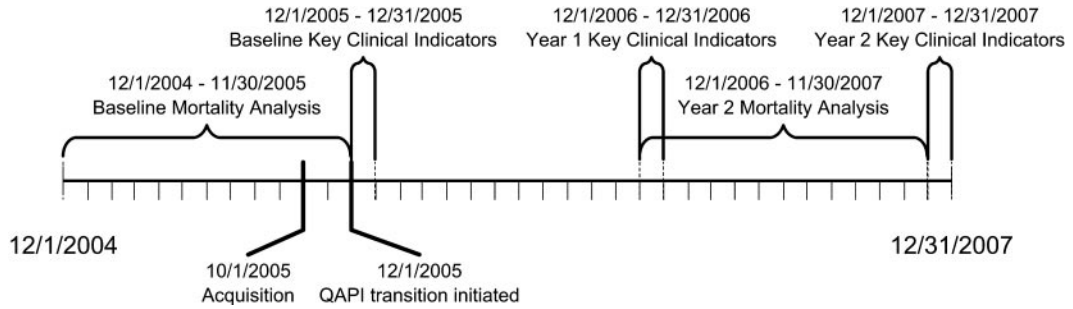

Figure 1. Intervals for outcomes evaluations. Acquisition took place October 1, 2005. In newly acquired facilities, transition to the DaVita quality assessment and process improvement (QAPI) program was initiated in December 2005.

Kt/V (<1.2), phosphorus (≤6.0 mg/dl), and urea reduction ratio (URR; ≥65%). These clinical indicators were taken from Centers for Medicare and Medicaid Services Clinical Performance Measures and Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines and recommendations that were prevalent between 2004 and 2007.

Mortality Measures

We evaluated 1-year mortality rates in the cohort of newly acquired facilities in the year before acquisition (December 1, 2004, through November 30, 2005) and year 2 after acquisition (December 1, 2006, through November 30, 2007). We compared the results with mortality rates observed at the same respective intervals in the cohort of existing DaVita facilities. In both cohorts, we included only patients who had survived at least 90 d from initiation of first dialysis.

Statistical Analysis

Patients were assessed on each laboratory value and KCI as a continuous characteristic *via* repeated measures mixed models. Least squares mean estimates were obtained for each laboratory value and KCI at each time period to provide the *t* tests of differences at each time period: baseline, year 1, and year 2. For relative risk for death analyses, Cox proportional hazards regression analysis was used with adjustment for covariates including age, race, diabetes, and vintage (duration since first day of dialysis) in a stepwise manner. $P < 0.05$ was considered significant.

Results

Clinical Performances Differed Significantly at Baseline

In December 2005, existing DaVita facilities performed significantly better than acquired facilities on clinical indicators for Hb, Ca × PO_4, iron saturation, Kt/V, phosphorus, and URR ($P < 0.05$; Table 1). Performance on calcium did not differ between cohorts, whereas newly acquired facilities performed better for albumin and ferritin ($P < 0.05$).

Clinical Performances at Newly Acquired Facilities Improved within 2 Years

Markers of dialysis adequacy and metabolic bone disease improved significantly from baseline to year 1 and continued to improve in year 2 in newly acquired facilities (Figure 2). Specifically, in recently acquired facilities, the percentage of patients who achieved ≥1.2 Kt/V increased significantly between baseline and year 1 and continued to improve through year 2 (baseline 83.1%; year 2 94%; $P < 0.001$ *versus* baseline). Anemia,

Table 1. Percentage of patients achieving clinical performance markers by length of center ownership

Clinical Measure	2005			2007		
	Existing	Acquired	P^a	Existing	Acquired	P^a
Adequacy management						
Kt/V ≥1.2	94.9	83.1	<0.001	95.2	94.0	<0.003
URR ≥65	92.6	88.3	<0.001	91.0	90.1	0.106
Metabolic bone disease management						
Ca × PO_4 <55 mg^2/dl^2	65.4	59.9	<0.001	71.1	70.1	0.268
Ca ≤9.5 mg/dl	56.7	57.7	0.188	73.4	72.1	0.057
phosphorus ≤6.0 mg/dl	72.4	64.9	<0.001	73.5	72.8	0.234
Anemia management						
Hb ≥11 g/dl	86.5	83.4	<0.001	82.6	80.3	<0.001
ferritin ≥100 ng/ml	94.7	97.6	<0.001	95.6	96.8	<0.001
TSAT ≥20%	82.6	78.5	<0.001	83.6	79.4	<0.001
Nutrition management						
albumin ≥3.5 g/dl	81.6	83.9	<0.001	83.5	83.9	0.407

TSAT, transferrin saturation.
[a]*P* value reflects existing compared with acquired.

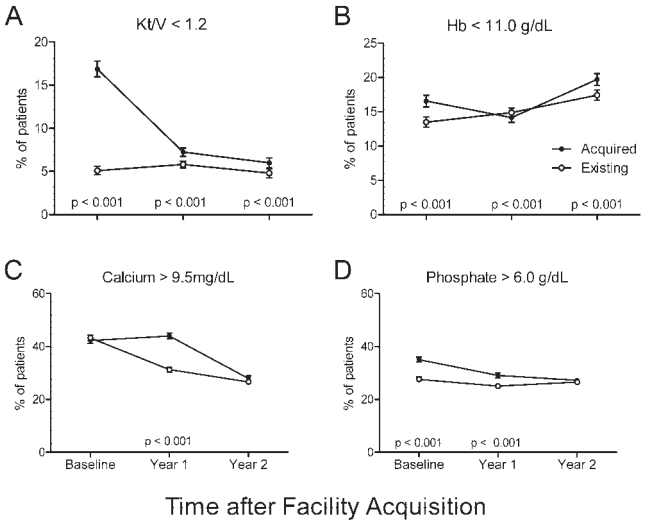

Figure 2. Differences between acquired and existing facilities (*P* values) were seen before and at intervals after acquisition despite dramatic improvement in performance on selected measures.

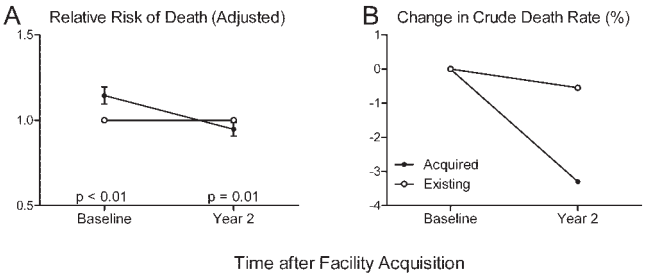

Figure 3. Adjusted relative risk for death and crude mortality rate among prevalent patients declined in both acquired and existing facilities. The change was particularly prominent in acquired facilities. *P* values reflect between-cohort differences.

as measured by insufficient Hb, increased in both newly acquired and existing facilities. Two years later, significant, albeit smaller, between-cohort differences were seen for adequacy and anemia outcomes but not for the metabolic bone disease outcomes calcium >9.5 mg/dl and phosphate >6.0 mg/dl, which showed dramatic improvements in both cohorts. Overall differences between existing and newly acquired facility–associated markers of clinical outcomes were highly significant. Furthermore, by the repeated measures mixed model, these between-cohort differences were highly significant ($P < 0.001$) as a function of length of ownership for all measures except phosphorus ($P = 0.087$).

Existing Facilities Improved with Time yet Remained Superior to Newly Acquired Facilities

During the study period, existing DaVita facilities showed improvement in several KCIs, including albumin, Ca × PO_4, calcium, iron saturation, Kt/V, and URR. Despite the large improvements in KCIs by newly acquired facilities, existing facilities continued to improve patient outcomes, and thus a relative deficit persisted 2 years after acquisition for selected measures (Table 1).

Mortality Rates Declined over Time in Newly Acquired Facilities

Mortality rates were compared between facilities. Within newly acquired facilities, adjusted relative risk for death was significantly higher in the year before acquisition and lower in year 2 (Figure 3A); however, overall mortality rates declined in both cohorts of facilities between baseline and year 2 (Figure 3B). Similar results were noted when incident patients were included.

Discussion

Ownership of dialysis facilities in the United States has undergone dramatic changes in the past decade, characterized by growth and consolidation of for-profit, chain-affiliated units; however, among chains, differences in rates of growth produced striking differences in length of facility ownership. In 2006, for example, the proportion of facilities that were owned for <2 years was 55% within DaVita compared with ≤15% within other LDOs (10). Our current findings confirm previous suggestions that quality management resources that for-profit LDOs provide to facilities can dramatically improve outcomes in patients (3) and that improvement in clinical performance measured by laboratory outcomes is associated with a decline in patient mortality; however, for newly acquired facilities, the full impact of these benefits may not be seen for up to 2 years. Taken together, our results provide new evidence to support the value of clinical practice guidelines and clinical practice recommendations in guiding quality of care in dialysis facilities. Too, they speak directly to the magnitude and complexity of the challenge of improving patient outcomes in newly acquired facilities.

There are limitations to these findings. A retrospective cohort study such as ours can suggest but cannot prove causality. Thus, our findings cannot discern whether patient mortality improved because surrogate outcomes improved or whether each arose independently from a shared cause. Observational studies consistently show that patients whose laboratory values meet clinical performance targets enjoy a more favorable prognosis compared with those whose values do not (2). The more targets that patients meet, the greater their apparent advantage in avoiding hospitalization or death (7). One potential explanation, that target range status confers a direct mortality benefit, seems unlikely in the case of anemia and dialysis adequacy, for which interventional trials have shown no survival advantage to higher compared with lower Hb (11) and Kt/V (12), respectively. In the case of nutritional and mineral bone disease measures, the hypothesis that hypoalbuminemia, hyperphosphatemia, hypercalcemia, or elevated parathyroid hormone each are reversible risk factors for mortality remains plausible but untested by controlled interventional trials (3,4).

In short, strong evidence that achieving any single laboratory outcome directly improves mortality is lacking. An alternative explanation is that the proportion of patients who achieve target surrogate measures provides an indirect marker of the facility's collective organizational effectiveness in preventing or forestalling hospitalization and death. By this line of reasoning, hospitaliza-

tion and mortality rates should be lowest among patients in facilities with the highest levels of facility performance on KCIs and should improve when facility performance on KCIs improve, even when results are adjusted for patient characteristics. Facility-based analyses that arise from the Dialysis Outcomes and Practice Patterns Study (DOPPS) firmly support these conclusions (14). Either scenario, however, is consistent with the conclusion that clinical practice guidelines and clinical practice recommendations prove useful in assessing dialysis facility performance and that the efforts of LDOs to improve dialysis facility performance yield benefits in direct patient outcomes.

Similarly, this study was not designed to identify the specific factors that contribute to the observed lag between facility acquisition and improved performance. Implementation of new policies and procedures, re-education and training of members of the patient care team, installation of new information technology systems to track and report patient outcomes, completion of facility audits, and development of plans to correct deficiencies are key quality-improvement steps that each are time-intensive and resource-dependent. Likely more important but difficult to quantify is the effort and time needed to establish a culture of quality necessary to drive outcomes in successful interdisciplinary care teams.

Because the structure of quality management in acquired facilities was replaced by that in existing facilities shortly after acquisition, the explanation for differences in patient outcomes between the two LDOs at baseline requires speculation. Our impression is that quality management activity in existing facilities before acquisition relied more heavily on directly engaging the patient in the care plan and on using interdisciplinary care teams, including the attending physician and facility medical director, in coordinated efforts to improve patient outcomes, compared with quality management activity in acquired facilities before acquisition. If these organizational differences contributed to the performance gap seen at baseline, then the strength of the patient-centered, team-oriented approach also likely contributed to the improvement observed in both sets of facilities in the 2 years after acquisition. Whatever the explanation, the findings suggest that both length of ownership and effectiveness of quality assessment and process improvement programs are important determinants of successful clinical performance.

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Disclosures

None.

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