

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**OFFICE OF
INSPECTOR GENERAL**

**Clinical Performance Measures
for Dialysis Facilities**

Practices of the Major Dialysis Corporations
Supplemental Report # 1



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EXECUTIVE SUMMARY

PURPOSE

To describe how the five largest dialysis corporations use clinical performance measures to hold their facilities accountable for the quality of care.

BACKGROUND

In our June 2000 report, *External Quality Review of Dialysis: A Call for Greater Accountability*, we urged the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration, to use facility-specific clinical performance measures as a key part of its oversight of dialysis facilities. Clinical performance measures are quantitative indicators, typically expressed as a percentage, that reflect the quality of care patients received. CMS concurred with the directions we suggested and presented a detailed action plan to strengthen its use of clinical performance measures. Since then it has been active in carrying out this plan.

In this follow-up inquiry, we describe the practices of the five largest dialysis corporations in using clinical performance measures to hold their own facilities accountable for the quality of care. This is a significant domain of external quality oversight that we did not address in our prior report and that has been largely ignored in the public sphere. We regard an inquiry into this domain as important because: (1) these corporations account for approximately 70 percent of all dialysis patients in the United States, the vast majority of whom are Medicare beneficiaries, and represent over 2,000 dialysis facilities, (2) they have a substantial body of experience in using performance measures, and (3) they have gained know-how that can be helpful to CMS and others.

This report is the first of two supplemental reports focusing on clinical performance measures for dialysis facilities. The main report is entitled *Building on the Experiences of Dialysis Corporations*. The second supplemental report, *Lessons Learned by the Major Dialysis Corporations and Implications for Medicare*, presents 14 lessons the corporations have learned in collecting and using performance measures. We also make several recommendations to the Medicare program and present comments we received from CMS and other stakeholders on the draft report. All three reports are based on our review of corporate documents, interviews with corporate medical directors, and visits to a number of the corporations' dialysis facilities. We sought to describe their processes and did not evaluate the overall effectiveness of their systems. We did not audit or validate the performance data the corporations collect from their facilities. The corporations voluntarily participated in this review and the data presented was self-reported by the corporations.

CORPORATE PRACTICES

Dialysis Corporations Rely Heavily on Facility-Specific Performance Measures.

This reliance has evolved and increased over more than 10 years. The key corporate practices encompass the following:

Collecting many different measures. Each corporation collects at least 14 different clinical performance measures. They collect data on all their patients within their facilities, usually on a monthly basis.

Collecting the data electronically. They collect much of the facility-specific data electronically, using several different approaches. Three collect some data electronically from clinical laboratories and two collect data directly from computerized dialysis machines; one relies on email to send data files.

Reviewing the data for accuracy. They review the data prior to analysis. The reviews most often take place at a central level by a data analyst or statistician.

Establishing minimum standards. They have established minimum standards for each performance measure. These standards specify a level below which care is unacceptable. If a facility fails to meet the minimum standard, the corporations expect the facility to take action to improve.

Establishing goals. Three of the corporations have established clinical performance goals. The goals seek to give each facility a higher level of performance to aim for.

Conducting comparative analysis at the facility level. Corporations typically compare a facility to its own past performance, its region and/or business division, the company as a whole, and the nation.

Disseminating facility-specific reports. They disseminate facility-specific reports at least every quarter. Two of the corporations disseminate the reports monthly. By the time the facilities receive their reports the data are often less than 3 months old.

Fostering improvements. They encourage their facilities to use performance measures to foster improvements in dialysis care. They look to facilities to conduct quality improvement projects. Toward this end, the corporations conduct training, provide manuals, and reward top performers.

Intervening with poor performers. They use several strategies to intervene with facilities that fail to meet minimum performance standards. First, they seek to determine if the data reveal some basis for concern about a facility's performance. If they do, then the corporations intervene through peer review, training, mandated quality improvement projects, or in the most serious cases, termination of facility staff or physicians.

CONCLUSION

At their own initiative, the five largest dialysis corporations are carrying out a wide range of activities intended to make performance measures a vital, ongoing tool of quality improvement. The corporations differ in some of their approaches and emphases, but more notable are their similarities. Each collects a large number of similar performance measures, relies largely on electronic reporting, generates facility-specific reports that provide comparative assessments, and conducts outreach to help facilities make constructive use of the measures. In our second supplemental report, *Clinical Performance Measures for Dialysis Facilities: Lessons Learned by the Major Dialysis Corporations and Implications for Medicare*, we look more closely at the corporate practices to identify lessons learned and we also make several recommendations to CMS.

TABLE OF CONTENTS

EXECUTIVE SUMMARY	i
INTRODUCTION	1
CORPORATE PRACTICES	5
Dialysis Corporations Rely Heavily on Facility-Specific Performance Measures	5
Collecting Many Different Measures	5
Electronic Data Collection	6
Data Review Process for Accuracy	6
Minimum Standards for Performance Measures	7
Goals for Performance Measures	8
Comparative Analysis at the Facility Level	8
Facility-Specific Reports	9
Using the Measures to Foster Improvements	9
Using the Measures to Intervene with Poor Performers	10
CONCLUSION	11
APPENDICES	12
Appendix A: Glossary of Clinical Performance Measures	12
Appendix B: Facility-Specific Performance Measures Collected by the Corporations ..	13
Appendix C: Comparison of the Corporations' Practices	14
Appendix D: Endnotes	15

INTRODUCTION

PURPOSE

To describe how the five largest dialysis corporations use clinical performance measures to hold their facilities accountable for the quality of care.

BACKGROUND

In 1972, Medicare began covering individuals with end-stage renal disease, or permanent kidney failure, making it the only entitlement criteria for Medicare based solely on a disease category. Patients receiving hemodialysis, the most common method of treatment, typically receive treatment in outpatient dialysis facilities three times a week.¹ About 3,500 dialysis facilities provide ongoing, life-sustaining dialysis treatments to about 240,000 patients around the country.²

Our Prior Inquiry

In June 2000 we released a report examining the Centers for Medicare & Medicaid Services' (CMS), formerly the Health Care Financing Administration, oversight of dialysis facilities as carried out by the End-Stage Renal Disease Networks and the State Survey Agencies (*External Quality Review of Dialysis: A Call for Greater Accountability*, OEI-01-99-00050).^{3,4} In that report we gave attention to the fact that performance measures can be an important tool to encourage facilities to improve the quality of care and to help ensure that they meet minimum standards. But we also found that CMS rarely uses such measures to hold individual facilities accountable.

In our recommendations, we urged CMS to collect and use facility-specific performance data as a key element of its external review system. Clinical performance measures are quantitative indicators, typically expressed as a percentage, that reflect the quality of care patients received. For example, the percentage of patients at a facility that achieved an adequate dose of dialysis as measured by a urea reduction ratio of ≥ 65 percent, is an indicator. (See appendix A for a glossary of terms.)

We urged CMS to identify a new core set of performance measures to collect regularly on all patients from all facilities. We recommended that it make these measures available to:

- ▶ **facilities** to support internal quality improvement activities,
- ▶ **Networks** to support regional quality improvement activities and to identify outliers for further review,
- ▶ **State survey agencies** to help guide and inform the Medicare survey process, and
- ▶ **the public** to foster public accountability.

CMS' Actions

CMS concurred with the directions we set forth and presented a detailed action plan that incorporated numerous efforts it had underway and would be initiating. It is drafting new Conditions for Coverage, Medicare regulations, for dialysis facilities, which it expects to release in draft in the coming months. In doing so, it plans to consider our recommendations to strengthen the role of the medical director, to require facilities to electronically report on a core set of performance measures, and to require facilities to conduct their own quality improvement activities.

CMS has also committed to strengthening its existing efforts to collect facility-specific data on all Medicare beneficiaries as soon as it is able to put into place its new information system, Vital Information System for Improvement of Outcomes in Nephrology.⁵ This new information system will allow facilities to electronically report data directly to CMS. The system will also help ensure accurate reporting through computer software that will contain automatic data edits that will notify the user when data that is illogical is entered. CMS has already implemented the Standard Information Management System for the End-Stage Renal Disease Networks, which connects all the Networks together and directly with CMS. CMS is also revising three administrative data forms that it collects from facilities that contain data used to calculate performance measures. Eventually these forms will be submitted to CMS electronically by the facilities.

Since 1995, CMS, via the End-Stage Renal Disease Networks, has distributed Unit-Specific Reports that provide comparative, facility-specific data, which includes mortality and hospitalization rates. Facility-specific urea reduction ratio and hematocrit levels were added to the reports after 1998. In January 2001, CMS publicly released comparative facility-specific reports that contained three performance measures: urea reduction ratio, hematocrit, and mortality. The reports are available on the Internet.⁶ In July 2001, CMS distributed to State survey agencies, facility-specific reports that also contain key performance measures. State survey agencies use these reports to assist in selecting facilities for review and to focus Medicare certification surveys. Currently the majority of the data in these reports comes from Medicare billing and administrative data and the data are over 2 years old. As the CMS implements its Vital Information System for Improvement of Outcomes in Nephrology it is expected that the data for these reports will be more timely (see appendix B for more detailed information about Federal sources of performance data).

Finally, CMS revised its process to review and approve each of the Networks annual quality improvement projects. The new process is intended to reduce variation in the quality of projects and help Networks design more sophisticated projects. The new process also gives Networks more guidance on what topic areas they should focus on for their quality improvement projects.

Dialysis Corporations Use of Clinical Performance Measures

In this follow-up inquiry we focus on the experiences of large, corporate dialysis providers in using clinical performance measures as a way of holding their own facilities accountable for the quality of care provided. This is a significant domain of external quality oversight that we did not address in our prior report and that has been largely ignored in the public sphere.

We regard it as important to learn more about the experiences of these providers for three major reasons. First, as the dialysis industry has consolidated in recent years, these corporations have become a major force in the dialysis field. The five largest corporations, which we focus on in this report, now account for about 70 percent of all dialysis patients in the United States, the vast majority of whom are Medicare beneficiaries.⁷ They account for over 2,000 of the nation's 3,500 dialysis facilities.⁸ Second, they have a substantial body of experience in using performance measures to monitor the quality of care at their own facilities. And, third, they have gained know-how that may be useful to Federal efforts.

Methodology

We limited our inquiry to the five largest providers: Fresenius Medical Care North America, Gambro Healthcare, Davita (formerly Total Renal Care), Renal Care Group, and Dialysis Clinic, Inc. In selecting the top five, we do not seek to imply that they are necessarily the best in using performance measures, nor to suggest that other corporations or independently owned facilities are not also experienced in using such measures. Each of the five corporations participated in our study voluntarily and made available to us information concerning its practices. The information we present is current as of June 2001. The information contained in this report was self-reported by the dialysis corporations.

At the outset, we considered including in our review measures that relate to clinical performance, patient satisfaction, and adverse events. Each is important to national policy and in each case the corporations have some relevant experience. However, for this inquiry, we decided to limit our focus to clinical performance measures in order to allow for greater detail. Clinical performance measures are the measures that the corporations have the most experience with, receive most of their attention, and bear most immediately on CMS' oversight.

Our data-gathering methods included two focus groups with the medical directors of the five corporations, further interviews with each of the corporate medical directors and other corporate officials, visits to several of the corporations' dialysis facilities, and reviews of pertinent documents of the corporations.

It is important to underscore that our inquiry is not an evaluation of the corporations' practices. They have been carrying out these practices at their own initiative, not in

response to any Federal requirements. We did not seek to assess how well they are using performance measures, nor did we obtain sufficient information to make such an assessment. We did not audit or validate the performance data the corporations collect from their facilities. We did seek to gain a clear understanding of their current practices.

This Report and its Companion Report

This report is the first of two supplemental reports based on the main report entitled, *Clinical Performance Measures for Dialysis Facilities: Building on the Experiences of the Dialysis Corporations* (OEI-01-99-0052). This first supplemental report offers a description of the corporate practices concerning the use of facility-specific performance measures. We address specifics concerning data collection, validation, analysis, dissemination, and corporate practices concerning fostering improvement and intervening with poor performers.

The second supplemental report, *Clinical Performance Measures for Dialysis Facilities: Lessons Learned by the Major Dialysis Corporations and Implications for Medicare* (OEI-01-99-00054), begins with two lessons associated with establishing a foundation for accountability within the dialysis facilities. It then turns to 12 lessons learned from implementing clinical performance measures. We also make several recommendations to CMS. In this report we include the complete comments we received from CMS and other stakeholders on the draft reports in appendix C.

We conducted this study in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

CORPORATE PRACTICES

Dialysis corporations rely heavily on facility-specific performance measures to foster accountability.

The corporations have been collecting performance measures for more than 10 years. They have invested considerably in staff, computers, training, and other resources needed to collect and apply facility-specific performance measures. One corporation estimated its annual budget related to using performance measures at around \$7 million.

Corporate officials shared several reasons for investing in performance measures. One of the major reasons was a strong desire to provide top-quality dialysis care. Performance measures allowed them to systematically monitor quality and identify areas for improvement. One corporate official stated, “Without the data we are blind.” Another reason was that, in the long term, high quality care will lead to increased profitability, “good care is good business.” Patients that are healthier have fewer hospital stays and live longer, and provide more business for the dialysis facility. They also underscored that higher quality of care leads to patient and personnel retention. Dialysis facilities compete intensely for patients, nephrologists, nurses, and other staff. The corporate representatives believed that facilities with a high commitment to quality are better able to attract and retain both staff and patients.

Each corporation collects at least 14 different clinical performance measures.

The corporations typically collect the data on all the patients within their facilities, with the exception in some cases of those patients in a managed care plan. The measures they collect are familiar to most renal professionals and capture various clinical aspects of dialysis treatment. They include measures that evaluate adequacy of dialysis treatment, anemia management, nutritional level, vascular access, bone disease, and hypertension (see box and appendix B). In addition, all the corporations collect data on mortality, hospitalization, and the number of missed treatments. The corporations collect the data regularly, typically on a monthly basis and, in some cases, every treatment.

Common Dialysis Performance Measures

Urea reduction ratio
KT/V
Hematocrit
Hemoglobin
Ferritin level
Transferrin saturation
Parathyroid
Albumin
Blood pressure
Hospitalization rate
Missed treatments
Mortality rates
Peritonitis rates
Vascular access
Clotting events
Transplantation rate
Creatinine clearance

See appendix A for a glossary of terms.

The corporations collect much of the facility-specific data electronically, using several different approaches.

The corporations use a combination of several strategies to collect data. To a varying extent all the corporations still rely on paper forms for some data elements, especially mortality and hospitalization. But the majority of measures are collected electronically. Three corporations collect some performance measures, such as KT/V or hemoglobin, directly from the laboratories, thereby eliminating any need for facility staff to enter or transmit these values. The lab enters the data and the company downloads it. Two of the corporations collect several measures, such as time of dialysis and blood pressure, directly from computerized dialysis machines. The corporation can then download the data at any time, thereby eliminating the need for any manual entry by facility staff. One corporation installed computer terminals at each dialysis treatment station, thereby allowing the nurses to manually enter data at the time of treatment. Later the data is downloaded into the company's central database. Similarly, electronic medical records allow for certain items to be abstracted and downloaded by a central repository. Finally, one company simply has its facilities email an attached data file to a central repository.

But even electronic data submission still requires someone to enter the data into the system in the first place. Most often this responsibility was left to the nurses. It was rare that a dialysis facility had a full-time person dedicated to data entry.

The corporations review the data for accuracy prior to analysis.

Each of the five corporations has a process in place to review the data. The reviews most often take place at a central level where all the data can be reviewed at once. All have full-time data analysts or statisticians at the central level that regularly monitor the data provided by the facilities. One corporate medical director told us that he spends a considerable amount of his time on the phone with facilities asking questions about the data to ensure its accuracy. When information is missing or seems questionable, the data analyst or statistician verifies or obtains the missing information from the facility. The corporations also rely on software programs for data analysis that have automatic data edits built in that prevent illogical data from being included in analysis.

Some of the corporations have also devised tools to help the facilities review the data themselves for accuracy at the local level prior to submitting it to a central location for analysis. One corporation provides a checklist detailing common errors to look for in each individual performance measure. Another corporation has each facility administrator and unit secretary review the data. The corporations have also built into their computer software program for data entry, automatic edits so that the facility nurse who happens to type "12" for a KT/V value instead of "1.2" is alerted and can immediately correct it. Several of the corporations provide facility-specific data audit reports that show the number of missing values and the percentages of errors.

All the corporations have established minimum standards for each performance measure.

The corporations refer to their minimum standards differently: standards of care, internal targets, threshold for evaluation, or action thresholds. Regardless of the name, the corporations defined minimum standards as performance levels below which care is unacceptable. If a facility fails to meet the minimum standards, the corporations expect the facility to take action to rectify the situation; in serious or continuous cases the corporations will intervene. (Later in the report we will discuss the various strategies that the corporations use to help facilities improve.)

Performance Measure	Facility Threshold for Evaluation
KT/V	90 % of patients with ≥ 1.4
Hemoglobin	65 % of patients with ≥ 11 g / dL
Unexcused Treatments	90 % of patients with < 1 missed treatment / quarter
Albumin	60 % of patients with an albumin ≥ 3.8 g / dL
Annual Hospitalization (Hospital days / patient year)	≤ 10 days / patient year
Crude Mortality (annual)	≤ 18 % / year

All the corporations determine their minimum standards using internal expert committees comprised of renal physicians that review the recent literature and practice standards. Minimum standards typically have two components: a target value and the percent of patients within a facility that are expected to meet the target value. For example, one corporation established its target value for KT/V at ≥ 1.4 and further established that 90 percent of the patients within a facility should meet that target (see table). Another corporation uses the targets established by the National Kidney Foundation's Dialysis Outcome Quality Initiative.⁹

The target value and corresponding percentages for each of the performance measures varied among the corporations. For example, the corporations used several target values for the KT/V ranging from ≥ 1.2 to ≥ 1.4 and the percentages also ranged from 85 percent to 90 percent. Similarly target values for albumin levels range from 3.5 to 3.8 with percentages varying from 60 percent to 85 percent of patients. For crude mortality rates one corporation had a target ≤ 18 percent per year and another had its target at ≤ 17 percent per year.

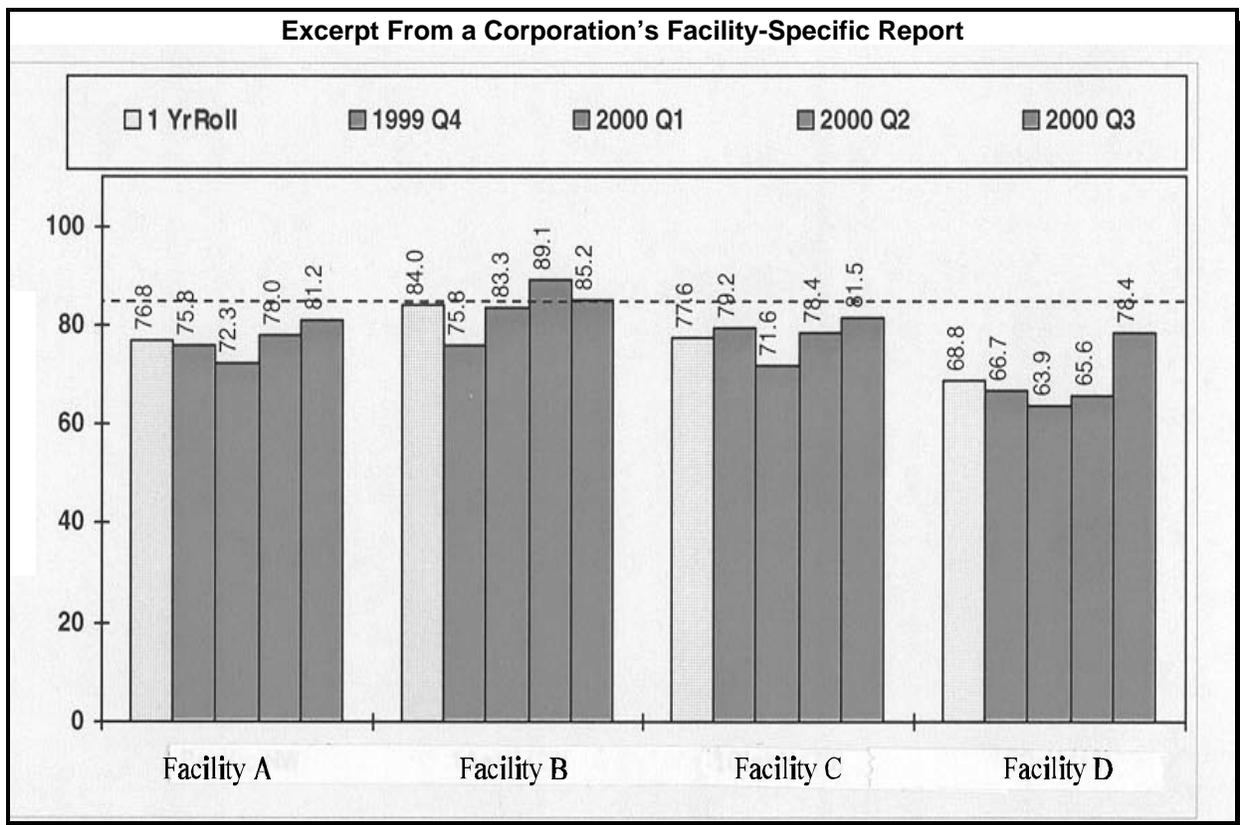
Three of the corporations have also established clinical performance goals.

Goals differ from minimums in that they set a higher bar. Corporations established the goals to encourage all facilities to improve. In the cases where a facility achieved the goals, corporations would often recognized that facility in some way, such as with an award or a bonus to the staff.

Like minimum standards, expert committees established the goals. One company established its goals by using the values achieved by the top 10 percent of its facilities. Another corporation stated that its goal is to have 100 percent of its patient meet the target values set for each measure.

All the corporations conduct comparative analysis of the performance measures at the facility level.

The corporations conduct analysis of all facility data at a central level. They have full-time staff to analyze facility data and create facility-specific reports. The most routine type of analysis performed is comparisons. The facility-specific reports show an individual facility's performance compared with its own past performance, its region's performance, its business division's performance, and its company-wide performance. (The figure below is an excerpt from one corporation's facility-specific report on the clinical performance measure the urea reduction ratio. It shows how four facilities compare to their own past performance, and other facilities in their region. The dotted line represents the minimum performance standard.) Another corporation lists the percentile the facility is in for each clinical performance measure on its reports.



Along with the results of the individual facilities, the corporations analyze the data at the regional or business division level and at a company-wide level. These reports show how each region or business division is meeting the stated clinical performance measure targets set by the corporation. Some of the corporations even compare the company-wide performance with the nation. For national clinical performance data the corporations rely on data collected by CMS.¹⁰

All of the corporations disseminate facility-specific reports at least every quarter.

Two of the corporations disseminate their facility-specific reports monthly and the remaining three disseminate their reports quarterly. By the time the facilities receive their own report, the data is often less than 3 months old and in some cases just weeks old.

Four of the corporations disseminate facility-specific reports through their corporate computer network. Once the reports are on the networks they can be accessed by facility medical directors, facility administrators, nurses and other key personnel at any time. One corporation has its facility-specific reports on the web, allowing physicians to log in from any computer connected to the Internet, enter their passwords, and see a facility's clinical performance measures.

Currently, none of the corporations make its facility-specific reports routinely available to the public. However, at least two of the companies indicated that if a patient requests facility-specific performance measures, they would share them. Some aggregate data on the company's performance as a whole is often available through public financial reports. One corporation routinely makes public aggregate data on the company's performance as a whole through various corporate publications.

The corporations encourage all their facilities to use their performance measures to foster improvement in dialysis care.

None of the corporations simply collect and disseminate the data. The corporations have built a support and accountability infrastructure to maximize the effectiveness of the measures. The corporations encourage all their facilities to conduct quality improvement projects, designed and implemented at the facility level. To foster this goal, all the corporations have developed training programs and materials for facility staff regarding the use of performance measures. These programs and materials help educate nurses and physicians about performance measures in general, how to interpret their facilities' results, and how to develop a plan of action to improve. The companies conduct many of these training sessions in central locations and sometimes the corporations conduct specialized training for just one facility. The training sessions tend to be interactive and focused on actual case examples so that, by the end of the training session, the participants have a plan they can implement at their facility.

Corporations also encourage the facilities to use the data in other ways besides training. One corporation regularly holds conference calls that physicians, nurses, and other

facility staff can call in and share their success stories or ask questions. All the corporations have devised tools to help facilities conduct various quality improvement projects. These tools include how-to guides, worksheets, and best practices. Finally, some of the corporations conduct corporate-wide improvement projects.

All the corporations have devised ways to reward top performers. Some of the corporations compensate the medical directors based on how well their facility meets the corporate performance measurements. In addition, several corporations rank their facilities based on various performance measures and recognize the best overall with a luncheon and/or staff bonuses.

Corporations use several strategies to intervene with facilities that continually fail to meet minimum standards.

Corporations tend to intervene if a facility performance continually declines on several performance measures, continually fails to improve on its performance measures, or the performance measures suggest a problem that is an immediate threat to patient lives. But, prior to intervening, the corporations will try to confirm that the data are accurately depicting the quality of care. This is often done by examining the patient population, complaints, results of State surveys, recent patient satisfaction surveys, and adverse events. In doing so, the corporations are trying to rule out that other factors such as patient demographics or comorbidities do not account for performance measures. Although all the corporations risk adjust some of their data, they are unable to account for everything. A facility could have poor outcomes because it has sicker patients.

The corporations first look to peer review when they need to intervene with a facility. They have committees of regional medical directors that analyze the facility's clinical performance measures. The committee discusses with the facility's medical director why the facility is not meeting the minimums and how to improve performance. Along with this collegial approach, corporations may require the facility to submit a continuous quality improvement project to address the specific problem that is adversely affecting its performance. Corporations also have a quality team comprised of doctors, nurses, dietitians, and social workers who work with the facility in a peer-to-peer manner.

When peer review fails, many of the corporations start to work with the facility on site. One corporation sends a group of clinicians to the facility and actually evaluates how well the facility has addressed the problem. Another corporation also sends a similar team to the facility and conducts a mock Medicare certification survey of the facility.

Another approach is to involve the corporate medical director. One corporation requires the medical director meet with the chief corporate medical director to formally discuss the facility's performance. Another corporation sends a letter outlining the facility's deficiencies and asks the facility's medical director to start addressing the problems. Finally, corporations can remove a medical director or an attending physician from the clinic.

CONCLUSION

At their own initiative, the major dialysis corporations are making significant commitments to using clinical performance measures as tools of quality improvement. While our review did not seek to assess how effective their efforts have been to date, it did make clear that their current practices cover a wide range of activities that are crucial to improving the quality of care and that parallel in fundamental ways activities that CMS is undertaking as part of its national leadership. Our review also made clear that the corporations have developed a considerable body of experience on the do's and don'ts of performance measurement.

Among the five corporations there are some differences in approaches and emphases, but what impressed us much more was the similarities. Each of them collects a large number of measures (by and large the same), relies largely on electronic reporting, generates timely, facility-specific reports that compare a facility's performance with other facilities and its own past performance, and conducts outreach to urge and help individual facilities to commit themselves to quality improvement projects (see appendix C).

In our second report, *Clinical Performance Measures for Dialysis Facilities: Lessons Learned by the Major Dialysis Corporations and Implications for Medicare* (OEI-01-99-00054), we delve more deeply into the corporate practices to identify the lessons that flow from them. We also provide several recommendations to CMS as it fosters the use of performance measures to improve the quality of dialysis care.

Glossary of Clinical Performance Measures For Dialysis

Albumin: A measure of the level of proteins in the blood, used to monitor the level of nutrition.

Anemia: Inadequate red blood cells, a common concern among dialysis patients that can lead to extreme fatigue and other complications.

Catheter: A type of vascular access. A tube placed in a patient's blood vessel, primarily used for temporary access to the blood stream.

Clotting events: Arteriovenous fistulas, both native and synthetic, can become clotted with the patient's blood causing complications for the dialysis patient.

Creatinine clearance: A measure used to determine adequacy in peritoneal patients. Creatinine clearance measures the removal of the protein creatine from the body.

Ferritin level: A measure of the level of iron stored within the body.

Hematocrit: A measure of the ratio of red blood cells to the plasma volume. Used to monitor anemia.

Hemoglobin: A measure of the amount of a specific protein in red blood cells that carries oxygen. Used to monitor anemia.

KT/V: A function of the amount of urea removed multiplied by the time on dialysis, divided by the volume of urea distribution, or approximately the amount of water in the body. Used to monitor the adequacy of the dialysis treatment.

Native arteriovenous (AV) fistula. A type of vascular access. A patient's own artery and vein are surgically joined to allow arterial blood to flow through a vein, usually placed in the forearm and takes several weeks to mature.

Parathyroid: A hormone that regulates calcium and phosphorus and is used to monitor bone disease.

Peritonitis: An inflammation of the peritoneum, a membrane that lines the stomach, that can occur in individuals receiving peritoneal dialysis.

Synthetic arteriovenous (AV) graft: A type of vascular access. A synthetic blood vessel is used to surgically join the patient's artery and vein, usually placed in the forearm and takes several weeks to mature.

Transferrin saturation (TSAT): A measure of iron immediately available to produce red blood cells. Used to manage and monitor anemia in dialysis patients.

Urea reduction ratio (URR): A measure of the amount of urea removed during dialysis, as determined by pre- and post-dialysis blood urea nitrogen levels. Used to monitor the adequacy of dialysis treatment.

Vascular access: The point of direct access to the blood stream for hemodialysis. There are three types: catheter, native arteriovenous fistula, and synthetic arteriovenous graft.

APPENDIX B

Facility-Specific Clinical Performance Measures Collected by Dialysis Corporations

Below is a table showing some of the common clinical performance measures, it does *not* represent all the measures that the corporations and CMS collect.

Performance Measure	Company #1	Company #2	Company #3	Company #4	Company #5	CMS
Urea reduction ratio	✓	✓	✓	✓	✓	✓
KT/V	✓	✓	✓	✓	✓	
Hematocrit	✓	✓	✓	✓	✓	✓
Hemoglobin	✓	✓	✓	✓	✓	✓
Iron indices (TSAT and Ferritin levels)	✓	✓	✓	✓	✓	
Parathyroid	✓	✓	✓	✓	✓	
Albumin	✓	✓	✓	✓	✓	✓*
Blood pressure	✓	✓	✓	✓		
Hospitalization rate	✓	✓	✓	✓	✓	✓
Missed treatments	✓	✓	✓	✓	✓	
Mortality rates	✓	✓	✓	✓	✓	✓
Peritonitis rates	✓	✓	✓	✓	✓	
Type of vascular access	✓	✓	✓	✓	✓	✓**
Clotting events with vascular access		✓			✓	
Transplantation rate		✓		✓		✓
Creatinine clearance	✓	✓			✓	

* CMS collects this information when the patient is first diagnosed.
 ** CMS obtains from the Center for Disease Control and Prevention
 This chart does not represent all the measures that the corporations and CMS collect.

APPENDIX C

Comparison of the Dialysis Corporations' Practices in Collecting and Using Facility-Specific Clinical Performance Measures

	Company #1	Company #2	Company #3	Company #4	Company #5	CMS
Years of experience in collecting facility-specific performance measures	10+	20+	10+	20+	5	10+
Percentage of patients within a facility for which measures are collected	100%	100%	100%	100%*	100%	All Medicare Patients
Data collected electronically from dialysis machine	no	no	yes	no	yes	no
Data submitted electronically from the facility	yes	yes	yes	yes	yes	no
Data collected electronically from labs	yes	no	yes	yes	no	no
Frequency of data collection	monthly	monthly	by treatment	monthly	monthly	varies
Frequency of dissemination of facility-specific performance reports	monthly	quarterly	monthly	quarterly	monthly	annually
Age of data by time it is disseminated	less than 4 weeks	1 day to 12 weeks	1-3 weeks	6-7 weeks	4 weeks	~3 years
Main format for facility-specific reports	intranet	intranet	intranet	intranet and mail	intranet and mail	internet and mail
Compares the facility to its region	yes	yes	yes	yes	yes	yes
Compares the facility to the past	yes	yes	yes	yes	yes	yes
Compares the facility to the company	yes	yes	yes	yes	yes	NA**
Compares the facility to the entire nation	yes	yes	yes	yes	yes	yes
Compares the facility to a minimum standard	yes	yes	yes	yes	yes	yes
Compensation for the facility medical directors is tied to performance measures	no	no	no	yes	yes	NA**
Facility-specific clinical performance measures are routinely publicly available	no	no	no	no	no	some
Provide physician-specific reports	yes	no	yes	no	yes***	no

*except for patients in managed care plans, **not applicable, *** only for facility medical directors

Endnotes

1. Dialysis is the process of removing toxins from the body by diffusion across a semipermeable membrane, thereby compensating for kidney failure. There are two types of dialysis: hemodialysis and peritoneal dialysis. Hemodialysis involves the removal of toxins directly from the patient's blood stream, requiring direct access to the bloodstream. The patient's blood is cycled through an artificial kidney, an external machine, that removes the toxins and excess fluids from the blood. The artificial kidney machine uses a semipermeable membrane, called a hemodialyzer, to filter out the toxins from the blood. Peritoneal dialysis utilizes the patient's natural peritoneal membrane, located in the abdominal cavity, to remove toxins and excess fluids.
2. *The 2001 USRDS Annual Data Report Reference Tables*, The United States Renal Data System, Section J. Accessed via the Internet at [<http://www.usrds.org/reference.htm>].
3. The End-Stage Renal Disease Networks, established in 1976, are CMS' main contractors for monitoring dialysis facilities, as they are entirely focused on dialysis facilities. CMS relies on the 18 regional Networks to collect data from facilities, conduct annual quality improvement projects, and evaluate and resolve complaints. The main mission of the Networks as set out in the Statute is to ensure "effective and efficient administration of the benefits" provided under the end-stage renal disease program. Section 1881(c) of the Social Security Act.
4. CMS contracts with the State survey agencies, typically within departments of public health, to conduct on-site Medicare certification surveys of facilities and to investigate complaints, both in accordance with Medicare Conditions for Coverage for dialysis facilities.
5. Department of Health and Human Services, Office of Inspector General, *External Quality Review of Dialysis Facilities: A Call for Greater Accountability*, OEI-01-99-00050, June 2000, page 47.
6. See [<http://www.medicare.gov/Dialysis/Home.asp>].
7. Based on figures from, "The Ten Largest Renal Providers," *Nephrology News and Issues*, Vol. 15 No. 8, July 2001 p. 30, and *The 2001 USRDS Annual Data Report Reference Tables*, The United States Renal Data System, Section J. Accessed via the Internet at [<http://www.usrds.org/reference.htm>].
8. Ibid.
9. See the following website for the targets established by the National Kidney Foundation, [<http://www.kidney.org/professionals/doqi/index.cfm>].
10. CMS collects several key clinical performance measures through billing and administrative forms. They are urea reduction ratio, hematocrit, mortality, and hospitalization. Facilities

typically submit these billing forms electronically to fiscal intermediaries that process Medicare claims submitted by the facilities, and then pass the data on to CMS.

CMS also collects over 16 clinical performance measures for its Clinical Performance Measures Project through the End-Stage Renal Disease Networks on a national sample of Medicare beneficiaries each year. The measures include the KT/V, urea reduction ratio, serum albumin, and hemoglobin. Facilities submit the data on paper forms to the Networks. Networks enter the data into CMS' data system. The Networks validate a sample of the data.