

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AVAILABILITY OF QUALITY OF
CARE DATA IN THE MEDICARE
END STAGE RENAL DISEASE
PROGRAM**



Daniel R. Levinson
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OBJECTIVE

To assess the extent to which data are available to assist Networks in identifying End Stage Renal Disease facilities with quality improvement needs.

BACKGROUND

Patients with End Stage Renal Disease (ESRD) rely on dialysis treatment to compensate for kidney failure. In 2003, Medicare spent \$18.1 billion on covered dialysis services for approximately 311,000 dialysis patients.

National aggregate data suggest that dialysis care has improved overall. However, questions remain about the quality of care provided at some ESRD facilities. According to the most recently available data (derived from 2002 claims data), about 270 ESRD facilities did not provide adequate dialysis care, as measured by the amount of waste removed from a patient's blood during dialysis, for 20 percent or more of their patients. Nearly 1,700 ESRD facilities did not meet guidelines for anemia management for 20 percent or more of their patients.

To help monitor and improve quality of care, the Centers for Medicare & Medicaid Services (CMS) oversees ESRD facilities through contracts with State survey and certification agencies and ESRD Networks (Networks). State survey and certification agencies survey ESRD facilities to ensure that ESRD facilities comply with current regulations. Networks are statutorily required to identify facilities in need of quality improvement and assist those facilities in developing plans to improve care. Network staff possess clinical expertise related to the care of ESRD patients, enabling them to both assess and assist facilities in the provision of dialysis.

In June 2000, both the Office of Inspector General (OIG) and the Government Accountability Office (GAO) issued reports documenting problems with CMS oversight of ESRD facilities and presented their concerns at a hearing before the Senate Special Committee on Aging. OIG found that, while oversight using standardized performance measures encouraged improvements in quality of care, CMS did not use these measures to hold individual facilities accountable. GAO found that the oversight of ESRD facilities was limited. CMS concurred with the findings and recommendations made by these reports. To address some of the concerns raised by these reports, CMS stated that it was

undertaking steps to begin collecting facility-specific data, including the collection of clinical measures through a project called the Core Data Set that would report accurate, meaningful, facility-specific performance measures.

Given the previously identified problems with the oversight of quality of care in ESRD facilities and ongoing concerns related to quality of care, we assessed the extent to which data are available to help identify facilities with quality improvement needs, an important element of quality oversight. We limited our scope to data available to Networks because Networks are, legislatively and contractually, the primary entities responsible for oversight of quality improvement.

To assess the extent to which data are available to assist Networks in identifying facilities with quality improvement needs, we based our analysis on three sources of information: (1) a review of data sources that measure the quality of care provided by ESRD facilities available to all Networks, (2) a review of documentation regarding how Networks use quality of care data to identify facilities with quality improvement needs, and (3) structured interviews with all Networks and CMS staff responsible for the oversight of quality improvement in ESRD facilities.

In our review of data sources that CMS either provided to all Networks or required all Networks to use, we considered factors such as whether a Network could use the source of data to identify quality improvement needs for specific facilities, whether the data source provided comprehensive quality data, and whether the information in the data source was current.

FINDINGS

While multiple sources of data are available to Networks to assist them in identifying facilities with quality improvement needs, each source has limitations. Based on our analysis, the sources of data available to all Networks, individually and as a system, have limitations in assisting Networks to identify facilities with quality improvement needs. Among other responsibilities, the Social Security Act and the Networks' current contracts with CMS require Networks to identify facilities in need of quality improvement and to assist those facilities in developing plans to improve care. Yet our review of available data sources reveals that Clinical Performance Measures data and Dialysis Facility Report data lack either the specificity or comprehensiveness necessary for Networks to use them to identify facilities that need

assistance. Fistula First provides current and facility-specific data, but only on a single clinical performance measure. Administrative data do not contain clinical performance measures.

CMS has taken action towards providing a streamlined source of data that could assist Networks in identifying facilities with quality improvement needs; however, it has not yet been implemented. In 2000, CMS stated that it was developing a Core Data Set project that would regularly collect facility-specific data on a comprehensive set of clinical performance measures. If implemented as described, the Core Data Set project could provide one national source of comprehensive facility-specific performance measures. However, CMS has faced technical and resource challenges and the implementation of the Core Data Set project is not complete.

RECOMMENDATION

This inspection found that while Networks have access to multiple sources of data about quality of care, each has limitations as a tool to assist Networks in identifying facilities with quality improvement needs. Limitations include lack of current, comprehensive, and facility-specific performance data. Under the current system, Networks' abilities to identify facilities in need of quality improvement may be impaired. CMS stated that it planned to provide a streamlined source of performance information through the Core Data Set project that would address these limitations. However, the Core Data Set project has been under development since 2000 and is not yet implemented.

The consequences of the limitations in the current quality improvement data sources are twofold. First, Networks' abilities to ensure that all patients in all facilities receive quality care may be hindered. To fulfill their legislative and contractual responsibility, Networks need current, facility-specific information about facility performance. Second, lack of facility-specific data negatively impacts CMS's ability to implement a pay-for-performance system for ESRD.

We recommend that CMS increase its efforts towards regularly collecting data from all patients and all facilities on all clinical performance measures identified by CMS to address quality of care issues in the ESRD program.

AGENCY COMMENTS

CMS stated that it has made progress in collecting data to improve the quality of care in the ESRD program; however, opportunities for improvement still exist. CMS outlined the steps it has taken to improve quality of care for the ESRD program, including the development of clinical performance measures, definition of the Core Data Set, and proposed regulations that would require facilities to electronically submit all CPMs on all ESRD patients. CMS also stated that it recently renewed its commitment to developing a new information system called Consolidated Renal Operations in a Web-based Network (CROWN), which would consolidate existing data sources into one system. CMS expects CROWN to be completed in 2008.

OFFICE OF INSPECTOR GENERAL RESPONSE

We recognize that CMS has taken action towards providing a streamlined source of quality data that could assist Networks in identifying quality improvement needs. However, we found that current sources of data have limitations in assisting Networks in identifying facilities with quality improvement needs. We recommend that CMS continue to work towards providing Networks with facility-specific data on all clinical performance measures.

▶ T A B L E O F C O N T E N T S

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OBJECTIVE

To assess the extent to which data are available to assist Networks in identifying End Stage Renal Disease facilities with quality improvement needs.

BACKGROUND

Patients with End Stage Renal Disease (ESRD) rely on dialysis treatment to compensate for kidney failure. In 2003, Medicare covered dialysis services for approximately 311,000 dialysis patients provided by approximately 4,500 Medicare approved ESRD facilities.¹ Medicare spent \$18.1 billion on ESRD patients in 2003.²

National aggregate data suggest that dialysis care has improved overall.³ However, questions remain about the quality of care provided at some individual ESRD facilities. According to the most recently available data (derived from 2002 claims data), about 270 ESRD facilities did not provide adequate dialysis care, as measured by the amount of waste removed from a patient's blood during dialysis, for 20 percent or more of their patients. In addition, nearly 1,700 ESRD facilities did not meet the guidelines for anemia management for 20 percent or more of their patients.

CMS Oversight of the ESRD Program

The Centers for Medicare & Medicaid Services (CMS) divides the responsibility for monitoring and improving the quality of care in the ESRD program between two offices within CMS. The Center for Medicaid and State Operations (CMSO) oversees the survey and certification of Medicare approved ESRD facilities by States. The Office of Clinical Standards and Quality (OCSQ) oversees the ESRD Network (Network) organizations, for which the goals are to develop and implement projects to improve quality of care within the ESRD program.

State Survey and Certification

CMS contracts with States to survey ESRD facilities to ensure that each facility complies with the ESRD regulations.⁴ ESRD regulations address patient care, as well as other conditions, such as the condition of the environment, water, and equipment. According to CMS staff, approximately one-third of ESRD facilities should be surveyed each year.

Networks

CMS currently contracts with 18 regional Networks to oversee the quality of care in ESRD facilities. Established under section 1881(c)(1)(A) of the Social Security Act, Networks are charged with improving the quality of ESRD facilities. Unlike State survey agencies that are responsible for regulatory enforcement, Network staff possess clinical expertise related to the care of ESRD patients, enabling them to both assess and assist facilities in the provision of dialysis. Network funding is approximately \$25 million for 2006.

Pursuant to the Social Security Act, Network responsibilities include, but are not limited to:

- o Developing criteria and standards relating to the quality and appropriateness of patient care,
- o Identifying facilities and providers that are not cooperating toward meeting Network goals,
- o Conducting onsite reviews of facilities and providers if necessary, and,
- o Collecting national ESRD data.⁵

CMS further delineates Network responsibilities through the 2003-2006 Network Statement of Work (SOW). Among other tasks, Networks are required under their contract to

[assist] ESRD providers and facilities (either individually or in groups) in developing and implementing facility-specific quality improvement actions to improve their patient care processes and outcomes, upon request and/or upon identifying poor performance or a specific need.⁶

Concerns Regarding the Oversight of ESRD Facilities

The Office of Inspector General (OIG) and the Government Accountability Office (GAO) have previously found problems with CMS oversight of ESRD facilities. In June 2000, OIG and GAO issued reports⁷ documenting problems with CMS oversight of ESRD facilities and presented their concerns at a hearing before the Senate Special Committee on Aging.

OIG found that while CMS oversight using standardized performance measures encouraged improvements in quality of care, CMS did not use these measures to hold individual facilities accountable. OIG also found that Medicare certification surveys played a limited role in ensuring that ESRD facilities met minimum standards.

I N T R O D U C T I O N

GAO found that the oversight of ESRD facilities needed improvement. In particular, GAO found that CMS surveyed a limited number of facilities and that many facilities went years between surveys. In addition, GAO found that data used by CMS to target surveys were neither timely, nor necessarily reliable.

CMS concurred with the findings and recommendations made in both of these reports. To address some of the concerns raised by these reports, CMS stated that it was undertaking steps to begin collecting facility-specific data, including the collection of clinical measures through a Core Data Set project that would report accurate, meaningful facility-specific performance measures. CMS also stated that it intended to collect these data on all ESRD patients regularly.

In response to a request from the Senate Finance Committee, in 2003 GAO conducted a follow-up study examining CMS oversight of ESRD facilities. GAO reported that problems with quality of care were prevalent at dialysis facilities, putting patients' health at risk. GAO found that limitations in the ESRD survey process inadequately addressed or failed to detect quality problems. In response to this report, CMS stated that, among other improvements, it planned to provide “. . . one patient-centered data set that can be used for program oversight.”⁸

ESRD Quality Initiative

In 2004, as part of a larger departmental Quality Initiative intended to ensure quality health care for consumers, CMS developed an ESRD Quality Initiative with the objective of stimulating and supporting significant improvements in the quality of dialysis care.⁹ Among other activities, this initiative “aims to refine and standardize dialysis care measures, ESRD data definitions, and data transmission to support the need of Medicare’s ESRD program.”¹⁰ CMS is also currently experimenting with ways to link quality to payment. As part of the ESRD Quality Initiative, CMS is developing a demonstration project for bundled payment that has a pay-for-performance element. This demonstration project is supported by the Medicare Payment Advisory Commission,¹¹ and is indicative of an overall effort by the Department of Health and Human Services (Department) to link performance and quality of care to reimbursement.¹²

Use of Data in Oversight of the ESRD Program

Several organizations have suggested that access to quality of care data is necessary to provide adequate oversight of the program. The

Institute of Medicine and the Medicare Payment Advisory Commission have recognized the necessity of data to provide meaningful oversight.¹³ These organizations recommended that providers be required to report performance measures to stimulate improvements in quality of care. Further, the Balanced Budget Act of 1997 required CMS to measure and report data about quality of care by the year 2000.¹⁴ In response, CMS began to develop the ESRD Clinical Performance Measures (CPM) and the Dialysis Facility Compare Web site, which publishes data from the Dialysis Facility Report (DFR) (described below).

Currently, Networks have access to several data sources containing information about the ESRD program.

ESRD Clinical Performance Measures Project

The ESRD CPM project is a national effort led by CMS and the Networks to collect and report clinical performance data. Currently, 13 clinical performance measures based on National Kidney Foundation clinical practice guidelines are reported as part of the CPM project. The National Kidney Foundation guidelines are commonly accepted standards on the quality of dialysis care. As such, CMS uses these measures as the key indicators of the quality of dialysis care. Each of the clinical performance measures addresses one of the following categories: adequacy of dialysis, anemia management, or vascular access.

Performance data on each of these clinical performance measures is collected and reported in aggregate each year. The data are derived from a medical record review of a national random sample of ESRD patients, stratified by Network.

Dialysis Facility Report

Issued by CMS, the DFR is a report containing facility-specific information on dialysis services. In 1998, CMS hired a contractor to produce a report for each Medicare-certified ESRD facility. The report contains summary data on each facility's dialysis patients for specific measures related to quality of care. The DFR data are derived from existing administrative and Medicare claims data. The DFR lists the State, Network, and national average for each performance measure for comparison. The DFR includes information on demographics, patient characteristics, adequacy of dialysis, anemia management, transplant rates, hospitalization rates, and mortality rates.¹⁵ The DFRs are issued annually.

National Fistula First Initiative

The National Fistula First Initiative (Fistula First) is a quality improvement project conducted by all Networks to promote the use of arteriovenous (AV) fistulas¹⁶ in all suitable dialysis patients. CMS, Networks, and other provider partners began to develop this project in July 2003.

As part of Fistula First, facilities collect data elements related to vascular access and submit this information to the Networks monthly. The Fistula First data collection tool provided by CMS requests patient information about the type of access in use on the last day of the month. This information is aggregated into a monthly national report for comparison to regional and national averages.

Administrative Data

Networks also have access to administrative data. Networks report administrative information to CMS on an ongoing basis that includes patient demographics, enrollment, deaths, complaints, and grievances.

Additional Process for Requesting Data

Finally, CMS reports that they have developed a process through which Networks may request permission to collect additional data. According to the SOW, Networks are required to have any data collection effort that is not specifically required by the SOW approved by CMS.

SCOPE AND METHODOLOGY

Scope

Given the previously identified problems with the oversight of quality of care in ESRD facilities and ongoing concerns related to quality of care, we assessed the extent to which data are available to help identify facilities with quality improvement needs, an important element of quality of care oversight. We limited our scope to data available to Networks because Networks are, legislatively and contractually, the primary entities responsible for oversight of quality improvement.

Methodology

To assess the extent to which data are available to help identify facilities with quality improvement needs, we based our analysis on three sources of information: (1) a review of data sources that measure the quality of care provided by ESRD facilities available to all Networks, (2) a review of documentation regarding how Networks use quality of care data to identify facilities with quality improvement

needs, and (3) structured interviews with all Networks and CMS staff responsible for the oversight of quality improvement in ESRD facilities.

Data Source Review

To assess the extent to which data are available to help identify facilities with quality improvement needs, we reviewed sources of data that CMS either provided to all Networks or required all Networks to use. In reviewing these sources, we considered factors such as whether a Network could use the source of data to identify quality improvement needs for specific facilities, whether the data source provided comprehensive quality data, and whether the information in the data source was current.

During our preliminary analysis, we identified the following four data sources that were available to all Networks:

- 2004 ESRD Clinical Performance Measures Project,
- 2004 Dialysis Facility Report,
- Fistula First, and
- Administrative data.

To assess whether these four data sources assist Networks in identifying facilities with quality improvement needs, we reviewed the scope and methodology for reports or projects associated with each data source. We reviewed the type, age, and method of information collected. We also reviewed reports from these data sources (e.g., the 2004 CPM Annual Report and the 2004 DFR) to understand how CMS and Networks may be using these data sources to measure and identify quality of care needs in ESRD facilities.

Documentation Review

In addition to our review of the data sources available to Networks, we reviewed documentation provided by Networks and CMS to understand how potential problems with quality of care in ESRD facilities are identified. We also reviewed documents that provided information on the oversight of the ESRD program including relevant sections of the Social Security Act, current CMS regulations, and proposed CMS regulations for the ESRD program, which govern the survey and certification of the ESRD program.

I N T R O D U C T I O N

From the Networks, we reviewed:

- Any analysis that Networks had completed using quality of care data to identify possible dialysis facilities in need of review or training,
- Documentation about the effectiveness of quality of care data,
- Documentation regarding Network requests to collect data, and
- Correspondence about any barriers to use of quality of care data.

From CMS, we reviewed:

- Current SOWs for Networks and CMS's data contractors,
- Evaluation criteria for the Networks,
- Correspondence between CMS and the Networks about the collection and use of data,
- Documentation regarding Network requests to collect data, and
- All of the Networks' quarterly reports for the first three quarters of calendar year 2005.

Structured Interviews

We conducted structured interviews with all Network and CMS staff responsible for the oversight of the quality of care provided in ESRD facilities to obtain information about how the various data sources are used to identify potential quality of care problems.

We conducted structured interviews with executive-level representatives and/or their staff responsible for quality improvement and data-related activities from all 18 Networks. Our interviews were conducted between October 13 and November 10, 2005. We conducted one interview with all relevant parties at each Network. Because 1 agency administers the contracts for 2 Networks, this resulted in 17 interviews.

During our structured interviews, we asked Networks how useful each of the data sources are in identifying needed improvements in quality of care in ESRD facilities. We also asked if Networks faced any barriers to using the data sources and inquired about the impact of those barriers. To ensure that we identified all sources of quality of care data, we inquired about any additional sources that Networks use to assist with their quality improvement activities.

I N T R O D U C T I O N

We also conducted structured interviews with CMS central office staff in November 2005. We spoke with staff responsible for the oversight of the ESRD program in OCSQ and CMSO to learn what quality of care data CMS provides to Networks, and to identify requirements regarding the use of quality of care data by Networks. We also asked for details on the sources of quality of care data CMS provides to all Networks and CMS's future data collection plans for the ESRD program.

We created a coding system to analyze our structured interviews. After creating the coding system, we analyzed the responses using both SAS® and Access®. In developing our findings, we used this analysis of interview data to supplement our review of the data sources and documentation.

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

► FINDINGS

While multiple sources of data are available to Networks to assist them in identifying facilities with quality improvement needs, each source has limitations

Among other responsibilities, the Social Security Act and the Networks' current contract with CMS require Networks to identify facilities in need of quality

improvement and to assist those facilities in developing plans to improve care. To identify these facilities, Networks need clinical performance data on each facility that would allow facilities to be assessed in a timely fashion. While Networks have access to a number of data sources related to the ESRD program, each of these sources has limitations as a tool to assist Networks in identifying facilities with quality improvement needs. Limitations of existing sources of data include lack of facility-specific data, lack of comprehensive clinical performance measures, and questionable timeliness. The multiple sources of data together compose a system of data about quality of care available to Networks. However, this system is fragmented, duplicative, and lacks comprehensive clinical performance measures.

Clinical Performance Measures data do not enable Networks to identify facilities with quality improvement needs

Our review of the CPM methodology revealed that the CPM project does not provide facility-specific clinical performance data. Rather, the CPM project collects aggregate performance data. The only way CPM data can be used to identify facilities with quality improvement needs is if facilities first identify their own performance problems by comparing their performance to the CPM data, and then self-report these problems to the Network.

In addition to our review, Networks also report that CPM data cannot be used to identify facilities with quality improvement needs. Representatives from all 18 Networks reported that they cannot use CPM data to target individual facilities in need of quality improvement. As one Network representative noted, if 90 percent of facilities meet Network goals on a clinical performance measure and 10 percent do not, the Network has no way to use the CPM data to identify the 10 percent of facilities who need assistance. Other Network representatives observed that each facility may only have a few patients in the CPM sample, which is not enough for the data to be statistically valid at the facility level, so no conclusions can be drawn about a specific facility's performance.

Staff at eight Networks reported that the lack of facility-specific performance information in the CPM data only allows for the identification of broad educational efforts. When these Networks have discovered a problem with a particular CPM, they have responded by educating the entire Network of facilities. While broad educational efforts may be beneficial, these efforts may also use resources that could have been more efficiently targeted at specific facilities with quality of care problems.

Dialysis Facility Report data provides data on only 3 of the 13 clinical performance measures. In addition, most Networks report timeliness of the data is a limitation

The DFR does contain some facility-specific data that may assist Networks in identifying facilities with quality improvement needs. The annual DFR contains facility-specific information about dialysis care, primarily derived from Medicare claims data. However, only 3 of the 13 CPMs identified by CMS are covered by the DFR.¹⁷ Networks are not required to use DFR data under their SOW, as they are with other sources. The DFR is primarily intended to be used by State surveyors to target ESRD facilities that will be visited for recertification each year.

The three CPMs reported in the 2004 DFR are derived from claims data that was between 8 and 20 months old at the time the Networks received it. For each of these three CPMs, the DFR reports one data point (an average or mode) derived from data from the previous calendar year.

Despite finding some aspects of the DFR useful, representatives from 14 of 18 Networks report that the age of the data is a limitation. Staff at one Network provided an example of how they tried to use the DFR data to identify and address quality improvement needs and had limited success. This Network developed a project to identify and assist facilities that did not meet the guideline for a particular DFR measure. The DFR data showed that 30 facilities in their Network were not performing adequately. However, when the Network began to assist these facilities, it discovered that nearly half of the facilities were, at that time of the intervention, meeting the identified goal. Further, the Network had no information on whether any facilities outside of the 30 that were originally identified had developed a problem since the time period reflected by the data.

While some Networks attempted to use the DFR data to identify facilities with quality improvement needs, others reported that they only used it after a concern is identified through other means, citing timeliness as the reason. Nearly half of the Networks volunteered that they only review DFR data when addressing a previously identified concern about a facility, or only use it in conjunction with other information sources. All but one of these Networks indicated their limited usage is due to the age of the data.

Six Networks also expressed concern about the accuracy of the DFR data. We did not review the accuracy of the data. We did ask the contractor who prepares the report about validation procedures for the DFR data. They reported that the data are not routinely validated, but facilities are allowed the opportunity to make corrections to their self-reported data prior to the reports being issued. A 2003 study compared DFR data to CPM data, a portion of which was validated against medical records.¹⁸ This study found that there was general agreement between clinical variables submitted on claims (used in the DFR) and in the CPM project.

Fistula First data address only one clinical performance measure

Our review of the Fistula First data collection tool revealed that Fistula First provides both facility-specific and current data related to the use of AV fistulas for hemodialysis access. Networks are evaluated on the performance of all facilities in their Network on vascular access measures. Our documentation review also identified examples of how Networks have successfully used this facility-specific information for quality of care oversight. Specifically, one Network uses the data to target facilities for site visits. In addition, several Networks use it to develop facility-specific quality improvement plans for vascular access.

However, the Fistula First data provide information on only 1 CPM, related to vascular access, out of the 13 CPMs identified by CMS. These data do not provide information on other CPMs, such as those related to adequacy of dialysis or anemia management.

Administrative data do not contain clinical performance measures

Administrative data provide information on patient demographics, enrollment, and deaths. Administrative data also provide information on complaints or grievances, which can be used to identify instances of poor performance, although not systematically. Further, administrative data do not contain CPMs. For these reasons, Networks cannot rely upon these data to identify facilities with quality improvement needs.

CMS reports an additional process for collecting facility-specific data; however, this process is not designed to identify facilities with quality improvement needs

CMS reported that they have developed a formal process through which Networks may request permission to collect additional data from facilities within their own Network. According to the SOW, Networks are required to have any data collection effort that is not specifically required by the contract approved by CMS. CMS established a data review committee to review such requests.

However, this process is not intended to assist Networks in identifying facilities with quality improvement needs. According to CMS staff, CMS expects that a quality improvement need be identified before the data can be collected. Therefore, this process does not seem to be a viable option for Networks to use to identify facilities with quality improvement needs.

Further, the process of Networks requesting additional facility-specific data is not routinely invoked. While the process of requesting data is available to all Networks, it requires a proactive effort to request it.

Taken together, the sources of available data compose a system with limitations for identifying facilities with quality improvement needs

All sources of data about quality of care together compose a system of data available to Networks. However, this system is fragmented, duplicative, and lacks comprehensive performance measures.

The current system of data about quality of care is fragmented. We have identified at least five different sources of data about quality of care in this report. For Networks to try to use existing data systematically to identify facilities with quality improvement needs, they would need to extract different data elements from each of the five sources and assemble those data elements together to profile each facility in their Network. On average, each Network has approximately 250 dialysis facilities.

The current system of data also contains some information that is duplicative and inconsistently reported. For example, data about anemia management, a key measure of dialysis care, is currently being collected as part of two different projects: the CPM project and the DFR. Each project collects the data in different ways from potentially different populations covering different periods of time. The CPM project anemia management data are obtained from the medical records of sampled patients. The DFR data come from data reported on

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Medicare claims. In addition, other duplicative data are reported using different measures. The 2004 DFR reported vascular access information, but not the same vascular access information reported in the CPM or Fistula First projects.

Finally, the current system lacks comprehensive clinical performance measures on each facility. Even when viewed together as a system of data, currently available sources provide facility-specific information about only 4 of the 13 CPMs.

CMS has taken action towards providing a streamlined source of quality data that could assist Networks in identifying facilities with quality improvement needs; however, it has not yet been implemented

In 2000, CMS stated they were developing a Core Data Set project that would collect facility-specific data on a comprehensive set of clinical performance measures regularly. If implemented as described, the Core Data Set

project could capture data currently collected from multiple sources in one national source of comprehensive facility-specific performance measures. However, CMS staff reported that technical and resource challenges have delayed implementation of the Core Data Set project, which is not complete.

CMS initiated a Core Data Set project that could assist Networks in identifying facilities with quality improvement needs

In response to the June 2000 OIG and GAO reports indicating flaws with the oversight of the ESRD program, CMS stated that it was developing the Core Data Set project. According to CMS's comments published in each of these reports, the Core Data Set project would strive to "determine and report accurate, meaningful facility-specific performance measures [to] allow comparisons across dialysis centers and will ultimately increase facility accountability and patient choice."¹⁹ CMS also stated that they intended to collect these data on all ESRD patients regularly. Further, the Core Data Set SOW issued by CMS specified:

that the Core Data Set will include data elements currently needed by the ESRD Networks under their contract with CMS to conduct quality improvement oversight activities and those data elements currently needed (or collected) by CMS to conduct ESRD program oversight activities.²⁰

F I N D I N G S

The Core Data Set project would include elements currently collected as part of other projects, such as the CPM, DFR, and Fistula First, as well as other measures.²¹ Rather than collect all of these data elements through separate projects, the Core Data Set project would consolidate and standardize these data into one project.

While CMS has made progress, over the past 6 years the Core Data Set project has not been implemented

CMS officials report that they have made progress towards implementing the Core Data Set project by identifying the data elements to be collected. In January 2000, CMS initiated a public process to identify the data elements of the Core Data Set. CMS finalized the list of desired data elements in 2005.

CMS has also started establishing systems to collect the Core Data Set. According to CMS staff, the next phase of implementation of the project is electronic data collection. CMS is currently developing two different methods of electronic data collection. First, CMS is testing electronic downloads of quality improvement information with the Large Dialysis Organizations (LDO).²² Second, CMS is developing and distributing a software product that would enable electronic data collection for non-LDO facilities.

CMS has continued to promote electronic data collection of quality improvement information by suggesting that it become mandatory. In the proposed regulations for ESRD facilities, CMS would require facilities to submit CPM data and future clinical performance standards electronically.²³ The proposed regulations do not define how often these data would be collected; the regulations state that this information would be required to be submitted at intervals specified by the Secretary of the Department of Health and Human Services.

In the meantime, CMS staff indicated that they have made recent progress by collecting facility-specific lab data. CMS staff report that Networks have access to at least 3 months of lab data from the preceding year from 70 percent of facilities, and that Networks are allowed to collect these same data from the remaining 30 percent of facilities.

Despite progress, CMS staff responsible for the quality oversight of the ESRD program report that the Core Data Set project has not been implemented due to technical and resource challenges. Most of the technical challenges CMS staff report are associated with electronic

F I N D I N G S

data collection and include: developing file specifications, standardizing definitions of data elements, and validation of Core Data Set elements.

In a 2004 SOW for an electronic information system, CMS stated that “. . . there is an immediate need to develop a standard quality improvement data collection instrument and file format with standard definitions of the data elements to support quality improvement activities defined in the Network SOW.”²⁴ However, CMS representatives reported during our interview that they do not have dedicated funding to implement the Core Data Set project. As such, CMS staff indicated that they are focusing on incremental changes to existing data systems in ways that would support the Core Data Set project.

► R E C O M M E N D A T I O N

This study found that while Networks have access to multiple sources of data about quality of care, each has limitations as a tool to assist Networks in identifying facilities with quality improvement needs. Limitations include lack of facility-specific, comprehensive, and current clinical performance measures. Taken together, these sources compose a limited system of data about the quality of the ESRD program.

Under the current system, Networks' abilities to ensure that all patients in all facilities receive quality care may be impaired. While facilities may take the initiative to compare their own performance to national targets and self-report deficiencies, this is not required. To fulfill their legislatively mandated and contractual oversight responsibilities, Networks need facility-specific, comprehensive, and current clinical performance measures.

In addition to implications for quality of care, limitations of the current system of data about the ESRD program may have implications for the movement in health care towards linking payment to quality. The Medicare Payment Advisory Commission has expressed an interest in a pay-for-performance system for ESRD facilities using quality improvement information. Also, the Department is currently developing a demonstration project that will include a pay-for-performance element. While CMS has not yet defined how they will implement a pay-for-performance system, it is reasonable to assume that such a system would require facility-specific, current information on a number of performance measures.

Finally, the type of available data about the ESRD program are not only important for Networks but for other users as well, such as State surveyors, CMS staff who administer the ESRD payment, CMS staff who establish regulations, lawmakers, and the public.

We recognize that CMS initiated a plan to provide a streamlined source of performance data through the Core Data Set project that could address the limitations of the current system. The Core Data Set project could provide facility-specific data on all of the clinical performance measures on all patients regularly to facilitate comparisons among facilities to increase facility accountability and patient choice. CMS has stated that it faces technical and resource challenges to collecting data for the Core Data Set. However, the Core Data Set project has been under development since 2000 and has not yet been implemented.

We recommend that CMS increase its efforts towards regularly collecting data from all patients and all facilities on all clinical performance measures identified by CMS to address quality of care in the ESRD program.

CMS could accomplish this through completing implementation of the Core Data Set project, or by some other means. This supports our earlier recommendation to CMS regarding development of facility-specific quality improvement information. In our 2000 report entitled “External Quality Review of Dialysis Facilities: A Call for Greater Accountability” (OEI 01-99-00050), we recommended that CMS use facility-specific performance measures to encourage facilities to improve quality of care and to help ensure that facilities meet minimum standards.²⁵ CMS concurred with this recommendation, stating that the Core Data Set project under development would accomplish this goal.

AGENCY COMMENTS

CMS stated that it has made progress in collecting data to improve the quality of care in the ESRD program; however, opportunities for improvement still exist. The complete text of CMS’s comments can be found in the appendix.

CMS outlined a number of steps it has taken to improve quality of care for the Medicare program and ESRD. In particular, CMS noted that it developed CPMs in response to the Balanced Budget Act of 1997 requirement that CMS measure and report the quality of renal dialysis services by January 1, 2000. CMS also noted that between 2003 and 2005 it defined the Core Data Set, which created a data dictionary of data elements including clinical performance measures. In addition, CMS stated that it proposed regulations for ESRD facilities that would require facilities to electronically submit all CPMs on all ESRD patients. CMS expects to finalize these proposed regulations in 2007.

CMS also stated that it recently renewed its commitment to developing a new information system called Consolidated Renal Operations in a Web-based Network (CROWN), which would consolidate existing data sources into one system. CMS expects CROWN to be completed by 2008.

OFFICE OF INSPECTOR GENERAL RESPONSE

We recognize that CMS has taken action towards providing a streamlined source of quality data that could assist Networks in

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identifying quality improvement needs. However, we found that current sources of data have limitations in assisting Networks in identifying facilities with quality improvement needs. These limitations include lack of current, comprehensive, and facility-specific performance data.

We recommend that CMS continue to work towards providing Networks with facility-specific data on all clinical performance measures. We encourage CMS to ensure that the Final Rule expected in 2007 in combination with the CROWN information system expected in 2008 will result in Networks being provided with facility-specific data on all clinical performance measures for all patients.

AGENCY COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 16 2006

TO: Daniel R. Levinson
Inspector General

FROM: Mark B. McClellan, M.D., Ph.D. 
Administrator

SUBJECT: OIG Draft Report: "Availability of Quality of Care Data in the Medicare End Stage Renal Disease Program," OEI-05-05-00300

Thank you for the opportunity to review and comment on this report. The Centers for Medicare & Medicaid Services (CMS) shares your interest in the availability of quality of care data to assure and enhance the quality of care provided to individuals with End Stage Renal Disease (ESRD). CMS supports the transformation of the health care system to one where interested parties can make informed decisions about the most effective medical care, based on timely access to the latest evidence, and in a way that delivers the highest value. To help achieve this transformation of the health care system, we are expanding quality and cost measurement in Medicare, including the ESRD program, and implementing payment and other reforms that promote better quality and more efficient care. As a result, by 2007, we expect to have an unprecedented set of thirteen clinical performance measures available. This transformation is especially pertinent to individuals with End Stage Renal Disease. Even though national aggregate data suggest significant and sustained improvements in care for ESRD beneficiaries, opportunities still exist to assure and enhance quality of care for this complex and vulnerable population, especially at the facility-level.

As noted in your report, ESRD Networks are charged by statute with undertaking activities to improve the quality of care provided by ESRD facilities. CMS believes that ESRD Networks currently have the data necessary to perform this valuable role but we also recognize that the quantity, quality, and timeliness of these data can be improved so that Networks perform their role more effectively and efficiently. We appreciate your thorough evaluation, which provides valuable insight, and your timely recommendation, which reinforces our efforts to continually improve the ESRD program.

The availability of valid, reliable, and timely data on clinical and economic performance will become an increasingly critical tool for quality assurance, quality improvement and other emerging efforts such as payment for performance. Our efforts to increase transparency and accountability in the ESRD Program have followed a linear process with three phases: implementation of a core set of ESRD performance measures; development of an expanded set of ESRD performance measures; and finally, implementation of this expanded set of measures. CMS believes that this linear process is consistent with good business practices.

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CMS' leadership in the area of quality measurement and its relationship with improvements in care for ESRD beneficiaries was recognized in the OIG report issued in 2000, "External Quality Review of Dialysis Facilities: A Call for Greater Accountability." Since 1994, CMS has measured the quality of care provided to patients with ESRD through the Clinical Performance Measures (CPM) Project or its predecessors.¹ The CPMs implemented Section 4558 (b) of the Balanced Budget Act, which requires CMS to develop and implement by January 1, 2000, a method to measure and report the quality of renal dialysis services provided under the Medicare program. Each year, the CPM Project surveys facilities using a paper process to collect 13 measures based on the National Kidney Foundation's (NKF) clinical practice guidelines on a national sample. In addition, ESRD Networks use the national CPM sample to identify opportunities for improvement within their geographic area and incorporate more frequent and detailed data collection as part of their quality improvement projects. Although CPM data are not facility-specific, through improvement projects Networks work with individual facilities. This process has resulted in documented improvements in care every year since the inception of the CPM Project and was recognized in the 2000 OIG report, which stated that the CPMs were the major strength of the external oversight system and that:

- CMS-generated data show measurable improvements in clinical outcomes at the national and regional levels.
- Network quality improvement projects show improvements at the regional level and, in some cases, at the facility level.

Since 2000, CMS has emphasized improving its ability to assure and enhance quality for individuals with ESRD. This emphasis is summarized in CMS' ESRD Quality Initiative, which concentrates in the areas of data quality; quality improvement support to dialysis providers; compliance with minimum accepted standards of care; transparency to assist beneficiaries in making informed decisions about their care; and partnerships within the ESRD community.²

A key element in the ESRD Quality Initiative is the specification of a Core Data Set which systematically defines the data that will be collected at the facility level. These data are necessary to drive better decision-making by beneficiaries and dialysis providers as well as CMS and its related quality organizations. The subject OIG report highlighted the value of CMS plans for the

Core Data Set, stating "If implemented as described, the Core Data Set project could provide one national source of comprehensive facility-specific data on a comprehensive set of clinical performance measures."

Between 2003 and 2005, CMS and the ESRD Networks partnered with the ESRD community to develop the Core Data Set, which created a common "kidney data dictionary" complete with standardized data elements, data definitions, and integrity constraints necessary for ESRD Networks to conduct quality improvement oversight activities and for CMS to conduct ESRD

¹ CMS is holding Technical Expert Panels in the fall of 2006 to evaluate and if necessary, update the existing CPMs based on recent updates to the National Kidney Foundation's K-DOQI clinical practice guidelines.

² <http://www.cms.hhs.gov/ESRDQualityImproveInIt/downloads/ESRDOverview.pdf>.

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Program oversight activities. Along with the development of the kidney data dictionary to standardize what data could be provided, CMS also worked on “why” and “how” the data should be provided. In early 2005, CMS proposed new dialysis facility Conditions for Coverage, which require facilities to electronically submit all administrative data and CPMs for all ESRD beneficiaries. CMS has received favorable feedback from the ESRD community on this new requirement and expects to publish a Final Rule in 2007.

CMS is also working to ensure the increased provision of electronic data will add value to facilities’ operations and patients’ lives. A primary example of this partnership is the Fistula First Breakthrough Initiative, where facilities’ submission of data to the ESRD Networks in more detail and frequency than the CPMs has resulted in a more coordinated approach to care evidenced by a significant increase in the number of AV Fistulas, which are associated with significant reductions in avoidable hospitalizations and death for ESRD beneficiaries. Because of this focus and partnership, the ESRD community exceeded the Nation’s Healthy People 2010 goal for vascular access 5 years ahead of schedule.³

With the kidney data dictionary completed in 2005, CMS started work on implementing the expanded set of ESRD performance measures in 2006 with a new web-based information system called CROWN (Consolidated Renal Operations in a Web-based Network). Instead of the disparate data sources, systems, and reporting that currently exist, CROWN will consolidate these into one system that complements the advanced information infrastructure used by many dialysis facilities.⁴

In June 2006, at a strategic planning session attended by a broad representation of the ESRD community, CMS announced its commitment to developing the new CROWN system and sought ongoing dialogue with the community to ensure the system achieves the goal of replacing the predominately paper process that currently exists with a system that is more timely, accurate, and efficient. CMS has also dedicated the funds and resources necessary to develop and implement this new information system. In 2006, CMS funded a contractor to solidify the early work of the Core Data Set by soliciting input from the ESRD Networks and other stakeholders and summarizing it in recommended business requirements to CMS for the new information system. In addition, CMS has funded a contractor to develop the information system and will start external testing of the first pre-production release of CROWN in late 2006 with an expected completion date in 2008.

OIG Recommendation

The OIG recommend that CMS increase its efforts towards regularly collecting data from all patients and all facilities on all clinical performance measures identified by CMS to address quality of care in the ESRD program.

³ <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1818>

⁴ This advanced information capability is detailed in the 2002 OIG series, “Clinical Performance Measures for Dialysis Facilities,” OEI-01-99-00052.

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CMS Response

We have taken steps to regularly collect data from all patients and facilities to improve the quality of care in the ESRD program. Despite our progress in improving the care provided to beneficiaries with ESRD, opportunities for further improvement still exist and the Agency is taking concrete steps to build the systems necessary to assist patients and providers as well as CMS and the ESRD Networks in making better decisions to support high-quality care.

Thank you for your insightful contribution that reinforces our ongoing efforts to continually improve the quality of care provided to individuals with ESRD.

▶ E N D N O T E S

¹ “Summary Report of the End Stage Renal Disease (ESRD) Networks’ Annual Reports 2003.” Available online at <http://www.cms.hhs.gov/ESRDNetworkOrganizations/Downloads/NetworkAnnualReport2003.pdf>. Accessed January 6, 2006.

² “USRDS 2005 Annual Data Report.” Precis. Available online at http://www.usrds.org/2005/pdf/0B_precis_05.pdf. Accessed March 1, 2006.

³ “2004 Annual Report ESRD Clinical Performance Measures Project.” Centers for Medicare & Medicaid Services. December 2004.

⁴ Current regulations governing the ESRD program are called the ESRD Conditions for Coverage, and can be found at 42 CFR 405 Subpart U.

⁵ Social Security Act § 1881(c)(2).

⁶ 2003-2006 ESRD Network SOW. Page 6.

⁷ “External Quality Review of Dialysis Facilities: A Call for Greater Accountability” (OEI 01-99-00050) and “Oversight of Kidney Dialysis Facilities Needs Improvement” (GAO/HEHS-00-114).

⁸ “Dialysis Facilities: Problems Remain in Ensuring Compliance with Medicare Quality Standards, (GAO-04-63),” Government Accountability Office. October 2003. Page 50.

⁹ CMS description of “CMS Quality Initiatives.” Available online at <http://www.cms.hhs.gov/QualityInitiativesGenInfo>. Accessed January 27, 2006.

¹⁰ CMS Fact Sheet “End Stage Renal Disease Policy and Payment Initiatives.” August 1, 2005. Available online at <http://new.cms.hhs.gov/apps/media/press/release.asp?Counter=1523>. Accessed January 6, 2006.

¹¹ “Report to the Congress: Medicare Payment Policy,” Medicare Payment Advisory Commission. March 2004.

¹² CMS Testimony before the Subcommittee on Health of the Committee of Ways and Means. March 15, 2000. Available online at <http://www.hhs.gov/asl/testify/t050315a.html>. Accessed March 22,2006.

¹³ Institute of Medicine “Performance Measurement: Accelerating Improvement” 2006 and Medicare Payment Advisory Commission “Report to the Congress: Medicare Payment Policy.” March 2004.

¹⁴ Balanced Budget Act of 1997, section 4558(b).

¹⁵ As noted earlier, the CPM and DFR data come from different sources. Therefore, while the CPM and DFR may report on the same category (e.g., adequacy of dialysis or anemia management), the projects often do not use the same clinical measure to address that category.

¹⁶ An AV fistula is the surgical connection of a vein and an artery to allow access to the vascular system, so blood can be removed and returned during hemodialysis.

¹⁷ However, two of the three CPMs measure the same outcome. They are listed as separate CPMs because they refer to two separate types of dialysis patients, hemodialysis and peritoneal dialysis patients.

¹⁸ Diane L. Frankenfield, et al., “Comparison of Urea Reduction Ratio and Hematocrit Data Reported in Different Data Systems: Results from the Centers for Medicare & Medicaid Services and The Renal Network Inc,” *American Journal of Kidney Diseases* 41 (February 2003) 2: 433-441. Note: This article was written by CMS staff and other researchers.

¹⁹ Agency Comments to OIG Report “External Quality Review of Dialysis Facilities: A Call For Greater Accountability” (OEI-01-00050), page 44 and “Oversight of Kidney Dialysis Facilities Needs Improvement” (GAO/HEHS-00-114). Page 33.

²⁰ “Frequently Asked Questions on the ESRD Core Data Set”, first page. Available online at <http://www.simsproject.com/downloads/cds/WhatIsCoreDataSet.pdf>.

Accessed January 3, 2006. Note: In addition to quality improvement information, the final Core Data Set measures include administrative information.

²¹ In addition to quality improvement information, the final Core Data Set measures include administrative information.

²² Large Dialysis Organizations are the four dialysis corporations that own or operate about two-thirds of Medicare-certified dialysis facilities.

²³ 70 Fed. Reg 6254 (February 4, 2005).

²⁴ CMS CROWN Statement of Work for Computer Sciences Corporation, § (I)(A)(3). June 22, 2004.

²⁵ “External Quality Review of Dialysis Facilities: A Call For Greater Accountability” (OEI 01-99-00050).



A C K N O W L E D G M E N T S

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas Komaniecki, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

Laura Torres Kordish, *Project Leader*

Nicole Hrycyk, *Program Analyst*

Natalie Coen, *Program Analyst*

Janet Kilian, *Program Analyst*

Doris Jackson, *Program Specialist*

Tricia Davis, *Director, Medicare Branch*

Barbara Tedesco, *Mathematical Statistician*

Kevin Farber, *Mathematical Statistician*