

SPECIAL ARTICLES

Developing Clinical Performance Measures Based on the Dialysis Outcomes Quality Initiative Clinical Practice Guidelines: Process, Outcomes, and Implications

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● **Background:** The National Kidney Foundation–Dialysis Outcomes Quality Initiative (NKF-DOQI) Clinical Practice Guidelines established a widely accepted set of recommendations for high-quality dialysis care. To enhance the End-Stage Renal Disease Core Indicators Project, an ongoing effort to assess and improve dialysis care in the United States, the Centers for Medicare and Medicaid Services (CMS) commissioned a project to develop clinical performance measures (CPMs) based on the NKF-DOQI guidelines. **Methods:** The CMS contracted with Qualis Health, a private nonprofit organization serving as a Medicare Quality Improvement Organization, to facilitate a 9-month project to develop dialysis CPMs with the participation of a broad range of stakeholders from the renal community. Work groups were established to develop CPMs addressing 4 areas: hemodialysis adequacy, peritoneal dialysis adequacy, vascular access management, and anemia management. The NKF-DOQI guidelines were prioritized based on the strength of the evidence supporting the guidelines, the feasibility of developing performance measures, and the significance of the areas addressed to the quality of care delivered to dialysis patients. Expert panels developed data specifications, sampling approaches, data-collection tools, and analytic strategies. **Results:** Sixteen CPMs were developed based on 22 of 114 NKF-DOQI guidelines. After establishing reliability through field-testing of data-collection instruments, the CPMs were applied to a sample of 8,838 randomly selected hemodialysis patients and 1,650 randomly selected adult peritoneal dialysis patients in summer 1999. **Conclusion:** The development of CPMs based on the NKF-DOQI Clinical Practice Guidelines for dialysis care was accomplished in a timely and effective manner by engaging a broad range of stakeholders and technical experts. The CPMs are important tools to assess and improve the quality of dialysis care in the United States. Few comparable efforts exist in other fields of medicine. *Am J Kidney Dis* 42:806-812.

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THE INSTITUTE of medicine, in its recent report regarding the quality of health care in the United States, issued a challenge to the nation to redouble its efforts to assess and improve health care quality in the 21st century.¹ Since the mid-1990s, a national surveillance sys-

tem has documented sustained and important improvements in dialysis care.^{2,3} This effort, initially known as the End-Stage Renal Disease (ESRD) Core Indicators Project, is now being implemented by the Centers for Medicare and Medicaid Services (CMS), formerly the Health

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The authors assume full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Centers for Medicare and Medicaid Services, which has encouraged identification of quality improvement projects derived from analysis of patterns of care. Ideas and contributions to the authors concerning experience in engaging with issues presented are welcomed.

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Care Financing Administration, as the ESRD Clinical Performance Measures (CPM) Project. A number of features of the project have the potential to inform efforts to assess and improve quality in other sectors of the health care system, because there are few equivalent examples of successful national health care quality improvement efforts.

The ESRD Core Indicators Project and the ESRD CPM Project have been described in detail elsewhere.²⁻⁴ A key milestone in the development of the ESRD CPM Project was the publication of the National Kidney Foundation–Dialysis Outcomes Quality Initiative (NKF-DOQI) Clinical Practice Guidelines in 1997.^{5,6} The NKF-DOQI guidelines were the product of an intensive 2-year effort to review the literature related to 4 key areas of importance to dialysis care and establish clinical practice guidelines based on the best available evidence. The 4 areas include adequacy of hemodialysis, adequacy of peritoneal dialysis, establishment and monitoring of hemodialysis vascular access, and management of anemia.

In general, the NKF-DOQI guidelines were widely accepted as authoritative within the renal community, and many of the 114 guidelines rapidly became the basis for local and regional efforts to improve clinical care. However, the widespread consensus regarding the value of the guidelines was not immediately accompanied by a generally accepted method to measure the extent to which dialysis care delivered was consistent with that recommended in the guidelines.

Shortly after the guidelines were published, section 4558(b) of the Balanced Budget Act of 1997 required the CMS to develop a method to measure and report the quality of renal dialysis services covered by Medicare. In response to this requirement, the CMS focused its efforts on creating a performance measurement system based on the NKF-DOQI guidelines. In this report, we describe the process used to translate guideline statements for dialysis care based on the NKF-DOQI publications into CPMs.

METHODS

In April 1998, the CMS contracted with Qualis Health (known at the time as PRO-West), a Seattle, WA–based private, nonprofit, health care quality improvement organization (QIO), to develop CPMs based on the NKF-DOQI guidelines. The project was conducted under a Medicare

QIO contract. Qualis Health engaged the participation of 4 additional firms, the Medicare QIOs California Medical Review Inc and the Colorado Foundation for Medical Care, Covance Health Economics and Outcomes Services Inc, and Epidemiology for Action, to assist with selected aspects of the process.

The CPM development process included several components. The first was to develop a mechanism to ensure appropriate participation from the renal community to facilitate the acceptability and utility of the CPMs. The second was to prioritize the NKF-DOQI guidelines based on the strength of the evidence supporting the guidelines, the feasibility of developing performance measures, and the significance of the areas addressed to the quality of care delivered to dialysis patients. The third was to identify a limited set of CPMs that could be used to support quality improvement activities, as well as assist the CMS in assessing the quality of care delivered to Medicare beneficiaries. The fourth was to develop sampling and data specifications for the CPMs to facilitate measurement. Finally, the CMS requested the development of data collection and analysis strategies to be used to augment the existing national performance measurement system.

Establishment of Collaborative Relationships With the Renal Community

The CPM project was conducted in close collaboration with and with input from a broad range of stakeholders in the renal community. To facilitate this involvement, participation was solicited through contacts with professional societies and voluntary associations, presentations at national meetings, and invitations to potentially interested individuals identified through a variety of sources.

Several mechanisms were used to enhance the participation of interested stakeholders. A Rapid Response Group, composed of representatives designated by 10 key organizations in the renal community, was established to facilitate timely communication and act as a liaison between Qualis Health and the renal community.

In May 1998, letters inviting participation in the project were sent to more than 125 stakeholders in the renal community, including ESRD Network personnel, renal organizations, and individuals recommended by the CMS, the Forum of ESRD Networks, and other representatives of the renal community. Recipients were urged to extend additional invitations to others interested in participating. Recipients were asked to indicate their interest in participating in various components of the project, including the prioritization of the NKF-DOQI Clinical Practice Guidelines and membership in an expert work group.

In June 1998, 4 expert work groups were convened to address each of the topic areas covered by the NKF-DOQI guidelines: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy, Vascular Access Management, and Anemia Management. The 4 workgroups, which included nephrologists, nurses, renal administrators, ESRD Network and dialysis facility personnel, methodologists, and others, conducted their activities through in-person meetings, teleconferences, and electronic communications. Special efforts were made to include in the work groups members of the NKF-DOQI

Table 1. Topics Addressed in the ESRD CPMs Based on NKF-DOQI Guidelines

Hemodialysis Adequacy	
I	Monthly measurement of delivered hemodialysis dose
II	Method of measurement of delivered hemodialysis dose
III	Minimum delivered hemodialysis dose
IV	Method of postdialysis blood urea nitrogen sampling
V	Baseline total cell volume measurement of dialyzers intended for reuse
Peritoneal Dialysis Adequacy	
I	Measurement of total solute clearance at regular intervals
II	Calculate weekly Kt/V_{urea} and creatinine clearance in a standard way
III	Delivered dose of peritoneal dialysis
Vascular Access Management	
I	Maximizing placement of arteriovenous fistulae
II	Minimizing use of catheters as chronic dialysis access
III	Preferred/nonpreferred location of hemodialysis catheters located above the waist
IV	Monitoring arteriovenous grafts for stenosis
Anemia Management	
I	Target hematocrit for epoetin therapy
IIa	Assessment of iron stores in anemic patients or those prescribed epoetin
IIb	Maintenance of iron stores: target
III	Administration of supplemental iron

guideline development panels to maintain consistency and continuity with the DOQI process.

Prioritization of the NKF-DOQI Guidelines

Between April and June 1998, the Internal Project Team developed a questionnaire that facilitated ranking of the NKF-DOQI Clinical Practice Guidelines for their suitability as candidates for the development of CPMs. Prioritization was conducted in a 2-step process. First, all 114 NKF-DOQI guidelines were included on a survey tool that was distributed to members of the Rapid Response Group and other expert consultants. Respondents were asked to evaluate the suitability of the NKF-DOQI Clinical Practice Guidelines according to clinical importance, feasibility of measurement, and the respondent's assessment of the strength of the evidence supporting the guideline. (In a later phase of the project, the expert work groups evaluated the strength of the evidence for each guideline based on a more systematic process.) In this first step, guidelines were divided into 2 categories for inclusion in a prioritization document intended to be distributed more widely. Approximately 45 of 114 guidelines were considered by a high proportion of the initial reviewers to be inappropriate candidates for initial CPM development based on the ranking criteria. These were included in an appendix to the final prioritization tool. The remaining 69 guidelines were included in a questionnaire distributed through ESRD Networks, professional associations, at national meetings, and by direct mail to a list of potential stakeholders. By July 1998, a total of 212 prioritization questionnaires were completed and analyzed.

The 4 expert work groups convened in Seattle, WA, in July 1998 to review the prioritization questionnaire results and begin the process of CPM development. All work group participants attended an orientation session that introduced the project in detail, described the tasks of the work groups, and provided direction for the prioritization process. The work groups then met individually to review responses to

the prioritization questionnaire and prioritize the NKF-DOQI guidelines. At the close of the meeting, each work group submitted a completed prioritization list to the Internal Project Team.

On July 30, 1998, a list of 36 of 114 numbered NKF-DOQI Clinical Practice Guidelines identified by the work groups and the Internal Project Team as candidates for CPM development was submitted to the CMS.

Development of Technical Specifications for the CPMs

After the CMS accepted the 36 proposed candidate guidelines for further evaluation, the 4 work groups reconvened in Denver, CO, in August 1998 to evaluate further the suitability of the candidate guidelines for CPM development and begin development of technical specifications for the CPMs.

The 4 work groups developed the specific review criteria, algorithms, and CPMs for the NKF-DOQI Clinical Practice Guidelines selected through the prioritization process. At the Denver meeting, work group members reviewed a report assessing the strength of the evidence associated with the evidence-based NKF-DOQI guidelines selected by the work groups as candidates for CPM development.⁷

The CPM development process was a modification of a method described by the Agency for Health Care Policy and Research (AHCPH), now known as the Agency for Healthcare Research and Quality.⁸ Several candidate guidelines that did not have a strong evidence basis or that could not be unambiguously operationalized for measurement purposes were eliminated from further consideration. Some performance measures were developed that addressed parts or all of more than a single clinical practice guideline. Sixteen CPMs were developed based on 22 of the 36 candidate NKF-DOQI Clinical Practice Guidelines. Areas addressed by the CPMs are listed in Table 1. For each of the proposed CPMs, a set of descriptive and technical elements was

Table 2. Elements of CPMs Based on the NKF-DOQI Clinical Practice Guidelines

CPM name and no. NKF-DOQI Clinical Practice Guideline(s) Name(s) and no.(s)	Descriptive name and number assigned to each CPM The text of the NKF-DOQI Clinical Practice Guideline(s) associated with each proposed CPM as reproduced from the NKF-DOQI Executive Summaries (© 1997 NKF)
Evidence basis	Assessment of the strength of evidence underlying each NKF-DOQI Clinical Practice Guideline or portion thereof from which the CPM is derived
Medical review criteria	Brief summary of criteria to be applied retrospectively by abstractors to identify whether a case satisfies the corresponding CPM
Numerator	Description of the subset of cases in the denominator that meet the medical review criteria for the corresponding CPM; reporting period dates noted in the numerators refer to the 1999 data-collection effort to abstract data from patients' 1998 medical records, except where specified in Hemodialysis Adequacy CPMs II and III; these reporting period dates will need to be adjusted in subsequent years as appropriate
Denominator	Description of criteria for inclusion and exclusion of a case from the sample for the corresponding CPM; reporting period dates noted in the numerators refer to the 1999 data-collection effort to abstract data from patients' 1998 medical records; these reporting period dates will need to be adjusted in subsequent years as appropriate
Data source	Source to be consulted to identify cases that satisfy medical review criteria for inclusion in the denominator and numerator for the corresponding CPM

prepared to assist users in understanding and applying the CPMs. These elements are listed in Table 2.

Development of Data-Collection Strategies

To facilitate a systematic national data-collection effort modeled on the ESRD Core Indicators Project, we developed 3 data-collection instruments. The first instrument was intended to collect data for the Hemodialysis Adequacy, Anemia Management, and Vascular Access Management CPMs from hemodialysis patient records. The second was to collect adequacy and anemia management data for peritoneal dialysis patients. The third instrument focused on information about facility policies, procedures, and practices related to selected Hemodialysis Adequacy CPMs.

The 2 medical record data-collection instruments were field-tested in dialysis facilities across the United States. In October 1998, a total of 125 draft data-collection instruments were distributed to 26 facilities that agreed to participate in preliminary field-testing of the instruments and their instructions. In total, 90 data-collection instruments, including 52 hemodialysis and 38 peritoneal dialysis instruments, were completed by 25 facilities during October and November 1998. Participating facilities also were asked to complete an evaluation form, and responses were tabulated in a spreadsheet and circulated to work group facilitators. Results from the field test were reported to work group members during work group teleconferences in November 1998 and considered during finalization of the data-collection instruments. After several cycles of review and revision by the work groups and project staff, final instruments were submitted to the CMS December 1, 1998.

The first application of the ESRD CPMs was conducted in summer 1999 and is described in the 1999 ESRD CPM Annual Report.⁹ Staff from 2,723 hemodialysis facilities abstracted data from medical records of 8,838 randomly

selected hemodialysis patients who received care from October 1998 through December 1998. In addition, staff from 828 facilities abstracted data from medical records of 1,650 randomly selected adult peritoneal dialysis patients who received care from October 1998 through March 1999. A 5% random sample of medical records abstracted by facility staff was reabstracted by ESRD Network staff to assess the reliability of results based on medical record abstraction. Details of this reliability study will be reported elsewhere in a separate report. In general, a high rate of agreement existed between data abstraction conducted by dialysis facilities and reabstraction by Network staff.

DISCUSSION

What is the relevance of the process of development of the new ESRD CPMs for the clinician or allied health professional who is involved with the day-to-day care of patients with ESRD? Most importantly, these CPMs represent the focus of the next generation of quality improvement activities that the CMS and other organizations will conduct during the next decade. ESRD treatment centers will collect data specified in the development of the CPMs and receive reports about the quality of care in the region and, increasingly, the facility in which they care for patients.¹⁰ Translating this information into quality improvement programs within a treatment center will be facilitated if those responsible understand the origin and design of the data reported to them.

The process of developing appropriate CPMs based on clinical practice guidelines is not always straightforward. For instance, the panel that developed the AHCPR-sponsored heart failure guideline in the early 1990s was asked to develop performance measures based on the guidelines and encountered significant philosophical and operational challenges in their efforts. An evaluation of the effort found that “the most striking finding. . . [was] the extent to which panelists objected to the use of most guideline recommendations for the purposes of assessing practice patterns.”¹¹ Some panel participants objected to creating performance measures based on the guidelines it created because of disagreements with the guidelines themselves.

However, development of the CPMs based on the NKF-DOQI guidelines occurred in the setting of a field that was generally supportive of performance measure development and an understanding by the participants in the guideline development process that performance measurement was a critical feature in the success of the guidelines in improving patient care. When the guidelines were released, the NKF-DOQI leadership described the need for developing a strategy for translation of the recommendations into practice, building a commitment to reducing practice variation, and evaluating compliance with the guidelines and the association of such compliance with improved outcomes. Development of CPMs is a necessary component of the third set of activities, and the NKF-DOQI leadership was supportive and cooperative of the present effort. Several other reports have voiced support for the importance of developing CPMs for dialysis care based on the NKF-DOQI and similar guidelines.^{12,13} For example, in 1995, the Renal Physicians Association and the American Society of Nephrology endorsed a set of policies recognizing the importance of CPM development.

The processes described—convening work groups, prioritizing and selecting guidelines, development of CPMs, and preparation and pilot testing of data-collection instruments—were completed in less than 9 months. The rapidity with which these activities were completed allowed for a national evaluation of adherence to the NKF-DOQI guidelines to be conducted within 2 years of their publication. Because of the compressed timeline for completion of the project, it

was necessary to balance the desire for continued refinement and revision of the CPMs on the part of some participants with the recognition that adherence to predetermined timelines would yield reasonable, albeit imperfect, tools for performance measurement.

Development of the CPMs was not without controversy. Because of the effort to engage a broad cross-section of the renal community in the CPM development process, a number of participants had little previous experience in population-based performance measurement. Some had difficulty distinguishing CPMs from measures implying a standard of care that should be delivered to all patients and objected when some measures might not apply to the care of every individual patient. Other stakeholders understood the concept, but were concerned that regulators and others might not appreciate that some appropriate care might not be categorized as such by the CPMs.

The CPM development process was constrained by several limitations. First, the relative paucity of a strong and unambiguous evidence basis for many of the clinical practice guidelines limited the number of CPMs that were developed. Second, many important aspects of ESRD care related to such issues as nutrition and renal osteodystrophy were not addressed in the original DOQI guidelines; therefore, CPMs addressing these areas could not be developed. Third, many participants in the process were concerned that the CPMs did not address pre-ESRD care. Because of the lack of appropriate guidelines addressing this issue, such CPMs could not be developed at that time.

Another principle guiding the development of performance measures was that the effort required to collect the data to populate the measures should be reasonable, and it should be feasible to compute each measure for most of the patients or facilities to which a CPM might apply. In most cases, this required that, at a minimum, data for the measures should be that collected and documented during the course of routine patient care. This constraint substantially reduced the feasibility of developing measures that required sophisticated risk adjustment to be useful.

Several aspects of the CPM development process have implications for future efforts in other

fields of medicine. First, development of the NKF-DOQI guidelines resulted in a broad set of guidelines amenable to prioritization based on strength of evidence, clinical importance, and feasibility. The general acknowledgement among the renal community of the soundness of the NKF-DOQI guidelines increased the likelihood of acceptance of the CPMs. Second, involvement of a broad cross-section of stakeholders in the development of the CPMs, rather than limiting the process to a small group of technical experts, facilitated support of the CPMs by clinical practitioners, industry, associations, and others interested in assessment of dialysis care. Although a surfeit of clinical practice guidelines have been developed and disseminated during the past decade, few have been accompanied by tools that assist physicians and others to reliably assess adherence to recommendations or to use the guidelines to support quality improvement efforts.

The major role of the CMS, the largest payer for dialysis care, in the development and application of the CPMs provided both an incentive for stakeholders to remain engaged in the process and an infrastructure to use the CPMs to evaluate the quality of dialysis care across the United States. CMS-sponsored efforts to evaluate and improve dialysis care have been associated with significant quality improvement in several components of dialysis care, and the availability of additional CPMs can be expected to facilitate similar progress in other important aspects of dialysis. To update the existing CPMs and identify clinical practice guidelines appropriate for conversion to CPMs, the CMS receives recommendations from the ESRD Networks and representatives from a number of organizations in the renal community. The cycle of CPM development, collection and dissemination of performance data, quality improvement, and regular review and updating of CPMs has been responsive to Congressional intent, as well as to the Institute of Medicine call to enhance efforts to assess and improve health care quality in the 21st century.

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