Monitoring Quality of Care at Dialysis Facilities: A Case for Regulatory Parsimony—and Beyond

John C. Stivelman

Summary
With the issuance of the new Conditions for Coverage in 2008 and the implementation of the Prospective Payment System in 2011, the Centers for Medicare & Medicaid Services has fundamentally altered the regulatory landscape of quality in the ESRD program. Although these changes—largely through use of tools comparing individual facility performance to regional and national quality expectations—have increased facility accountability for the quality of patient care in many quarters, they have also complicated both substance and process of facility adherence to quality rules in that component of the program. This editorial critically assesses the main quality tools now in use for dialysis facilities and reviews the issues arising from their conjoint use. A scheme for improving the effectiveness of each quality tool is proposed, and an assessment of their future value and effectiveness in quality improvement is offered.


Introduction
With two sweeping regulatory changes over the last 4 years, the Centers for Medicare & Medicaid Services (CMS) has redesigned much of the basic structure of the ESRD program. First, new, long-awaited Conditions for Coverage (Conditions), appearing in 2008 after 32 years, have made important changes in the nature of physician and provider accountability and quality of care (1). Second, as of January 1, 2011, CMS has instituted the Prospective Payment System (PPS) to improve quality and efficiency of care and to provide greater stewardship of the Medicare trust fund (2). With the implementation of these measures, the number of regulatory oversight tools designed to measure treatment quality at facilities has grown as well. This discussion addresses tools that now establish dialysis facility benchmarks for quality and outcome improvement (Table 1), weighs their future value as tools to improve patient outcomes, and examines how both these instruments and this program will need to accommodate to new analytical demands in provision of quality improvement.

Since institution of the new Conditions, providers must satisfy the requirements contained in up to four often disparate and, in some instances, potentially conflicting performance tools at their facilities. Some of these have come directly from the Conditions; others have different points of origin. All, however, are accountable to—or countenanced by—CMS (Table 1). These tools consist of the following: (1) the CMS quality benchmarks listed in the Measures Assessment Tool (MAT) accompanying the Conditions (3); (2) quality improvement projects pursued with individual dialysis facilities by ESRD Network Medical Review Boards both to improve care and to fulfill their contractual obligations to CMS; (3) performance expectations derived from the Kidney Epidemiology and Cost Center (KECC) Dialysis Facility Reports (Reports) used by facilities, state surveyors, and Networks (4); and (4) internal quality measures that providers set for their facilities, medical directors, and staff.

Although commonalities exist between these tools, they originate from different oversight bodies and thus may have differing performance expectations. This poses several issues for dialysis facilities: Which benchmarks are most clinically appropriate among them? Toward which should staff and physician energies be directed if they differ for the same indicator? Finally, will fulfilling their benchmarks advance patient survival, satisfaction, and quality of life? Given that facilities are held to addressing each by its regulatory body of origin, they must apply due diligence in addressing all. Each of these tools merits discussion in detail, first with respect to these issues and thereafter with respect to each tool’s future in the quality assessment component of the ESRD program.

The MAT
The MAT is the quality metric instrument for care involving in-center or home dialysis therapies accompanying the Conditions, dating from 2008 (briefly summarized in Table 2). This broadly structured tool outlines biochemical, biophysical, nutritional, access, and quality-of-life expectations for the care of patients receiving dialysis. The benchmarks it provides reflect best-practice consensus for care, and its standards are referenced from a variety of sources, among which include the American Association of Medical Instrumentation’s most recent standards for water quality in dialysis (5–7), the Conditions, CMS Clinical Performance Measures (2008), the Dialysis Outcome and Practice Pattern Study, the National Kidney...
Table 1. Facility quality tools, sources, uses by the accountable regulatory bodies, and present and future value

<table>
<thead>
<tr>
<th>Tool</th>
<th>Source</th>
<th>How Applied</th>
<th>Intermediaries or Agency Accountable</th>
<th>Benefits</th>
<th>Shortcomings</th>
<th>Future?</th>
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</thead>
<tbody>
<tr>
<td>MAT</td>
<td>CFC, CMS</td>
<td>Yardstick standard for state surveyors; QA/PI meetings</td>
<td>State, Network, and CMS ultimately accountable</td>
<td>Uniformity</td>
<td>Not current in part; lacks flexibility</td>
<td>Unitary standard? Rapid cycling?</td>
</tr>
<tr>
<td>Network Projects</td>
<td>MRB of Network</td>
<td>Per Network with CMS Project Officer approval; addressed through facility QA/PI, medical director, and medical staff members</td>
<td>Network MRB, CMS, ultimately accountable</td>
<td>Familiarity with local facilities, providers, and physicians</td>
<td>Potential redundancy with other projects, selection criteria occasionally unclear; issue may be resolved by time of study; potential perception as of modest value</td>
<td>Change focus toward nonbiochemical indicators without ignoring gross outliers</td>
</tr>
<tr>
<td>DFR</td>
<td>KECC through multiple databases, including 2728 and USRDS</td>
<td>Network provides to state surveyors for each facility</td>
<td>State, Network, and CMS ultimately accountable</td>
<td>Quality and refinement of data; provides clarity to quality improvement; offers local and national comparisons</td>
<td>Data highly refined; may be 1 year behind; reviews individual facilities only, without further aggregation; potentially used for QIP payment withholding</td>
<td>Used as facility educational and trending tool, not as quality instrument for inspectors or payment criteria</td>
</tr>
<tr>
<td>Providers</td>
<td>Dialysis provider</td>
<td>Internally, through facility QA/PI and governing body</td>
<td>Must comply with CFC and have at least comparable benchmarks; Network and CMS, indirectly</td>
<td>May push quality standards higher; may have novel quality markers</td>
<td>Require external validation or good internal statistical support</td>
<td>May provide yet more sophisticated global and subgroup analysis</td>
</tr>
</tbody>
</table>

MAT, Measures Assessment Tool; CFC, Conditions; CMS, Centers for Medicare & Medicaid Services; QA/PI, Quality Assessment and Performance Improvement process; MRB, Network Medical Review Board; DFR, Dialysis Facility Reports; KECC, Kidney Epidemiology and Cost Center; USRDS, U.S. Renal Data System; QIP, Quality Incentive Programs.
Foundation’s Kidney Disease Outcome Quality Initiative (NKF-K/DOQI 2000–2008), and Food and Drug Administration rulings (3). Facilities and individual practitioners use this tool in compliance with the Conditions in two settings: (1) addressing facility-wide fulfillment of a variety of quality expectations, such as analysis of outliers (the Quality Assessment and Performance Improvement process) and (2) individually, in which the patient’s doctor addresses that patient’s fulfillment of similar, analogous expectations (the Comprehensive Assessment, Plan of Care, and care planning meetings with facility interdisciplinary teams) (1). Both facility and individual-patient data, which together reflect a facility’s degree of MAT fulfillment, may be used by State Health Department surveyors representing Medicare at facility visits to evaluate unit performance and compliance, and may be forwarded to ESRD Networks thereafter.

The MAT appeared with the Conditions in 2008 and is now in version 2.1 (2012) (3). (Of note, this tool was initially designed to assist state survey agencies in the use and application of the interpretative guidelines of the Conditions. Although it accompanies the Conditions in printed form, as of this date, it has not been incorporated into it [or, therefore, into regulation], and is noted in version 2.1 as an “interim version.”) Its use within this document is by and large a consequence of transforming evidence- and opinion-based guidelines (of which NKF-K/DOQI is illustrative and substantially drawn upon) into many benchmark cards. Each edition of NKF-DOQI and NKF-K/DOQI through 2007, however, has been accompanied by a disclaimer that its guidelines are “not intended to define a standard of care, and should not be construed as one” (8–11).

Other issues are of note in the routine use of this tool. MAT-established benchmarks rely heavily on opinion-based versions of KDOQI, and in some instances, are based on older information (in particular, those relating to renal osteodystrophy, which date from 2003; ref. 12). Although several Technical Expert Panels (13) and the National Quality Forum (NQF) have devoted attention within the last 2 years to updating many evidence-based clinical performance measures that might potentially find reference in the MAT, progress in that area has been modest.

**Network-Based Projects**

Each of the 18 ESRD Networks contracts individually with CMS to provide local regulatory surveillance of dialysis facilities, oversight of treatment quality and its improvement (including modality choice), investigation and resolution of grievances, and data collection (14, 15). Part of the “quality” charge to each Network from CMS requires its Medical Review Board (composed of physicians, nurses, social workers, dietitians, and patients) to establish local benchmarks for facility quality improvement in a variety of areas. These most often correspond to the major biologic, hematologic, and adequacy categories customarily addressed in ESRD care. Because Medical Review Boards may establish their own guidelines for special projects with the approval of the regional CMS Project Officer variations in benchmarks relative to the MAT (or Reports-based Quality Incentive Programs [QIP], see below) may occur. Since achieving these benchmarks is a contractual deliverable to CMS, Networks understandably pursue their attainment to demonstrate their attribution to quality improvement within their geographic area.

This strategy has several complex dimensions. Satisfying more than one benchmark in comparable categories (e.g., a Network project targeting a hemoglobin range or hemoglobin distribution differing from the MAT, Dialysis Facility Reports, or QIP) requires staff to operationalize more than one value within a single facility. Further, selection for Network quality improvement projects can be based on data that can be 1 year old or more, during which the issue raised may have been addressed by the time of the facility’s selection for a special study. Thus, in some instances, the Networks’ contractual obligations to CMS for local projects may drive quality maneuvers that could be redundant or of potentially marginal yield.

**Dialysis Facility Reports (KECC Annual Reports)**

Dialysis Facility Reports are data sets generated by the University of Michigan (KECC) in Ann Arbor, one for each facility provider number (4). This organization collects data from several databases, among which are its own database (derived largely from the CMS Program Medical Management and Information System), the Standard Information Management System used by ESRD Networks, the Fistula First Project, the CMS Annual Facility Form (Form 2744), the CMS Medical Evidence Form (Form 2728), and the CMS Death Notification Form (Form 2746), as well as other databases addressing renal transplantation, nursing home occupancy, and facility surveys (4). KECC amalgamates key elements of these reports into tables; each table addresses one major component of facility demographic characteristics or performance. This publication describes a variety of facility characteristics over the prior calendar year, over each of several (up to 3) previous consecutive years and summed over the last 3 years, including the index year. Reports include mortality (standardized mortality ratio compared with the entire country, the local ESRD Network, and the specific state) and hospitalization and transplantation statistics (expressed similarly as standardized hospitalization ratios and standardized transplantation ratios), biologic goal attainments, performance with vascular access, and a variety of other demographic factors. It is the parent document for data ultimately displayed to the public on CMS’s “Dialysis Facility Compare” and now also the website of the public advocacy organization, ProPublica (16). This tool is used in two ways: (1) by facility staff (in Quality Assessment and Performance Improvement) and state surveyors (at facility visits) to compare facility quality attainment to that of the state, Network, and nation and (2) by CMS to identify facility jeopardy for payment withholding should it not attain federal quality targets (QIP, discussed below).

**Assessment of Facility Quality Attainment Relative to State, Network, and Nation in Similar Categories**

Several caveats benefit mention in the interpretation of the Reports for facility self-analysis. First, both KECC and CMS identify a dialysis facility by its provider number alone, not by its ownership as a member of a larger aggregated
<table>
<thead>
<tr>
<th>Tag</th>
<th>Condition/Standard</th>
<th>Measure</th>
<th>Values</th>
<th>Reference(s)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>494.40</td>
<td>Water/dialysate</td>
<td>Chloramines, bacteria, endotoxin</td>
<td>permissible thresholds and action levels by AAMI</td>
<td>AAMI Records</td>
<td>Records</td>
</tr>
<tr>
<td>494.50</td>
<td>Reuse: dialyzers and bloodlines</td>
<td>Dialyzer effectiveness</td>
<td>Bundle volume; discard when &lt;80% of original</td>
<td>KDOQI 2006, AAMI Records</td>
<td>Records, interview</td>
</tr>
<tr>
<td>494.80</td>
<td>Patient-based</td>
<td>Physical and biochemical attributes, laboratory values, transplant exclusion if so</td>
<td>Values are enumerated in Plan of Care and QA/PI in full MAT</td>
<td>Conditions, KDOQI Chart, interview</td>
<td></td>
</tr>
<tr>
<td>494.90</td>
<td>Patient-based</td>
<td>ECFV; Kt/V values, albumin, BMI, normalized protein catabolic rate, calcium/phosphate values; iPTH values; hemoglobin, TSAT, and ferritin values; access type; modality choice; survey of mental and physical functioning; rehabilitation; home dialysis referral; transplant referral; vocational rehabilitation; experience of dialysis care</td>
<td>15 minimum, maximum, value ranges or other benchmarks</td>
<td>Various KDOQI 2000–2008; FDA notifications; Medicare reimbursement criteria; Fistula First, Conditions, DOPPS; Clinical Performance Measures</td>
<td>Chart, interview</td>
</tr>
</tbody>
</table>
Table 2. (Continued)

<table>
<thead>
<tr>
<th>Tag</th>
<th>Condition/Standard</th>
<th>Measure</th>
<th>Values</th>
<th>Reference(s)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>494.110 Facility-based QA/PI:</td>
<td>14 conditions, including health outcomes, hospitalization, survival, HD and PD adequacy; nutritional status, bone disease; anemia management; vascular access; injuries/errors, reuse; satisfaction/grievance, infection control, vaccinations</td>
<td>Quality-of-life surveys; standardized mortality/hospitalization ratios; Kt/V for HD/PD and facility goals; calcium/phosphate values; PTH values; mean hemoglobin, anemia symptoms, transfusions; TSAT, and ferritin values; access distribution, cuffed catheters &gt;90 days; access infections; other access events; injuries/error-reporting; reuse; grievance trending; in-center patient satisfaction survey, facility infection control (baseline and trends); hepatitis B, influenza, and pneumococcal vaccination</td>
<td>14 quantitative benchmarking distributions (percentage attainment of given range in given facility; ranges and benchmarks previously defined in comprehensive patient assessment/plan of care); or tracking of fractional improvement in given indicator relative to previous months/years; documentation of patient education; values are enumerated in the full MAT</td>
<td>Conditions; CMS Clinical Performance Measures 4/08; KDOQI 2006; Medicare Improvement for Patients and Providers Act; Fistula First</td>
<td>Records, reports, interview</td>
</tr>
</tbody>
</table>

This summary details achievement measures for water and dialysate quality, reuse, patient Comprehensive Assessment, Plan of Care, and facility Quality Assessment and Performance Improvement. Cross-references to the relevant interpretative guidelines for the Conditions are noted at the left, under “Tag,” which are also used by state surveyors for review at inspections. The specific measures, references, and their source material are noted, reading the columns from left to right. Specific values for measures are listed in the original document. AAMI, American Association of Medical Instrumentation; KDOQI, Kidney Disease Outcome Quality Initiative; QA/PI, Quality Assessment and Performance Improvement; MAT, Measures Assessment Tool; HD, hemodialysis; ECFV, extracellular fluid volume; PTH, parathyroid hormone; BMI, body mass index; iPTH, intact parathyroid hormone; TSAT, transferrin saturation; FDA, Food and Drug Administration; DOPPS, Dialysis Outcomes and Practice Patterns Study; PD, peritoneal dialysis.
group, or as a component of a statistical contribution to that group. Second, there is occasional discordance between these reports and facility-based statistics, which are not due to “errors” on the part of provider or KECC, but may originate in the selectivity of the data that constitute the Report. Reports represent a statistical distillation of data for a given facility due to specific filters used in determining patient eligibility for inclusion in analysis per Reports criteria, and some patients may thus “fall out” of certain elements of the facility analysis (e.g., quality measures are largely limited to Medicare beneficiaries). Given this, raw facility-derived data, such as the fraction of patients with hemoglobin levels <10.0 g/dl or the percentage of patients with urea reduction ratios (URRs) >65% (among several of other indicators), may differ substantially from those seen in the Reports. Use of this tool may be further complicated by the fact that new facilities open for 3 years or less, or that possess small patient populations, may not yet have results, or have results that are statistically problematic, respectively. These reports, at their most current, are up to 1 year old.

Taken together, these issues merit attention because of this tool’s use by regulators. ESRD Networks forward facility Reports to state Departments of Health yearly. Health Department surveyors, serving as local surrogates for Medicare, perform routine, unannounced, or ad hoc inspections, in which they use these reports to evaluate facility performance compared with state, Network, and national benchmarks. They anticipate each facility will address its shortcomings from regional and national performance benchmarks or offer plans to rectify significant outlying features noted in its Report.

Reports and the QIP
Reports also serve as the source document for the PPS’s new “pay-for-performance” benchmark of the ESRD program, known as QIP. As noted earlier, CMS uses aggregated Reports data to establish national benchmarks for care in several categories (for payment year 2012, they include the percentage of patients with URR >65%, the percentage of patients with hemoglobin levels <10.0 g/dl, and the percentage of patients with hemoglobin levels >12.0 g/dl) over specific index years, and then assesses how well an individual facility’s recent performance fulfills them during a subsequent calendar year. The degree to which a facility falls short of those benchmarks determines whether a portion of that facility’s per treatment reimbursement will be withheld for the duration of a later year (up to 2% per treatment).

The contents and structure of these and other QIP measures generated considerable attention during their CMS comment period as they will have significant effect on the delivery of care.

First, in response to a recent FDA-mandated change in the black-box warning for erythropoiesis-stimulating agent (ESA) treatment (which now specifies the lower threshold for ESA therapy as using “the lowest Epogen dose sufficient to reduce the need for red blood cell transfusions” (17), as opposed to indicating a floor value for a desired hemoglobin range), CMS has eliminated its QIP hemoglobin <10.0 g/dl benchmark for payment years 2013 and 2014. The hemoglobin >12.0 g/dl benchmark will be retained. Although this decision certainly reduces the fraction of patients with hemoglobins of potential concern at >12.0 g/dl, as well as potentially sparing them high ESA doses, other clinical consequences of its implementation could entail a decrease in the mean national hemoglobin value, an increase in both transfusion frequency and the number of patients needing transfusions, the potential for increased panel-reactive antibody sensitization, and the loss of clarity among patients and staff as to the current benchmarks for their care. Thus, although addressing the issue of high hemoglobin and in some instances high ESA doses, elimination of this lower benchmark removes an important safety net for ESA treatment and hemoglobin surveillance.

Second, additional QIP categories have been added as benchmarks for payment year 2014. CMS has set vascular access standards for reporting, particularly the facility distribution of access type. Here, emphasis on reporting of facility arteriovenous fistula rate has gained attention: Concern has been expressed that such an indicator de-emphasizes the elimination of catheters as an equally—if not more—critical maneuver in patient survival than fistula creation. Both have been weighted equally in the final rule (18); however, grafts (which may be preferred alternatives to catheters or fistulas in certain clinical settings) are not discussed. Other new quality measures to apply for payment year 2014 include evidence of patient infection reporting to the Centers for Disease Control and Prevention, demonstration of the facility-wide use of surveys of patient dialysis experience, and evidence of monthly monitoring of mineral metabolism. The percentage of patients attaining a URR >65% and of patients with hemoglobin levels >12.0 g/dl will persist.

Of note among these measures, hemodialysis adequacy is confined to in-center therapy; home hemodialysis and peritoneal dialysis adequacy are not addressed. Infection reporting is also confined to in-center hemodialysis patients, as is the survey regarding the experience of dialysis. The percentage of patients with hemoglobin concentrations >12.0 g/dl, however, is a QIP measure for in-center and home hemodialysis, as well as peritoneal dialysis. The vascular access measures are applied to in-center and home hemodialysis patients, and the mineral metabolism reporting measure is applied to all patients regardless of modality (ref. 18, slide 39).

Individual Provider Benchmarking
In compliance with the new Conditions, providers of dialysis care must offer a specified level of quality over a wide range of clinical areas. Although held to MAT expectations as a common denominator, providers’ internal standards may represent a higher level of performance, or use additional, different performance benchmarks from those noted in the regulatory tools above. These standards reflect provider-wide expectations for care, often for very large numbers of facilities. Many providers have acquired or engineered informatics systems capable of sophisticated statistical analyses that permit nuanced profiling of both individual facility and aggregated populations. Thus, they may assess sources of variability within larger systems of care beyond the federal scope of work. Such data may be widely divergent from those seen in the Reports, MAT,
Clarity and Regulatory Parsimony: Is That Enough?

The tools under the CMS umbrella designed to assess the quality of care merit reexamination both separately and as a group as to their currency, overlap, potentially conflicting metrics, and—most important—long-term value as quality improvement instruments. Generated from agencies with differing quality agendas, when taken together, they may be repetitive, occasionally conflicting, and address similar biochemical, hematologic, and demographic issues in patient care. Quality targets such as these therefore are best served by unambiguous, unitary values capable of addressing facilities as a whole, and their outliers, using one accepted tool.

Addressing regulatory discontinuities alone, however, does not guarantee these tools’ effectiveness in improving patient survival and quality of life. The following thoughts address both the need for regulatory economy, and—of equal or greater importance—offer an analysis of how these measures might gain even more effectiveness as tools for quality improvement in this rapidly changing regulatory environment.

MAT

Properly updated for consensus in the contemporary fund of knowledge, the MAT could address primarily biochemical, hematologic, biophysical, and other easily expressible indices of care, which are areas of concentration appropriate for state surveyors. With this, however, national quality standards should be rendered more flexible and addressed expeditiously in response to changes in the scientific knowledge base. Such unitary standards could serve as the baseline both for facility self-examination and for Network evaluation, if needed.

ESRD Networks

Networks could enhance the value of their quality improvement focus by leaving biometrically relevant and quality assurance-oriented issues to CMS surveyors (particularly in the era of 100% data collection predicted to come via CrownWeb), while focusing on more varied issues of potentially greater yield in improving outcomes, including root causes for failure to achieve dialytic adequacy (particularly shortened treatments), reducing hospitalizations, enhancing referral for transplantation, transportation failures and their effect on fulfilling dialysis prescription, fall risk and prevention, patient rehabilitation, effects of economic privation on nutritional status, and issues relating to patient satisfaction with facilities. Such an agenda could offer less redundancy than that of the present system of biometric benchmarking, and could also drive a program with the potential to significantly improve the process of care. This reorientation of effort in fact might not require significant new data collection. Redistribution of Network efforts in this fashion away from benchmarking “acceptable care” (frequently quality assurance activities and CMS-contracted projects) would not only exploit their huge advantage of familiarity with local caregivers and providers, but would make them vanguards in the rejuvenation of quality improvement at the Network level.

Making so broad a change in quality focus at the Network level is not simple and will depend on two evolving developments in the apportionment of its future work:

1. The contents of the final draft of the new Network Scope of Work, which in its initial version (19) raises the possibility of greater flexibility in Network choice of quality improvement activities (“Metrics for Innovation Pilot Projects,” particularly in the area of diminishing hospital admissions). Realizing greater value in more varied and broadly conceived activities as opposed to continuing benchmarking projects will require creativity of each Network, the enthusiasm of the local CMS Project Officer for such undertakings, and the investment of the Network’s Medical Review Board in crafting and executing such an agenda.

2. The degree to which CrownWeb will reallocate Network workload. If this is substantial, much data processing work will move from the Network’s docket to CrownWeb, offering a unique opportunity to prioritize more imaginative, patient-oriented Network-based quality-improvement activities. The accountability structure for such a change in quality focus beyond that of CMS, the regional Project Officer, and Medical Review Board must remain speculative at present because there are as yet no provisions for other forms of Network oversight.

Reports

These documents deserve more intensive use, as they are employed primarily as evaluative tools for state surveyors assessing facility fulfillment of quality indicators, and for financial withholds in the new QIP program. The Reports should be used for facility enrichment, self-analysis, and discussion with regulators. Most important, however, these documents may have the potential to serve as a breakthrough quality tool if they can enable more rapid analysis of facility, Network, or national data than occurs at present (i.e., over months or less, as opposed to up to a year’s time).

As noted earlier, a Report is assembled by KECC from several sources for each facility and communicates information that is often up to a year old. Improving the timeliness and relevance of this tool is complicated by these issues. Whether CrownWeb will improve assembly of these documents in far shorter time—significantly enhancing continuous quality improvement through rapid quality trending at facility, Network, and national levels—is unclear at this time and must await the implementation and refinement of the tool. Such accelerated quality analysis using Reports data might serve several functions. In addition to aiding facilities in early identification of otherwise unapparent trends in care, it could also enable CMS and Networks to appreciate more rapidly the effect of changes in patient demographic characteristics, drug labeling, payment policy, the effect of new quality targets, and national trends in biochemical indices without waiting nearly a year to draw comparable inferences. If the database is of sufficient size and inclusiveness, the Report could expand the scope of its analysis into a more comprehensive, useful document for each facility as well.
Quality tools to evaluate facility performance such as those discussed earlier must demonstrate value not only to CMS but to the facility and its employees, for it is there that quality improvement takes place. In that light, the advent of the new Conditions, PPS, QIP, Network Scope of Work, and CrownWeb present an unmatched opportunity for CMS, providers, Networks, and payers to reconsider more uniform standards for facility performance where they are needed, and to fundamentally rethink the orientation of quality improvement in the ESRD program.

Although the preceding discussion suggests strategies for both realigning and strengthening our present quality metrics, it also alludes to the larger, more difficult question entertained by many contemporary observers of quality improvement in the ESRD program (20–22): If the prevalent benchmarks for care are both clarified and more frequently achieved, will patient outcomes in fact improve as well, given that minimal improvement in mortality of patients with ESRD has been seen in the last 20 years (20,22)? It has also been acknowledged that the present quality benchmarking system is oriented to assuring a floor or discrete value ranges for acceptable treatment quality and that monitoring such standard indicators appears to have only a modest effect on overall patient survival (20,22). Implementation of novel, potentially more effective quality improvement maneuvers, however, is difficult because their evidence basis may not be sufficient to warrant adoption by CMS. Indeed, shepherding new quality improvement tools that address issues of immediate clinical relevance from notion, to Technical Expert Panels, to vetting, and ultimately, to approval by the NQF can be a very slow process (20). This quandary, certainly apparent in the frontline of care (and perhaps in the regulatory sphere as well), has been highlighted very recently by Parker et al. (20), with the implication that continued adherence to the current program of quality benchmarks—particularly when their contribution to patient mortality risk is modest—may not result in substantially better health outcomes.

Although an important first step in simplifying facility quality effort, synchronization and refinement of the present quality instruments alone will not assure delivery of effective care. We can bridge this new “quality chasm” by using fewer traditional quality improvement tools and more instruments that address the obvious critical problems that directly threaten the lives of our patients (cardiovascular disease, especially left ventricular hypertrophy; extracellular volume expansion and suboptimal BP control; access failures and catheter reduction; recurrent bacteremias; and marginal nutritional status; see refs. 20 and 21). This strategy will require greater inventiveness among caregivers and providers to structure such projects and increased flexibility among regulators to counterbalance the use of more clinically compelling tools for problem-solving. By virtue of the speed and confluence of so many regulatory changes in the last 4 years, there has been no time in the history of renal replacement therapy more propitious than the present for caregivers, providers, Networks, and CMS to examine these complex issues together anew (such as through a Consensus Development Program as Parker et al. have recently suggested; see ref. 20), engage in the necessary and—above all—pragmatic conversations with one another as to how to improve the lives of patients with this illness, and to forge ahead together, now.

Disclosures
J.C.S. has an advisory board membership with AMAG and Affymax; previous service as Board Chair, and current service as MRB Chair of Northwest Renal Network (NW 16); and membership on 2010 and 2012 ESRD Technical Expert Panels (anemia).

References

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