

**UNRESOLVED ISSUES IN
THE CARE OF DIALYSIS PATIENTS**

Guest Editor: Steven Fishbane

Do current quality measures truly reflect the quality of dialysis?

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Email: jaywish@earthlink.net**Abstract**

The US End Stage Renal Disease (ESRD) Program, which came into existence in 1973, was initially envisioned to provide needed financial coverage for about 50 000 patients through Medicare. Over the past 45 years the evolution of the ESRD program has been quite different, and it now serves over one half million dialysis and transplant patients. The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 Section 153(c) requires the Centers for Medicare and Medicaid Services (CMS) to develop and implement quality measures for dialysis patients as part of the ESRD Quality Incentive Program (QIP) beginning in payment year (PY) 2012. The annual ESRD Prospective Payment System (PPS) rulemaking process allows CMS to create ESRD QIP rules that specify the measures, scoring methods, and payment reduction ranges applicable to the respective PY. CMS assesses each facility's performance and calculates a score for each measure, according to the method detailed for that PY. Scores for each measure are combined to create the Total Performance Score (TPS) for each facility. If a facility's TPS does not meet or exceed the performance standards established during the earlier comparison period, the facility will incur a payment reduction of up to 2% for the entire PY. The QIP program has evolved over the several years since its inception. There have been deletions and additions of various measures. CMS uses additional measures in its Dialysis Facility Compare (DFC) website which is available to the public and forms the basis of the 5-star rating system for dialysis facilities. The evidence underlying inclusion many of these measures in the QIP and DFC remains an area of debate. In this review, we discuss the evolution of these measures and their appropriateness. We recommend that some of the current QIP and DFC measures should not be used for public reporting and/or payment as unintended consequences may occur. Nonetheless, all the current QIP and DFC measures and others are suitable for internal quality review.

1 | INTRODUCTION

The US End Stage Renal Disease (ESRD) Program began in 1973 and was initially envisioned to provide dialysis coverage for about 50 thousand patients through Medicare with an annual cost to the Federal government of around \$2 billion. Over the past 45 years, however, the growth of the ESRD program far exceeded expectations

and currently provides coverage for over half a million patients (dialysis and transplant) and an annual cost to the Federal government of over \$30 billion. Total Medicare spending in 2010 rose 6.5% over the prior year, to \$522.8 billion, but spending for ESRD rose 8.0% to \$32.9 billion. These numbers include the Medicare Part D prescription drug benefit, as the USRDS Coordinating Center receives up-to-date data on Part D use in the ESRD population.¹

In the 1980s and early 1990s, the quality environment in the United States emphasized quality assurance, which is a case-by-case and not a systemic approach to quality. In 2001, the Institute of Medicine (IOM) published their paradigm for the future of healthcare provision in the United States titled "Crossing the Quality Chasm: A New Health System for the 21st Century." The IOM proposed six key goals for the 21st century healthcare system: safe, effective, patient centered, timely, efficient, and equitable.² This led to nationwide attention to quality metrics in healthcare. Because the ESRD program is funded primarily by Medicare, it became a laboratory for the application of quality metrics in healthcare at a national level. Whether this has directly affected patient outcomes is debatable, but mortality rates have decreased for dialysis and transplant patients, falling by 32% and 44%, respectively, since 1996.³

2 | PRINCIPLES OF QUALITY

Quality in healthcare has taken on increased importance over the past 2 decades as payers as regulators and payers demand an improved product from the healthcare industry. Healthcare providers were initially resistant to the concept of quality metrics because they often are not evidence based and may lead to deselection of high-risk patients ("cherry-picking"). Donabedian⁴ transformed the approach to thinking about health systems. In his seminal paper, he introduced the paradigm for evaluating and monitoring the quality of healthcare through three interrelated (but distinct and not necessarily causal) aspects of the patient's experience: structure, process, and outcome, connected by unidirectional arrows in that order. Donabedian proposed using this triad to evaluate the quality of healthcare. He defined "structure" as the settings, qualifications of providers, and administrative systems through which care takes place. The "process" is defined as the components of care delivered; and "outcome" as recovery, restoration of function, and survival.

These concepts laid the foundation of quality assessment today. The "structure" is assessed through board certification of physicians and Joint Commission accreditation of hospitals. Process and outcome measures are now vetted and endorsed by the National Quality Forum (NQF) and National Committee for Quality Assurance, and Medicare publicly reports the performance of hospitals, nursing homes, and health plans on such measures. Donabedian emphasized the importance of outcomes as the primary measure for quality of care.

However, outcomes must always account for context (such as case-mix) and cannot distinguish between efficacy and effectiveness.⁴ Donabedian's work was a precedent for an influential report produced by the IOM in 1990 entitled "Medicare: A Strategy for Quality Assurance." This laid the groundwork for the 2001 "Crossing the Quality Chasm" report from the IOM.² The NQF adapted the IOM recommendations into a National Quality Strategy,⁵ the domains of which are illustrated in Figure 1.

In quality improvement multidisciplinary teams are organized to help understand the issue in which there is an opportunity for improvement. There may structure issue (eg, lack of advance care planning in a dialysis unit), process issue (eg, healthcare team not

engaged or patient unwilling to participate) or an outcome issue (eg, increased symptom burden in dialysis patients). The team works together to list the possible structure issues such as procedures, equipment, policies, staff factors, and patient factors. The team identifies the factors that potentially affect the outcome. The outcome data are collected before and after a change in structure or process is implemented. If there is significant improvement in outcome, the change is adopted.

Nephrology was among the first specialties to develop evidence-based clinical practice guidelines (CPGs) with the Dialysis Outcomes Quality Initiative (DOQI, later renamed KDOQI) in 1997. The Centers for Medicare and Medicaid Services (CMS) used these guidelines to establish performance metrics for dialysis facilities with the ESRD Clinical Performance Measures (CPM) Project. Dialysis providers were able to perform internal quality improvement activities using national benchmarks reported by the CPM Project. The CPM Project established a data collection and reporting system infrastructure for dialysis providers that laid the foundation for ESRD Quality Incentive Program (QIP).

3 | ESRD QUALITY INCENTIVE PROGRAM

In February 2008, the US Congress proposed the ESRD prospective payment system (PPS), which became law with the passage of the Medicare Improvements for Patients and Providers Act (MIPPA). The PPS began on January 1, 2011. MIPPA mandated the introduction of the ESRD Quality Incentive Program (QIP). The intent of the



FIGURE 1 The six domains of National Quality Forum's National Quality Strategy³⁰ [Color figure can be viewed at wileyonlinelibrary.com]

program was to promote high-quality care in outpatient dialysis facilities. Payment is linked to certain performance/quality metrics in a “value-based purchasing” (VBP) program. Unlike other VBP programs, however, the ESRD QIP is a pure financial penalty program for underperformance without an opportunity for financial gain for excellent performance. Facilities which do not meet certain standards in a particular year (performance year) are subject to a global Medicare payment reduction of up to 2% 2 years later for the entire year (payment year, PY). An overall facility score for applicable measures (total performance score, TPS) will determine whether payment will decrease. The TPS score is publicly reported on the performance score certificate, which must be prominently displayed in the dialysis facility where it can be viewed by staff, patients, and their caregivers. Dialysis Facility Compare,⁶ a publicly accessible website which reports quality data on each Medicare-certified outpatient dialysis facility, features metrics that are included in the QIP and some that are not. Rather than the QIP TPS score, Dialysis Facility Compare uses a 1-5 “star” system to provide an overall rating for each dialysis provider. CMS provides a total performance score certificate annually to all centers, including those with high scores and those with scores resulting in payment reductions.

The QIP was conceived to counteract the underutilization of resources included in the bundled payment such as medications and dialysis technology, but has expanded to include metrics that were not specified in the MIPPA legislation. The objectives of the QIP are summarized in Table 1.

4 | DEVELOPMENT OF QUALITY METRICS

ESRD data are aggregated at the dialysis facility level and reported through claims, the CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), and the Centers for Disease Control and Prevention using the National Healthcare Safety Network (NHSN). There is a statutory requirement for the inclusion of certain measures in the QIP: anemia, dialysis adequacy, patient satisfaction, bone/mineral metabolism, and vascular access. CMS attempts to select measures for the QIP that span multiple domains of the

National Quality Strategy (Figure 1). The NQF is the chosen entity for endorsement of facility-based metrics for use in the QIP.

Measures considered for endorsement by the NQF may be proposed by the CMS after contractors have conducted literature reviews and Technical Expert Panels (TEPs) have opined. Measures may also be submitted for endorsement by the NQF from others in the community, including professional societies.⁵ Once a measure is proposed, the contractor conducts a literature review and solicits nominations for experts from the community. The contractor appoints a committee chair. The contractor and committee chair solicit nominations for committee members from the stakeholder community. Committee members are selected to serve on the TEP from the pool of nominees. The TEP convenes in person and is provided with the necessary background materials including relevant literature and data. The TEP then recommends a select number of measures and these recommendations are converted into measure specifications by the contractor. The measure recommendations are sent by CMS or another sponsor (if applicable) to NQF for endorsement. The newly developed measures may be incorporated into an annual CMS proposed ESRD rule and are subject to public comment from the community. CMS's process for measure development, testing, implementation, and evaluation is summarized in Figure 2.⁷

5 | EVOLUTION OF ESRD QIP PROGRAM

Initially, in PY 2012 and 2013, the QIP was quite simple, based only on anemia and dialysis adequacy because these were measures included in Medicare claims data.⁶ From 2010 to 2014, Arbor Research Collaborative for Health, in collaboration with the University of Michigan Kidney and Epidemiology Cost Center (UM-KECC), developed, maintained, and updated the ESRD QIP measures for CMS. These include the Dialysis Facility Report which is sent to each dialysis facility and regulatory agencies, the Dialysis Facility Compare

TABLE 1 CMS objectives for the quality incentive program

- **Identify and require reporting** of evidence-based measures that promote the adoption of best practice clinical care
- **Advance transparency of performance** across all sites of care to drive improvement and facilitate patient decision making around quality
- **Implement and continually refine payment models** that drive high standards of achievement and improvement in the quality of healthcare provided
- **Stimulate the meaningful use of information technology** to improve care coordination, decision support, and availability of quality improvement data
- **Refine measurements and incentives** to achieve healthcare equity, to eliminate healthcare disparities, and to address/reduce unintended consequences

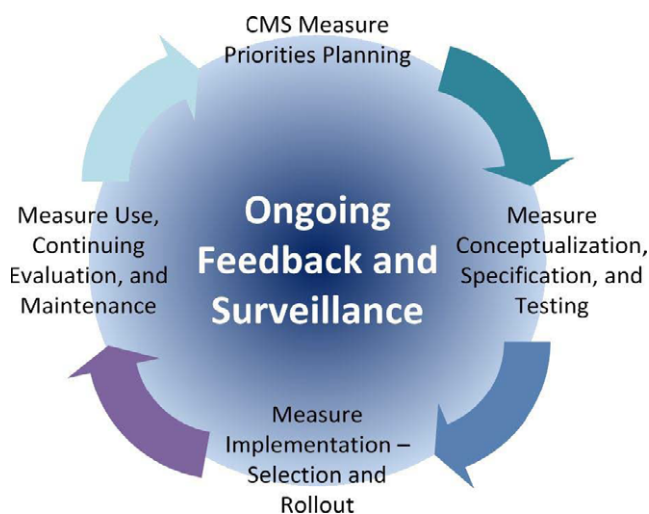


FIGURE 2 CMS measures management system model²⁸ [Color figure can be viewed at wileyonlinelibrary.com]

(DFC) measures which is posted online and available to all, and the development of new quality measures for the QIP. In PY 2014, the number of quality measures expanded and scoring methodology became more complex. For PYs 2015-2020, the program's structure remains the same but there is further expansion in the number of quality measures, weighting of scores, and changes to the minimal TPS to avoid penalties. The scoring and weighting of measures for the QIP in PY 2020 is summarized in Figure 3.

As noted above, initial QIP measures included only dialysis adequacy and anemia management. Many retrospective observational studies have demonstrated an association between dialysis adequacy (based on small solute clearance, Kt/V urea) and patient survival, but there have been no prospective studies directly linking patient survival and achieving a Kt/V urea threshold or increase. The original NCDS study, the HEMO study, or the more recent frequent hemodialysis trials group were able to demonstrate an absolute increase in patient survival in the short term related to $spKt/V$ urea higher than 1.2.^{7,8} The importance of residual renal function has often been overlooked, as even a relatively small amount of residual renal function can aid clearance of middle-sized and protein bound azotemic toxins and also reduce interdialytic weight gains.^{9,10} Evidence of the toxicity of urea is limited, and its impact on patients' outcomes has not been documented. Urea clearance determined by any method may not represent the kinetic behavior of other potentially toxic molecules. The use of dialysis adequacy as a measure for the QIP is an example of a one size fits all approach to quality. It also does not account for palliative dialysis; to require that patients on dialysis for comfort meet adequacy benchmarks provides no added advantage to their end of life care.

Recombinant human erythropoietin (rHuEPO) was approved by the FDA in 1989 for treatment of anemia in patients with chronic kidney disease (CKD). Early studies demonstrated that treatment of anemia related to kidney disease with rHuEPO increases hemoglobin (Hb) levels, reduces transfusion requirements, and improves patient

quality of life (QOL).^{11,12} Treatment to higher Hb targets in clinical trials has been associated with increased vascular access thrombosis, cerebrovascular events, cardiovascular events, earlier need for renal replacement therapy, and higher mortality. The use of erythropoietic stimulating agents (ESAs including rHuEPO and its derivatives) among dialysis patients has significantly decreased since 2011 due to safety concerns from the clinical trials, FDA warnings, and inclusion of ESAs into a bundled payment system to dialysis facilities.

In PY 2012, the QIP penalized dialysis providers for having an excessive percentage of patients with Hb <10 g/dL, but this measure was discontinued for PY 2013 when the FDA changed the product label for ESAs in 2011. In PYs 2012-2016, the QIP penalized dialysis providers for having an excessive percentage of patients with Hb >12 g/dL who are receiving ESAs. CMS noted in the 2014 ESRD PPS final rule that Hb >12 g/dL among patients receiving ESAs had decreased to a sufficiently low percentage that this measure was removed for PY 2017.¹³

ESA use decreased by an average of 27% in 2011 compared with 2010. Concomitantly, Hb levels decreased and RBC transfusion events increased from a monthly rate of 2.5% in 2009-2010 to 3.2% in 2011.¹⁴ There was 10% increase in transfusion rate, from about 0.50 transfusion events per patient per year in 2008-2010 to 0.54-0.55 transfusion events per patient per year in 2011 and 2012.¹⁵ This led to development of the standardized transfusion ratio (STrR) for all adult dialysis patients which is designed to reflect the number of red blood cell transfusion events occurring among patients dialyzing at a facility, relative to the number of transfusions events that would be expected in that facility-based accounting for the patient characteristics (demographics and comorbidities) within that facility.

In the above studies, the distribution of the number of transfusions per patient show little change in the likelihood of receiving the first transfusion in a given year. Rather, the increase in transfusions seen post-PPS was concentrated among patients receiving multiple transfusions. This subset of the dialysis population may be sicker

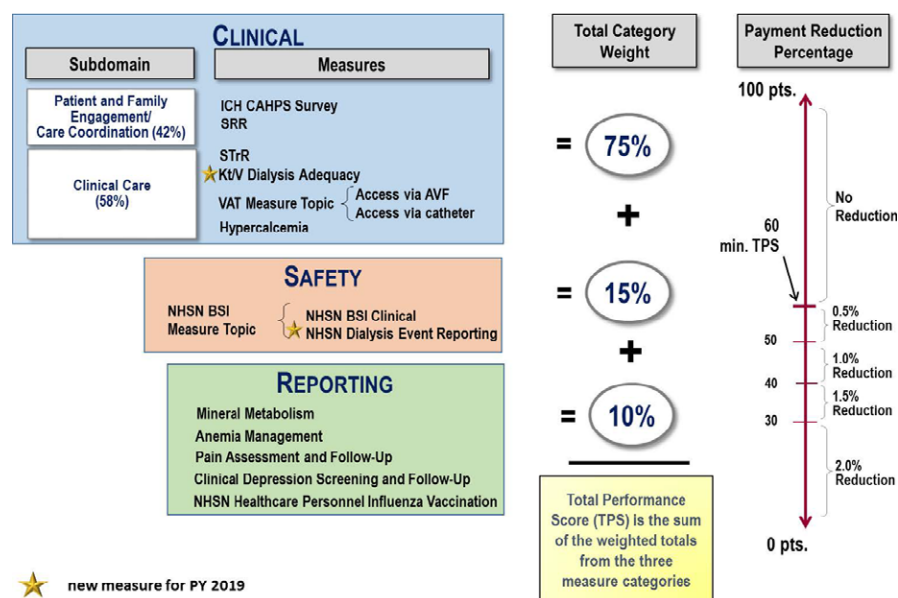


FIGURE 3 PY 2020 scoring and payment reduction methodology²⁹ [Color figure can be viewed at wileyonlinelibrary.com]

and less likely to be eligible for kidney transplantation regardless of antibody status. Similarly, the increase in transfusions was somewhat lower among the younger-than-60 population (more likely to be transplant eligible). More studies should evaluate whether the increasing transfusion rates actually affect patients' transplantation status. There is lack of evidence whether the increase in STrR occurred in populations who sustained a greater reduction in ESA dose because of the PPS, change in FDA labeling, and the results of the RCTs. More importantly, the use of the STrR for payment penalty ignores the likelihood that the benefit from a decrease in CV and thrombosis events due to decreased Hb levels and ESA doses for the many far outweighs the risk of transfusions for the few, especially if it is nontransplant eligible patients who are receiving the transfusions.

Another controversial quality metric in the QIP is the standardized readmission ratio (SRR). The high rate of 30-day readmissions is at least, in part, related to the frailty, disease burden, and medical complexity of patients on dialysis. A TEP addressing the proposed SRR measure convened in May 2012. Despite the unfavorable evaluation by the TEP, the SRR measure moved to the NQF for consideration for endorsement. A negative endorsement by the NQF membership continued even after the measure was included in the final rule for PY 2017.¹⁶ Finally, in 2015, the executive committee of the NQF, after considering the problems with the SRR measure noted by the Renal Physicians Association and other stakeholders, voted to withdraw endorsement, yet it has survived as a QIP measure.

In our opinion, SRR is a poor measure. It inappropriately assigns attribution to the dialysis provider for many rehospitalizations over which this outpatient facility has no control. The measure inadequately accounts for the case-mix of the facility's patient population and may induce facilities to cherry-pick less sick patients to improve the facility's QIP score. Such measures engender doubt in physicians regarding the validity of the process of QIP measure development and lead to skepticism regarding the validity of other measures that are appropriate and worthy of buy-in.

Over the years, the nephrology community has increasingly appreciated the importance of improved patient quality of life and experience of care as a desirable outcome. Standardized surveys ask the patients to reflect on their experience and to report their observations about the quality of the encounter by reporting "how often" a specific activity occurred, or if it occurred at all ("yes" or "no"). Satisfaction surveys are a tool to characterize both the patients themselves and the healthcare delivered, but should not be used to identify or risk stratify vulnerable patients who may be dissatisfied and therefore missing their treatments.¹⁷ The use of surveys can provide a strong stimulus for continual change in the relationship among patients, families, providers, and systems in healthcare.

CMS proposed in the July 11, 2014 Federal Register the implementation in PY 2018 of the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) as a clinical measure and patient pain assessment and follow-up as well as depression screening and referral as reporting measures.¹⁸ The

ICH-CAHPS survey includes 62 questions with an average interview duration of 18 minutes. The ICH-CAHPS measures patients' attitudes toward the quality of care they receive from nephrologists, other dialysis staff, and the treatment center. It is a patient-centered measure but it remains unclear about how the information gained from the survey should be used to improve processes and outcomes. The ICH-CAHPS survey is long and its administration imposes a substantial respondent burden. The survey is not adjusted for race, ethnicity, or socioeconomic status. A recent publication reported a comprehensive review of 34 studies describing associations between hospital CAHPS surveys and both process and clinical outcomes.¹⁹ In more than 2000 hospitals reporting CAHPS survey data, there was a significant association between higher scores and quality of care scores related to patients with acute myocardial infarction (AMI), congestive heart failure, and pneumonia.²⁰ However, in a published systematic review, the vast majority of studies found either positive or null associations between patient experiences and best practice clinical processes, lower hospital readmissions, and desirable clinical outcomes.¹⁹ There are many unanswered questions including characteristics of nonresponders and bias, associations between survey responses and clinical factors, benchmarks, meaning of scores, and differences in scores.

The results of patient satisfaction surveys do not always correlate with the quality of care. They are appropriate as an internal quality improvement tool, but inappropriate as a quality metric that affects public reporting (DFC) and reimbursement (QIP) because there may be cherry-picking against patients who are dissatisfied. If a patient leaves a facility due to dissatisfaction with his/her care, the last thing one would want would be for that patient to be "black-balled" from other facilities for being dissatisfied (whether or not that dissatisfaction is appropriate).

6 | DIALYSIS FACILITY COMPARE

Dialysis Facility Compare (DFC) is a publicly available website (www.medicare.gov/dialysisfacilitycompare) that allows any individual to view quality metrics from dialysis facilities and compare selected facilities side by side. DFC quality metrics at the time of this writing include: standardized transfusion ratio (case-mix adjusted); dialysis adequacy (based on Kt/V); fistula prevalence; prevalence of dialysis catheters longer than 90 days; hypercalcemia (percentage of patients with 3-month average serum calcium >10.2 g/dL); standardized mortality ratio; standardized hospitalization ratio; standardized hospital readmission ratio; and frequency of bloodstream infections (case-mix adjusted). In addition, DFC includes patient satisfaction scores (doctors' and staff communication, caring, and providing information and ratings of doctors, staff, and facility with regional and national averages for each of these scores for comparison). The DFC quality metrics are grouped into 3 domains: (1) standardized outcomes, (2) vascular outcomes, and (3) other outcomes. Each domain is given a score from 0 to 100 by averaging the normalized scores within that domain. A final score between 0 and 100 is obtained by averaging

the 3 domain scores. A dialysis facility is awarded its star rating based on its total score's relative position compared with all other facilities and the change in its score from year to year, rather than the total score itself. The facilities with the best scores receive 5 stars and the facilities with the worst scores receive 1 star. Given the adverse public perception of a lower star rating which may lead to a loss in market share and financial viability, it is essential that the quality metrics used to calculate those ratings are appropriately validated, case-mix adjusted, attributable to the dialysis provider, and actionable by the dialysis provider.

7 | PROPOSED STRATEGIES FOR ESRD QIP AND DFC

The ESRD QIP and DFC were conceptually based on Donabedian principles of quality improvement in healthcare. In 2010, Chassin et al,²¹ in their seminal paper regarding the quality measures in healthcare, noted that "a measure must be based on a strong foundation of research showing that the process addressed by the measure, when performed correctly, leads to improved clinical outcomes." There are no measures in ESRD QIP and DFC that meet this criterion. For example, there have been meta-analyses which show that serum parathyroid hormone, calcium, and phosphorus levels are weakly and inconsistently correlated with all-cause and cardiovascular mortality and other important outcomes.^{22,23} Many studies consistently show that patients with chronic kidney disease prioritize quality of life, mental health, impact on family, and fatigue. These factors should play major role in clinical decision making.^{24,25}

Given these shortcomings of the status quo, there is an overdue shift in the focus of healthcare toward more patient-centered care research and clinical outcomes. The ESRD QIP and DFC continue to emphasize metrics that have no strong evidence, are not actionable by the dialysis provider, and/or are not adequately case-mix adjusted to avoid cherry picking. Although data obtained from surveys such as ICH-CAHPS and quality of life instruments such as the Kidney Disease Quality of Life (KDQOL) are intended to focus on patient-specific issues, they are often not actionable by the dialysis provider and there is no evidence that their use leads to improved outcomes.

There is urgent need to move beyond such metrics, and to develop an improved focus on patient-centered outcomes. Nissen's quality pyramid, which has patient quality of life at top, provides a conceptual basis for this reprioritization.²⁶ The SONG-HD initiative is step toward research focusing on patient-preferred outcomes with input from patients and healthcare professionals.²⁷ A set of 34 outcomes previously identified by the research team were developed into an online Delphi survey that was administered to a wide range of stakeholders, including patients/caregivers (17%-18% in each round of the survey) and healthcare professionals (82%-83% in each round of the survey). Participants ranked each item on a 9-point scale according to its perceived level of importance. They could enter comments and suggest new outcomes not included in the survey. Three sequential rounds of the survey were conducted. The top

3 items among patients/caregivers were dialysis adequacy, ability to travel, and vascular access problems. Among healthcare professionals, the top 3 items were vascular access problems, cardiovascular disease, and mortality. The top 5 areas of consensus between the 2 groups included cardiovascular disease, mortality, dialysis adequacy, fatigue, and vascular access problems. There were definite differences between the 2 groups. The SONG-HD initiative demonstrates the feasibility of finding common ground between patients/caregivers and healthcare professionals. It also illustrates how much could be gained by engaging patients/caregivers in research design.

It is recommended that the focus of future clinical research and quality metrics be based on outcomes identified by patients and healthcare providers, not by payers and regulators who may have a different agenda. Such initiatives have limitations including a high professionals:patients ratio and survey limited to English speaking population, but these initiatives provide the foundation for future development of patient-driven clinical outcomes and metrics.

Patients and other stakeholders would benefit from a change in the implementation of the QIP and DFC. Measures that are poorly evidence based, poorly actionable by the provider, and/or poorly case-mix adjusted should continue to be used for internal quality improvement purposes at the individual facility or dialysis corporation level, but should not be used for payment or public reporting. These measures are also suitable for confidential reporting to the ESRD Networks so that trends can be identified for regional quality improvement projects. The role of CMS should be to convene stakeholder panels to review the results of quality improvement projects at the Network level, clinical evidence in the peer-reviewed literature, and priorities articulated by patients and their caregivers to determine which metrics are sufficiently (1) patient driven, (2) evidence-based regarding a cause and effect relationship between process at the dialysis provider level (attribution) and outcome, and (3) adequately case-mix adjusted to warrant adoption for payment and/or public reporting. MIPPA requires QIP measures for anemia, dialysis adequacy, patient satisfaction, and bone/mineral metabolism, but MIPPA does not specify the weight of those measures in the TPS which determines payment.

Once measures addressing the issues of greatest importance to patients (eg, dialysis adequacy, ability to travel, and vascular access problems as identified the SONG-HD initiative) are developed, vetted, and pilot tested with assurances of data accuracy and case-mix adjustment, then they should be considered for inclusion in the QIP and/or DFC with greater weighting than metrics with less importance to patients. Metrics should only be given weight for payment/public reporting if there is a clear attribution to the dialysis provider, otherwise the measure should have low weight in the QIP (given the requirements of MIPPA) or be relegated to quality improvement activities at the facility, corporate, and ESRD Network level. With adequate evidence basis from clinical studies or quality improvement activities, attribution to the dialysis provider may become sufficient to move a measure into the payment/public reporting domain or increase its weight in that domain. CMS should encourage and fund the outcomes research needed to generate this evidence. It is anticipated that the appropriate use of properly designed and vetted

measures will address many of the national healthcare goals depicted in Figure 1. The danger of inappropriately vetted or case-mix adjusted metrics is that they will lead to cherry-picking as providers attempt to “game” their QIP score and payment, which will penalize the most vulnerable patients.

The evolution of quality metrics in the ESRD program has paralleled the improvement in the data collection and reporting infrastructure from claims to CROWNWeb and NHSN; the increased evidence basis in the literature and development of clinical practice guidelines (many of which are poorly evidence based); the understanding that easy metrics (such as hemoglobin and Kt/V) are not necessarily the best metrics since they are surrogates; and the increased and appropriate emphasis on patient-centered outcomes such as QOL because ultimately patients do not care about great

laboratory values if they feel miserable. Although measures such as QOL, hospitalization, and mortality are paramount, their use as metrics for payment and public reporting is challenging due to attribution and appropriate case-mix adjustment issues. On the other end of the spectrum, influenza vaccination is a process measure which is highly actionable and attributable to the provider and has been associated with improved outcomes.

Simple outcome measures such as Hb, Kt/V, and hypercalcemia have the advantage of easy data retrieval, actionability, and attribution at the dialysis provider level, but have poor correlation with “hard outcomes” such as hospitalization and mortality based on RCTs (as opposed to observational studies) and are therefore poor surrogates. Complex outcome measures such as vascular access and infection are more difficult to attribute to the dialysis provider due to

TABLE 2 Classification of quality metrics in dialysis

Process measures	Intermediate/Surrogate outcome measures	“Hard” outcome measures	Patient-centered measures
• Patient influenza vaccination • Administration of pain assessment instrument (not treatment) • Administration of depression screening instrument (not treatment) • Medication management • Administration of experience of care instrument^a	• Anemia (hemoglobin, ESA dose) • Bone/mineral metabolism (hypercalcemia) • Fluid management • Vascular access • Infections (dialysis related) • Nutrition • Dialysis adequacy	• Hospitalization • Rehospitalization • Mortality	• Quality of life • Experience of care^a • End of life care
High <-----	Attribution to the dialysis provider-----		> Low
High <-----	Actionability by the dialysis provider-----		> Low
Low <-----	Need for case-mix adjustment-----		> High
Low <-----	Data collection and analysis burden/complexity-----		> High
High <-----	Appropriateness for public reporting/payment-----		> Low
High <-----	Appropriateness for internal and ESRD Network QI activities-----		> High

Note: Low and high are relative qualitative terms for each measure's attributes and do not reflect any quantitative methodology for evaluating measures.

^aExperience of care appears in both columns because it is patient centered and related to processes at the dialysis facility. See text regarding recommendations for this use of this measure.

QI, quality improvement.

TABLE 3 Proposed reporting of quality metrics for PY-2021 (performance year 2019)

	Publicly reported quality measures (QIP and DFC) High weight	Publicly reported quality measure (QIP and DFC) Low weight (Mandated by MIPPA)	ESRD network reported measures
Clinical measures	• ICH-CAHPS • Vascular access measure topic (fistula, catheter)	• Kt/V dialysis adequacy (comprehensive) • Hypercalcemia • Standardized transfusion ratio	• Standardized readmission ratio
Safety measures	• Patient influenza vaccination • BSI (blood stream infections) if higher than national average		• NHSN BSI measure topic (NHSN BSI clinical, dialysis event reporting)
Reporting	• Pain assessment and follow-up • Clinical depression screening and follow-up		• NHSN healthcare personnel influenza vaccination • KDQOL

QIP, Quality Incentive Program; DFC, Dialysis Facility Compare; ICH-CAHPS, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems; MIPPA, Medicare Improvements for Patients and Providers Act; NHSN, National Healthcare Safety Network; KDQOL, Kidney Disease Quality of Life.

many patient and system factors, but there is sufficient evidence that improved processes lead to improved outcomes in these domains that they are suitable for public reporting and payment determination. On the other hand, while pain and depression are common in dialysis patients, it could be argued that interventions to address these issues are beyond the scope of the dialysis provider's expertise and funds were not allocated in the PPS payment to provide the appropriate resources. Therefore, these metrics should remain as reporting measures only, as to include them as clinical measures would be counter to the principles of attribution in clinical measures and would predispose to cherry-picking.

On the other hand, the ICH-CAHPS score is highly attributable to the dialysis provider, is a significant contributor to patient-centered outcomes, and its administration is appropriate for inclusion in the QIP and DFC, but the use of ICH-CAHPS scores for the QIP and DFC is premature for reasons discussed above. Other healthcare providers such as hospitals and nursing homes are accountable for their CAHPS scores and there are data in these domains that lower scores drive quality improvement activities which increase patient satisfaction. This is likely to be the case in the dialysis domain as well, but high-quality evidence to provide this link is not yet available. If such a link can be established, improvement in a ICH-CAHPS score should be weighed as heavily as the score itself. Table 2 summarizes the classification of quality metrics in dialysis based on attribution, actionability, need for case-mix adjustment, and data collection/analysis burden/complexity. A proposal for the reclassification of QIP measures in PY 2021 based on these recommendations is summarized in Table 3.

8 | CONCLUSION

It is indisputable that many quality metrics, such as those outlined in Nissenon's quality pyramid,²⁸ are not only suitable for, but should be employed on a regular basis as internal quality improvement tools at the facility, corporate, and ESRD Network level. However, few of these metrics, when subjected to the scrutiny of evidence basis, case-mix adjustment, attribution, and actionability at the dialysis provider level, are suitable for public reporting and/or payment at the present time. CMS is mandated by MIPPA to employ certain measure domains in the QIP such as adequacy, anemia, vascular access, bone/mineral metabolism, and patient satisfaction. The emphasis on patient centeredness in the IOM report² and in the SONG-HD Initiative²⁹ suggests there should be a reweighting of the metrics in the QIP to emphasize the domains that are of greatest importance to patients and deemphasize the metrics that are of limited evidentiary value in impacting the quality of life of this very vulnerable population.

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