Dialysis at a Crossroads—Part II: A Call for Action

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Summary
A previous commentary pointed out that the renal community has led American healthcare in the development and continuous improvement of quality outcomes. However, survival, hospitalization, and quality of life for US dialysis patients is still not optimal. This follow-up commentary examines the obstacles, gaps, and metrics that characterize this unfortunate state of affairs. It posits that current paradigms are essential contributors to quality outcomes but are no longer sufficient to improve quality. New strategies are needed that arise from a preponderance of evidence, in addition to beyond a reasonable doubt standard. This work offers an action plan that consists of new pathways of care that will lead to improved survival, fewer hospitalizations and rehospitalizations, and better quality of life for patients undergoing dialysis therapy. Nephrologists in collaboration with large and small dialysis organizations and other stakeholders, including the Centers for Medicare and Medicaid Services, can implement these proposed new pathways of care and closely monitor their effectiveness. We suggest that our patients deserve nothing less and must receive even more.


Introduction, Scope, and Purpose
The purpose of this commentary is to outline new pathways of care to achieve improved outcomes for patients with ESRD treated by dialysis. Minor adjustments to 30+-year-old practices, refining acceptable limits of biochemical markers or mathematical formulas, and blaming reimbursement policies for the agonizingly slow pace of improvements in such care will not materially transform outcomes.

Previously, we have suggested that the care for patients with ESRD was at a crossroads, traveling on the same path for 50 years with historic achievements but now seemingly unable to bring about changes needed for patient-centered outcomes to reach their full potential (1). In this follow-up commentary, the obstacles, gaps, and metrics that characterize our situation are critically examined. Workable remedies are proposed that potentially could energize new pathways of care and lead to better outcomes for patients at less or equivalent cost—a value-based proposition for ESRD care. Our position is simple—in the current reimbursement environment, savings would result from a reduction in hospitalizations and rehospitalization; clearly, the result is Part A Medicare savings over Part B. In the emerging models of reimbursement, there will be more of an alignment of these savings across categories of care.

The issues that loom large in this discussion include (1) high and relatively unchanged hospitalization rates for ESRD patients for over two decades, (2) only marginal improvement in mortality that remains in the vicinity of 20% per annum and up to two times that rate (i.e., 40% annualized rate) during the first year of treatment, and (3) modest rehabilitation to the workplace for only a small fraction of patients. These sobering facts suggest that we still fall considerably short of optimal care in dialysis (2).

Acknowledgment of the shortcomings of current ESRD care practices and the metrics used to assess their efficacy is a first step. We propose that the accountability for patient outcomes must shift primarily to treating nephrologists, vascular access physicians, and dialysis providers and to patients as a second essential step. We highlight that maintenance of the status quo is untenable. Risks and uncertainties involved in advocacy of such new pathways of care will evoke controversy, but we collectively propose that the goals are worthy of the effort.

Clinical Metrics and the Political and Regulatory Environment
The US healthcare system spends more per capita on healthcare than any other country in the world, but the quality is often no better than and sometimes inferior to other developed nations (3,4). The US healthcare political and regulatory environment in 2012 demands improved quality in all areas, notably including the dialysis sector. Table 1 lists some recent initiatives intended to enhance quality of care in dialysis.

The dialysis industry along with organizations such as the National Kidney Foundation (NKF) and Renal Physicians Association have been at the forefront of developing clinical metrics for patients with complex chronic illnesses, but only limited quality improvement initiatives have emerged that resulted in meaningful changes in outcomes. Our proposed actions are not contingent on the application of payment reform processes, such as the Accountable Care Organization model, and will work with or without it.
Clinical metrics in dialysis can be described to embrace three categories. Those metrics in category 1 are the most rigorous, because they relate to public reporting of aggregate outcomes and reimbursement from government funds for services rendered that meet or exceed a predetermined level of quality (e.g., Clinical Performance Measures [CPMs]). These metrics have tended to be evidence-based, might be time-limited, and may be subject to review and endorsement by oversight organizations such as the National Quality Forum (NQF). They also primarily address populations rather than individual patients. Category 2 metrics, often called Clinical Practice Guidelines, are overall somewhat less rigorous, because they are often developed internally by specialty organizations or providers themselves; examples are the NKF and the International Society of Nephrology (i.e., Clinical Performance Measures [CPMs]). Although using best-available evidence, they also embrace expert opinion and best-practice philosophies. The Institute of Medicine phrases it as “systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific circumstances” (8). Clinical Practice Guidelines are intended to define minimum targets or suggestions for the care of individuals rather than for an exclusive course of management for populations of patients; however, experience has shown that these minimum targets can morph into CPMs defining average outcomes for populations of patients. Category 3 metrics are those metrics used to ensure safe practices, and they come under the aegis of the public health and safety provisions of state and federal administrative law and regulations. These metrics serve as a minimally acceptable floor, below which no practice or care system should be allowed to consistently fall.

Despite the strengths afforded by this trilevel system for quality assurance and improvement, we posit that the composite of these efforts to date has been minimally effective in the necessary and feasible improvement in patient outcomes advocated in this commentary.

The process-dominated ESRD network, state/federal surveys, and certification inspections (largely directed at category 3 metrics) have been relatively ineffective because of (1) inadequate funding, (2) infrequent surveys, and (3) importantly, a focus on the minimally acceptable floor rather than exemplary care. Although such oversight and certification processes are a necessary component of overall monitoring and quality of care improvement plans, they do not currently function in the manner to address issues posed by this essay, namely fostering a dramatic decrease in mortality, hospitalizations, and cost. In our view, it is not prudent to use them for this purpose given their other responsibilities. We suggest that patient-centered outcomes will not materially improve simply by increasing such oversight and regulation. Fundamental change will occur when physicians and providers alter how they measure their practice and processes/outcomes of care by creating aspirational standards instead of minimal performance criteria of acceptable care (the safety imperative) and incorporate the basic concepts of continuous quality improvement process.

Development and implementation of category 1 metrics are expensive and often contentious and cumbersome processes; they respond poorly to the ever-changing dynamics of ESRD care. Considering the positions of CMS and the NQF, dialysis quality metrics in category 1 still lack patient-centered clinical relevance. These metrics are largely directed to population-based measures and not at the individual patient. It is noteworthy that ESRD, despite its prevalence and high costs, is not generally recognized as having high importance by legislators, healthcare policy makers, payers, and the general public (4).

A dilemma surrounding the need for new metrics and the potential unintended consequences of advocacy of unproven metrics is apparent. Safety is paramount. A recent investigative journalist’s article arguably charged that the dialysis system in the United States has major patient safety and quality lapses, with lack of will or ability to address the concerns (6). Nevertheless, achieving the desired patient-centered
outcomes within an imperative of optimum safety must not incapacitate the agents who provide the care. Changes in the clinical metrics and care that they measure must provide positive results: patients living longer with improved quality of life and preventable hospitalizations/rehospitalizations avoided. The political, regulatory, and financial environment begs for leadership and action in the dialysis world. As healthcare givers, we need to be proactive in this worthwhile endeavor.

Gaps between Current Clinical Metrics and Better Dialysis Care

Medical practice based on clinical evidence is intended to enhance both patient safety and outcomes of care. The metrics describing such practices can be used for (1) continuously improving quality, (2) comparing performance among physicians (both publicly and privately), (3) informing patients so that they can choose providers who best meet their needs, (4) advocacy of quality incentive payments linked to meaningful outcomes, and (5) monitoring the safety of the treatment setting (7,9,10). All of these metrics should ideally be valid, reliable, and reproducible, and they should undergo periodic review/revision and adjustment for patient characteristics that confound the outcome in question.

The work by Lowrie (11) has shown that achieving target values for the usual process-based metrics is necessary but insufficient to drive optimal mortality, morbidity, and quality of life outcomes—the critical objectives of any quality assurance program. Current process-based clinical metrics, both categories 1 and 2, do not make enough of a difference, accounting for only 14%–30% of the variability in patient-centered outcomes across the spectrum of providers (11,12). Recent attempts by Center for Medicare and Medicaid Services (CMS) through Technical Expert Panels have, in large part, failed to develop those measures that might make the kind of differences in outcomes, because the NQF rejected the recommendations, largely because of the lack of large randomized clinical trials (RCTs) ostensibly needed for a category 1 metric. An NQF endorsement requires rigorous scientific and evidence-based reviews, with the major (but not the only) determinant being the RCT (13). The paucity of evidence from high-quality RCTs in nephrology has led to a delay in the development and implementation of potentially life-saving/altering therapies, because CKD and ESRD are frequently exclusion criteria in large RCTs (unless focused directly on these issues). However, should the evidentiary standards be placed so high that they stifle innovative approaches to the problem in a field with relatively stagnant outcomes? We answer this question unequivocally no. Complementing and perhaps preceding the RCT should be a preponderance of evidence methodology from large observational studies driving the needed changes (14). We believe the changes can be achieved quickly through the comparative effectiveness research provision of the Affordable Care Act and implemented on a time-limited basis to assess validity.

The gaps between the quality of the evidence and the need for change in treatment pathways create a dilemma for providers of care. In this setting, the advice of the Institute for Health Policy is germane (15): "Measurement of physician clinical performance in quality improvement activities need not be precise, but only sufficiently accurate to reassure physicians of the validity of the data and to engage them in redesigning the processes of care and microsystems to improve patient outcomes."

Basic Elements of an Action Plan

There are medical interventions that can significantly improve survival in our patients, but these interventions require a coordinated effort among physicians, staff, providers, regulatory agencies, and patients—the entire ESRD community. A collaborative action plan can be implemented and sustained.

Avoidance and Rapid Transition from the Use of Indwelling Catheters for Hemodialysis Vascular Access

The use of indwelling catheters for vascular access in incident patients has been shown in multiple observational studies to be associated with a threefold increase in the risk of mortality and a corresponding increase in hospitalizations compared with patients with arterio-venous fistulas, even after adjustments for all known comorbidities and laboratory findings. Despite the ominous predictions implicit in excessive catheter usage, approximately 82% of patients initiate hemodialysis with a catheter in the United States (1). Even in patients who have been followed by nephrologists for at least 6 months, patients initiating dialysis with a catheter remain at 75% (1,16). It is a preventable injury and an iatrogenic problem. In the new environment of care, permanent or temporary access catheters will need to decrease to a very low percentage (as achieved in other parts of the industrialized world) (16–22). We suggest that a goal of fewer than 20% of patients with catheters at 90 days after starting dialysis and fewer than 40% of patients should initiate treatment with a temporary vascular catheter. Although arbitrary, these goals seem achievable over the short term (Table 2). This example shows that the preponderance of evidence is strong enough that an RCT is not necessary.

Intensifying Hemodialysis Treatment Time at Initiation and Then Maintaining It

The only prospective study that examined the impact of dialysis treatment duration (independent of dialysis treatment dose) was the National Cooperative Dialysis Study, which showed a borderline statistical significance ($P=0.06$ in one publication and $P=0.04$ in another) for dialysis treatment duration on patient mortality (23,24). Imagine the difference that 0.01 might have made on our care today.

Confounding between statistical significance and clinical relevance has led many nephrologists to ignore dialysis treatment duration as an independent treatment factor influencing outcomes. The focus almost solely has been on the dose of dialysis (expressed as $Kt/V$ or urea reduction ratio). Retrospective data analysis of several multinational studies supports a prolonged dialysis treatment time being associated with improved patient outcomes independent of total dialysis dosage. Dialysis treatment duration of 4 hours or more is associated with a significant improvement in patient survival (25,26) and has been advocated for by one of the dialysis providers.

The issue of whether prolonged treatment time is more helpful in avoiding excessive extracellular volume (ECV)
expansion or avoiding cardiac stunning because of slower ultrafiltration rates or both needs to be addressed prospectively, but it seems reasonable that longer treatment times with less aggressive intradialytic fluid removal are likely to be beneficial (27–29). Treatment frequency and treatment interval also have effects on time-averaged ECV expansion and thereby, come into play in influencing outcomes. In essence, we advocate moving beyond the focus of providing patients with a minimum dose of dialysis as expressed by Kt/V.

We propose to initiate all incident patients with a dialysis duration of at least 4 hours (30), aiming for an ultrafiltration rate of <10 ml/kg per hour. For patients who initiate dialysis with a catheter, a minimum of 4.5 hours is recommended, with a clear message to the patient that dialysis duration may be reduced when the patient has a permanent access in use (31).

Managing Depression and Anxiety on Dialysis Initiation

Initiation of dialysis is very stressful to patients and often accompanied by heightened anxiety and exacerbation of pre-existing depression (32,33). There has been little effort to address this issue. The positive impact of a focused and intense psychosocial intervention by all caregivers for patients initiating dialysis that addresses emotional needs coupled with extensive efforts in the first 90–120 days of dialysis has been documented (34). We propose this plan as an action plan.

Reducing Hospitalization and Rehospitalization

According to the US Renal Data System, the mean number of hospital days for dialysis patients is approximately 14 days/year, and the frequency of hospitalization events is 2 episodes/year, which is relatively unchanged for more than a decade (1). The most frequent causes of hospitalization include infections (usually associated with catheters), fluid overload/congestive heart failure, metabolic problems associated with diabetes, and adverse effects of medications (the first two causes, by far, being the leading causes). Infection requires hospitalization (often prolonged) for parenteral antimicrobial therapy. Subsequent hospitalizations for complications related to the indwelling vascular catheter also occur at a much higher rate (35,36). The second cause results from lack of intensive removal of excess ECV during the first days and weeks of dialysis (37,38), often related to a normalized ECV not being determined. We do believe that hospitalization and rehospitalizations can be prevented by concentrating on those factors that demonstration projects have clearly shown to be the culprits. The aforementioned ones plus attention to medication errors, diabetic foot management, timely coordinated homecare visits, and referrals (especially after hospitalizations) have been shown to accomplish a substantial decrement in hospitalizations and readmissions.

Another risk for hospitalization is prior hospitalization. The risk for rehospitalization for dialysis patients is two times the risk of all Medicare patients discharged with a medical (not surgical) diagnosis (39,40). The resume previous orders response is a dominant one when hospitalized patients return to their outpatient dialysis units. Prompt attention to the patient status (hemoglobin, white blood cell count, estimated dry weight, etc.) as soon as they present to the dialysis unit after hospitalization often results in a significant decrease in rehospitalization rates (41,42). We propose that a checklist approach for all new and returning patients, such as the approach recommended in the work by Gawande (43), needs to be developed through the process noted at the conclusion of this commentary. CMS has recently recognized the significance of hospitalization and rehospitalization by organizing Technical Expert Panels to address this issue. We support this panel and the near-term adaptation of checklists by hospitals and dialysis providers to coordinate medication lists, target weight (often changed in the hospital), follow-up appointments, and needed home services that are prescribed during hospitalization episodes.

Improving ECF Volume Control

It is becoming increasing evident that inadequate control of the chronically expanded ECV volume contributes significantly to high morbidity and mortality of dialysis patients. Such a failure adds to the burden of left ventricular hypertrophy (LVH), hypertension, and congestive heart failure. The consequences of LVH may also promote
sudden cardiac death attributed to ventricular fibrosis and arrhythmogenic electrical remodeling (44). Attempts to achieve euvoilema with aggressive ultrafiltration (>10 ml/kg per hour) only worsen this problem through intermittent cardiac stunning (27–29). If hypertonic saline boluses are also used during dialysis for hypotension, the net positive sodium gain can be as much as 5–7 g during the dialytic treatment session. A dialysate sodium (DNa+) prescription resulting in a higher sodium gradient is associated with increases in thirst, interdialytic weight gain, and possibly, BP. However, controversy exists regarding the effects of DNa+, with several studies questioning whether adverse events are more associated with lower rather than higher DNa+ (45–47). Observational studies have shown a direct relationship between interdialytic weight gain and risk of cardiovascular mortality (48). To maximize patient care, we believe the focus should be on achieving euvoilema during dialysis rather than specific plasma or DNa+.

A shift in focus from volume of fluids consumed and removed to a focus on time-averaged sodium chloride and ECV volume balance is needed through patient education. The goal should be to achieve as close an approximation of euvoilema as possible within the framework of conventional three times per week hemodialysis sessions. Those patients who do not achieve a reasonable degree of euvoilema should be prescribed alternative strategies, such as longer or more frequent therapy accompanied by more intense and objective monitoring of volume status (normalized ECV) using one of the recently available tools (such as hemoglobin concentration monitoring during dialysis or calf electrical bioimpedance) rather than subjective assessment of dry weight.

For many patients, an extension of the total time of dialysis and/or extension of treatment session duration is essential for improved outcomes. Therapeutic guidelines should be tightly linked to dialysis time, ultrafiltration rate, and ECV normalization in addition to Kt/V or other measures of solute removal. Dialysis adequacy is, thereby, redefined.

Care in the First 120 Days

Providing the patient with optimal care during this crucial early period of dialysis is essential to reduce the high death rate (49) and includes much of what we recommend above. (1) Minimum of 4 hours of dialysis (more if an indwelling vascular catheter is used for access). (2) Attention to LVH, with meticulous control of ECV and hypertension and not exceeding an ultrafiltration rate of 10 ml/kg per hour (50). (3) Removal of indwelling vascular catheters as soon as possible (<60 days after initiation of treatment). (4) Aggressive nutritional support (eat, eat, eat but not salt; avoid the renal diet in the hospital and in-center facility). (5) Optimal attention to comorbid events, especially diabetes and depression. (6) Focused and vigorous continuous education of patients and staff (51).

More Kidney Transplantation and Home Dialysis

This factor requires no additional explanation but should not dilute the conversation about correcting the current deficiencies of dialysis care. Peritoneal dialysis and home hemodialysis both need to be fostered aggressively by all providers.

Focus on Nutritional Status

Although several measures of nutritional status of dialysis patients have been proposed, the one measure that has received the most attention is serum albumin concentration. It has been estimated that a modest 0.3 g/dl improvement in serum albumin in only 50% of the patients might reduce mortality by 2000 deaths and hospitalization days by 32,000 days (52). Protein-energy wasting is one of the strongest predictors of mortality in the CKD/ESRD population. Adjunctive pharmacological therapies, such as appetite stimulants, anabolic hormones, and antioxidative or anti-inflammatory agents, might augment dietary interventions. In-center meals and/or oral supplements provided during the dialysis therapy are feasible and inexpensive interventions (53). Observational data on more than 4000 dialysis patients note the positive effects of oral nutritional supplements, with a 26% reduction in mortality and decreased hospitalization rate (54). This finding fits into the preponderance of evidence conclusion. Although the above interventions seem both reasonable and promising, controlled trials and/or additional large observational studies are needed.

Perspectives and Implementation

In this work, we opine that, despite slow incremental improvements in patient outcomes and admirable intentions by all stakeholders, the dialysis field still struggles to identify those processes and metrics that will significantly improve survival, decrease hospitalizations, and enhance the quality of life of kidney patients. Herein, we propose the basic tenets of a new pathway for care and its oversight. Standing at the crossroad is no longer acceptable. The conundrum, of course, is how to do it. Admittedly, there are no RCTs that support many of the proposed measures. Although RCTs are desirable, they take years to organize and execute (if they can be done at all). Do we need an RCT to confirm that the use of catheters is harmful and expensive? We believe that control of and reducing excessive ECV by the most efficient means possible, with avoidance of LVH, is better for the patient. Longer dialysis sessions (4 hours each or more) or more frequent treatments (daily or nocturnal) offer great promise for better patient outcomes, especially in the vulnerable period shortly after initiating treatment. An LDO recently recommended to all attending nephrologists that these treatment strategies be implemented, despite the lack of RCT evidence. However, medical practice cannot be dictated or enforced by an LDO. Changes in practice need to occur by consensus-based initiatives from a preponderance of evidence, such as we advocate in this commentary, while waiting for an RCT (which may or may not be done).

Nephrologists and dialysis providers can and will make a difference. We believe that these two mutually interconnected entities, with support from the federal government (CMS), can catalyze a move to implementing needed changes in the treatment paradigm. We cannot await only new CPM development but must move to less traditional means, asking nephrologists and dialysis providers to step up to the plate and catalyze needed change in practice patterns.

As a starting position, we suggest a Consensus Development Program of key stakeholders expertly facilitated around specific, actionable items. Maintaining the integrity
of the Consensus Development Program is a high priority of the NQF (13). Such a conference, composed of chief medical officers, providers, and other stakeholders, would be charged to examine how to address the issues that we raise. This process is translational clinical research, with a cycle of innovative ideas, pilot testing, and wider implementation along with a high prospect for success.

The goal will be to determine if the preponderance of evidence is sufficient to implement changes as suggested above within the current framework of reimbursement. The financial implications of what we propose will be the topic of another manuscript.

For too long, we have been engaged in adherence to process-dominated metrics of limited value. Change needs to incorporate programs and metrics that are likely to have the greatest promise for monitoring and improving patient care and outcomes. Linking superior patient-centered outcomes to better payment for services could be a benefit to incentivize the processes that we outline.

This commentary will hopefully provoke a spirited dialogue among caregivers and providers directly responsible for patient care to begin an evolution to a new pathway of care. We anticipate that a collaborative effort among all caregivers will transform the crossroads analogy into a new dynamic exercise that improves the value of our care. The patients entrusted to our care deserve nothing less and must receive more.

Disclosures None.

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