Clinical Practice Guidelines in End-Stage Renal Disease: A Strategy for Implementation

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Abstract. Clinical practice guidelines (CPGs) for end-stage renal failure (ESRD) were recently published, and represent a comprehensive review of available literature and the considered judgment of experts in ESRD. To prioritize and implement these guidelines, the evidence underlying each guideline should be ranked and the attributes of each should be defined. Strategies to improve practice patterns should be tested. Focused information for each high priority guideline should be disseminated, including a synopsis and assessment of the underlying evidence, the evidence model used to develop that guideline, and suggested strategies for CPG implementation. Clinical performance measures should be developed and used to measure current practice, and the success of changing practice patterns on clinical outcomes. Individual practitioners and dialysis facilities should be encouraged to utilize continuous quality improvement techniques to put the guidelines into effect. Local implementation should proceed at the same time as a national project to convert high priority CPGs into clinical performance measures proceeds. Patients and patient care organizations should participate in this process, and professional organizations must make a strong commitment to educate clinicians in the methodology of CPG and performance measurement development and the techniques of continuous quality improvement. Health care regulators should understand that CPGs are not standards, but are statements that assist practitioners and patients in making decisions.

The National Kidney Foundation (NKF) Dialysis Outcomes and Quality Initiative (DOQI) Clinical Practice Guidelines (CPGs) have been published recently (1,2). The 114 guideline statements represent the most comprehensive and systematic review of available literature on dialysis practice and outcomes published yet. Covering the areas of hemodialysis adequacy, peritoneal dialysis adequacy, vascular access, and anemia management. Many of these guideline statements are based on published evidence, and where evidence was not available or was insufficient, on consensus opinion of expert work group members. A systematic review of the literature was performed, and an in-depth assessment of quality of the literature was done to guide panel deliberations. The practicing nephrologist, other nephrology professionals, and patients now will have several questions and issues to ponder as they focus on implementing practice guidelines:

1. CPG Definition: What are CPGs, and what is the process by which they are developed? How good is the evidence supporting each of these guidelines and how does one judge the quality of each?

2. Need for Prioritization of CPGs: There are numerous guideline statements—114 in all. The work groups developing these guidelines believed that all 114 are important for practitioners to deliver optimal care. However, the practical issue is, where does one start? How can one review these guidelines and develop a plan to implement them?

3. Implementation of CPGs: There is a need to link CPGs with continuous quality improvement (CQI). If a guideline is used to change a particular practice pattern, how does one know whether this change will in fact result in improved patient care?

4. Potential Misuse of CPGs: Practice guidelines are generally written to inform care teams and patients, and to help improve the quality of care. When CPGs are used instead as standards of practice, or as measures of adequate care, are these appropriate uses of CPGs?

5. What Role Will Patients Play in this Process? Practice guidelines are written largely by health care professionals. However, informed patients will want to understand their derivation and implications, and then make informed decisions about their implementation. How can the patient’s role be integrated into the process of CPG implementation?

6. What is the Future Agenda? What should be the future role of the professional societies and other organizations to facilitate the implementation of these guidelines?

The purpose of this special article is to explore these questions, to help provide renal disease professionals and patients with an approach to the use of CPGs in general, and to the NKF/DOQI publication in particular. Since many renal care teams are working with the DOQI CPGs, this is an opportune time to review the usefulness and the limitations of practice guidelines. We propose a strategy for implementing CPGs,
including a national level collaborative effort of professional organizations, with a local effort to engage practitioners and patients by encouraging their participation in this process.

What are Clinical Practice Guidelines (CPGs)?

CPGs, as defined by the Institute of Medicine (3) and the American Medical Association (AMA) (4), are systematically developed statements based on current professional knowledge, which are not standards of care, but are intended to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. In actual practice, each clinical circumstance is unique, and many factors other than published clinical results contribute to clinical decisions. These factors include patient and physician choices and characteristics including cultural beliefs, personal values, experiences, and education (5). Other factors contributing to clinical decisions are constraints, such as formal policies, laws, community standards, time, and reimbursement (5). Practice guidelines can help guide clinical decision-making in this complex environment. Just how powerful a tool a particular CPG can be to assist practitioner and patient decisions depends on the attributes of that guideline, and on the strength of the published evidence underlying it.

How were the NKF/DOQI CPGs developed? The authors state that criteria developed by the Agency for Health Care Policy and Research (AHCPR) were used to select guideline topics (1,2): (1) prevalence of the clinical condition; (2) morbidity and mortality associated with the condition; (3) costs of the condition to third party payers and patients; (4) variability in practice; (5) adequacy of scientific evidence related to the topic; and (6) likelihood of being able to change clinical practice. Based on these criteria, four topics for initial guideline development were chosen: hemodialysis adequacy, peritoneal dialysis adequacy, management of vascular access, and management of anemia. Work groups were assembled, including recognized experts in each field. The available literature was reviewed using a defined method, and each group developed a series of statements that were designated as evidence-based, opinion-based, or a combination of evidence and opinion, with a rationale given for each statement. A larger group of clinicians, experts, and organizations participated in the review of this work before publication.

The AHCPR methodology used in the development of these CPGs (6) suggests that for each CPG the domain of interest must be specifically defined and an evidence model should be developed that describes how clinical outcomes are influenced. The patient population studied by each CPG should be clearly defined by inclusion and exclusion criteria. A definition for admissible evidence should be established. Clinical measures in the domain of interest for each CPG should be defined and should be inherently “actionable” by the clinician. The scientific evidence underlying each CPG should be reviewed and ranked according to the quality of the study. Possible benefits and harms of implementing each CPG should also be described. Public policy considerations should include cost and feasibility of implementation, concerns of patients, practitioners and payers, and the potential use by regulatory agencies. These and other AHCPR guideline attributes are helpful in assuring clinicians that all of the appropriate issues have been considered. Despite the rigorous methodology of the DOQI CPG development, the unevenness of available literature in areas of guideline development produced a variable content with regard to these AHCPR criteria. Some guideline statements possess inherent qualities that can be measured, while others do not. Several guideline statements suggest interventions for the management of specific clinical circumstances, while others do not.

The following example illustrates how a guideline can be described using the AHCPR characteristics. Guideline 1 for Hemodialysis Adequacy concerns the regular measurement of the delivered dose of hemodialysis (evidence-based). It states, “The failure of a dialysis care team to routinely measure and monitor the delivered dose of hemodialysis is not an acceptable clinical practice.” This guideline has strong support in the literature, with ample evidence that the clinical outcome for hemodialysis patients can be correlated to the delivered dose of dialysis. The population to be studied is all hemodialysis patients. The domain of interest is the measured delivered dose of dialysis. It can be measured, and the clinician has the inherent ability to increase the number of patients with regularly measured dose (e.g., Kt/V urea). The expected outcomes of a change in practice patterns to routinely measure delivered dose can be measured, as percent of patients each month with measured Kt/V urea. This guideline is defined clearly and can be implemented easily in clinical practice. A similar assessment of each CPG statement will help define how likely they are to improve clinical care. For those that do not contain the needed attributes, it is possible that further refinement will result in a guideline that will be acceptable to clinicians and useful in day-to-day practice.

Evaluating the Strength of Evidence

What is the strength of evidence underlying each guideline, and how can it be judged? Of the 114 DOQI guideline statements, 27 are evidence-based, 56 are opinion-based, and 31 are combined evidence- and opinion-based (1,2). Although the published DOQI guidelines do not detail the process used to review the scientific evidence underlying each CPG, critical appraisals of the quality of evidence were performed (Earl Steinberg, personal communication). A published classification or ranking of the evidence cited with each guideline statement would be helpful to integrate heterogeneous data sources (7). The AHCPR has published a methodology for ranking clinical studies and has suggested a hierarchy of types of evidence from randomized clinical trials to observational studies (8). The new discipline of evidence-based medicine likewise defines criteria that can be used to evaluate the strength of published information (9). Factors other than study design affect the strength of evidence, including sample size, recruitment bias, losses to follow-up, atypical patient groups, and impractical clinical settings (10). An evaluation of the evidence underlying each guideline would be helpful to nephrologists as they decide how to use these guidelines (11).
Prioritizing the Guidelines
With 114 guidelines, where do we start? How can a nephrologist and the care team select for implementation those CPGs most likely to result in improved patient care? In addition, how can we look nationwide at practice patterns to make excellent care more uniformly available? We believe that CPGs need to be prioritized—on a local level for focused quality improvement, and on a national level for identification of best practice models and dissemination of strategies to improve patient care. Practice guidelines can be ranked in several ways: (1) How clinically important is this guideline? Does it address a problem area? (2) How convincing is the underlying evidence or opinion supporting this guideline? (3) What are the ease of measurement and the practicality of implementing this guideline? Locally ranked guidelines can be used for CQI, while a national ranking will be used to develop clinical performance measures (tools that can be provided to local care teams to be used to measure performance in the domain of the CPG).

Implementing Practice Guidelines
Berwick writes that improving daily practice of medicine requires making changes in the processes of care (12). He suggests that individual clinicians have a powerful tool to do this—the process of plan, do, study, and act that defines CQI. Nephrologists and care teams can use CPGs as a starting point in this process. To implement a CPG, several steps are necessary. First, current practice must be measured in the domain of interest, and compared to the CPG recommendation. If current clinical practice does not “measure up” to the recommendation, then a change in practice patterns that is expected to change in a positive way the measurable outcome must be designed (PLAN), then implemented (DO). The clinical outcome of this new practice pattern is then measured to see if it indeed was improved (STUDY). Results of these outcome measures are reviewed and practice patterns are refined as necessary (ACT). The process of CQI goes beyond the guidelines (13). Furthermore, the data generated by this process are used to review and revise the CPG. To perform this iterative process, the specific processes or outcomes must be defined for each guideline, and ways to measure them must be established. Clinical performance measures are being developed to quantify outcomes or processes defined by the CPGs.

Avoiding Misuse of Clinical Practice Guidelines
Clinical practice guidelines can be used for several different purposes. As summaries of best available evidence and expert opinion about specific aspects of care, they inform the care team and the patient for optimal decision-making and prescription formulation. In this way, CPGs are used as information tools. Furthermore, care teams use CPGs in their CQI activities—as goals and benchmarks of best-known care. There is a risk, however, that CPGs can be misused. Regulators may use CPGs to define minimally acceptable standards of care for licensing, accreditation, and even to determine reimbursement to practitioners. In addition, selected guidelines may be incorporated into the Health Care Financing Administration (HCFA) Conditions of Coverage for dialysis facilities. It is indeed important that minimally acceptable standards of care and conditions of coverage be established for dialysis care. If CPGs are selected for these purposes, however, they must be defined differently than CPGs used for quality improvement. CPGs defining standards of care must have the strongest support of underlying evidence, must be easily and serially measured with well defined measurement techniques, and must have wide community support as appropriate standards of care. In comparison, if CPGs are used for local quality improvement activities, they may be opinion- or evidence-based, and local care teams can be creative in devising ways to measure adherence to the guidelines. The best or most important guidelines for quality improvement activities may be different from those selected for standards of care or conditions of coverage. It is important that the HCFA, state Departments of Health, and other regulators understand these differences and not misuse CPGs. For example, if a delivered hemodialysis dose (e.g., Kt/V urea 1.2) is used in quality improvement, patients receiving a lower dose can be analyzed and factors identified that might increase the urea clearance. If, on the other hand, Kt/V ≥ 1.2 is defined as a minimal standard of care, patients receiving a lower dose (e.g., those declining longer dialysis time, or large patients with poor vascular access) may be shunned by practitioners anxious to adhere to care standards, or even denied care. Great care must be taken to select standards of care that will ensure patient safety and encourage optimal care.

Engaging Patients in the Process
Eddy (14) has described medical decision-making as a two-step process: In step 1, facts are assembled and the evidence is analyzed. In step 2, each decision-maker (patient and caregiver) uses informed personal judgment about the importance of the outcomes and risks of each treatment option to make a medical decision. Elements of personal judgment include individual values, cultural beliefs, education, and previous experiences (5). The facts and evidence in step 1 are objective, while the judgments in step 2 are subjective. For this reason, each patient and caregiver given the same information in step 1 may come to a variety of conclusions and medical decisions in step 2. This observation on the anatomy of clinical decision-making has important practical implications in CPG development and implementation. First, patients and patient organizations should play an integral role in the process of guideline refinement and implementation. In this way, patients can be empowered to participate in a process to improve their health, an experience that is likely to inform their personal judgments. Several patients participated in the DOQI CPG development, and patient organizations participated in the peer review process. Second, it must be explicitly acknowledged that individual patients always have the right to make decisions about their care. Whatever the view of the expert community in a given CPG area, it is the patient who must live with the consequences of a medical decision, and his/her view must prevail (15). When clinicians and individual patients come to different conclusions about medical decisions, even after they have consid-
Examine the Evidence Underlying CPGs. The current CPGs, we believe that we should:

To continue the quality improvement process for the nutrition, bone disease and calcium metabolism, initiation and removal is an important aspect of dialysis adequacy, it is not addressed in the current CPGs. Guidelines in other important areas are under consideration or in development, including fluid and small solute control, patient education, and use of laboratory tests. To continue the quality improvement process for the current CPGs, we believe that we should:

Where Do We Go from Here?

The publication of the NKF/DOQI is a major first step in the process of quality improvement. Although their work was extensive, it was not exhaustive. For example, although fluid removal is an important aspect of dialysis adequacy, it is not addressed in the current CPGs. Guidelines in other important areas are under consideration or in development, including nutrition, bone disease and calcium metabolism, initiation and withdrawal of dialysis, pediatric ESRD, and use of laboratory tests. To continue the quality improvement process for the current CPGs, we believe that we should:

1. **Examine the Evidence Underlying CPGs.** A classification or ranking of the scientific evidence underlying the CPGs should be made available to clinicians and patients. Studies have shown greater variability in clinical practice when evidence is lacking or unconvincing (16). Care teams will best utilize and prioritize CPGs for quality improvement once they examine the quality of the evidence supporting each guideline. Until such time as this ranking is made available, local care teams should proceed with implementation efforts based on the rationale provided in the published guidelines as well as their own assessment of the available literature.

2. **Facilitate the Prioritization of the CPGs at both Local and National/Regional Levels.** Clinicians and care teams need a way to select high priority guidelines for initial implementation efforts. There is a role for both local and national/regional level prioritization efforts. At the local level, practitioners should be provided a prioritization guide and tool that will help enable them to choose those CPGs that have the most potential for quality improvement in their own facilities. At the national level, prioritization and selection is necessary to develop clinical performance measures. Also, there will be value in analyzing prioritization results at a regional (Network) and national level. Select CPGs, for example those that may relate to variability in practice and therefore may represent an opportunity for improvement in overall national level quality, can be further refined. Results of national/regional prioritization can then be disseminated to local care teams to use in their quality improvement activities. Thus, local teams will have two implementation strategy options: (1) local prioritization and implementation via locally designed CQI efforts guided by locally determined strengths and weaknesses of existing processes; and (2) national/regionally facilitated prioritization and implementation activities as part of an overall global strategy and refinement effort. The former efforts are expected to aid the development of the latter and vice versa, thereby creating a dynamic and robust process.

3. **Develop Clinical Performance Measures.** For selected CPGs, performance measures should be developed that will cover the specific domain of interest in a defined population of patients. These will be clinical measures, “actionable” by the clinician, with specific attributes as defined by the Institute of Medicine (17). Not all CPGs are appropriate for conversion to national Clinical Performance Measures. Some CPGs do not describe domains that can be measured with defined sensitivity or specificity. For others, cost/benefit analysis suggests they be of low priority. CPGs that are likely to be of most clinical import, and those that are feasible and practical to measure will be selected for development of performance measures. These measurement tools will allow clinical care teams to measure current practice patterns, and to assess the impact of changing practice strategies on clinical processes and outcomes. The HCFA has engaged a group of peer review organizations headed by Pro-West of Seattle, with appropriate input from the renal community, to develop the specifications of selected CPGs for conversion to clinical performance measures.

4. **Pilot Test Implementation of High Priority Guidelines.** Individual nephrologists and care teams, using the CQI method (plan, do, study, act), should devise strategies to implement high priority guidelines. On a national level, CPG work groups can make recommendations for implementing select guidelines. Pilot tests can be performed in several selected dialysis centers, and outcomes measured using clinical performance measures. Results can then be used to refine implementation strategies for the whole renal community.

5. **Encourage Patient Participation.** Patients and patient organizations should play a role in the refinement, prioritization, and testing of CPGs. Meaningful ways to measure and document the elements of personal judgment in the clinical decision-making process should be included as an important element in implementing CPGs.

6. **Disseminate Information.** The dissemination of guidelines alone may not result in widespread implementation. Actual implementation occurs at the local level, by the providers and patients directly involved in decision-making. To help facilitate and foster implementation, dialysis units, patients, nephrologists, and care teams should receive several focused documents from CPG and performance measure work groups, including: (1) For each nationally ranked high priority guideline, a synopsis of the underlying evidence with an assessment of the relative strength of evidence cited; (2) The evidence model for select CPGs, including the description of patients to be affected by the guideline, a definition of the domain of interest, the specific clinical performance measure or other measurement tool to be used, and a summary of expected benefits and possible harms; and (3) Suggested effective strategies to implement specific CPGs,

derived from pilot studies of practice guideline implementation. If this information is delivered in a “user-friendly” format, easily understood by practicing clinicians, we expect that it will be used widely for quality improvement.

7. **Provide Professional Education.** Organizations such as ESRD Networks, the Renal Physicians Association (RPA), American Society of Nephrology (ASN), the NKF, and other professional organizations must commit themselves to ongoing education for physicians and care team members in quality management and measurement. Effective teaching formats should include not only lectures and seminars, but also interactive workshops and other self-learning tools. The content of the education should focus not only on the science underlying clinical practice, but also on the methodology for CPG and clinical performance measures development, and the tools and techniques of CQI.

8. **Conduct both Local and National Review of Care and Ongoing Refinement of the CPGs.** CPGs are not “written in stone.” They are informed by new evidence, by patient choices and other constraints, and by the practical results of CQI. ESRD Networks, the national Forum of ESRD Networks, and other national organizations should analyze the results of CPG implementation, and then where appropriate reformulate the CPGs.

9. **Involve Government and Other Regulators in the Process.** The HCFA, state Departments of Health, and other regulators should understand that CPGs are not standards, but statements that assist practitioners and patients in making decisions (3,4). It should be understood by regulators that measures of clinical practice processes and outcomes by CQI are the preferred method to continuously improve patient care, and that taking these guidelines out of context would compromise this process. The role of patient judgments and decisions should be included in these measures of clinical practice processes and outcomes.

**Summary**

The publication of the NKF/DOQI CPGs is an important first step in a process of quality improvement for dialysis patients. A review of these CPG statements using AHCPR methodology and a ranking of the underlying evidence for each guideline will help clinicians prioritize the guidelines and will help foster widespread implementation. An effective plan for implementation will include pilot testing strategies to change practice patterns, and using clinical performance measures to assess the success of these changes. Patients and patient organizations should be encouraged to participate in this process, and methods to measure the effects of patient judgments on outcome measures should be developed. Professional organizations such as the RPA, the NKF, the ASN, and the Forum of ESRD Networks should make a strong commitment to continuing education of clinicians in the methodology of CPG and clinical performance measure development, and the tools and techniques of CQI. If a process of quality improvement for our patients is to succeed, it will ultimately depend on local action by nephrologists, the care team, and the patients.

The entire renal community has a stake in this process. The development, implementation, and continuous refinement of CPGs will, if applied properly, result in improved survival and quality of life for ESRD patients. The success of quality improvement depends on the use of CPGs, performance measures, and CQI by individual nephrologists, care teams, and patients. Organizations of renal professionals, patients, and administrators also must work together toward this end. In the process of gaining such whole community “buy-in,” we should not lose sight of the fact that every organization and individual comes to the table with its own unique perspective. By taking all of these perspectives together, and by drawing on our various skills and experiences, we can craft a process that will best serve our patients. The NKF has already published its commitment to the education of patients and ESRD professionals (18). The RPA and ASN, in collaboration with the Forum of ESRD Networks, has undertaken the task of organizing a community effort toward implementing this process. We are pleased that the American Association of Kidney Patients, the American Nephrology Nurses Association, and National Renal Administrators Association has joined this effort, and we hope that other individuals and organizations will follow.

**Acknowledgments**

The authors thank Drs. Chaim Charytan, Louis Diamond, Allen Nissenson, and Earl Steinberg for their suggestions and advice.

**References**

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