

# Revised Dialysis Clinical Practice Guideline Promotes More Informed Decision-Making

Alvin H. Moss

West Virginia University Center for Health Ethics and Law, Morgantown, West Virginia

Over a decade ago, the Renal Physicians Association and the American Society of Nephrology published the clinical practice guideline, *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis*, to assist nephrologists, patients, and families in making decisions to initiate and withdraw dialysis. Since then, researchers have extensively studied dialysis decision-making, and there is a substantial body of new evidence with regard to 1) the poor prognosis of some elderly stage 4 and 5 chronic kidney disease patients, many of whom are likely to die before initiation of dialysis or for whom dialysis may not provide a survival advantage over medical management without dialysis; 2) the prevalence of cognitive impairment in dialysis patients and the need to periodically assess them for decision-making capacity; 3) the under-recognition and undertreatment of pain and other symptoms in dialysis patients; 4) the underutilization of hospice in dialysis patients; and 5) the distinctly different treatment goals of ESRD patients based on their overall condition and personal preferences. The Renal Physicians Association developed this second edition of the guideline to provide clinicians, patients, and families with 1) the most current evidence about the benefits and burdens of dialysis for patients with diverse conditions; 2) recommendations for quality in decision-making about treatment of patients with acute kidney injury, chronic kidney disease, and ESRD; and 3) practical strategies to help clinicians implement the guideline recommendations.

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Accumulating evidence indicates that many elderly patients started on dialysis fare badly. In a study of >3000 nursing home residents who had a mean age of 73 years, by 12 months after the start of dialysis, 58% had died and all but 13% had experienced a substantial and sustained decline in functional status (1). Additionally, the evidence shows that there is significant regional variation in how elderly ESRD patients are treated. Elderly patients who received treatment in higher health care intensity regions at the end of life were less well prepared to start dialysis, less likely to have discontinued dialysis, less likely to have received hospice care, and more likely to have died in the hospital. These findings underline the importance of a comprehensive informed consent process before ESRD treatment based on the best available evidence and pertinent clinical practice guidelines (2).

Over a decade ago, the Renal Physicians Association and the American Society of Nephrology published the clinical practice guideline, *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis*, to assist nephrologists, patients, and families in making decisions in initiating and withdrawing dialysis (3). In the decade since the publication of this guideline, nephrologists have been challenged as they increasingly encounter an older population of patients with substantial comorbidities (4), and concurrently, researchers have extensively

studied multiple aspects of dialysis decision-making for patients with acute kidney injury (AKI), chronic kidney disease (CKD), and ESRD.

## Guideline Goals

In developing the second edition of this guideline, the Renal Physicians Association sought to provide clinicians, patients, and families with 1) the most current evidence about the benefits and burdens of dialysis for patients with diverse conditions; 2) recommendations for quality in decision-making about treatment of patients with AKI, CKD, and ESRD; and 3) practical strategies to help clinicians implement the guideline recommendations.

## New or Expanded Topic Areas in the Second Edition of the Guideline

The second edition provides the following new or expanded topic areas that build on the evidence presented in the original guideline:

- The poor prognosis of some elderly stage 4 and 5 CKD patients, many of whom are likely to die before initiation of dialysis or for whom dialysis may not provide a survival advantage over medical management without dialysis.
- New evidence on estimating prognosis in ESRD patients including an integrated prognostic model that incorporates the patient's age, serum albumin level, comorbidities, and clinician use of the "surprise" question—"Would I be surprised if this patient died in the next year?"—available at <http://touchcalc.com/calculators/sq>.

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**Correspondence:** Dr. Alvin H. Moss, WVU Center for Health Ethics and Law, 1195 Health Sciences North, Morgantown, WV 26506-9022. Phone: 304-293-7618; Fax: 304-293-7442; E-mail: [amos@hsc.wvu.edu](mailto:amos@hsc.wvu.edu)

- The identification of distinctly different treatment goals for ESRD patients based on their overall condition and personal preferences: 1) patients who choose aggressive therapy with dialysis without limitations on other treatments; 2) patients with poor prognosis who choose dialysis but with limitations on treatments such as cardiopulmonary resuscitation, endotracheal intubation, and mechanical ventilation because they want to balance life prolongation and comfort; and 3) patients who decline dialysis and prefer that the primary goal of their care be their comfort.
- The frequent prevalence of cognitive impairment in dialysis patients and the need to periodically assess them for decision-making capacity.
- A recognition of the evidence that advance directives have failed to impact patient care and that advance care planning with a discussion of the patient's goals for care and completion of a Physician Orders for Life-Sustaining Treatment Paradigm form (only available in some states and regions) is the preferred approach for decision-making for patients who have lost or are likely to lose decision-making capacity over time.
- The under-recognition and undertreatment of pain and other symptoms in dialysis patients.
- The underutilization of hospice in dialysis patients.
- An understanding of the communication challenges in discussing prognosis and treatment options with CKD and ESRD patients and their families and a presentation of evidence-based strategies to assist nephrologists in this communication.

## Methodology

The second edition uses the same two analytic frameworks that were developed for the original guideline: one for AKI and one for ESRD. These frameworks represent dynamic chronological sequences of decision-making that are informed by multiple factors such as patients' preferences, prognosis, feasibility of dialysis, and quality of life. The San Antonio Evidence-based Practice Center and Veterans Administration Cochran Center developed the frameworks for the original guideline using methodology adapted from the Agency for Health Care Policy and Research Guideline process and the American Medical Association's Attributes for Clinical Practice Guideline Development document.

For the second edition, pertinent adult and pediatric English language literature published from January 2003 to October 2009 was identified from an electronic literature search of PubMed, references from articles, recommendations from experts, and hand searches of medical and nephrology journals. In addition to the search terms used in the original guideline development (dialysis, end-stage renal disease, and acute renal failure), the search terms "palliative care" and "end-of-life care" were also included. In the second edition search, 4593 articles were identified, 3188 articles were excluded by title, 1405 articles abstracts were retrieved, 1144 articles were excluded by abstracts, 261 articles met selection criteria, and an additional 124 articles were added in the guideline develop-

ment. As a result, in addition to the 300 studies in the original guideline, 385 new studies constituted the evidence base.

For the second edition, the article selection criteria, data abstraction process, levels of evidence, and formulation of recommendations were the same as used in the original guideline development process. More than 40 nephrology clinicians and intensivists, a bioethicist, and a pediatric psychologist were divided into eight workgroups and participated in the data abstraction process, with each article reviewed by two persons. If the two reviewers disagreed on whether an article should be included in the guideline evidence base, a third reviewer, usually the workgroup chair, broke the tie. To aid standardization of abstraction, the workgroups were assigned articles related to the specific thematic areas of the original guideline's recommendations: shared decision-making, informed consent, and conflict resolution; prognosis of AKI; prognosis of ESRD; withholding and withdrawal of dialysis; advance directives and advance care planning; and palliative care. The workgroups for adult patients reviewed the evidence and revised the recommendation and the rationale accordingly. Because of perceived need, two workgroups developed new recommendations and rationales for the second edition: communication of diagnosis and prognosis; and pediatric decision-making. The pediatric workgroup used the same methodology as the adult workgroups and developed recommendations for neonate, infant, child, and adolescent dialysis decision-making for AKI, CKD, and ESRD.

The rationales for each recommendation give the grade for the level of evidence. Level A evidence was the highest. For example, level A observational evidence was based either on multiple large studies or a single nationally representative study with a >80% response rate. The research evidence, case and statutory law, and ethical principles were used by the guideline workgroups in the formulation of the guideline recommendations and rationales.

## Peer Review and Endorsement

Peer review of the guideline was solicited at multiple points. First, for the adult patient recommendations and rationales, peer review of the revisions suggested for each workgroup was performed within the workgroups. Second, the seven workgroup chairs for the adult recommendations reviewed all seven workgroups' suggested changes. Each workgroup chair had previously been involved only in the literature review and revision of his or her assigned original guideline recommendation and rationale. Third, the adult recommendations and rationales were reviewed by a wide array of nephrologists, palliative care physicians, members of the kidney end-of-life coalition, representatives from the American Society of Nephrology, American Nephrology Nurses Association, American Association of Kidney Patients, and National Renal Administrators Association, and a health economist. Individuals or committees from the American Academy of Hospice and Palliative Medicine, American Association of Critical Care Nurses, American College of Nurse Practitioners, American Geriatric Society, Center to Advance Palliative Care, National Hospice and Palliative Care Organization, and Society of Critical Care

Medicine also reviewed the draft and made recommendations. The pediatric recommendations were reviewed formally by the American Society of Pediatric Nephrology and the American Academy of Pediatrics. This peer review was done to identify any major omissions in the research evidence or errors in the recommendations and rationales. Peer reviewers were either selected by the Renal Physicians Association Quality, Safety, and Accountability Committee who oversaw the development of the second edition or nominated by stakeholder organizations. Endorsement was sought from all organizations who endorsed the original guideline plus additional organizations whose members care for patients with AKI, CKD, or ESRD.

## Guideline Content

Figure 1 summarizes the recommendations for adult patients. A separate article for the pediatric literature is being written with the recommendations for pediatric patients. The content of the guideline is listed below in the bullets. In the guideline, boxes provide suggestions for specific action items to facilitate implantation of the recommendations.

- Scope, objectives, and target audience: Section 2 gives the scope of the guideline topic. Specific objectives are given and the intended target audience is described.
- Guideline development process: Section 3 details the methodology that was used to develop the guideline. Analytic frameworks and questions that were used to guide the entire process are presented. Literature searches, selection criteria, and methods of evidence critique and ratings are explained. Peer review processes and mechanisms for formulating final guideline recommendations are explicated.
- Guideline recommendations and their rationales for adult and pediatric patients: Sections 4 and 5 present the guideline recommendations, the principles, laws, and systematic reviews of evidence on which they were based. Ratings of the quality of evidence are provided.
- Prognostic data: Figures and tables with prognostic data for recommendation no. 3 are presented in the Appendix. They provide evidence-based information that may help health care professionals estimate prognosis for individual patients.
- Tool Kit-Useful instruments for implementing the guideline recommendations: Section 9 provides numerous validated tools that clinicians may use to implement the guideline recommendations. These include the Patient Health Questionnaire to screen for depression, the Trail Making Test Part B to test for cognitive impairment, the modified Charlson Comorbidity Index to calculate a comorbidity score, the French Renal Epidemiology and Information Network Registry Clinical Score to predict 6-month prognosis, the Karnofsky Performance Status Scale to assess functional status, and the Dialysis Symptom Index to assess symptom frequency and severity.

As an example, the following are practical suggestions from Box 3 in the guideline for implementing recommendation number 3, Fully inform AKI, stage 4 and 5 CKD, and ESRD patients about their diagnosis, prognosis, and all treatment options.

<p><b>Establishing a Shared Decision-Making Relationship</b></p> <p><b>Recommendation No. 1</b> Develop a physician-patient relationship for shared decision-making.</p> <p><b>Informing Patients</b></p> <p><b>Recommendation No. 2</b> Fully inform AKI, stage 4 and 5 CKD, and ESRD patients about their diagnosis, prognosis, and all treatment options.</p> <p><b>Recommendation No. 3</b> Give all patients with AKI, stage 5 CKD, or ESRD an estimate of prognosis specific to their overall condition.</p> <p><b>Facilitating Advance Care Planning</b></p> <p><b>Recommendation No. 4</b> Institute advance care planning.</p> <p><b>Making a Decision to Not Initiate or to Discontinue Dialysis</b></p> <p><b>Recommendation No. 5*</b> If appropriate, forgo (withhold initiating or withdraw ongoing) dialysis for patients with AKI, CKD, or ESRD in certain, well-defined situations.</p> <p>These situations include the following:</p> <ul style="list-style-type: none"> <li>• Patients with decision-making capacity, who being fully informed and making voluntary choices, refuse dialysis or request that dialysis be discontinued.</li> <li>• Patients who no longer possess decision-making capacity who have previously indicated refusal of dialysis in an oral or written advance directive.</li> <li>• Patients who no longer possess decision-making capacity and whose properly appointed legal agents/surrogates refuse dialysis or request that it be discontinued.</li> <li>• Patients with irreversible, profound neurological impairment such that they lack signs of thought, sensation, purposeful behavior, and awareness of self and environment.</li> </ul> <p>*Medical management incorporating palliative care is an integral part of the decision to forgo dialysis in AKI, CKD, or ESRD, and attention to patient comfort and quality of life while dying should be addressed directly or managed by palliative care consultation and referral to a hospice program (see <b>Recommendation No. 9</b> on palliative care services).</p> <p><b>Recommendation No. 6</b> Consider forgoing dialysis for AKI, CKD, or ESRD patients who have a very poor prognosis or for whom dialysis cannot be provided safely.</p> <p>Included in these categories of patients are the following:</p> <ul style="list-style-type: none"> <li>• Those whose medical condition precludes the technical process of dialysis because the patient is unable to cooperate (e.g., advanced dementia patient who pulls out dialysis needles) or because the patient's condition is too unstable (e.g., profound hypotension).</li> <li>• Those who have a terminal illness from non-renal causes (acknowledging that some in this condition may perceive benefit from and choose to undergo dialysis).</li> <li>• Those with stage 5 CKD older than age 75 years who meet two or more of the following statistically significant very poor prognosis criteria (see <b>Recommendations No. 2 and 3</b>): 1) clinicians' response of "No, I would not be surprised" to the "surprise" question; 2) high comorbidity score; 3) significantly impaired functional status (e.g., Karnofsky Performance Status score less than 40); and 4) severe chronic malnutrition (i.e., serum albumin less than 2.5 g/dL using the bromocresol green method).</li> </ul> <p><b>Resolving Conflicts about What Dialysis Decisions to Make</b></p> <p><b>Recommendation No. 7</b> Consider a time-limited trial of dialysis for patients requiring dialysis, but who have an uncertain prognosis, or for whom a consensus cannot be reached about providing dialysis.</p> <p><b>Recommendation No. 8</b> Establish a systematic due process approach for conflict resolution if there is disagreement about what decision should be made with regard to dialysis.</p> <p><b>Providing Effective Palliative Care</b></p> <p><b>Recommendation No. 9</b> To improve patient-centered outcomes, offer palliative care services and interventions to all AKI, CKD, and ESRD patients who suffer from burdens of their diseases.</p> <p><b>Recommendation No. 10</b> Use a systematic approach to communicate about diagnosis, prognosis, treatment options, and goals of care.</p>
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Figure 1. Summary of adult patient recommendations.

- For ESRD patients, estimate prognosis based on patient's age, functional status, medical condition, including comorbidity and recent sentinel events, and the "surprise" question (Would I be surprised if this patient died in the next year?). The website <http://touchcalc.com/calculators/sq> provides a calculator for use of the "surprise" question response and

other variables to estimate prognosis in dialysis patients. The same degree of precision does not exist for tools that estimate prognosis for patients with AKI.

- Present the prognosis in a manner that is considerate of the patient's emotional condition. Balance the patient's desire for quality and quantity of life and provide reassurance that the physician has kept the patient's best interest in mind. With the patient's permission, strongly encourage the patient's legal agent/family to participate in the discussion of prognosis and treatment options. See Recommendation No. 10 for suggested approaches to discussing prognosis, treatment options, and goals of care with AKI, CKD, and ESRD patients.
- Identify patient's wishes and goals for treatment at onset of dialysis and again after any irreversible change in medical condition.
- For ESRD patients, reassess and communicate prognosis on at least an annual basis and more often as indicated by any major change in status.
- For CKD and ESRD patients, during each annual Comprehensive Assessment and Plan of Care discussion, communicate appropriate options based on the patient's condition, prognosis, and goals for care. Regardless of choice, palliative care should be offered for pain and symptom management and advance care planning. Hospice referral is appropriate for ESRD patients stopping dialysis and for those continuing dialysis who have a predicted prognosis of <6 months.
- Provide recommendation to withhold/stop dialysis in patients who are not likely to benefit.
- If conflicts arise in shared decision-making, consider palliative care or ethics consultation (see Recommendation No. 8).

The guideline recommends shared decision-making—the process by which physicians and patients agree on a specific course of action based on a common understanding of the treatment goals and risks and benefits of the chosen course compared with reasonable alternatives. It notes, however, that there are limits to shared decision-making that protect the rights of patients and the professional integrity of health care professionals. The informed patient with decision-making capacity has the right to refuse dialysis even if the renal care team disagrees with the patient's decision and wants the patient to

undergo it. Similarly, even if the patient or family demands dialysis, the renal care team has the right to refuse to offer it when the expected benefits do not justify the risks. Recognizing that there are circumstances in which patients and renal care teams might disagree about decisions to start, continue, or stop dialysis, the guideline provides a recommendation and practical approaches for how to resolve such conflicts.

The true worth of the second edition of the guideline will be determined by the extent to which it is used and found helpful by clinicians, patients, and families making decisions to start or stop dialysis. U.S. and Canadian nephrologists who were aware of and used the original guideline reported themselves significantly more prepared to make end-of-life decisions with their dialysis patients than those who were not aware of the guideline (5).

This second edition of the clinical practice guideline is available for purchase through the Renal Physicians Association's online store at [www.renalmd.org](http://www.renalmd.org).

## Disclosures

None.

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