

Clinical Practice Guideline on Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis

JOHN H. GALLA

Renal Physicians Association/American Society of Nephrology Working Group, Washington, DC

Executive Summary

The Renal Physicians Association (RPA) and the American Society of Nephrology (ASN) in conjunction with representatives from multiple disciplines and organizations in the dialysis community, kidney patients and family members, and internal medicine physicians as well as a bioethicist and a public policy expert comprised a working group that completed the *Clinical Practice Guideline on Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis* late last year. The guideline presents recommendations concerning withholding or withdrawing dialysis in adult patients with either acute renal failure (ARF) or end-stage renal disease (ESRD).

These recommendations are based on the expert consensus opinion of the RPA/ASN Working Group. The members of the working group included:

Alvin H. Moss, M.D., chair
William F. Owen, Jr., M.D., vice chair
Richard Albert, M.D.
Eileen Brewer, M.D.
Helen Danko, M.S., R.N.
John H. Galla, M.D.
Roman M. Hendrickson, M.D.
Albert R. Jonsen, Ph.D.
Judith Kari, M.S.W.
Bertram Kasiske, M.D.
Karren King, M.S.W.
Jenny Kitsen
John M. Newmann, Ph.D., M.P.H.
Christy A. Price, R.N., M.S.N.
Richard Rettig, Ph.D.
Dale Singer, M.H.A.

Group members developed *a priori* analytic frameworks for decisions to withhold or withdraw dialysis in patients with ARF and ESRD. Systematic literature reviews were conducted to address pre-specified questions derived from the frameworks. In most instances, the relevant evidence that was identified was contextual in nature and only provided indirect support to the recommendations. The research evidence, case and statutory law,

and ethical principles were used by the Working Group in the formulation of their recommendations. The recommendations are not mandatory, but rather flexible guidelines that may be tailored to a particular patient, provider, and geographic circumstance. They allow the renal care team to use discretion as they are applied to individual patients. They are intended for use by providers and patients (and their families or advisors) in the United States and its trust territories to aid in dialysis decision-making. They are not intended for use by regulatory agencies for reimbursement or other decisions.

The working group proposed and prioritized key questions related to the models using a combined nominal and modified Delphi process. Questions specified information that was either desirable or necessary to make informed and ethical decisions about withholding or withdrawing dialysis. Such questions were categorized as directly informative to the evidence model or as background and contextual in nature. These key questions guided analysis of the evidence.

Standard forms were used to abstract data from each study. Such data included information about study purposes and designs, participant descriptors, methodologic characteristics, outcome measures, and results.

Peer review of the guideline was obtained after development of the evidence model and selection of relevant literature to identify any major oversights in formulation of the evidence model and any seminal research evidence that was missed in the literature search. A second level of peer review was conducted when the draft guideline document and recommendations were completed. Peer reviewers were nominated by stakeholder organizations and other volunteers from the nephrology community. The final guideline was submitted to multiple organizations to request their endorsement.

At press time the following organizations had endorsed the guideline recommendations: Renal Physicians Association, American Society of Nephrology, American Society of Pediatric Nephrology, American Nephrology Nurses Association, National Kidney Foundation, American Association of Kidney Patients, National Renal Administrators Association, and Forum of End-Stage Renal Disease Networks.

The guideline includes nine recommendations that are listed below. The recommendations are supported by 15 prognostic tables and 302 references.

Recommendations

1. Shared Decision-Making. A patient-physician relationship that promotes shared decision-making is recom-

Correspondence to Dr. John H. Galla, Division of Nephrology and Hypertension, University of Cincinnati Medical Center, P. O. Box 670585, Cincinnati, OH 45267-0585. Phone: 513-558-5471; Fax: 513-558-4309; E-mail: john.galla@uc.edu

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mended for all patients with either ARF or ESRD. Shared decision-making should involve at a minimum the patient and the physician. If a patient lacks decision-making capacity, decisions should involve the patient's legal agent. With the patient's consent, shared decision-making may include family members or friends and other members of the renal care team.

2. Informed Consent or Refusal. Physicians should fully explain diagnosis, prognosis, and all treatment options to each patient. The explanation of treatment options should include: (1) available dialysis modalities; (2) not starting dialysis and continuing conservative management which should include end-of-life care; (3) a time-limited trial of dialysis; and (4) stopping dialysis and receiving end-of-life care. Choices among options should be made by patients or, if patients lack decision-making capacity, their designated legal agents. Their decisions should be informed and voluntary. The renal care team, in conjunction with the primary care physician, should ensure that the patient or legal agent understands the consequences of the decision.

3. Estimating Prognosis. To facilitate informed decisions about starting dialysis for either ARF or ESRD, discussions should take place with the patient or legal agent about life expectancy and quality of life. Depending on the circumstances (*e.g.*, availability of nephrologists), a primary care physician or nephrologist who is familiar with prognostic data should conduct these discussions. These discussions should be documented and dated. Chances for survival should be estimated for all patients requiring dialysis, with the realization that the ability to predict survival in the individual patient is difficult and imprecise. The estimates should be discussed with the patient or legal agent, the patient's family, and the medical team. For patients with ESRD, these discussions should take place as early as possible in the course of the patient's renal disease and continue as the disease progresses. For patients who encounter major complications that may substantially reduce survival or quality of life, it is appropriate to discuss and/or reassess treatment goals, and to consider withdrawing dialysis.

4. Conflict Resolution. A systematic approach for conflict resolution is recommended when disagreement exists regarding the benefits of dialysis between the patient or legal agent (and those supporting the patient's position) and a member(s) of the renal care team. Conflicts may also occur within the renal care team or between the renal care team and other health care providers. This approach should review the shared decision-making process for the following potential sources of conflict: (1) miscommunication or misunderstanding about prognosis; (2) intrapersonal or interpersonal issues; and/or (3) values. If dialysis is indicated urgently, it should be provided while pursuing conflict resolution, provided the patient or legal agent requests dialysis.

5. Advance Directives. The renal care team should attempt to obtain written advance directives from all dialysis patients. These advance directives should be honored.

6. Withholding or Withdrawing Dialysis. It is appropriate to withhold or withdraw dialysis for patients with either ARF or ESRD for:

- Patients with decision-making capacity who, being fully informed and making voluntary choices, refuse dialysis or request that dialysis be discontinued.
- Patients who no longer possess decision-making capacity who have previously indicated refusal of dialysis in an oral or written advance directive.
- Patients who no longer possess decision-making capacity and whose properly appointed legal agents refuse dialysis or request that it be discontinued.
- Patients with irreversible, profound neurologic impairment such that they lack signs of thought, sensation, purposeful behavior, and awareness of self and environment.

7. Special Patient Groups. It is reasonable to consider not initiating or withdrawing dialysis for patients with ARF or ESRD who have a terminal illness from a nonrenal cause or whose medical condition precludes the technical process of dialysis.

8. Time-Limited Trials. For patients requiring dialysis, but who have an uncertain prognosis or for whom a consensus cannot be reached about providing dialysis, nephrologists should consider offering a time-limited trial of dialysis.

9. Palliative Care. All patients who decide to forego dialysis (or for whom such a decision is made) should receive continued palliative care. With the patient's consent, those with expertise in such care, such as hospice health care professionals, should be involved in managing the medical, psychosocial, and spiritual aspects of end-of-life care for these patients. Patients should be allowed to decide if they wish to die in a health care facility or at home with hospice care. Bereavement support should be offered to patients' families.

Using selection criteria similar to those recommended by the Agency for Health Care Policy Research and the Institute of Medicine, RPA/ASN selected this topic based on the following conditions:

- Prevalence of the clinical problem,
- Burden of the illness associated with the problem,
- Significance of social, ethical, and legal considerations surrounding the problem,
- Unnecessary variability of clinical practice in managing the problem,
- Potential for the development of an evidence-based, clinical practice guideline to improve patient outcomes,
- Availability of scientific evidence to support a clinical practice guideline, and
- Financial implications of the clinical practice guideline.

In 1991, the Institute of Medicine recommended developing a clinical practice guideline "for evaluating patients for whom the burdens of renal replacement therapy may substantially outweigh the benefits." Since then, nephrologists have reported being increasingly asked to dialyze patients for whom they perceive dialysis will be of marginal benefit. Not surprisingly, almost a decade later, this topic was given highest priority for guideline development because the renal professional community recognizes that the incident and prevalent ESRD population has changed substantially.

An increasing number of patients who are initiating renal replacement therapy are elderly and suffer from a variety of comorbid conditions that adversely affect the health-related quality of life. Furthermore, voluntary withdrawal from dialysis has become an increasingly common occurrence. Recent United States Renal Data System (USRDS) data show that approximately one of five patients voluntarily withdraws from dialysis.

External forces have raised awareness within the renal community of the need to address the issues of starting and stopping dialysis. Much public attention has focused on patients' rights to discontinue medical therapies and the debate regarding the propriety of physicians actively assisting patients to end their lives. As a component of this public deliberation, increasing numbers of patients and their care providers have developed advance directives. Therefore, it is likely that the public will be interested in this guideline of patients' rights and the use of palliative care.

In the context of an expanding American dialysis program that includes an increasing number of patients who have substantial comorbid conditions, the RPA/ASN leadership believe that an evidence-based clinical practice guideline that will assist patients, families, and the nephrology team in making decisions about initiating, continuing, and stopping dialysis will be timely and beneficial. This guideline will benefit patients and families by presenting more information about various options for the treatment of ESRD and by calling for their active participation in these decisions in recognition of their rights. Similarly, the evidence-based recommendations will help nephrologists and other members of the renal care team better inform and counsel patients and families about potential outcomes of acute renal failure and ESRD.

This guideline does not make explicit recommendations for pediatric patients, although many of the principles may apply to that population. In the pediatric setting, shared decision-making involves physicians and parents, unless the child has decision-making capacity. Shared decision-making is more difficult without adequate outcome data, and data on long-term outcomes for children treated with acute or chronic dialysis are sparse and do not address many quality of life issues or potentially long-term sequelae, especially for the infant. Parents have the legal authority to make decisions on behalf of their children, assuming that they act in the best interest of their child. Generally, parents give permission for the treatment of their children unless their legal authority has been removed and

granted to others (*e.g.*, the state). However, the American Academy of Pediatrics (AAP) emphasizes that physicians and parents should give great weight to clearly expressed views of child patients regarding life-sustaining medical treatment, regardless of the legal particulars. Child patients should participate in decision-making commensurate with their developmental capacity, and child assent should be sought whenever reasonable. In some states, adolescents under the age of 18 may be assessed to be sufficiently mature to make medical decisions for themselves. The AAP believes that the views of even younger children should be factored into end-of-life decisions.

Decisions to either withhold or withdraw dialysis are complex and depend on circumstances unique to individual patients and their providers. Although these recommendations are meant to aid in dialysis decision-making, they do not cover every possible contingency. Furthermore, the guideline recommendations do not cover the technical management of patients receiving dialysis or the selection of patients for renal transplantation.

The objectives of this guideline are to:

- Synthesize available research evidence on patients with ARF and ESRD as a basis for making recommendations about withholding and withdrawing dialysis,
- Enhance understanding of the principles and processes useful for and involved in making decisions to withhold or withdraw dialysis,
- Promote ethically as well as medically sound decision-making in individual cases,
- Recommend tools that can be used to promote shared decision-making in the care of patients with ARF or ESRD, and
- Offer an understandable and acceptable ethical framework for shared decision-making among health care providers, patients, and their families.

The primary target audience of this guideline is health care providers involved in the care of patients with either ARF or ESRD: nephrologists, intensivists, primary care physicians, nephrology nurses, advanced practice nurses, and nephrology social workers. It may also be useful to patients and their families, renal dietitians, dialysis technicians, renal administrators, clergy, and policy makers.

Copies of the clinical practice guideline may be purchased from the RPA by contacting rpa@renalmd.org or calling 301-468-3515.