

A New Clinical Practice Guideline on Initiation and Withdrawal of Dialysis That Makes Explicit the Role of Palliative Medicine

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ABSTRACT

More than 50,000 long-term dialysis patients die per year, with roughly 20% of these deaths after a decision to stop dialysis. After dialysis discontinuation, the average dialysis patient lives for only 8 to 12 days. The renal community recognizes and recommends a role for palliative care in the end-of-life treatment of these patients. This article describes the new clinical practice guideline developed by the renal community, *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis*, that makes explicit the role of palliative medicine in the treatment of dialysis-dependent patients who stop this treatment with the expectation that death will follow shortly.

INTRODUCTION

MORE THAN 50,000 LONG-TERM DIALYSIS PATIENTS die per year. Withdrawal from dialysis is the second most common cause of death for these patients; it accounts for roughly 20% of dialysis patient deaths.¹ The average dialysis patient lives for 8 to 12 days after dialysis is withdrawn.² The renal community recognizes and recommends a role for palliative care in the end-of-life treatment of these patients.³ Those practicing palliative medicine need to be aware of these recommendations and the role that palliative medicine professionals can play to improve patient outcomes in this population. Based on the experience at the hospitals affiliated with the Robert C. Byrd Health Sciences Center of West Virginia University, consultations for patients for whom dialysis has been stopped constitute 5% to 10% of palliative care service consultation requests. The fol-

lowing new clinical practice guideline, *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis*,⁴ makes explicit the role of palliative medicine in the treatment of dialysis-dependent patients who stop this treatment with the expectation that death will follow shortly.

WHY THIS GUIDELINE WAS DEVELOPED

In 1991, the Institute of Medicine (IOM) recommended developing a clinical practice guideline "for evaluating patients for whom the burdens of renal replacement therapy may substantially outweigh the benefits."⁵ Since then, nephrologists have reported being increasingly asked to provide dialysis for patients for whom they perceive it to be of marginal benefit. Not sur-

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prisingly, almost a decade later, this topic was given highest priority for guideline development because the renal professional community recognizes that the incidence and prevalence of end-stage renal disease has changed substantially. An increasing number of patients who are initiating renal replacement therapy are elderly and suffer from substantial comorbid conditions. These in turn adversely affect the patient's health-related quality of life. Based on data from the United States Renal Data System (USRDS) from 1993 to 1995,⁶ the incident dialysis patient treatment rate per million population per year increased for all age categories. For Americans 55 years old or older, the highest incident treatment rates in rank order were delivered to 75 to 79, 70 to 74, and 80 to 84 year olds, respectively (see Fig. 1). Over the last 5 years, 75 to 84 year olds have had the greatest increase in incident treatment rate. Older patients have the most comorbid conditions and are at the greatest risk for developing illnesses during their subsequent course on dialysis. Validation of this contention is provided by the USRDS catalog of comorbid conditions. Fifty percent of these patients had diabetes mellitus; 42% had coronary artery disease (CAD); 40% had congestive heart failure (CHF); 23% had peripheral vascular disease (PVD); and 19% were malnourished.

In the 1997 USRDS cohort of new dialysis patients, 5% were unable to ambulate, and 1% could not transfer without substantial assistance. Fur-

thermore, voluntary withdrawal from dialysis has become an increasingly common occurrence. Recent USRDS data show that approximately 20% of patients who die per year die as a result of voluntary withdrawal from dialysis.^{7,8} When categorized by age, indifferent of the presence or absence of diabetes mellitus, older patients were the most likely to stop dialysis (see Fig. 2).⁶

External forces have raised the renal community's awareness of the current need to address the issues of starting and stopping dialysis. There has been much public attentiveness to patients' rights to discontinue medical therapies and debate regarding the propriety of physicians actively assisting their patients to end their lives. As a component of this public deliberation, patients and their care providers have increasingly developed advance directives. Therefore, it is likely that the public will be engaged by the discussion in this guideline of patients' rights and the use of palliative care.

In summary, in the context of an expanding American dialysis program with an increase in the number of patients who have substantial comorbid conditions, the Renal Physicians Association (RPA) and American Society of Nephrology (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 quite beneficial. This guideline will benefit patients and families by presenting

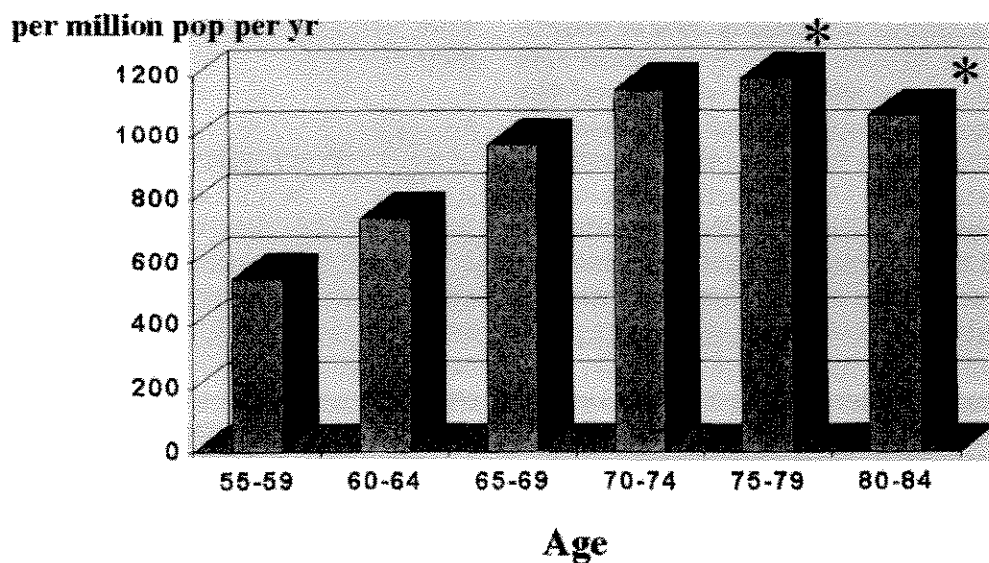


FIG. 1. Treated Medicare end-stage renal disease (ESRD) incidence 1993-1995 (USRDS). Note the * designates the ages with the fastest growth in incidence treatment over the last 5 years.

Deaths/100 pt yrs

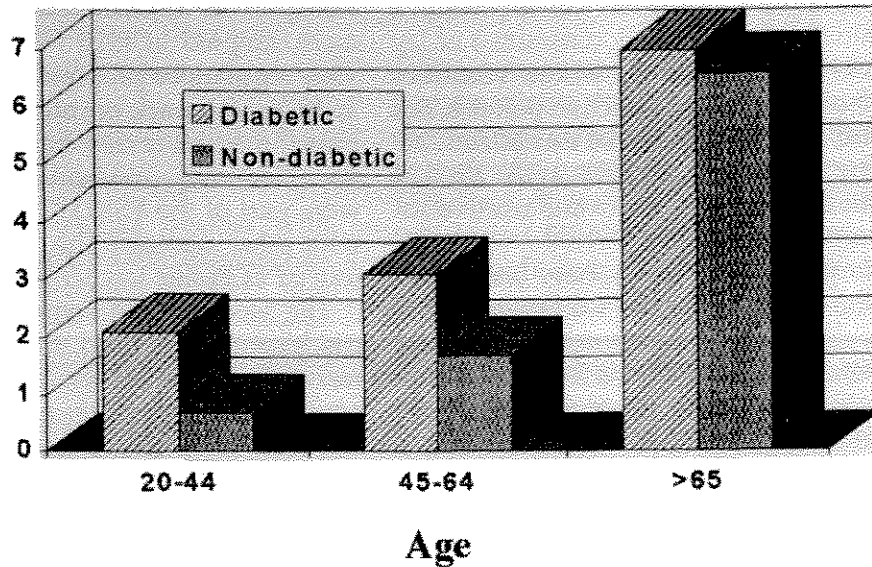


FIG. 2. Voluntary withdrawal rates from dialysis 1993–1995 (USDRS) as a function of patients' ages and presence or absence of diabetes mellitus.

more information about various options for treatment of end-stage renal disease (ESRD) and by calling for their active participation in these decisions in recognition of their rights. Similarly, nephrologists and other members of the renal care team will benefit from recommendations based on evidence that can inform their counseling of patients and families about potential outcomes with acute renal failure and ESRD.

GUIDELINE OBJECTIVES

The objectives of this Guideline are to:

- Synthesize available research evidence on patients with acute renal failure (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 a publicly understandable and acceptable ethical framework for shared decision making among health care providers, patients, and their families.

HISTORICAL AND POLICY PERSPECTIVES

The contentious issue of limiting the access of potential patients to life-saving dialysis has existed since the emergence of "continuous intermittent hemodialysis" in Seattle, Washington, in the early 1960s. At that time, in contrast to the present, the only ethical issue discussed by the nephrology community was that of withholding treatment for chronic kidney failure. Neither withdrawal from dialysis treatment nor withholding treatment for acute kidney failure was an issue at that time.

The rationing of access to dialysis treatment in Seattle arose because of a scarcity of trained personnel and artificial kidney "machines." Behind the scarcity of machines lay the absence of a means to pay for treatment. The dilemma of too many eligible patients, too few machines and personnel to run them, and staggering costs that would fall on parties other than patients led the Board of Trustees of the King County Medical Society to devise a procedural solution to the problem of resource allocation.⁹

Rationing occurred in this way. Beginning in 1962, prospective patients were thoroughly evaluated for treatment in clinical terms, including psychological assessment.¹⁰ However, clinical evaluation did not reduce the number of potentially eligible patients sufficiently to permit ac-

ceptance of all in the limited bed capacity of the Seattle Artificial Kidney Center. Consequently, a second evaluation occurred. A committee of lay members of the community, whose identities were not known to the prospective patients nor to the public, reviewed potential candidates, accepting some and rejecting others on the basis of the committee's judgment about the relative social worth of the individuals.^{11,12}

This anonymous lay committee, sometimes known as the God Committee, was prominently featured in a November 1962 article in *Life* magazine by Shana Alexander, "Who Shall Live, Who Shall Die?"¹³ The Seattle decision process received national television coverage in November 1965 when NBC did an hour-long documentary, with Seattle featured at the center, narrated by Edwin Newman.¹⁴ These two news stories, one print and the other electronic, gave generally favorable publicity to dialysis as a medical breakthrough, even while drawing attention to the dilemma created by the financial need to ration access to treatment.

The response to the Seattle experience occurred at two different levels. Clinically, as others around the United States sought to provide dialysis therapy, they also confronted the necessity of rationing access to treatment. However, learning from Seattle, they did so generally by burying the need to make invidious distinctions among individuals within the "medical criteria" for patient acceptance.^{15,16} At the level of the public reaction to rationing, Seattle was subjected to very substantial critical publicity.¹⁷ For example, Paul Freund, distinguished professor at Harvard University School of Law, wrote a very strong attack on this practice in an issue of *Daedalus* in the late 1960s.¹⁸ He was not alone among commentators who were appalled by rationing in the wealthy United States.^{19,20}

When Congress enacted Sec. 299I of the Social Security Amendments of 1972,²¹ it established a near-universal entitlement under Medicare for treatment of chronic kidney disease by dialysis or kidney transplantation. It thus apparently eliminated the need for rationing that had been explicit in Seattle and implicit elsewhere. The original statutory language did include the requirement that there be "at least . . . a medical review board to screen the appropriateness of patients for the proposed treatment procedures."²¹ There was no legislative history to indicate the meaning of this language. And neither the Social Security Ad-

ministration nor the Public Health Service added clarity to it. Implementing regulations for payment adopted in 1973 were silent²²; medical review regulations proposed in 1975²² and adopted in 1976²³ fell back on process, relying on the required medical review boards to deal with the issue. Generally, medical review boards, which were part of the ESRD "Network" system, dealt with other matters. The 1972 language was removed in Public law 95-292 of 1978.

The Medicare entitlement removed the financial incentive, or need, to ration access to treatment. The nephrology community, moreover, scarred by its experience of the 1960s, was not disposed to dwell on the issue of rationing, occupied as it was with organizing to provide services to an ever-increasing patient population. However, as that growing population became increasingly older, as diabetes moved from a clinical contraindication for treatment to the primary diagnosis of kidney failure, as hypertension became the second leading cause of kidney failure, concern was voiced that some patients were being accepted whose prognosis was poor and whose quality of life on dialysis was marginal.

Consequently, the 1991 report of the IOM, *Kidney Failure and the Federal Government*, included a chapter on ethics.⁵ In turn, this chapter addressed the issue of patient acceptance and patient withdrawal from treatment, at least for chronic kidney failure, as well as how to deal with problem patients. The IOM committee articulated the principle that "patient acceptance criteria should be based on the medical assessment of the benefits and burdens of treatment and on the best interests of individual patients, not on economic objectives of cost containment." The committee also stated that "Nephrologists have a professional responsibility to deal with the issues of initiation and termination of treatment" and called for guidelines that would assist patients, families, and physicians "who must make decisions about the use of any life-sustaining therapy."

The recommendations of the IOM committee are worth citing here, because they stand in some measure as direct antecedents to this clinical practice guideline.

The [IOM] committee recommends that patients, professionals in adult and pediatric nephrology, and bioethicists develop guidelines for evaluation of patients for whom the burdens of renal replacement therapy may

substantially outweigh the benefits. These guidelines should be flexible and should encourage the physician to use discretion in the assessment of the individual patient.

Any guidelines for children should be child-specific and should describe the role of the parents in the decision-making process.

Renal professionals should discuss with ESRD patients their wishes for dialysis, cardiopulmonary resuscitation (CPR), and other life-sustaining treatments and encourage documented advance directives. ESRD health care professionals should be encouraged to participate in continuing education in medical ethics and health law.

There is a need for some specialists in the medical ethics of renal disease to educate healthcare providers, to train members of ethics committees, and to do research on ethical issues in dialysis and transplantation.

Other features of the IOM ethics chapter worth noting in passing are the following. The issues of patient acceptance and withdrawal were identified as the domain of patients, families, and caregivers; a role for government was ruled out. Medical assessment in the best interest of the patient was stipulated, ruling out cost containment as a criterion for decision making. Chronological age was deemed unacceptable as a decision criterion for patient acceptance. The conceptual basis of decisions regarding who should receive dialysis was the relationship of the benefits to the burdens of treatment and patients' preferences.

From the policy perspective there is one further concern. In contemporary political commentary the propensity to refer to "stakeholders" is deeply ingrained, having displaced the older and broader concept of the public interest. The implication of the use of the former term is that the issue is one confined to the renal community. Acceptance of such an inference would, in the judgment of the Working Group, be a profound ethical mistake. Any discussion of patient acceptance and patient withdrawal from treatment must recognize that all individuals have a stake in this discussion, regardless of their immediate clinical or family situation. The public interest lies in acknowledging that these issues arise not only in the renal setting but widely in other contexts and that how we deal with them marks our understanding of our common humanity.

GUIDELINE RECOMMENDATION SUMMARY

These recommendations are based on the expert consensus opinion of the RPA/ASN Working Group. They developed *a priori* analytic frameworks regarding decisions to withhold or withdraw dialysis in patients with acute renal failure and ESRD. Systematic literature reviews were conducted to address prespecified 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 that appear below. The guideline includes a rationale for each recommendation, 25 prognostic tables, and 302 references.

Recommendation No. 1: Shared Decision Making

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

Recommendation No. 2: Informed Consent or Refusal

Physicians should fully inform patients about their diagnosis, prognosis, and all treatment options, including: (1) available dialysis modalities, (2) not starting dialysis and continuing conservative management that 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 insure that the patient or legal agent understands the consequences of the decision.

Recommendation No. 3: Estimating Prognosis

To facilitate informed decisions about starting dialysis for either ARF or ESRD, discussions should occur with the patient or legal agent about life expectancy and quality of life. Depending upon 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. All patients requiring dialysis should have their chances for survival estimated, 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, patient's family, and among the medical team. For patients with ESRD, these discussions should occur as early as possible in the course of the patient's renal disease and continue as the renal disease progresses. For patients who experience major complications that may substantially reduce survival or quality of life, it is appropriate to discuss and/or reassess treatment goals, including consideration of withdrawing dialysis.

Recommendation No. 4: Conflict Resolution

A systematic approach for conflict resolution is recommended if there is disagreement 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, or (3) values. If dialysis is indicated emergently, it should be provided while pursuing conflict resolution, provided the patient or legal agent requests it.

Recommendation No. 5: Advance Directives

The renal care team should attempt to obtain written advance directives from all

dialysis patients. These advance directives should be honored.

Recommendation No. 6: Withholding or Withdrawing Dialysis

It is appropriate to withhold or withdraw dialysis for patients with either ARF or ESRD in the following situations:

- Patients with decision-making capacity, who being fully informed and making voluntary choices, refuse dialysis or request 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 neurological impairment such that they lack signs of thought, sensation, purposeful behavior, and awareness of self and environment.

Recommendation No. 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.

Recommendation No. 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.

Recommendation No. 9: Palliative Care

All patients who decide to forgo dialysis or for whom such a decision is made should be treated with continued palliative care. With the patient's consent, persons 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 offered the option of dy-

ing where they prefer including at home with hospice care. Bereavement support should be offered to patients' families.

WHO DEVELOPED AND ENDORSED THE GUIDELINE

The RPA and the 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 developed the clinical practice guideline, *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis*.

As of February 2000, the following organizations have endorsed the guideline: the 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, Forum of End-Stage Renal Disease Networks, and the American Association of Critical Care Nurses.

GUIDELINE TARGET AUDIENCE AND HOW TO OBTAIN THE GUIDELINE

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, nephrology social workers, and palliative medicine professionals. 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.

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