

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

Renal Physicians Association
and
American Society of Nephrology

CLINICAL PRACTICE GUIDELINE

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The following acronyms and abbreviations are used in the guideline.

95% CI	Ninety-five percent confidence interval
AAP	American Academy of Pediatrics
ACE	Aid to Capacity Evaluation
ADR	adjusted death rate
AHCPR	Agency for Health Care Policy and Research
AKA	above the knee amputation
AMI	acute myocardial infarction
ARF	acute renal failure
ASN	American Society of Nephrology
ATN	acute tubular necrosis
CAD	coronary artery disease
CHF	congestive heart failure
COPD	congestive obstructive pulmonary disease
CPR	cardiopulmonary resuscitation
CQI	continuous quality improvement
DNR	do not resuscitate
ESRD	end-stage renal disease
G/dL	grams per deciliter
HD	hemodialysis
ICD-9-CM	Clinical Modification of the International Classification of Diseases, Ninth Revision
ICU	intensive care unit
IOM	Institute of Medicine
KDQOL	Kidney Disease Quality of Life
KPS	Karnofsky Performance Status Scale
mmHg	millimeters of mercury
NKF	National Kidney Foundation
OSHA	Occupational Safety and Health Act
PD	peritoneal dialysis
PSDA	Patient Self-Determination Act
PVD	peripheral vascular disease
RPA	Renal Physicians Association
RR	risk ratio
SF-36	Medical Outcomes Study 36-item Short Form
SF-20	Medical Outcomes Study 20-item Short Form
SPS-R	Simplified Acute Physiologic Score-Reduced
USRDS	United States Renal Data System

A GUIDE TO THIS DOCUMENT

This document, *Clinical Practice Guideline on Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis*, addresses recommendations concerning withholding or withdrawing dialysis in adult patients with either acute renal failure (ARF) or end-stage renal disease (ESRD). The guideline was developed by the Renal Physicians Association (RPA) and the American Society of Nephrology (ASN) in conjunction with representatives from multiple disciplines and organizations represented in the dialysis community, kidney patients, and family and internal medicine physicians. A bioethicist and a public policy expert also were members of the Working Group. A list of the members serving on the Working Group and individuals serving as peer reviewers appears in Section 8.

The document is organized in a way that allows readers to quickly access the following key pieces of information:

- **Guideline recommendation summary:** A brief summary of recommendations and their bases is given on pages 3 through 4.
- **Foreword:** Section 1 provides historical and other background data defining the importance and relevance of the guideline topic. An overview of ethical considerations in dialysis decision-making also is provided.
- **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 methodology that was used to develop the guideline. Analytic frameworks and questions that were used to guide the entire process are given. 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 rationale:** Section 4 presents fully the guideline recommendations, the principles, laws, and systematic reviews of evidence on which they were based. In most instances, the research evidence was contextual in nature and only provided indirect support to the recommendations. Ratings of the quality of evidence are provided.
- **Suggestion boxes:** Along with most guideline recommendations are boxes that specify action items health care providers can initiate to implement the recommendation into their own practices.
- **Prognostic tables:** Prognostic tables are situated within the discussions of guideline Recommendation No. 3. They provide evidence-based information that may help health care providers estimate prognosis for their patients.
- **The disruptive patient:** In Section 5, ideas about addressing disruptive patients are presented.
- **Research directions:** Throughout this study, several gaps in the evidence were found and noted; suggestions for future research to address these gaps are described here in Section 6.
- **Suggestions for dissemination and implementation and toolkit:** Section 7 offers suggestions for educating providers about the guideline and ideas for local implementation. Exemplative tools such as instruments for assessing decision-making capacity are provided.
- **Acknowledgements:** A number of individuals and organizations made significant contributions to this guideline; they are identified in Section 8.

- **Glossary:** Several key terms are fully defined in the glossary at the end of the document in Section 9.

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 end-stage renal disease. 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.

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

SECTION 1: FOREWORD AND RATIONALE FOR GUIDELINE

Process of Topic Selection

Using selection criteria similar to those recommended by the Agency for Health Care Policy Research (AHCPR) and the Institute of Medicine (IOM), the Renal Physicians Association and the American Society of Nephrology (RPA/ASN) surveyed their leadership to select a topic for the next RPA/ASN evidence-based clinical practice guideline. Selection was based on the following:

1. prevalence of the clinical problem
2. burden of the illness associated with the problem
3. significance of social, ethical, and legal considerations surrounding the problem
4. unnecessary variability of clinical practice in managing the problem
5. potential for the development of an evidence-based, clinical practice guideline to improve patient outcomes
6. availability of scientific evidence to support a clinical practice guideline
7. financial implications of the clinical practice guideline

The selected topic was “Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis.”

Why This Guideline Was Selected

In 1991, the IOM recommended developing a clinical practice guideline “for evaluating patients for whom the burdens of renal replacement therapy may substantially outweigh the benefits.”¹ Since then, nephrologists have reported being increasingly asked to dialyze patients for whom they perceive dialysis to 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 end-stage renal disease population has changed substantially. An increasing number of patients who are initiating renal replacement therapy are elderly and suffer from substantial numbers of 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 1995,² the incident 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 Figure 1). Over the last five 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. Furthermore, voluntary withdrawal from dialysis has become an increasingly common occurrence. Recent USRDS data show approximately 1 of 5 patients voluntarily withdraw from dialysis.^{3,4} When categorized by age, indifferent of the presence or absence of diabetes mellitus, older patients were the most likely to stop their treatments (see Figure 2).²

Figure 1. Treated Medicare ESRD Incidence 1993 –1995 (USRDS). Note: The “*” designates the ages with the fastest growth in incidence treatment over the last five years.²

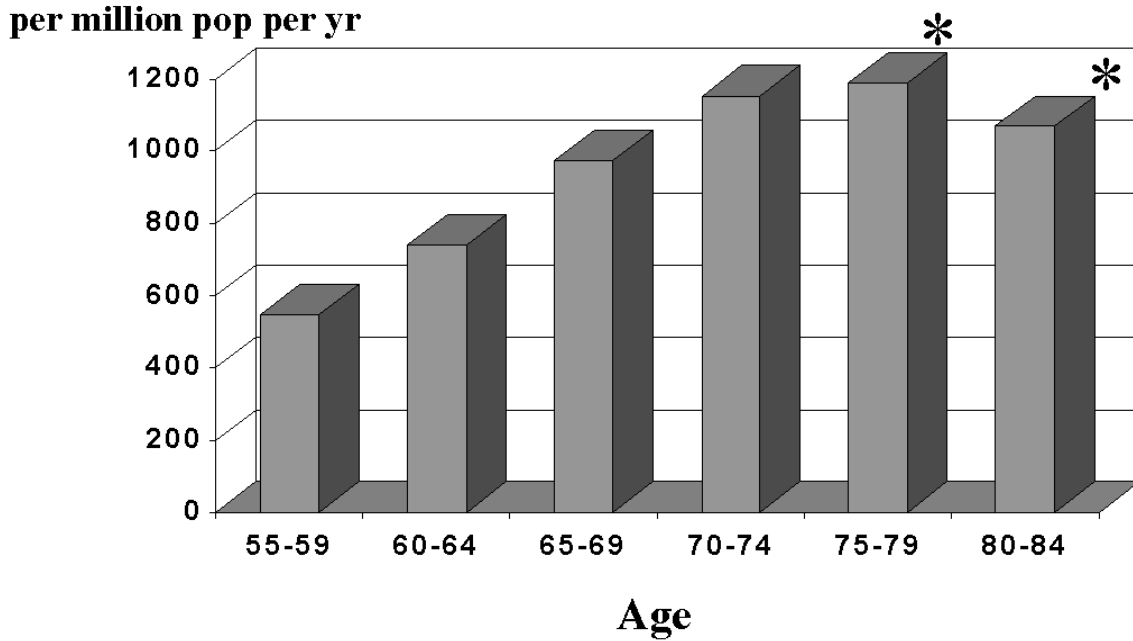
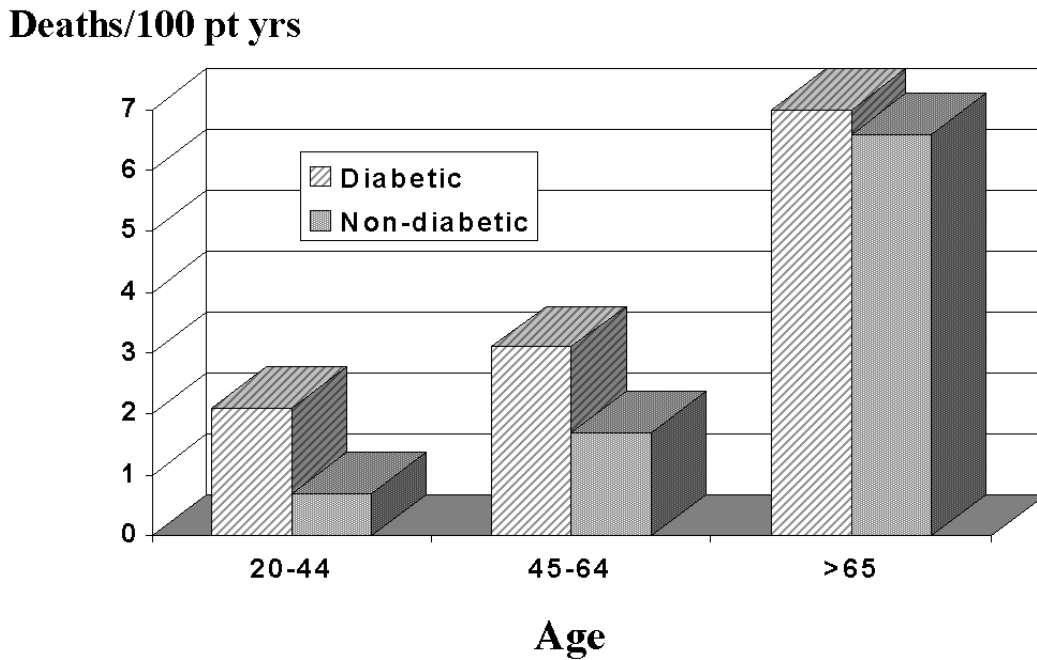


Figure 2. Voluntary Withdrawal Rates from Dialysis 1993 – 1995 (USRDS) as a Function of Patients’ Ages and Presence or Absence of Diabetes Mellitus.²



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 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 quite beneficial. This guideline will benefit patients and families by presenting more information about various options for treatment of 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.

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 in the early 1960s. At that time, in contrast to the present, the only issue 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.⁵

Rationing occurred in this way: beginning in 1962, prospective patients were thoroughly evaluated for treatment in clinical terms, including psychological assessment.⁶ However, clinical evaluation did not reduce the number of potentially eligible patients sufficiently to permit acceptance of all in the limited bed capacity of 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.^{7,8}

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?"⁹ 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.¹⁰ 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.^{11,12} At the level of the public reaction to rationing, Seattle was subjected to very substantial critical publicity.¹³ 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 1960s¹⁴ He was not alone among commentators who were appalled by rationing in the wealthy United States.^{15,16}

When Congress enacted Sec. 299I of the Social Security Amendments of 1972,¹⁷ 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 which 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.”¹⁷

There was no legislative history to indicate the meaning of this language. And neither the Social Security Administration nor the Public Health Service added clarity to it. Implementing regulations for payment adopted in 1973 were silent;¹⁸ medical review regulations proposed in 1975¹⁸ and adopted in 1976¹⁹ 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.¹ 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.”¹

The recommendations of the IOM committee are worth citing here,¹ 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 health care 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 be dialyzed 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.

Ethical Considerations in Dialysis Decision-Making

Guidelines are not rules requiring rigid conformity. They are formulations based on relevant considerations and evidence that can guide the process of thinking through a problem. As such, guidelines do not eliminate the discretion that every clinician must use as he/she considers the circumstances of particular cases. Rather, guidelines must be seen as a basis for assessment and/or management that requires an understanding of the unique features of specific cases. This particular guideline addresses a question that is intrinsically an ethical one: "Who should be dialyzed?" Thus, in its formulation, the shared values of the dialysis community, patients, families, physicians, nurses, social workers and other health care professionals and administrators, were consulted. This guideline adds to the clinical data about medical indications and outcomes of dialysis some evidence about the values of that community. One of the values of that community is fairness. Recognizing that the public largely funds the ESRD program through Medicare, the Working Group hopes that the public will perceive this guideline to be fair and one that promotes the public welfare.

Because of the inherently ethical aspect of this guideline, the Working Group thought it was necessary to present a systematic way for looking at the ethical issues raised by this guideline and for guiding clinical decisions being made in the context anticipated by this guideline. The Working Group recognizes, however, that there is a potential tension between an evidence-based approach that leads to a particular recommendation for a particular group of patients (e.g., those who are terminally ill from cancer) and a normative approach that addresses what should be done

for the individual patient with a unique set of values. Neither the outcomes for the particular group of patients nor the preferences of the individual patient should be ignored. In dialysis decision-making as in other types of medical decision-making, clinicians need to strike a balance between the two as they engage patients in the process of reaching shared decisions. The following discussion is offered to provide a framework for such decision-making.

Ethical Decision-Making

Ethical decisions should be analyzed by means of four topics: medical indications, patient preferences, quality of life, and contextual features, that is, the social, economic, legal, and administrative context in which the decision occurs. Every case can be viewed in terms of these four topics; no case can be adequately discussed without reference to them. Although the facts of each case differ, these four topics are always relevant. The topics organize the varying facts of the particular case and, at the same time, the topics call attention to the ethical principles appropriate to the case.

Medical Indications

This topic comprises the usual content of a clinical discussion: diagnosis, prognosis, and treatment of the patient's physiological and pathological condition. "Indications" refers to the relation between the pathophysiology presented by the patient and the diagnostic and therapeutic interventions that are "indicated," that is, appropriate to evaluate and treat the problem. Diagnostic and therapeutic interventions are deemed to be indicated and appropriate if the expected medical or physical benefits justify the risks. Although this is the usual material covered in the presentation of any patient's clinical problems, the ethical discussion will not only review the medical facts, but also attend to the purposes and goals of any indicated interventions. Medical indications reflect the ethical principles of beneficence and nonmaleficence, since the decisions based on medical indications must be guided by the ethical duty to benefit patients and do them no harm.

Patient Preferences

In all medical treatment, the preferences of the patient, based on the patient's own values and personal assessment of benefits and burdens, are ethically relevant. In every clinical case, the following questions must be raised: "What are the patient's goals? What does the patient want?" The systematic review of this topic requires further questions. "Has the patient been provided sufficient information? Does the patient comprehend? Does the patient understand the uncertainty inherent in any medical recommendation and the range of reasonable options that exist? Is the patient consenting voluntarily? Is the patient unduly influenced?" In some cases, an answer to these questions might be "We don't know because the patient is incapable of formulating a preference or expressing one." If the patient lacks decision-making capacity at the time a decision must be made, we must ask, "Who has the authority to decide on behalf of this patient? What are the ethical and legal limits of that authority? What is to be done if no one can be identified as surrogate decision maker?" The patient preferences topic reflects the ethical principle of respect for autonomy, since providers of care, family members and others have an ethical duty to accept the decisions made by competent patients and, in the absence of competence, to formulate decisions that would respect patients' wishes, or if wishes are unknown, advance the best interest of their patients.

Quality of Life

Any injury or illness threatens persons with actual or potential reduced quality of life, manifested in the signs and symptoms of their disease. The object of all medical intervention is to restore, maintain, or improve quality of life. Thus, in all medical situations, the topic of quality of life must be raised. The patient is the best judge of his/her quality of life, and his/her view should be respected. Many questions surround this topic: “What does this phrase, ‘quality of life’ mean in general? How should it be understood in particular cases? How do persons other than the patient perceive the patient's quality of life and of what ethical relevance are their perceptions? Above all, what is the relevance of quality of life to ethical judgment about whether it is right to withhold or withdraw dialysis?” This topic, which is less well worked out in the literature of medical ethics than the two previous ones, is perilous because it opens the door for bias and prejudice. Still, it must be confronted in the analysis of clinical ethical problems in dialysis. This topic is based on the ethical principle of beneficence and autonomy.

Contextual Features

Patients come to physicians because they have a problem that they hope the physician can help to correct. Physicians undertake the care of patients with the intent and the duty to make all reasonable efforts to help them. The topics of medical indications, patient preferences, and quality of life bring out these essential features of the case. Yet every medical case is embedded in a larger context of persons, institutions, and financial and social arrangements. Patient care is influenced, positively or negatively, by the possibilities and the constraints of that context. At the same time, the context itself is affected by the decisions made by or about the patient: these decisions have psychological, emotional, financial, legal, scientific, educational, and spiritual impact on others. In every case, the relevance of the contextual features must be determined and assessed. These contextual features may be crucially important to the understanding and resolution of the case. The topic of contextual features allows consideration of questions of justice, that is, attention to the effect on the welfare of parties other than the patient and the equitable distribution of burdens or benefits arising from treatment decisions among the parties and within the institutions.

The Process of Ethical Decision-Making

When ethical principles conflict—for example the family of a patient lacking decision-making capacity requests dialysis but the renal care team believes it will cause more harm than good—further communication and negotiation may be needed to resolve the conflict. In making ethical decisions when principles or values conflict, the goal is to promote the value or values identified as most important in the case while causing the least infringement on the other recognized values in the case. The process outlined in Table 1 on the next page provides a systematic, step-by-step way to identify, analyze, and resolve most ethical problems arising in dialysis decision-making. In using this process, the renal care team should document the range of solutions considered, the one chosen, and the reasons for choosing the particular solution.

Table 1. The Process of Ethical Decision-Making in Patient Care.

<ol style="list-style-type: none">1. Identify the ethical question(s).2. Gather the medical, social, and all other relevant facts of the case.3. Identify all relevant guidelines and values. Be sure to consider any distinctive values of the patient, family, physician, nurse, other health care professionals, or the health care institution.4. Determine if there is a solution that respects all the relevant guidelines and values in the case; if there is, use it. If not, proceed to step 5.5. Propose possible solutions to resolve the conflict(s) in values, or in other words, answer the question, “What could you do?”.6. Evaluate the possible solutions for the particular case, determine which one is best, justify your choice, and respond to possible criticisms. In other words, answer the questions, “What should you do?” and “Why?”. Consider the following points in evaluating possible solutions:<ol style="list-style-type: none">a. Do some solutions better promote the values that are most important in the particular case?b. Do some solutions involve the least infringement possible of other values?

SECTION 2: BACKGROUND

Scope and Intended Use

This guideline addresses withholding and withdrawing dialysis in adult patients with either ARF or ESRD. The guideline represents consensus expert opinion informed by ethical principles, case and statutory law, and systematic review of research evidence. Meta-analysis was not used to summarize research evidence because of heterogeneity in patient populations and study designs, and because quantitative techniques for summarizing multiple prognostic studies with varying multivariate analyses are not available. The guideline provides recommendations on the targeting, timing, and content of discussions related to either withholding or withdrawing dialysis, and the care of patients who forgo dialysis. The guideline also provides recommendations on when it is appropriate to withhold or withdraw dialysis. The recommendations are not mandatory, but rather flexible guides that warrant tailoring based on particular patient, provider, and geographic circumstances. They allow the renal care team discretion in their application to individual patients. They are intended for use by providers and patients (and their families or advisors) in the United States of America and its trust territories to aid in dialysis decision-making. They are not intended for use by regulatory agencies for reimbursement or other decisions.

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--is recommended.²⁰ Shared decision-making recognizes the importance of both patient preferences and medical indications. In shared decision-making, the health care provider is the expert in diagnosis, prognosis, and treatment alternatives, and the patient is the expert in his or her own history, values, preferences, and goals. The two work together to reach decisions that are individualized to the patient's particular circumstances and preferences. There are limits, however, to the shared decision-making process that protect the rights of patients and the professional integrity of health care professionals. The patient has the right to refuse dialysis even if the renal care team disagrees with the patient's decision and wants the patient to undergo dialysis. Similarly, the renal care team has the right to refuse to offer dialysis 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, this guideline provides recommendations for how to resolve such conflicts.

This guideline does not make explicit recommendations for pediatric patients, though many of the principles outlined here may apply. In the pediatric setting, shared decision-making involves physicians and parents, unless the child patient 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.²¹⁻²⁵ Parents have the legal authority to make decisions on behalf of their children, assuming that they act in the best interest of their child.^{21,26-28} 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.²⁷ 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 the end-of-life decision-making process. These principles should be applied for any shared decision-making about pediatric patients.

Decisions to either withhold or withdraw dialysis are complex and dependent upon 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. Further, the guideline recommendations do not cover the technical management of patients receiving dialysis nor the selection of patients for renal transplantation, topics which were recently addressed by the RPA, the National Kidney Foundation, and the American Society of Transplantation, respectively.²⁹⁻³⁵

Guideline Objectives

The following are the objectives of this guideline:

- 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 a publicly understandable and acceptable ethical framework for shared decision-making among health care providers, patients, and their families.

Target Audience

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.

SECTION 3: GUIDELINE DEVELOPMENT PROCESS

Sponsorship

The RPA and the ASN selected the topic for the guideline, committed resources towards its development, and organized the creation of a multidisciplinary Working Group to oversee the development process. The RPA and ASN appointed a steering panel that was charged with framing the scope of the guideline, identifying the relevant stakeholders and groups that should be represented on the multidisciplinary working group, and outlining the requirements for technical and administrative contractor support to develop the guideline. The panel selected staff from the San Antonio Evidence-Based Practice Center (EPC) and VA Cochrane Center to provide such support using methodology adapted from the AHCPR guideline process and outlined in the American Medical Association's Attributes for Clinical Practice Guideline Development document. The RPA and ASN announced the guideline process in mid 1998 and invited interested parties to share pertinent ideas and comments with members of the Working Group and the San Antonio EPC/VA Cochrane Center.

Multidisciplinary Working Group

Multiple stakeholder organizations had representatives on the Working Group:

- American Academy of Family Practice
- American Association of Kidney Patients
- American College of Physicians-American Society of Internal Medicine
- American Nephrology Nurses Association
- American Society of Nephrology
- American Society of Pediatric Nephrology
- American Society of Transplantation
- Council of Nephrology Social Workers
- Health Care Financing Administration
- National Kidney Foundation
- National Renal Administrators Association
- Renal Physicians Association
- The Forum of ESRD Networks

In addition, a health policy analyst with expertise in the Medicare ESRD program and a bioethicist with extensive knowledge of dialysis issues served as Working Group members. The Working Group was closely involved in all aspects of the guideline process: refining its scope, objectives, and target audience; formulating conceptual evidence models and questions; selecting and appraising relevant research evidence; developing and specifying recommendations; identifying possible measurement tools for continuous quality improvement (CQI) activities; and refining document drafts. Working Group members also kept their constituencies informed of the guideline process and solicited comments and input from their representative organizations.

Methodology

Analytic Frameworks

Two analytic frameworks, one for ARF and one for ESRD, were developed that provide a conceptual framework for decisions about withholding or withdrawing dialysis. The models are presented in Figures 3 and 4. They depict a dynamic chronological sequence of decision-making that is informed by multiple factors, such as patient preferences, prognosis, and feasibility of dialysis.

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. Key questions are listed at the end of this section.

Search Strategy for Relevant Research Evidence

Pertinent English language literature published from 1985 to December 1998 was identified from the following:

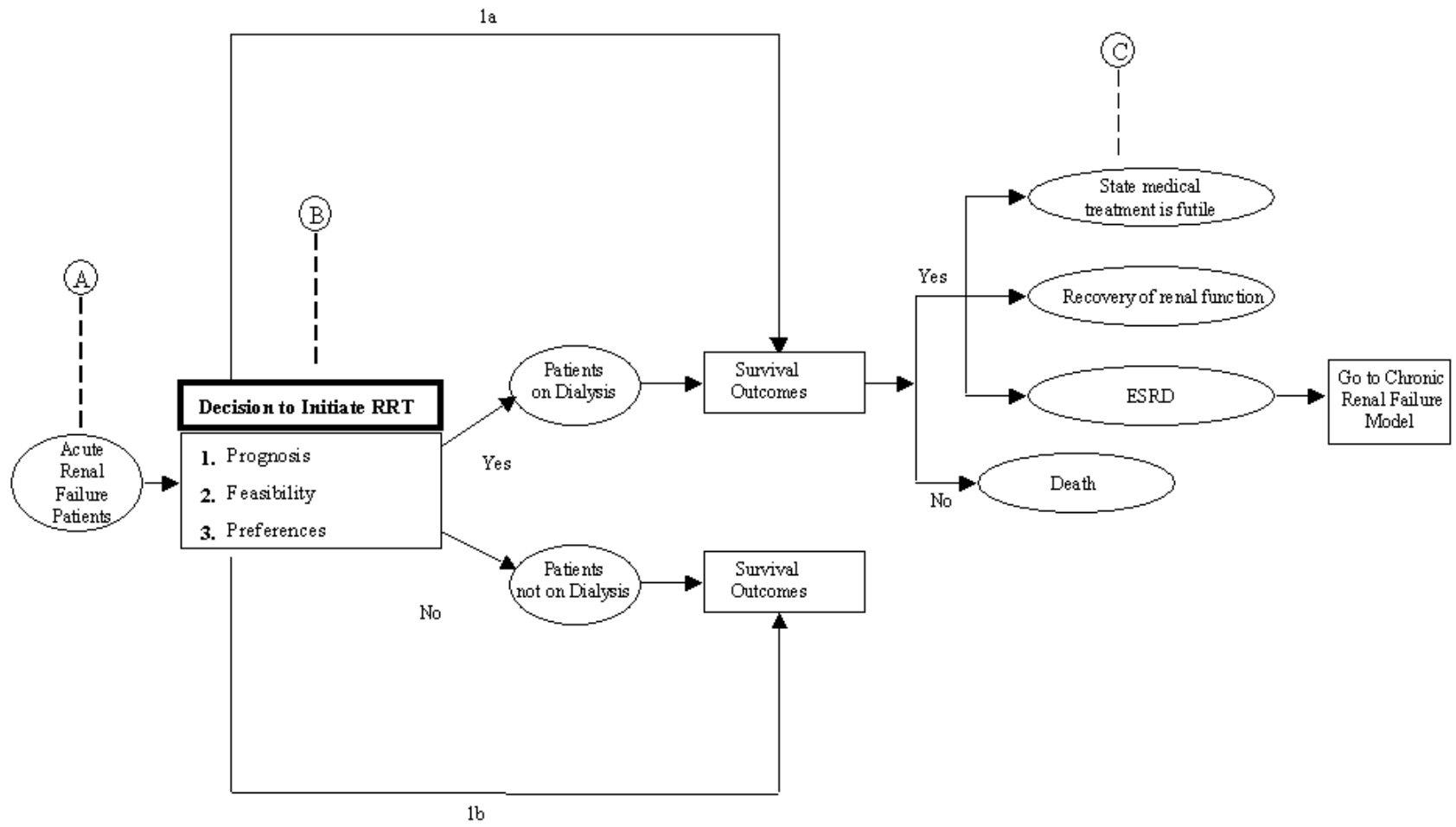
- Electronic databases (MEDLINE, CINAHL, HealthStar, PsycINFO, and EMBASE)
- References from articles
- Experts
- Hand searches of eight medical and nephrology journals of issues covering the last six months of 1998

Research evidence based on data collected before 1985 was not sought because marked technological advances in dialysis delivery have occurred since that time. Preliminary searches of the electronic databases using specific search terms, such as dialysis, acute renal failure or end-stage renal disease and withdrawal, preferences, prognosis, or quality of life, did not adequately capture the array of literature of interest to the Working Group. Thus a very broad search strategy that only included terms for dialysis, end-stage renal disease, and acute renal failure, and that excluded unpublished studies, case reports, editorials, and letters was used.

Selection of Relevant Research Evidence

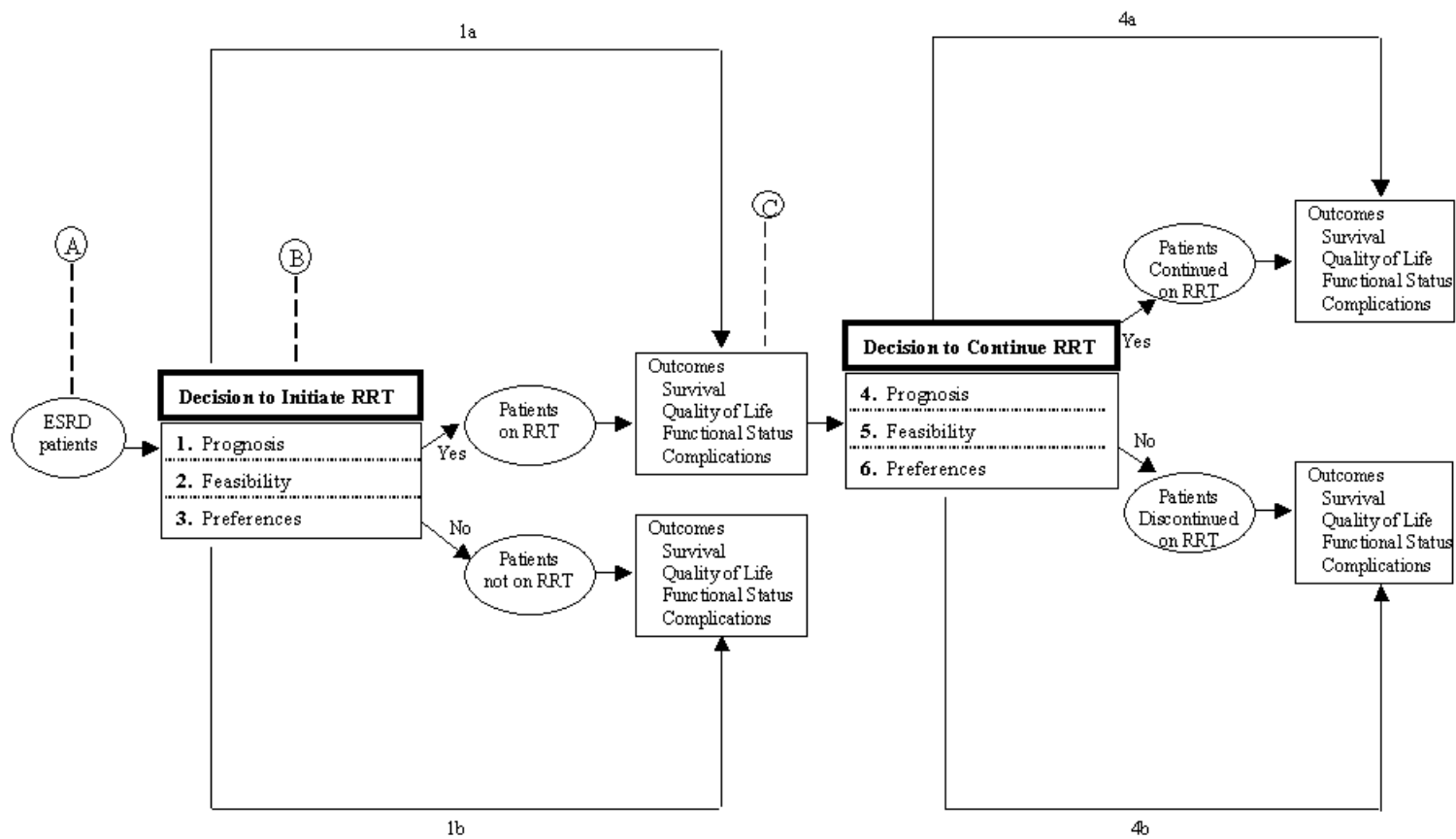
Several types of information were deemed relevant to the key questions (see Selection Criteria, Table 2). For information about prognosis in patients with ESRD, large retrospective or prospective cohort studies with at least 100 patients that examined multivariate predictors of mortality or morbidity were selected. For information about prognosis in patients with ARF, smaller retrospective or prospective studies involving at least 20 dialysis patients and reporting mortality outcomes were used. Information relevant to who gets referred for dialysis and when, feasibility, withdrawal frequencies and reasons, patient preferences, shared decision-making, advance directives, and quality of life assessments was taken from descriptive surveys, case-control studies, cohort studies, or randomized trials with at least 20 patients who were receiving or awaiting dialysis. Research evidence from Asian and developing countries was not used because differences in access to dialysis, patients' values and preferences, and decision-making processes were considered likely to limit generalizability and applicability to patients in the United States.

Figure 3. Analytic Framework for Decision-Making about Dialysis in Acute Renal Failure.



See list for Specific Evidence Questions that refer to numbers 1 through 3 and letters A through C.

Figure 4. Analytic Framework for Decision-Making about Dialysis in End-Stage Renal Disease.



See list for Specific Evidence Questions that refer to numbers 1 through 6 and letters A through C.

Table 2. Selection Criteria.

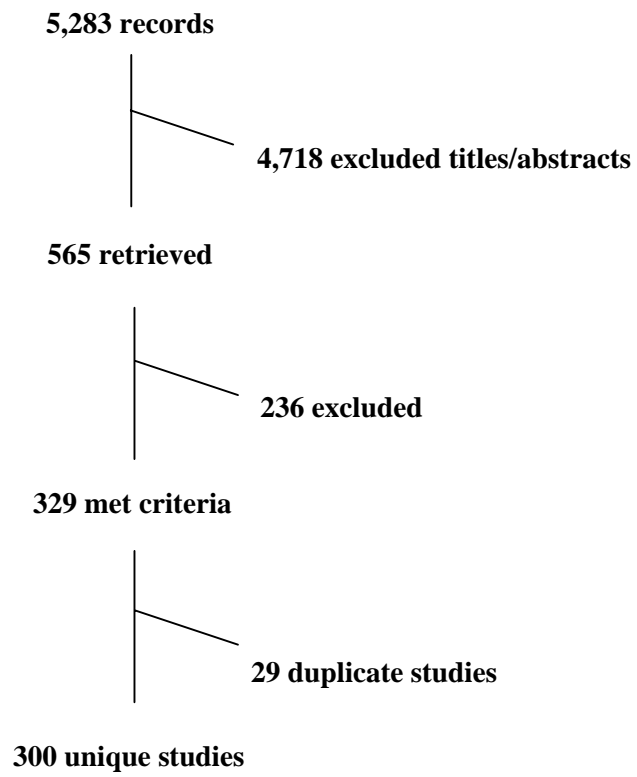
<p>Selection Criteria for Prognosis Studies:</p> <ul style="list-style-type: none"> ▪ Original data from Western industrialized country such as U.S., Canadian, European, or Scandinavian country, (exclude Japan and other Asian, Mideastern, Central American, South American, and African countries, also exclude non-English literature). ▪ At least 80% of patients followed since 1985. ▪ Clinical outcome such as mortality and years of survival, morbidity, hospitalizations, quality of life, functional status, procedures. ▪ Adults with acute or chronic renal failure on peritoneal or hemodialysis (not hemoperfusion or hemopheresis).
<p>Selection Criteria for Chronic Renal Failure:</p> <ul style="list-style-type: none"> ▪ Prospective cohort or prospective registry study with at least three months follow-up (exclude case series limited to long term survival, unless clear cut denominator of original data available). ▪ If general unselected population or diabetic $n > 100$. ▪ If selected population such as HIV or myeloma $n > 20$ and may be retrospective or prospective. ▪ Multivariate analysis unless special population.
<p>Selection Criteria for Acute Renal Failure:</p> <ul style="list-style-type: none"> ▪ Descriptive study regardless of length. ▪ Retrospective or prospective. ▪ Outcomes as above and/or additional recovery of renal function, progression to chronic renal failure. ▪ $n > 20$.
<p>Selection Criteria for Predicting Withdrawal/Withholding Studies:</p> <ul style="list-style-type: none"> ▪ Original data from Western industrialized country such as U.S., Canadian, European, or Scandinavian country (exclude Japan or other Asian, Mideastern, Central American, South American, and African countries, also exclude non-English literature). ▪ Retrospective or prospective cohort with at least 80% of patients followed since 1985. ▪ Outcome: numbers of patients withheld or withdrawn from dialysis. ▪ Sample size > 20. ▪ Multivariate analysis.

Table 2 Continued.

<p>Selection Criteria for Studies of Preferences/Attitudes/Psychosocial Issues/Advance Directives/Shared Decision-Making:</p> <ul style="list-style-type: none"> ▪ Original data from Western industrialized country such as U.S., Canadian, European, or Scandinavian country (exclude Japan or other Asian, Mideastern, Central American, South American, and African countries, also exclude non-English literature). ▪ Survey/case controlled, cohort, or modeling (decision analysis) study with at least 80% of subjects seen since 1985. ▪ Outcomes: preference/opinions/numbers of patients with advance directives/empirically-developed model of shared decision-making. ▪ Sample size > 20.
<p>Selection Criteria for Who Does and Does Not Get Referred for Dialysis and When:</p> <ul style="list-style-type: none"> ▪ Original data from Western industrialized country such as U.S., Canadian, European, or Scandinavian country (exclude Japan or other Asian, Mideastern, Central American, South American, & African countries, also exclude non-English literature). ▪ Descriptive survey or retrospective or prospective cohort. ▪ Unit of study patient or provider. ▪ Outcome numbers of patients referred and/or numbers of patients receiving dialysis, deaths, preferences, opinions (exclude studies that focus on rate of decline in renal function prior to dialysis). ▪ n > 20.
<p>Selection Criteria for Functional Status/Quality of Life Studies:</p> <ul style="list-style-type: none"> ▪ Original data from Western industrialized country such as U.S., Canadian, European, or Scandinavian country (exclude Japan or other Asian, Mideastern, Central American, South American, and African countries, also exclude non-English literature). ▪ Descriptive survey, case/control, prospective or retrospective cohort, or randomized trial. ▪ Functional status or quality of life measure must be clinical not physiologic measure such as reaction time. ▪ Unit of study is patient. ▪ n > 20.

Results of the selection process are depicted in Figure 5. Abstracts of the 5,283 potentially eligible records were screened by at least two persons to identify those meeting selection criteria. Of these, 4,718 were excluded, usually because they addressed short-term complications, physiologic parameters, management or adequacy of dialysis, or because they did not contain primary data. The full texts of the remaining 565 articles were retrieved and reviewed by at least two persons to ascertain final eligibility. Of 329 articles meeting criteria, 29 contained information from the same study populations leaving 300 unique studies for review. A physician with clinical and methodological expertise adjudicated disagreements about eligibility criteria.

Figure 5. Flow Diagram of Selection Process.



Data Abstraction Process

Standard forms were used to abstract data from each study. Such data included information about study purposes and designs, participant descriptors, methodological characteristics, outcome measures, and results. Items related to the internal validity of studies that were assessed included: selective recruitment of study participants, problematic outcome assessment, high drop-out or nonresponse rates, discordance with current standards of care, confounding cointerventions, inappropriate analysis, and inadequate power.

Eighteen individuals participated in the abstraction process. These included five persons with clinical and methodological training from the San Antonio EPC/VA Cochrane Center, eight Working Group members, and five volunteers from the nephrology community. Persons who participated in the abstraction process were trained and calibrated with each other using a pilot set of 3 articles. They were not blinded to study titles or authors.

To aid standardization of abstraction, teams of abstractors were assigned articles related to specific thematic areas such as prognosis of ARF, prognosis of ESRD, feasibility of dialysis, referral of patients for dialysis, quality of life of dialysis patients, withdrawal of dialysis, preferences, decision-making capacity, and advance directives. San Antonio EPC/VA Cochrane Center members served as team leaders. Working Group members were assigned to thematic teams based upon their clinical or methodological expertise. The team leaders abstracted every article assigned to their category, while Working Group members and nephrology volunteers performed independent abstractions on approximately 70% of the articles. Reliability checks were conducted by a physician with clinical and methodological expertise; disagreements were resolved by consensus.

Levels of Evidence and Formulation of Recommendations

The Working Group formulated specific guideline recommendations taking into account several parameters: a) ethical principles, b) legal statutes, c) shared decision-making, c) the amount, type, quality, and consistency of supporting research evidence, and d) the anticipated feasibility of implementation. There was considerable heterogeneity in the types of questions that the Working Group posed and in the types of research studies that were deemed relevant to those questions. Most often, relevant studies were prognostic cohort studies or observational studies (e.g., surveys, case series) that provided descriptive information. In a few instances, randomized controlled trial evidence was considered relevant. The criteria that were used to rate the quality of evidence are described in Table 3. Criteria for rating studies addressing therapy, prevention, and prognosis were adapted from the Centre for Evidence-based Medicine at Oxford's criteria for rating evidence.³⁶ Criteria for rating observational evidence were developed by the San Antonio Evidence-based Practice Center. In most instances, research evidence was contextual in nature and only provided indirect support to the recommendations. The text in the rationales for each recommendation gives the ranking for the body of research evidence relevant to individual statements. When multiple relevant studies of varying quality were available, the evidence was rated according to the highest ranked study. Meta-analysis was not used to quantitatively summarize study data because of marked heterogeneity in study designs and study populations, and because quantitative techniques for summarizing prognostic studies that use multivariate analysis are not well developed.

Table 3. Levels of Evidence for Different Types of Studies.

Level of Evidence	Observational/ Descriptive Evidence	Therapy/Prevention	Prognosis
A	Multiple large studies or single nationally representative study with greater than 80 percent response rate(s).	Multiple randomized controlled trials or single trial with narrow confidence interval.	Inception cohort studies (multiple or single large representative study) with > 80% follow-up, and/or models from such studies validated with test sets
B	Multiple small studies from diverse populations with response rates of 60%-80%.	Cohort study or low quality randomized trial (e.g., < 80% follow-up, small sample size, unequal cointerventions or biased outcome assessment).	Retrospective cohort study, prevalent cohort study, or follow-up of untreated control patients in a randomized trial, or multiple studies find similar risk ratios for a given risk factor.
C	Few studies, selective samples, or low response rates.	Case-control studies.	Case-control studies or biased cohort studies with inadequate control for confounding variables, biased outcome, or biased exposure ascertainment.

The Working Group was provided with background information regarding principles of ethical decision-making. They were also given information regarding guideline development processes and desirable attributes of performance measures that may be used to help insure guideline implementation. They were provided evidence tables that summarized the available research evidence relevant to the analytic framework questions. Based on these materials, teams within the Working Group formulated draft guideline recommendations. A general consensus process involving the entire group was used to reach agreement on final recommendations.

Peer Review and Endorsement

Peer review of the guideline was solicited at two points. First, peer review of the proposed guideline process was obtained after development of the evidence model and selection of relevant literature. This peer review was done to identify the following: a) any major oversights in formulation of the evidence model, and b) any seminal research evidence that was missed in the literature search. Second, peer review of the guideline document and recommendations was obtained. Peer reviewers at both stages included persons nominated by stakeholder organizations and volunteers from the nephrology community (see Section 8: Acknowledgements). The final guideline has been submitted to multiple professional organizations for endorsement.

Piloting and Plans for Updating

Although this guideline was not piloted prior to publication, helpful suggestions for local implementation of the recommendations are provided. Many of the suggestions for implementation were adopted from existing ESRD Network practices. The literature search strategies used for this guideline were documented and evidence tables archived to facilitate future updates of this guideline by the RPA. The literature search for the guideline was completed January, 1999 and the guideline was completed by the Working Group in September, 1999. The Working Group recommended that pertinent literature searches be repeated in 2002 to identify

potentially significant new evidence that could affect recommendations. If such evidence is identified, the Working Group recommended updating the guideline.

Pertinent Questions for the Analytic Framework

Specific Evidence Questions for Decision-Making about Dialysis in ARF

1. Expected outcome/prognosis for patients with ARF

- a. What are survival rates of dialyzed patients with ARF? Do survival rates vary by different etiologies of ARF, particular patient demographic characteristics, particular physiological and functional parameters, or different comorbid conditions?
- b. What is the likelihood of recovery of renal function such that dialysis is no longer required?
- c. What are survival rates without dialysis for patients with ARF?

2. Feasibility of initiating dialysis

Are there comorbid illnesses, such as hypotension, multiple organ system failure, bleeding diathesis, heart failure, or unstable angina, that present feasibility problems with dialysis delivery?

3. Preferences/shared decision-making/advance directives regarding withholding dialysis

- a. What are patients' knowledge, preferences, and level of involvement in making decisions relevant to initiating or withholding dialysis? Relevant evidence includes the following:
- b. What factors predict the level of patient interest in participating in decisions about advance directives or withholding dialysis and other life-sustaining therapies?
- c. How many dialysis patients are competent or incompetent to make a decision about withholding dialysis or are unable to make their preferences known?
- d. How have patients with a limited ability to participate in shared decision-making been identified?
- e. What types of shared decision-making (e.g., shared decisions with family) have been used in discussing initiating or withholding dialysis?
- f. How many patients have advance directives regarding such decisions as withholding dialysis or other life sustaining therapy? How often do patients complete advance directives? What factors are associated with completing or not completing advance directives? What are patient preferences regarding advance directives and how closely do they want their advance directives followed?
- g. What are patient/family and nephrology team preferences and associated factors regarding initiating, withholding, or choosing dialysis modality? Do preferences regarding withholding dialysis vary according to patient factors, and are they similar to preferences regarding withholding life sustaining therapies in general?
- h. When, how often, and by whom are discussions about withholding or initiating dialysis raised?

Specific Evidence Questions for Decision-Making about Dialysis in ESRD

1. Expected outcome/prognosis for patients receiving dialysis

- a. What are survival rates of dialyzed patients with ESRD? Do survival rates vary by different etiologies of ESRD, particular patient demographic characteristics, particular physiological and functional parameters, different comorbid conditions, or alternative modalities of dialysis?
- b. What is the likely functional status and quality of life for patients with ESRD who receive dialysis?
- c. What is the likelihood of recovery of renal function such that dialysis is no longer required?

2. Feasibility of initiating dialysis

- a. Are there comorbid conditions, such as extensive vascular disease preventing placement of a catheter for vascular access, that preclude particular dialysis methods?
- b. Are there lifestyle factors that suggest the need for a particular dialysis method?
- c. Are there comorbid illnesses, such as heart failure or unstable angina, that lead to particular problems with specific types of dialysis methods?

3. Preferences/shared decision-making/advance directives regarding withholding dialysis

(same questions as under ARF #3)

4. Prognosis for continued dialysis

- a. What are the survival rates for patients who have already survived the first 3-, 6-, and 12 months on dialysis? Do survival rates vary for patients with: 1) different etiologies of ESRD, 2) particular demographic characteristics, 3) particular physiological or functional parameters, 4) different comorbid conditions, or 5) dialysis modality?
- b. What is the likely functional status and quality of life for patients who continue dialysis?

5. Feasibility of continued dialysis

- a. For what types of medical situations is continued dialysis not feasible?
- b. Are there certain types of psychosocial situations (e.g., abusive patient, patient unable or unwilling to comply with dialysis procedures) that make continued dialysis difficult?

6. Preferences/shared decision-making/advanced directives related to withdrawal of dialysis

(same questions as under ARF #3)

Important Contextual Questions for Evidence Models

1. Referral to nephrologists

- a. When are patients most likely to be referred to nephrologists?
- b. What percentage and kinds of patients with severe ARF or ESRD are never referred to nephrologists?

2. Background questions relevant to initiating or withholding dialysis

- a. How many and what kinds of patients are never offered dialysis by their nephrologists?
- b. How many patients are initiated on dialysis when their nephrologists do not think it is clinically beneficial?
- c. How many and what types of patients have dialysis withheld?
- d. What is the population of patients who refuse dialysis (percentage/demographics/diagnostic characteristics)?
- e. What is the course of death and what type of palliative care is offered to patients who are never initiated on dialysis?

3. Background questions relevant to withdrawal of dialysis

- a. How often and for what kinds of patients do nephrologists actually recommend withdrawal?
- b. How many patients or their surrogates choose to continue dialysis when their nephrologists do not think it is clinically beneficial?
- c. How often are DNR or advance directives ignored?
- d. How many and what types of patients are withdrawn from dialysis?
- e. How many and what types of patients choose to withdraw from dialysis?
- f. What are patients' or surrogates' reasons for withdrawing dialysis?
- g. How many patients choose to withdraw from dialysis when they have a good chance of survival?
- h. What is the course of death and what type of palliative care is offered to patients who discontinue dialysis?
- i. Who makes decisions about medical futility? Is the decision to withdraw dialysis made independent of or in conjunction with the decision to withdraw other life support?

SECTION 4: GUIDELINE RECOMMENDATIONS AND THEIR RATIONALE

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 end-stage renal disease. Systematic literature reviews were conducted to address pre-specified questions derived from the frameworks. In most instances, the relevant evidence that was identified was indirect and contextual in nature. The research evidence, case and statutory law, and ethical principles were used by the Working Group in the formulation of their recommendations.

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.

Rationale

The recommended process by which providers and patients come to agreement on a specific course of action is shared decision-making. It is based on a common understanding of the goals of treatment and the risks and benefits of the chosen course compared with any reasonable alternative.²⁰ Ethical principles supporting this process include respect for patient autonomy, beneficence, and nonmaleficence. Observational evidence indicates that shared decision-making, especially the legal requirements for full disclosure and informed decisions, is often not achieved in the dialysis setting.³⁷⁻⁴¹ (Level B Observational Evidence) Many patients initiating dialysis receive or perceive inadequate information and may not understand the information they do receive, despite the fact that most dialysis occurs in the setting of chronic renal insufficiency where the prognosis is known well before the actual need for dialysis arises.⁴² (Level B Observational Evidence)^{37,41,43-46}

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 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 insure that the patient or legal agent understands the consequences of the decision.

Rationale

There is widespread consensus that patients with decision-making capacity should participate in medical decisions if they so choose.⁴⁷⁻⁵⁴ Competent patients have an absolute right to accept or refuse medically indicated treatment. This recommendation is supported by the ethical principle of respect for patient autonomy. Case law requires informed consent or refusal, and state and

federal statutes provide for advance directives as written legal documents to be used to make decisions for patients when they lose decision-making capacity. Most states have health care surrogate acts that provide for the selection and authority of a surrogate decision maker when the patient lacks decision-making capacity and has not completed a written advance directive. Treating physicians are ethically and legally obligated to insure that these decisions are well-informed and documented. Observational studies show that patients infrequently think about end-of-life issues, discuss them with family, friends, or the renal care team, or complete advance directives.^{38,38-40,42,55-60} (Level B Observational Evidence) Dialysis patients may discuss advance directives more with their families than physicians, but 50 to 90% report no or inadequate discussions with health care professionals about therapeutic options including forgoing dialysis.^{37-46,51,61,62} (Level B Observational Evidence) Observational studies show most patients want information about their medical conditions and many (75-90%), though not all, desire to participate in care decisions.^{37,40,42,43,51,56,63-68} (Level B Observational Evidence) A review of shared decision-making in non-dialysis patient populations suggests that increased patient involvement in decision-making can lead to more fully informed consent, shared responsibility for treatment decisions, improved patient compliance, increased patient satisfaction, improved outcomes, and an overall increase in the quality of care.⁶⁹

Box 1. Suggested Steps for Implementing Recommendation Nos. 1 and 2.

- Identify provider(s) who will coordinate communication with the patient or legal agent and family (e.g., nephrologist in conjunction with the primary care provider for ESRD patients or intensivists for ARF).
 - Assess patient decision-making capacity and whether it is diminished by major depression, encephalopathy, or other disorder (see Toolkit section for helpful instruments). Obtain psychiatric and/or neurological consultation as appropriate, and institute treatment for conditions impairing decision-making capacity.
 - Communicate diagnosis to patient (or legal agent) and family (if the patient agrees).
 - Discuss prognosis based upon patient's medical condition, functional status, and age (see Toolkit section for information about assessing functional status and quality of life, and estimating prognosis).
 - Communicate options, taking advantage of educational resources, such as other patients or videotapes and brochures.
 - Elicit patient or legal agent and family understanding of information and response.
 - Identify the patient's wishes.
- [See Toolkit for National Kidney Foundation (NKF) checklist for initiating dialysis.]
- If the patient wants to forgo dialysis, determine why.
 - Are the patient's perceptions about dialysis accurate? Does the patient know what to expect if dialysis is not started or discontinued?
 - Does the patient really mean what he/she says or is the decision to refuse or stop dialysis made to get attention, help, or control?
 - Are there changes that might improve quality of life and would the patient be willing to start or continue dialysis while the factors responsible for the patient's request are addressed?
 - Are there persons (e.g., social worker, chaplain) with whom the patient would be willing to discuss the decision?
- (Also, see Toolkit for NKF checklist on withdrawing dialysis.)
- Reach decision based on medical indications and patient's preferences.
 - Encourage patient to discuss end-of-life issues with others such as family, friends, or spiritual advisors (see Toolkit section for helpful questions to use).

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.

Rationale

Pertinent ethical principles for this recommendation are respect for patient autonomy, beneficence, and nonmaleficence.

When Discussions of Prognosis Should Occur

The majority of chronic renal diseases have relatively slow courses, such that counseling about treatment options could and should occur prior to the time that dialysis is absolutely necessary. Additionally, the patient's cognitive capacity for decision-making may diminish as renal insufficiency worsens, impairing the patient's ability to participate fully in shared decision-making. Several small observational studies suggest that 40-70% of patients with ESRD are either not referred to nephrologists prior to commencing dialysis or have emergent first dialysis sessions rather than electively planned first sessions.^{68,70-72} Data from USRD patients beginning dialysis in 1996 showed 33% and 21% of patients were first seen by a nephrologist < 3 months and < 1 month, respectively of beginning dialysis.³ (Level B Prognostic Evidence) If the patient has already begun dialysis, such discussion should begin as soon as the nephrologist and the other members of the renal care team determine the patient or legal agent can engage in a useful, rational conversation. The occurrence of sentinel events (see below) should also prompt further discussion of prognosis, values, preferences, and treatment goals.

ARF

Multiple recent prospective and retrospective studies documented intensive care unit (ICU) and in-hospital mortality rates of approximately 50 to 75% for patients with ARF receiving dialysis (Table 4 below and Table 17 in the Toolkit).⁷³⁻¹²¹ (Level A Prognostic Evidence) Medical and surgical patients had roughly similar mortality rates in these studies. The one retrospective study in bone marrow transplant patients showed a mortality rate of 85%. Mortality prognosis can be quantified using routinely available measurement tools (see the Toolkit and the website at www.bio.ri.ccf.org/arf).^{80,118,120-131} Development of such measurement tools has involved various multivariate modeling techniques and testing of over 75 potential prognostic variables. Variables most often independently associated with increased mortality have been liver failure, mechanical ventilation, and multiorgan failure.^{73,74,76-78,80,121,132} Two retrospective and three prospective studies, with sample sizes ranging from 100 to 500, have shown prognostic models do not have better than 80 to 85% discriminating ability in identifying individual patients with poor prognosis.^{74-77,80} Recognizing inability to precisely predict individual prognosis, the Working Group supported provision of gross estimates of prognosis based on the belief that this

information facilitates realistic patient and family expectations and promotes informed decision-making.

Several recent studies report dialysis-free rates of approximately 70% to 90% among survivors of ARF that required renal replacement therapy.^{73,77,78,81,82,87,91,98-101,105,106,119} (Level B Prognostic and Observational Evidence) Most of these studies were small, retrospective, and only followed patients to hospital discharge. Adequate evidence regarding how many patients recover normal function and how long it takes for them to recover function was not found. The Working Group recommended that patients with ARF who no longer require dialysis but who still have significant renal dysfunction continue to be followed by a renal care team. The follow-up care should be individualized to the patient's needs and community resources. It may be provided by the patient's primary care physician in conjunction with a renal care team. The Working Group agreed that patients with ARF of duration greater than two months have a strong likelihood of ESRD. They should be told that they have ESRD and counseled accordingly within six months.

Table 4. Expected Intensive Care Unit and Hospital Mortality for Dialysis Patients with Acute Renal Failure.

	Heterogeneous Patient Populations	Bone Marrow Transplant Patients	Post-Surgical Patients	Post-Trauma Patients
ICU Mortality	≈ 50 – 65%		≈ 60%	
Hospital Mortality	≈ 50 – 85%	≈ 85% ^a	≈45 – 65%	≈50 – 80%

^aBased on one small (n < 100) retrospective study.

ESRD

Estimating Prognosis for Survival: Many studies report the effect of prognostic factors on survival for patients with ESRD on dialysis but no precise mathematical models have been developed and tested for predicting a given individual's prognosis. Magnitude of risk conferred by individual risk factors can be estimated from existing data with increasing numbers of risk factors conferring increasing risk. Comparison of relative risks or hazards between studies in this literature poses a challenge. Diversity in studies includes both retrospective and prospective data collection, wide variation in number of patients observed (anywhere from less than 20 to 150,000), and wide variation in data sources (single dialysis facilities, multicenter studies, commercial dialysis chains, and regional and national registries). Additionally, the same variable may be defined differently either in data collection or for analytical purposes. For example, age may be analyzed in 1-,5-, or 10-year increments or may be analyzed by groups with uneven distribution of years in them (e.g. 18-44, 45-64, and ≥65). The variable “age” may be used to represent age at start of dialysis or age at time of data collection. Nutritional status may be represented by a global assessment of the health care provider or may be single or multiple laboratory and/or physical measures. Understanding the varying definitions of variables may shed some light on the differences between study results.

Other sources of variation include the type of population enrolled in each study, length of follow-up, and how deaths are designated. In the U.S. most, but not all, studies exclude the first 90 days of dialysis and so exclude deaths and withdrawals within this same time frame. Some studies enroll incident patients (patients who start dialysis in a defined time period) only while most enroll both prevalent (patients who are already being treated with dialysis for a variable amount of time prior to the start of the study) and incident patients. Length of follow-up can be as short as

six months and as long as 20 or more years. Results from the studies may be reported annualized or within the time frame of the observations. Withdrawal is not always reported as a cause of death. On the cause of death form submitted to HCFA, “withdrawal yes/no” is a separate item from cause of death. In the U.S., approximately one of every five dialysis patients withdraws from dialysis before death (USRDS annual reports, 1999 and 1998).^{3,4} The rates of withdrawal vary by age and ethnicity; effects of differential withdrawal rates were not addressed in the prognostic studies.

Age is a powerful and consistent risk factor for death. The older the patient, the shorter the patient’s survival is likely to be. For 1-year increments in age beginning at age 18, there is a remarkable consistency of risk ratios (RR) between 1.03 and 1.04 or a 3 to 4% increase in death rate per additional year of age.¹³³⁻¹⁴⁸ (Level A Prognostic Evidence) The effect of age is illustrated in Tables 5 and 6 below. In comparison to the U.S. population as a whole, dialysis patients live about one-third as long as non-dialysis patients of the same age and gender.

Table 5. Expected Remaining Years of Life For 1996 U.S. Prevalent Hemo- and Peritoneal Dialysis Populations by Age, Race, and Sex (USRDS, 1998 ADR, p.76).³

Age	Black Male	Black Female	White Male	White Female
20-24	16.8	15.9	14	13
25-29	14.5	14.1	11.3	11
30-34	12.7	12.5	9.4	9.3
35-39	11.3	11.4	8	7.9
40-44	10	9.8	6.9	7.1
45-49	8.6	8.5	6.1	6.3
50-54	7.3	7.1	5.2	5.2
55-59	6.3	6.3	4.4	4.5
60-64	5.2	5.3	3.7	3.9
65-69	4.2	4.4	3.1	3.3
70-74	3.5	3.7	2.7	2.9
75-79	2.9	3.0	2.4	2.5
80-84	2.5	2.5	2.1	2.1
85+	2.1	2.0	1.7	1.7

Table 6. One (from Day 91-One Year +90 Days), Two-, Five-, and Ten-Year Survival Probabilities by Age in All USRDS Patients (from USRDS, 1998 ADR, Reference Tables E14-20).³

Age	1-year (1995) ^a	2-year (1994)	5-year (1991)	10-year (1986)
20-24	95.54	94.41	83.73	71.26
25-29	91.5	88.2	76.17	61.28
30-34	89.43	83.66	70.85	53.92
35-39	89.77	83	63.19	45.17
40-44	89.89	81.67	60.91	40.06
45-49	89.25	79.05	53.23	32.33
50-54	87.73	77.69	47.01	22.54
55-59	84.63	71.01	39.43	14.13
60-64	80.51	65.63	30.31	8.89
65-69	75.70	58.44	22.55	4.81
70-74	71.88	51.63	17.67	2.61
75-79	66.05	46.07	13.69	1.4
80-84	61.61	39.74	8.6	0.81
85+	53.91	32.26	5.2	0

^aNumber in parentheses denotes year of incidence.

Serum albumin level, both at baseline and during the course of dialysis treatment, is a consistent and strong predictor of death, with all but one¹³⁴ of the studies showing a statistically significant relationship.^{133,135-138,140,141,148-160} (Level A Prognostic Evidence) The lower the serum albumin level, the higher the risk of death (Tables 7 and 8). For example, an albumin of <3.0 grams per deciliter (g/dL) versus >4.0 g/dL confers a 4.4 times greater risk of early death.¹⁴⁹ An albumin level <3.5 g/dL is associated with one year mortality of approximately 50%.¹⁴⁹ (Level A Prognostic Evidence)^{136,151,155,161,162}

Table 7. 1-Year and 2-Year Survival by Albumin for HD Patients Starting Dialysis between 1987 and 1991 (Goldwasser, 1993).¹³⁶

Albumin (g/dL)	1-Year	2-Year
≥3.5	86%	76%
<3.5	50%	17%

Table 8. 18-Month Survival for 1988 Prevalent Patients by Level of Albumin Concentration (Lowrie, 1990).¹⁵⁵

Average Albumin Concentration (g/dL)	N exposed	N Died	Risk of Death	RR to Index of 4.01-4.5
>4.5	124	10	0.0806	0.83
4.01-4.5	3,931	382	0.0972	1.00
3.51-4.0	6,517	1399	0.2147	2.21
3.01-3.5	1,266	598	0.4724	4.86
2.51-3.0	157	107	0.6815	7.01
≤2.5	29	21	0.7241	7.45

Nutritional status is another powerful predictor of survival. Numerous markers of nutritional status have been studied: “cachexia”(provider assessment, not further defined), “undernourished”(documentation in the medical records of these words), obesity (based on information in the medical record from between one month prior to the onset of ESRD to six weeks after the first treatment), body mass index, subjective global assessment of nutritional status (per the method of Baker and Detsky),^{163,164} protein catabolic rate, skin fold thickness, and creatinine level. Cachexia, poor subjective global assessment of nutritional status, and “undernourished” all convey a significantly elevated risk of death.¹⁴⁵ (Level B Prognostic Evidence)^{140,144,148,160,165}

Poor functional status is highly predictive of early death (RR ranges of 1.5 to 3).^{133,138,140,149,150,153,156,158,159,166-172} (Level A Prognostic Evidence) Fifteen of 16 studies reporting functional status show worse functional status is associated with early death. In studies where functional status and comorbidity are both measured, functional status sometimes displaces comorbidity in the multivariate analyses. A potential explanation of this finding may be that comorbidity measures are highly variable with regard to the manner in which they are defined and may not always capture severity. Functional status captures the severity of disability the patient is experiencing from whatever comorbid illness she or he may have. Measures of functional status used in these studies include ability to ambulate (yes/no),^{140,148,150,173} mild-severe mobility impairment,¹⁴⁹ Karnofsky or modified Karnofsky scale,^{133,153,156,159,167-169,174} Gutman functional status,¹⁶⁷ Activities of Daily Living,^{166,170} and the Medical Outcomes Study 36-item Short Form (SF-36).¹⁷² In most studies, functional status was assessed by the health care providers rather than the patients, who may rate their quality of life higher. Table 9 gives the results from one study as an illustration of the magnitude of the effect of functional status.¹⁶⁸

Table 9. Patient Functional Status and Mortality Among 10,355 Incident HD and PD Patients, Network 6, 1989 to 1991.¹⁶⁸

Functional Status	N	Mortality		
		%	Rate*	RR(95% CI)
Normal*	1,128	13.1	8.3	
Mildly Impaired	3,215	37.3	10.6	1.28(1.08-1.52)
Moderately Impaired	2,748	31.8	19.0	2.29(1.94-2.70)
Severely Impaired	1,538	17.8	28.7	3.46(2.93-4.10)

*Unadjusted mortality rate expressed as deaths per 100 dialysis years

†Reference Group

Multiple different comorbid illnesses are related to risk of death on dialysis. These have been studied individually and aggregated into overall comorbidity scores. Unfortunately, definitions of congestive heart failure (CHF), ischemic heart disease, cardiovascular disease, etc. vary significantly from one study to the next. Despite these methodological shortcomings, comorbid illness must be taken into account in counseling patients about their prognosis. Scoring systems run the gamut from simply noting the presence of at least one comorbid illness,^{143,175,176} to grading the comorbidity burden,¹³⁴ to using aggregations of ICD-9 codes from hospitalizations.¹⁷⁷ One study specifically developed a severity of illness index for patients with ESRD.¹⁷⁷ In all of these studies, having comorbid illness conferred higher risk although the magnitude of relative risk varied widely 1.11 to 12.8.(Level A Prognostic Evidence)

Numerous comorbid conditions have been studied for their effect on survival: diabetes, CHF, coronary artery disease (CAD), peripheral vascular disease (PVD), chronic obstructive pulmonary disease (COPD), and cancer. Diabetes conferred a higher mortality risk in the majority of cohorts in which it was studied (for example, see Table 10).^{133,135,140,142,144,147,152,155,157,165,167,168,171,178-183} (Level A Prognostic Evidence) Some studies find diabetes' significance diminishes when laboratory abnormalities are included in multivariate models.^{141,155} A few studies have explored whether having Type 1 or Type 2 diabetes confers more risk. After controlling for age, at least two studies suggest that Type 1 DM confers a significantly higher risk of death.^{145,146,184} Most studies found CHF to be predictive of poorer survival, with a relative risk anywhere from 14% to 84% higher than those without CHF.^{133,135,147-149,152,185} (Level A Prognostic Evidence) Numerous different names and definitions are used to describe the category of CAD (cardiovascular illness, angina, ischemic heart disease, CAD, cardiovascular comorbidity, heart disease, and vascular disease). These syndromes are inconsistently associated with increased mortality: seven studies showed no significant impact^{133,135,145,148,150,171,179,181} and 14 studies showed an increased risk of anywhere from 26% up to 780%.^{140,142,144,144-146,148-150,158,160,161,165,167,182,186} (Level A Prognostic Evidence) In 6 of 7 studies, PVD conveyed an increased risk of death between 11 and 862%.^{133,135,140,148,150,160,185} (Level A Prognostic Evidence) Cancer confers anywhere from 30 to 250% increased risk of death.^{133,142,144,149,150,171,185} (Level A Prognostic Evidence) The variability probably relates to the type of cancer that is lumped together within this variable. COPD confers an increased risk of 14 to 44%.^{133,148-150,152} (Level A Prognostic Evidence)^{135,140,147,185}

Table 10. Diabetic versus Non-Diabetic Survival Rates for All Canadian Patients 1981-1992 (Fenton, 1995).¹⁸⁷

	1-Year	2-Year	3-Year	4-Year	5-Year	6-Year	7-Year	8-Year
DM	78%	60%	48%	40%	32%	28%	25%	21%
Non-DM	83%	74%	67%	60%	55%	50%	48%	44%

Estimating the effect of blood pressure on risk of death presents a particular challenge. Blood pressure as a risk factor has been defined variably: diagnosis of hypertension as a comorbidity or etiology of the patient's ESRD,^{155,161,168,171,174} duration of hypertension (<10 years versus ≥10 years),^{178,179} mean arterial pressure for five years prior to starting dialysis,¹⁸⁴ monthly mean arterial pressure during the years the patient is receiving dialysis^{178,179} immediately pre-dialysis blood pressures,^{153,156,188,189} and immediately post-dialysis blood pressures.^{156,189,190} Regardless of the definition, chronic hypertension has been shown to convey either a lower risk of mortality^{155,174} or to have no significant impact.^{161,171} (Level B Prognostic Evidence) Lower immediate pre-dialysis blood pressures (per 5 mmHg fall in diastolic;¹⁸⁸ <129 mmHg systolic¹⁹⁰) confer an increased risk of all-cause mortality and higher immediate pre-dialysis systolic blood pressures may be protective (≥150 mmHg) for all cause mortality.¹⁹⁰ For cardiovascular mortality, the relative risk of a low immediate predialysis systolic blood pressure is even higher. There is a mild increase in risk at the highest level of systolic blood pressure as well (≥180 mmHg¹⁹⁰). Blood pressures in the 150-179 mmHg range are protective as compared to 140-149 mmHg.¹⁹⁰ Immediate pre- and post-dialysis diastolic blood pressures ≥90 mmHg convey an increased risk for cardiovascular but not all cause mortality.¹⁹⁰ (Level B Prognostic Evidence)

Summary Risks: Although mathematical models for estimating an ESRD patient's mortality risk are not readily available, results from multivariate analyses of various prognostic studies allow comparison of the magnitude of effect between risk factors. Table 11 displays the ranges of risk estimates from these studies.

Table 11. Comparative Percent of Increased or Decreased Risk for Death for Eight Factors Studied in ≥ Two Studies with Multivariate Analyses.

Risk Factor	Age	Race	Gender	Serum Albumin	Under-nourished/ Cachexia	Functional Status	Diabetes	CAD/ CHF/ Heart Disease
References	133,140,141, 144,155,183, 191	133,141,155,16 8,173,183,191	140,141,144,15 5,168,173,183, 191	133,140,141,183	140,144	133,168	140,144,155,16 8,183,191	133,140,144,16 8,173
Percent increase or decrease risk	2-4% increase per year of age	7-38% increase for whites over blacks	5-73% increase for men compared to women	33-81% decrease per every one g/dL increase in serum albumin	25-36 % increase	52-158% increase for moderate impairment and 100-216% increase for severe impairment	10-74% increase	11-41% increase

The data above show having diabetes increases the risk of death to a similar degree as having moderate functional status impairment or being male. A 70-year-old person without diabetes has a similar risk of death to a 55-year-old with diabetes. A woman with diabetes has a similar risk to a man without diabetes. The time frame over which this risk is conferred depends on the length of study follow-up, which ranged nine months to four years.

Predicting Who Will Die Within the First Year on Dialysis: Four articles^{149,191-193} specifically address issues in predicting early mortality and a number of other articles give data covering the first 90 to 180 days. In a prospective incident cohort, Barrett¹⁹² found that although a scoring system using age and comorbidity did predict prognosis, no score cutoff point combined high true-positive and low false-positive rates for predicting early death. Age, severity of heart failure, PVD, arrhythmias, malnutrition, malignancy, or myeloma were independent prognostic factors identified in the multivariate models. However, the best fit discriminant and logistic models were also unable to accurately predict early death within six months. Clinicians were accurate in assigning patients to prognostic groups up to a 50% risk of death by six months, above which they tended to overestimate risk. Clinicians were only marginally better than the predictive models in determining whether a given high-risk patient would die. Soucie¹⁴⁹ found that age, white race, male gender, severe activity impairment, lower albumin level, previous myocardial infarction, cancer, CHF, hypertension, depression, and smoking were all associated with death less than 91 days after initiating dialysis. This study did not attempt to look at the predictive value of their model for accurately identifying those who died. Barrett and Chandna¹⁹³ concluded that trials of therapy may be a better idea than denying dialysis based on these results. (Level A Prognostic Evidence)

Effect of Sentinel Events on Prognosis: A few studies have addressed the specific issue of risk of death after intercurrent medical events while on dialysis. Two striking examples of events that have very high post-event mortality in ESRD patients on dialysis are acute myocardial infarction (AMI)¹⁸⁵ and above the knee amputation (AKA).¹⁶² (Level A Prognostic Evidence) For both of these events survival at one year is less than 50% (38 to 44% for AMI and 27% for AKA), (Tables 12, 13, 14, and 15). These events might be considered as reminders for discussions about end-of-life care and the benefits and burdens of ongoing dialysis with patients and their families. There is not sufficient data to determine if similar declines in survival occur after stroke (especially large strokes as opposed to lacunar), after diagnosis of certain cancers, and after diagnosis of other metabolic or infectious diseases.

Table 12. Cardiac Mortality (%) After Acute Myocardial Infarction by Year Myocardial Infarction Occurred for HD and PD (Herzog, 1998).¹⁸⁵

Year of AMI	1 Year	2 Year	3 Year	5 Year
1985-1989	39.3	51.3	60.0	71.7
1990-1995	42.2	52.0	59.3	65.4

Table 13. All Cause Mortality (%) After Acute Myocardial Infarction by Year Myocardial Infarction Occurred for HD and PD (Herzog, 1998).¹⁸⁵

Year of AMI	1 Year	2 Year	3 Year	5 Year
1985-1989	56.0	71.3	80.7	90.0
1990-1995	61.7	74.2	82.0	89.1

Table 14. All Cause Mortality (%) After Acute Myocardial Infarction by Etiology of ESRD: 1977-1995 Incident Patients with a Myocardial Infarction ESRD (Herzog, 1998).¹⁸⁵

Etiology	1 Year	2 Year	3 Year	5 Year	10 Year
Diabetes	62.3	77.2	86.1	93.3	99.1
Hypertension	60.79	73.5	81.3	90.4	97.9
Other	55.4	68.9	77.5	86.9	95.8

Table 15. Cumulative Survival Following First Amputation After Renal Failure For Medicare End-Stage Renal Disease HD and PD Prevalent Patients 1991 through 1994.¹⁶²

Sub-Group	Days Post Amputation						
Total	N	30	60	90	180	365	730
Age	24877	88.9	80.1	74.2	62.8	49.3	32.7
25-34	419	96.4	93.2	89.7	83	73.8	61.3
35-44	2342	95.8	91.3	88	78.6	67.3	53.3
45-54	4038	93.8	88	84	74.1	60.7	44
55-64	6365	90.2	82	76.5	65.1	51.3	33.1
65-74	7956	86	75.7	68.7	56.5	41.7	24.5
≥75	3324	80.4	66.3	57	43.9	30.9	15.8
Diagnosis							
Diabetes	16970	90.5	82.4	76.7	65.7	51.7	34.8
GMN	892	83.7	74.3	66.8	54.6	41.3	27.8
HTN	4059	84.7	73.7	66.6	55.3	42.3	26.2
Level of Amputation							
Toe	7806	95.2	89.8	85.4	75.8	63	44.8
Below Knee	12380	89.6	81	75.2	63.2	49	31.7
Above Knee	4691	76.3	61.6	52.7	40.3	27.1	15.2

Box 2. Suggested Steps for Implementing Recommendation No. 3.

- Identify patient's wishes and goals for treatment at onset of dialysis and again after any irreversible change in medical condition.
- Estimate prognosis based upon patient's age, functional status, and medical condition, including comorbidity and recent sentinel events. Present the prognosis in a manner that is considerate of the patient's emotional condition and that provides reassurance that the physician has kept the patient's best interest in mind.
- Reassess and communicate prognosis on at least an annual basis, and more often as indicated by any major change in status.
- Communicate options, including option of stopping dialysis and receiving end-of-life care, at each reassessment.

Recommendation No. 4: Conflict Resolution

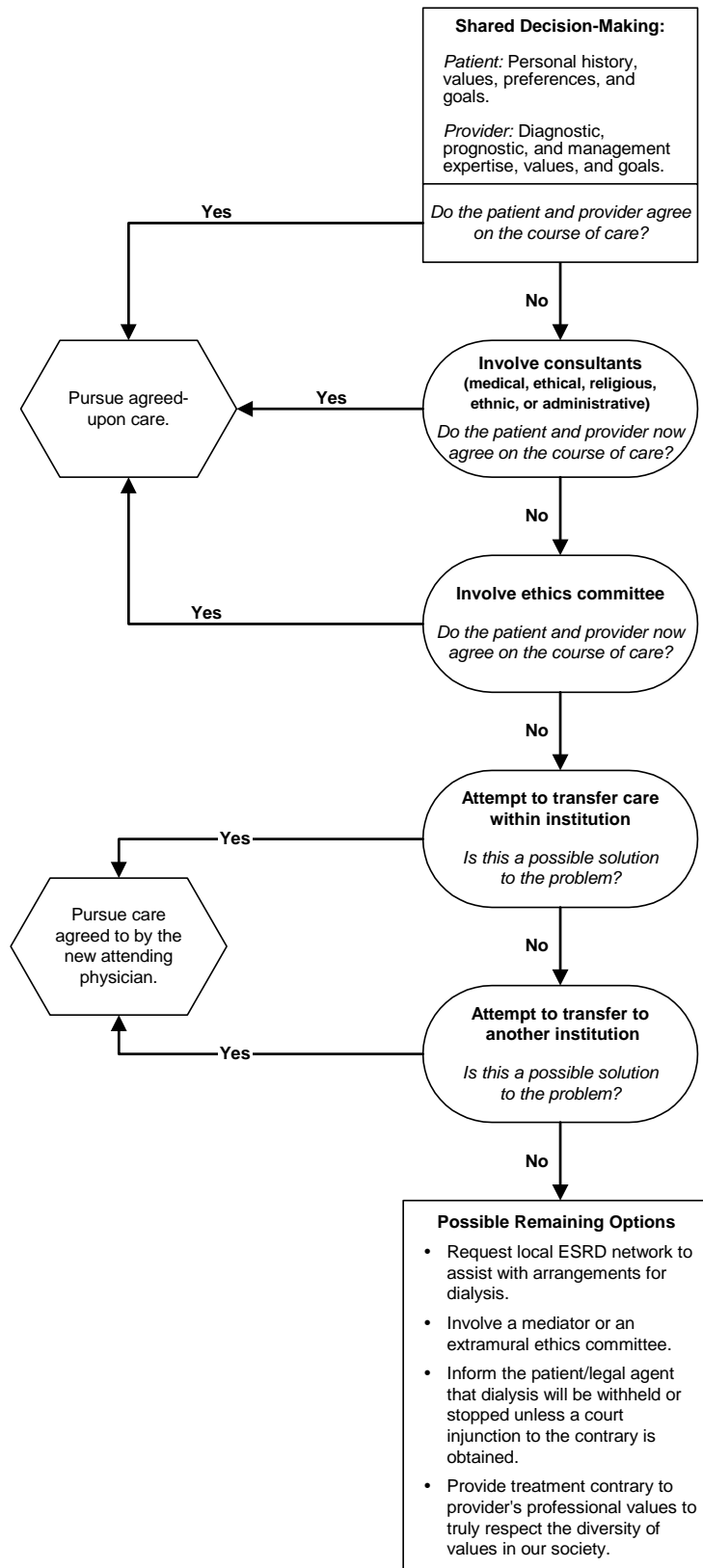
A systematic approach for conflict resolution is recommended if there is disagreement regarding the benefits of dialysis between the patient or legal agent (and those supporting the patient's position) and a member(s) of the renal care team (Figure 6). Conflicts may also occur within the renal care team 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.

Rationale

The ethical principles of beneficence, justice, nonmaleficence, and respect for patient autonomy support this recommendation. Disagreement regarding initiating or continuing dialysis may occur among the patient or legal agent, family members, renal care team, and/or other health care providers (e.g., intensivists and primary care physicians). Observational evidence about disagreements suggests that patients' or legal agents' wishes are usually, but not always, honored.^{52-54,194-197} (Level C Observational Evidence) A single study indicates that nephrology nurses sometimes disagree with nephrologists' decisions to continue dialysis. In this study, nurses perceived such disagreements as ethical conflicts, had no formal structure for raising and resolving the issue, and felt unable to resolve their dilemma.¹⁹⁷ (Level C Observational Evidence) The Working Group and other experts recommend conflict resolution, including an ethics consult or mediation, to facilitate clarification of the conflict and promote resolution. If it is felt by the renal care team or the patient that an extramural ethics committee or consultant has more expertise, the renal care team or patient should feel free to consult them. There are no controlled studies of the outcomes of ethics consultation or mediation for dialysis patients, but the medical literature documents the benefits of ethics consultation in situations similar to dialysis in which the use of a life-sustaining treatment is at issue.

Ethics consultation is a service provided by an ethics consultant or an ethics committee to help patients, legal agents, families, health care professionals or other involved parties address uncertainty or value conflicts that arise in patient care. Ethics consultants and committees possess knowledge and skills in ethics, law, interpersonal communication, and conflict resolution. Ethics consultations have been found to be helpful by physicians in clarifying ethical issues in patient care and assisting in patient management.¹⁹⁸⁻²⁰⁴ (Level B Observational Evidence) For a discussion of issues regarding disruptive patients, see Section 5.

Figure 6. Systematic Approach to Resolving Conflict between Patient and Renal Care Team.



Box 3. Suggested Steps for Implementing Recommendation No. 4.

- Extended conversation
 - Why does the patient or legal agent desire dialysis when it is not recommended by the renal care team?
 - Why does the patient or legal agent refuse dialysis when it is recommended by the renal care team?
 - Does the patient or legal agent misunderstand the diagnosis, prognosis, and treatment alternatives?
 - Does the nephrologist misunderstand the patient’s or legal agent’s reasons for requesting dialysis?
 - Does the nephrologist understand the psychosocial, cultural, or spiritual concerns and values the patient or legal agent have?
 - Has the nephrologist consulted a psychologist, social worker, or chaplain for assistance in fully understanding the concerns of the patient or legal agent family?
- Consultation with other physicians
 - Do other physicians agree or disagree with the attending physician’s recommendation to withhold or withdraw dialysis?
 - Is the request for dialysis by the patient or legal agent medically appropriate?
- Consultation with ethics committee or ethics consultants.
 - Has the patient or legal agent been informed that the purpose of the ethics consult is to clarify issues of disagreement, and ideally, to enable resolution?
 - Has the patient or legal agent met with the ethics committee or ethics consultants to explain their perspective and reasoning behind their request for dialysis?
 - Can the ethics committee identify the reasons why the patient or legal agent is resistant to the physician’s recommendation to forgo dialysis?
 - Can the ethics committee identify the reasons why the health care provider is resistant to the patient’s or legal agent’s desire to begin or continue dialysis?
 - Has the ethics committee explained in understandable terms to the patient or legal agent its conclusions and the reasoning behind them?
 - Can the impasse be resolved with accommodation, negotiation, or mediation?
- Documentation
 - The physician must document the medical facts and his/her reasons for the recommendation to forgo dialysis and the decision not to agree to the request by the patient or legal agent.
 - The consultants should also document their assessment of the patient’s diagnosis, prognosis, and their recommendations in the chart.
- An attempt to transfer the patient’s care
 - If reconciliation is not achieved through the above procedure and the physician in good conscience cannot agree to the patient or legal agent’s request, the physician is ethically and legally obligated to attempt to transfer the care of the patient to another physician.
 - Another physician and/or institution may not be found who is willing to accept the patient under the terms of the family’s request. Physicians and institutions that refuse to accept the patient in transfer and their reasons should also be documented in the medical record.
 - Consider consultation with a mediator, extramural ethics committee, or the ESRD Network in the region.

Box 3 Continued.

- Request regional ESRD network to assist with arranging dialysis.
- Notification of the patient, legal agent, and/or family
 - If no other physician or institution can be found in the community or region by the treating nephrologist to provide dialysis as requested, the physician should inform the patient or legal agent that the nephrologist will cancel the patient’s dialysis orders and the dialysis center will no longer provide dialysis to the patient. The nephrologist is obligated to give the patient sufficient advance notice and the names and addresses of other nephrologists and other dialysis facilities in the area.
- The options of filing a grievance with the ESRD network (chronic patients only) or seeking legal or regulatory recourse by the patient or legal agent should be communicated.

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.

Rationale

Written advance directives are always preferable to oral directives in that they provide better legal protection of the renal care team. For example, a written directive guides a situation in which a patient requests treatment termination yet becomes incapacitated before death and then decision-making authority transfers by statute to a legal agent who demands treatment for the patient. Some patients may not prefer or refuse written directives. In such instances, it is acceptable to obtain an oral statement with a witness present and to document the oral advance directive in the chart. Patients who decide to forgo dialysis should have an agreement to a do-not-resuscitate/do-not-intubate order and appointment of a legal agent on their charts.

Advance directives are a legal and ethical means for communicating patients’ preferences for end-of-life care to legal agents, families, renal care teams, and others. They are a mechanism for facilitating adherence to patients’ end-of-life wishes by legal agents and health care providers. Advance care planning is grounded in the ethical principle of respect for patient autonomy. Multiple observational studies demonstrate many, though not all, patients desire to communicate about their future medical care and to discuss their preferences for care in the event they lose decision-making capacity.^{40,42,43,54,56,63-68,205,206} (Level A Observational Evidence)

Studies show variability in how well patients understand and trust advance care documents.^{207,208} (Level C Observational Evidence) Several observational studies show that while most patients support the concept of advance directives, a minority actually complete them.⁵⁷ (Level A Observational Evidence)^{38,40,58-60,194,209-211}

In observational studies and opinion surveys, nephrologists report that patients’ and families’ preferences are very important to them in decision-making, but physicians may not know their patients’ preferences or may incorrectly assume patients’ preferences.^{52-54,111,195,196} (Level B Observational Evidence) Few physicians, nurses, and social workers on renal care teams discuss advance directives electively with patients; most discussion appears prompted by a deterioration in the patient’s health status.^{209,212} (Level C Observational Evidence) Surveys show physicians in general are willing to honor advance directives,^{44,52,53} but that approximately a quarter express difficulty honoring directives when the directives conflict with what they personally think is best for patients.¹⁹⁶ (Level C Observational Evidence) A scenario-based study of physicians at one

academic center found more specific preferences listed in advance directives were more likely to be followed.²¹³ (Level C Observational Evidence) Seventy-three percent of the physicians said they would be willing to withhold resuscitation based on a general advance directive, 84% based on a specific statement, and 100% if the specific statement was supported by a prior discussion and a surrogate decision maker. Unfortunately, a cohort study of advance directives showed advance directive documents rarely contained specific information to guide care.²¹⁴ (Level C Observational Evidence)

Several attempts have been made to increase the use of advance directives. The Patient Self-Determination Act (PSDA),²¹⁵ effective in 1991, mandated that health care providers advise patients of their rights to make health care decisions and to complete advance directives. The PSDA was mandated for facilities such as hospitals and nursing homes, and not specifically for free-standing dialysis units. Since the PSDA, one study has shown the proportion of inpatients with advance directives has not increased though documentation of their existence in the medical chart has increased from 6 to 35%.²¹⁶ (Level C Observational Evidence) Having advance directives has been correlated with having discussions with health care providers about life-sustaining therapies.^{40,216} (Level C Observational Evidence) Providing patients educational material about advance directives has had variable impact on completion rates.²⁰⁵⁻²⁰⁸ (Level C Observational Evidence) Physician counseling has been shown to increase frequency of specification of a health care proxy in a geriatrics clinic, and an uncontrolled multidisciplinary intervention involving social workers and volunteers stimulated 71% of frail elders to complete an advance directive, among whom 96% specified a proxy.²¹⁷ (Level C Observational Evidence)

Few studies have examined effects of advance care directives on clinical outcomes. A retrospective study of 182 chronic hemodialysis patients who died found those who completed advance directives were more likely to die in a planned, non-emergent fashion and to have a greater sense of control.²¹¹ (Level C Observational Evidence) Two randomized trials and a prospective uncontrolled study have failed to demonstrate that advance care planning affects clinical outcomes, while one observational study demonstrated advance directives can be widely promulgated, successfully communicated to physicians, maintained in continuity across health care venues, and guide care at end of life. Nearly all specified preferences were followed in this latter small homogenous community study.²¹⁸ (Level C Observational Evidence) One of the randomized trials that involved 204 sick outpatients found no differences in health outcomes, perceived well-being, patient satisfaction or health care costs between patients randomized to receive advance directive instruction versus those randomized to usual care.²¹⁹ (Level B Therapy/Prevention Evidence) A large multisite trial of 9,105 medically ill hospitalized patients (including 204 in whom decisions to withhold dialysis were sometimes made) studied interventions aimed at improving end-of-life decision-making and reducing the frequency of a mechanically supported, painful, and prolonged process of dying.²²⁰ (Level A Therapy/Prevention Evidence) Interventions were designed to provide physicians with serial prognostic information for their patients, provide physicians with patient and surrogate responses to questions about preferences, and have specially trained nurses attempt to conduct advance care planning. The study found the following: half of the physicians misunderstood patient's preferences to forgo CPR; nearly half of DNR orders were written within two days of death; approximately a third of patients who died spent at least ten days in an ICU; and half of conscious patients who died reported moderate to severe pain at least half of the time prior to death. The intervention failed to affect any of these factors. Retrospective analysis suggested the designed intervention failed to stimulate physician-patient communication about end-of-life care.²²¹ A prospective uncontrolled study of written advance directives for nursing home patients found that while most life-sustaining therapy was provided in a manner consistent with patient's or surrogate decision maker's expressed preferences, there was no relationship between the written advance directive

and the care provided.²²² (Level C Observational Evidence) The study also found that care in the nursing home was more likely to be in conflict with patients' wishes than care in the hospital, emphasizing the importance of transferring advance care planning between health care venues. Taken together these studies show many aspects of end-of-life care, especially including advance care planning, need to be improved. Several recent studies suggest that nephrologists may be able to enhance communication of patients' preferences for end-of-life care by facilitating patient-family discussions of patients' specific treatment preferences and values regarding suffering.²²³⁻²²⁵

Box 4. Suggested Steps for Implementing Recommendation No. 5.

- Assess decision-making capacity (see Toolkit).
- Determine whether the patient has an appointed legal agent through a written advance directive.
- If the patient lacks decision-making capacity and has not completed an advance directive, arrange for or initiate the process for appointment of a surrogate according to state law.
- Encourage patients to be specific about their preferences with legal agent, family, friends, and providers.
- Discuss advance care planning with patient or legal agent yearly or more often as needed by asking:
 - If you become unable to make decisions for yourself, whom do you want to make decisions for you?
 - If you had to choose between being kept alive as long as possible regardless of personal suffering or living a shorter time to avoid suffering and medical procedures such as breathing machines and feeding tubes, which would you pick?
 - Under what circumstances, if any, would you want to stop dialysis?
 - Under what circumstances, if any, would you not want to be kept alive with medical means such as cardiopulmonary resuscitation, a feeding tube, or mechanical ventilation?
 - Where do you prefer to die and whom do you wish to be with you when you die?
- Document provider's discussion and understanding of patient's preferences, show the patient the documentation, and offer to assist the patient in documenting the patient's agreement or modification of the documentation.
- Place a copy of advance directives in multiple medical records as appropriate, including dialysis facility, commonly attended clinics, hospital, and nursing home.
- Encourage the patient, family and/or legal agent to carry a current copy of the patient's advance directive whenever traveling or being admitted for overnight medical care.

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.

Rationale

The legal and ethical principles supporting this recommendation include informed refusal, respect for patient autonomy, beneficence, nonmaleficence, justice, and professional integrity. In both state and federal case law and by federal statute (PSDA), competent patients have an absolute right to accept or refuse medically indicated treatment. Conversely, physicians are not ethically obligated to offer or deliver treatment that is not medically indicated. Relevant observational evidence is limited but suggests that withdrawal is common, with rates ranging from 17% to 50% of deaths in different dialysis populations.²²⁶⁻²²⁹ (Level C Observational Evidence) Most patients on chronic dialysis appear to know that withdrawal is an option. However, few have thought about it or other end-of-life issues, communicated and discussed their preferences with family or renal care team members, or completed written advance directives.^{38,38-40,42,56-60} (Level B Observational Evidence) A few studies suggest patients with decision-making capacity most often initiate the discussion of withdrawal of dialysis themselves, while physicians most often raise the issue for patients without decision-making capacity.^{226-228,230} (Level C Observational Evidence) For patients who lack decision-making capacity, substituted judgment in the absence of documentation of the patient's feelings on life support may not be permitted in some states.

The evidence regarding patients' preferences for continuing or discontinuing dialysis in the event of certain health states is based on studies using hypothetical vignettes. This evidence demonstrates some variability in hypothetical preferences among patients, with approximately 50 to 85% saying they would want to stop dialysis in conditions of severe permanent neurologic impairment such as severe dementia or permanent coma.^{42,210,231,232} (Level C Observational Evidence) Evidence is lacking regarding agreement between what patients say they would prefer hypothetically and what they actually do. Surveys and observational studies show nephrologists may be inconsistent and variable in their withdrawal practices. Prominent factors that they have reported affect their withdrawal decisions include patient's neurological and physical functional status, comorbidities, family wishes, and age.^{52-54,194,196,230,233} (Level C Observational Evidence) Other patient factors that have been associated with withdrawal have included diabetes, severe pain, lack of a significant partner, Caucasian race, female gender, nursing home residence, and terminal illness.^{53,196,211,226-228,230,231,233-235} (Level C Observational Evidence) Data on withholding of dialysis is limited. Information on withholding can be inferred from studies of referral practices. Of six relevant studies on dialysis referral, one large prospective cohort study indicates that the withholding rate for ARF is substantial (29%) and that increasing age and dementia were independent predictors of withholding in multivariate analyses adjusting for confounders.¹¹¹ (Level B Observational Evidence) Two retrospective cohort studies and two studies using cross-sectional surveys suggest that withholding in ESRD increases with age (15% to 83% over age strata from 16 to >70 years old), and may be higher in women.^{194,195,236,237} (Level C Observational and Prognostic Evidence) These studies also suggest that cultural or financial contexts may influence physicians' rates of initiating dialysis. A large Canadian survey study suggests that family practitioners and internists consider the following in their decisions on whom to refer for dialysis: age, serum creatinine level, mental and psychiatric status, distance from dialysis center, overcrowding of dialysis centers, and comorbid illnesses.²³⁸ (Level C Observational Evidence) Over half of the Canadian physicians felt rationing should be based on patient wishes, cognitive status, life expectancy, quality of life, age, and long-term institutionalization.

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.

Rationale

The ethical principles of beneficence and nonmaleficence allow and support a judgment that, in certain conditions, dialysis does not offer a reasonable expectation of benefit.^{239,240} Further, the right of patients or their legal agents to request dialysis must be balanced against continuing treatment that violates the ethical principle of professional integrity and that is considered medically inappropriate.²³⁹⁻²⁴³ The Working Group, however, felt that the renal team should be sensitive to patient goals and individual circumstances. For example, a person with a terminal illness may desire to have dialysis to help them live long enough for a special family event (e.g., the pending birth of a grandchild).

A situation where dialysis may be considered medically inappropriate is a patient with terminal illness from a nonrenal disease. In this guideline, terminal illness is defined as a life expectancy of ≤ 6 months from non-renal disease(s) in patients not deemed candidates for solid organ transplant. Conditions that may fall into this category are end-stage cirrhosis with hepatorenal syndrome, severe CHF, widely metastatic cancer unresponsive to chemotherapy, end-stage pulmonary disease, end-stage acquired immunodeficiency syndrome, bone marrow transplant recipients with multiorgan failure, and advanced neurodegenerative diseases. Such conditions affect the survival of patients requiring renal replacement therapy.^{73,74,76-80,132} (Level A Prognostic Evidence) The survival for patients with intact renal function and such selected terminal comorbid conditions may be estimated. When the expected survival for patients with intact renal function and particular comorbid conditions is less than six months, it is logical to conclude that dialysis for patients with ARF or ESRD and one or more of the above conditions is unlikely to extend survival.

Another situation where dialysis may be considered medically inappropriate is a patient with permanent inability to purposefully relate to others. This is defined as being unable to recognize familiar persons, lacking orientation to self, place, and time, and the absence of higher cognitive functioning. All forms of severe irreversible dementia and persistent vegetative states fulfill this definition. Dialysis may also be inappropriate for patients with significant and ongoing problems with access for dialysis or failure to thrive. In addition, dialysis may be inappropriate for some patients who are unable to cooperate with the dialysis process. Such patients may be harmful to themselves, other patients, and personnel in the dialysis unit and may create an unsafe working environment.²⁴⁴ Examples of patients who might be in this category include those who require physical or chemical restraints or a sitter during dialysis to prevent harm to self or others in the unit.

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.

Rationale

Experts recommend time-limited trials of life-sustaining treatment such as dialysis in certain situations.^{47,245-247} The ethical principles of beneficence, nonmaleficence, and respect for patient autonomy provide support for this recommendation. The patient's clinical course during the period of time-limited dialysis may provide patients and families with a better understanding of dialysis and its benefits and burdens and may provide the renal care team with a more informed assessment of the likelihood of the benefits of dialysis outweighing its burdens. For example, a patient who is uncertain about their QOL on dialysis may benefit from a time-limited trial. In this

way, a time-limited trial of dialysis may promote informed shared decision-making. No research data regarding outcomes of time-limited trials of dialysis was found. The exact time period for the trial may be made on a case-by-case basis. For patients with ARF, time periods of days to two weeks may be reasonable; for patients with ESRD, time periods of one to three months are reasonable. If there is uncertainty about the inability of a patient to cooperate with dialysis, the patient should be considered for a time-limited trial of dialysis before it is withdrawn to enable all parties to evaluate the appropriateness of continuing 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 dying where they prefer including at home with hospice care. Bereavement support should be offered to patients' families.

Rationale

The ethical principles of respect for patient autonomy and beneficence support this recommendation. Palliative care provided throughout illness includes pain and other symptom management, attention to psychosocial and spiritual concerns, and identification of what matters most to the patient in the dying process. Psychosocial and spiritual care includes addressing grief and bereavement needs, religious and spiritual issues, and appropriate communication with family and/or friends. These components are based on observational studies demonstrating common symptoms and issues of dying patients,^{220,248} qualitative studies eliciting patient and provider views of "good death,"^{249,250} and general consensus of best practices regarding end-of-life-care.^{49,66,251-264} (Level C Observational Evidence) Palliative care, including end-of-life care, is usually delivered by a multidisciplinary team including physicians, nurses, social workers, spiritual counselors, dietitians, and pharmacists. This approach is able to address the diverse and complex needs of dying patients and their families (and/or friends). (Please see the Toolkit for the NKF Preparation for Dying Checklist for helpful suggestions.)

SECTION 5: THE DISRUPTIVE PATIENT

During the process of guideline development, several issues related to appropriate handling of disruptive patients were discussed. The Working Group did not make specific recommendations regarding these issues because they were considered beyond the scope of the guideline charge and there was no real consensus about what to do with disruptive patients. Nonetheless, the following points and suggestions for due process were noted.

First, the magnitude of the problem was perceived as large because even small numbers of disruptive patients can place undue burden on multiple other patients and dialysis facilities. A spectrum of disruptive patients and disruptive behaviors was noted. Patients who physically endanger others were considered the most extreme. Other examples were verbally abusive patients, patients who repetitively disrupt a unit's care, and patients who create an unsafe care environment for others. No evidence was found regarding the incidence of specific types of disruptive or problematic patients or the success of different types of interventions to resolve problem situations, but the dialysis literature contains many recent citations about this problem.^{244,265-274} Systematic acquisition of such data was considered very important.

Second, distinguishing disruptive patients from those that are challenging or frustrating was difficult. Individual renal team members or dialysis facilities may have differing levels of tolerance for certain types of patient behaviors. Adversarial positioning may result from battles for control between team members and patients, personality conflicts, and staff assuming responsibility for behaviors which are actually in the domain of the patients' self-responsibility. Furthermore, renal care team members may inadvertently contribute to problem situations by unnecessary or inappropriate adversarial positioning that may potentiate or escalate disruptive or unsafe behavior. In such instances, consultation and training in behavior strategies to improve patient management skills may be helpful. Stress management and strengthening of personal coping skills of staff may also be appropriate in some situations.

Third, discharge of disruptive patients, transfer of patients from one dialysis facility to another, time-limited trials, and sharing of problem patients among dialysis units were discussed. Some Working Group members felt that discharge or transfer was a viable option, predicated on detailed documentation of repeated failed psychosocial interventions and a conflict resolution process. Others felt that limited case law (see below) did not support discharge. Several members noted that rotating particular disruptive patients among dialysis facilities is logistically difficult, not sustainable, and unlikely to lead to improved outcomes.

Fourth, resorting to court action was recognized as a viable option in instances where psychosocial interventions, mediation, or ethics consultation were unsuccessful. In case law (*Brown vs Bower* and *Payton vs Weaver*), individual nephrologists have not been required to continue to treat disruptive dialysis patients after they have made repeated failed psychosocial interventions and have followed due process. In these cases an individual dialysis facility (*Brown vs Bower*) or dialysis facilities within an ESRD network have been required to dialyze such patients (*Payton vs Weaver*). These cases may not provide adequate clarity for addressing disruptive patients and further court decisions were thought likely.

Lastly, ethical obligations of the renal care team should be reasoned through on a case-by-case basis. In each instance, protection of the disruptive patient's rights, protection of other patients' rights, and staff rights and safety must be considered.

Some potentially helpful steps for dealing with disruptive patients are given below. A detailed example set of recommendations from ESRD Network 6 for dealing with disruptive patients is also provided in the Toolkit.

Box 5. Suggested Steps for Dealing with Disruptive Patients.

- Identify and document problematic behaviors and discuss them with patient.
- Seek to understand the patient's perspective.
- Identify the patient's goals for treatment.
- Share control and responsibility for treatment with the patient.
 - Educate the patient so that he or she can make informed decisions.
 - Involve the patient in the treatment as much as possible.
 - Negotiate a behavioral contract with the patient.
- Set limits and negotiate a behavioral contract with the patient.
- Consult a psychiatrist, psychologist, or social worker for assistance in patient management or determination of decision-making capacity.
- Be patient and persistent.
- Allow the patient to ventilate concerns but do not tolerate verbal abuse or threats of staff or patients.
- Contact law enforcement officials when physical abuse is threatened or occurs.
- If satisfactory resolution has not occurred with the use of these strategies, contact the local ESRD Network to discuss the situation further and to insure due process.
- As a last resort, consider transfer to another facility or discharge.
- Consult with legal counsel before proceeding with plans for discharge and do not discharge without advance notice and disclosure of future treatment options.

SECTION 6: FUTURE RESEARCH DIRECTIONS

The Working Group and peer reviewers of this guideline noted several major gaps in evidence relevant to decision-making about initiation of and withdrawal from dialysis. The following are their recommendations for appropriate future research:

Acute Renal Failure

- Continue to refine and prospectively validate prognostic models for ARF.
- Develop prognostic models for ARF that are disease- and outcome-specific.
- Assess long-term morbidity, functional status, quality of life, frequency of recovery of normal renal function, and survival of patients with recovery from ARF.

End-Stage Renal Disease

- Identify predictors of deaths occurring within the first 90 days of dialysis.
- Evaluate whether time-limited trials are used as a viable option: whether they are being done; whether patients are being reassessed; and whether it makes a difference in regard to future decisions.
- Assess the benefits and costs of periodic measurement of functional status and/or quality of life in patients on dialysis.
- Determine how often it is appropriate to review with the patients their wishes regarding end-of-life care.
- Determine frequency and outcomes of disruptive patients.
- Study attitudes of and effects on staff and other patients of disruptive patients.

Acute Renal Failure and End-Stage Renal Disease

- Study content and benefits of palliative care and who delivers it for patients who never initiate or withdraw from dialysis.
- Study use of palliative care to treat pain and other symptoms.
- Study long-term outcomes and quality of life in pediatric patients undergoing dialysis.
- Study whether patients really have informed consent and make informed decisions.
- Study what role patients and families want in the shared decision-making process.
- Study frequency and results of shared decision-making in initiating and withdrawing dialysis
- Study emotional reactions and job satisfaction of involved health care professionals when patients decide not to initiate or stop dialysis.
- Study emotional reactions and job satisfaction of involved health care professionals when patients are started on dialysis or are kept on dialysis against their wishes.
- Study whether relationships between staff and patients or families affect life and death decision-making.
- Determine how often dialysis is either withheld or provided when it is inconsistent with patient preferences and prognosis.

- Develop and assess methods to insure timely referral to nephrologists for patients with ESRD or ARF.
- Develop and assess methods to insure palliative care and/or timely referral to hospice for patients who do not wish to initiate or who stop dialysis or who otherwise have a life-expectancy of less than six months.
- Study methods to improve communication about prognosis and treatment preferences.
- Study most effective methods of educating patients and families for enhancing completion of advance directives/advance care planning.
- Study different methods for diagnosing depression and anxiety and examine their role in patient decisions to discontinue treatment.
- Describe and measure how dialysis patients die.
- Develop standards regarding “quality of dying” and assess their utility in monitoring quality of care.
- Study the families’ perspective of dialysis discontinuation, their satisfaction with end-of-life care, and their bereavement and adaptation to the patients’ deaths.
- Study methods for implementing guidelines relevant to dialysis and associated outcomes.
- Study attitude of patients and professionals toward respect of DNR orders in dialysis units.
- Study frequency and outcomes of cardiac arrests in dialysis facilities.
- Study long-term outcome at more than 5 years from initiation of dialysis for pediatric dialysis patients, especially infants.
- Study quality of life in pediatric patients during dialysis.
- Determine how often dialysis is withheld for children, especially infants.
- Determine how often dialysis is initiated for a time-limited trial in pediatric patients.

SECTION 7: IMPLEMENTATION OF GUIDELINE RECOMMENDATIONS AND TOOLKIT

Dissemination and Educational Initiatives

A first step in guideline implementation is dissemination and education. The Working Group recommended that the guideline document be disseminated throughout the ESRD Networks, as well as to individual providers. They also recommended incorporation of the guideline into training programs and continuing education workshops for practicing renal care professionals. ESRD Networks, professional organizations, and/or providers may use the guidelines to develop patient education materials. Training programs and workshops should provide opportunities for participants to develop and practice skills necessary for implementing the guidelines, such as skills in communication and palliative care.

Local Implementation

Clinical practice guidelines are successful only in so far as they improve patient care and outcomes. The limited data available suggest substantial variation among dialysis facilities with regard to advance care planning, completion of advance directives, and provider/patient (family or legal agent) communication regarding treatment options (including the right to refuse dialysis). One of the fundamental principles of Continuous Quality Improvement (CQI) is that opportunities for improvement exist whenever there is variability in process and outcomes. Dialysis facilities and their patients could benefit from CQI activities that seek to increase communication and shared decision-making between providers and patients or their legal agents regarding treatment and end-of-life decisions.

Quality improvement consists of a cycle of identifying areas in need of improvement, setting achievable goals, targeting activities to achieve these goals, and remeasurement of performance. Choosing reliable, specific, valid, reproducible, and interpretable quality indicators will help insure successful implementation and desired improvements in care.

With these factors in mind, potential quality indicators derived from this guideline are suggested below to assist local facilities in their CQI efforts. Depending upon current local practices and available resources, individual facilities are encouraged to consider selecting one or more of the following areas for CQI activities.

- Assessment and documentation of decision-making capacity for patients entering the unit and at annual evaluations. Assessment of decision-making capacity should include a formal mental status exam and depression screening. Patients who were previously functioning within normal range and who are found to have significant deterioration/impairment may be referred for further evaluation and possible treatment.
- For those patients who lack decision-making capacity, documentation of legal agent name and contact information.
- Annual advance care planning as part of treatment planning that documents (easily accessible on facility chart) advance directives (e.g., living wills, durable power of attorney for health care) or refusal to complete same after staff/physician education and counseling.
- Reassessment of decision-making capacity and care plan review triggered by specific intercurrent events that are known to dramatically increase mortality (e.g., MI, stroke, foot

amputation) or by a deterioration in functional status as evidenced by a loss of independence in daily living.

- Staff/physician training in counseling techniques for advance care planning and shared decision-making.
- Specific staff member(s) designated as responsible for providing education and counseling for advance care planning and/or tracking that it is taking place.
- Provision and documentation of continued palliative care for patients who decide to discontinue dialysis and satisfaction of patient and family with palliative care.
- Evaluation and documentation of decisions to perform time-limited trials of dialysis for patients with uncertain prognosis or for whom consensus regarding dialysis could not be reached, and documentation of formal reassessment at the end of the time-limited trial date.
- Establishment, use, and outcomes of mediation and ethics consultation services provided by local ethics committees and the ESRD Networks.

Suggestions and examples of some tools (e.g., methods for assessing decision-making capacity) that might be used to implement these recommendations are provided in the following Toolkit.

TOOLKIT FOR ASSESSING OR DOCUMENTING DECISION-MAKING CAPACITY, DEPRESSION, MENTAL STATUS, ADVANCE DIRECTIVES, PROGNOSIS, AND QUALITY OF LIFE

General Checklist Regarding Shared Decision-Making Recommendations

The Working Group developed the following checklist that gives examples of items that could be added to long-term care plans to monitor implementation of shared decision-making recommendations.

- yes no Patient has been screened for depression.
- yes no Patient score indicates possible depression.
- yes N/A If screened positive, patient has been referred for possible treatment.
- yes no Patient has been screened for mental status.
- yes no Patient score indicates possible cognitive impairment.
- yes N/A If cognitive impairment is indicated, have potentially reversible contributors been ruled out?
- yes no Patient has been assessed for decision-making capacity.
- yes no Patient's preference for a legal agent has been elicited.
- yes no Patient or designated legal agent has been provided information on advance directives.
Date: _____ Staff: _____
- yes no Patient has signed durable power of attorney for health care on chart.
- yes no Patient has signed living will in chart.
- yes no Circumstances, if any, under which patient would desire discontinuation of dialysis have been documented on chart.
- yes no Circumstances, if any, under which patient would not want CPR, mechanical ventilation, or tube feeding.
- yes no Patient or designated legal agent has been provided prognostic information.
Estimated survival prognosis is:
_____ from _____, date _____.
(e.g., table, model, clinician)
- yes no Present and projected future quality of life and/or functional status has been discussed. If assessed, instrument used _____, score: _____, date: _____.
- yes NA Has an intervention been planned to improve quality of life or functional status?

Examples of Useful Tools

There are multiple validated tools that can be used to assess depression, mental status, decision-making capacity, quality of life, and prognosis. Choice of a particular tool is dependent upon issues such as preferences, resources, and provider familiarity and training. The Working Group did not endorse particular instruments, but provide the following examples that they believe to be useful.

Depression Screening Instruments

There are many validated instruments that can be used to screen for depression. A systematic review of nine of these instruments shows they all have approximately equal sensitivity in detecting depression.²⁷⁵ Below is an example of two-item depression screening instrument: *The PRIME-MD*.²⁷⁶ Anyone who screens positive should have his or her diagnosis confirmed with a diagnostic interview or tool.

Example: The PRIME-MD

These questions will help your doctor better understand problems that you may have. Your doctor may ask you more questions about some of these items. Please make sure to check a box for every item.

During the PAST MONTH, have you OFTEN been bothered by little interest or pleasure in doing things? yes no

During the PAST MONTH, have you OFTEN been bothered by feeling down, depressed, or hopeless? yes no

If patient answers “yes” to either question, proceed with the following patient evaluation, otherwise stop.

Major Depression				
For the last 2 weeks, have you had any of the following problems nearly every day?	YES		NO	
1. Trouble falling or staying asleep, or sleeping too much?	YES		NO	
2. Feeling tired or having little energy?	YES		NO	
3. Poor appetite or overeating?	YES		NO	
4. Little interest or pleasure in doing things?	YES		NO	
5. Feeling down, depressed, or hopeless?	YES		NO	
6. Feeling bad about yourself – or that you are a failure – or have let yourself or your family down?	YES		NO	
7. Trouble concentrating on things, such as reading the newspaper or watching television?	YES		NO	

8. Being so fidgety or restless that you were moving around a lot more than usual? If “No,” What about the opposite – moving or speaking so slowly that other people could have noticed? Count as “Yes” if “Yes” to either question, or if psychomotor agitation or retardation observed during interview.	YES		NO	
9. In the last two weeks, have you had thoughts that you would be better off dead or hurting yourself in some way? If “Yes,” tell me about it.	YES		NO	
10. Are answers to five or more of No. 1 to No. 9 “Yes” (one of which is No. 4 or No. 5)?	YES	Major depressive disorder; go to No. 12	NO	
Partial Remission of Major Depression				
11. Have you ever had a time when you were either much more down or depressed, or had even less interest or pleasure in doing things? If Yes: At that time, did you have many of the problems that I just asked you about, like trouble sleeping, concentrating, feeling tired, poor appetite, little interest in things? Count as “Yes” only if, in the past, patient probably had five of symptoms No. 1 to No. 9 and acknowledges some current depressed mood, or little interest or pleasure.	YES	Partial remission of major depressive disorder.	NO	
Dysthymia				
12. Over the last 2 years, have you often felt down or depressed, or had little interest or pleasure in doing things? Count as Yes only if also Yes to: Was that on more than half the days over the last 2 years?	YES		NO	Go to No. 14.
13. In the last 2 years, has that often made it hard for you to do your work, take care of things at home, or get along with other people?	YES	Dysthymia; go to No. 16.	NO	
Minor Depression				
14. Was Major Depression (including partial remission) diagnosed at #10 or #11?	YES	Go to No. 16.	NO	
15. Are answers to two or more of #1 to #9 Yes (one of which is #4 or #5)?	YES	Minor depressive disorder.	NO	EXIT.
Bipolar				
16. Did a doctor ever say you were manic-depressive or give you lithium? If Yes: When was that? Do you know why?	YES	Add R/O depressive disorder.	NO	


Depression Due to Physical Disorder, Medication, or Other Drug				
17. Are current depressed symptoms probably due to the biological effects of a physical disorder, medication or other drug?	YES	Add R/O depressive disorder due to physical disorder, medication, or other drug; EXIT.	NO	
Summary of Diagnoses Made (ICD-9-CM codes appear in parentheses)	YES		NO	

Cognitive Impairment Screening Instruments

There are multiple standardized psychological and neuropsychological tests to help screen and diagnose dementia (*Measuring Health: A Guide to Rating Scales and Questionnaires*, 2nd ed.²⁷⁷ contains discussion and examples of multiple instruments). The Mini-Mental State Examination below is one example of a validated screening instrument that is widely used in medical settings and has been found to be helpful in detecting cognitive impairment in dialysis patients.^{45,278} The diagnosis of dementia can be complicated; any person scoring positive on a screening test warrants further careful examination.

Example: Mini-Mental State Examination²⁷⁹

The instructions for this exam are on the following page.

<i>Max. Score</i>	<i>Score</i>	
ORIENTATION		
5	()	What is the (year) (season) (month) (date) (day)? (5 points)
5	()	Where are we? (state) (country) (town) (hospital) (floor) (5 points)
REGISTRATION		
3	()	Name 3 objects: 1 second to say each. Then ask the patient to repeat all three after you have said them. 1 point for each correct answer. Then repeat them until he learns all 3. Count trials and record. Trials: _____
ATTENTION & RECALL		
5	()	Serial 7's. 1 point for each correct. Stop after 5 answers. Alternatively spell "world" backwards. (Number correct equals letters before 1st mistake – i.e., d l o r w = 2 correct). (5 points)
RECALL		
3	()	Ask for the objects above. 1 point for each correct. (3 points)
LANGUAGE		
2	()	Name a pencil and watch (2 points)
1	()	Repeat the following "No ifs, ands, or buts." (1 point)
3	()	Follow a 3-stage command: "Take the paper in your right hand, fold it in half, and put it on the floor." (3 points)
1	()	Read and obey the following: (1 point)
CLOSE YOUR EYES		
1	()	Write a sentence spontaneously below (1 point)
1	()	Copy the design below (1 point)
		
30	()	Total Score
ASSESS level of consciousness along a continuum:		
Alert Drowsy Stupor Coma		

Scores less than 23 are generally assumed to reflect cognitive impairment (unless the patient has eight or fewer years of education), scores of 18 to 23 suggest mild impairment, and scores of less than 18 suggest moderate to severe impairment.

Instructions for Administration of Mini-Mental State Examination

Orientation

Ask for the date. Then ask specifically for parts omitted, e.g., “Can you also tell me what season it is?”. One point for each correct.

Ask in turn “Can you tell me the name of this hospital?” (town, county, etc). One point for each correct.

Registration

Ask the patient if you may test his memory. Then say the names of three unrelated objects, clearly and slowly, about one second for each.

After you have said all three, ask him to repeat them.

Although this first repetition determines the score (0 to 3), keep saying them until the patient can repeat all three, up to six trials.

If he does not eventually learn all three, recall cannot be meaningfully tested.

Attention and Calculation

Ask the patient to begin with 100 and count backwards by 7. Stop after five subtractions (93, 86, 79, 72, 65). Score the total number of correct answers.

If the patient cannot or will not perform this task, ask him to spell the word “world” backwards. The score is the number of letters in correct order (e.g., dlrow = 5, dlorw = 3).

Recall

Ask the patient if s/he can recall the three words you previously asked him/her to remember. (score 0 to 3).

Language

Naming: Show the patient a wristwatch and ask him/her what it is; repeat same instructions for pencil. Score 0 to 2.

Repetition: Ask the patient to repeat the sentence; allow only one trial. Score 0 or 1.

Three-Stage Command: Give the patient a piece of plain blank paper and repeat the command. Score 1 point for each part correctly executed.

Reading: On a blank piece of paper print the sentence “Close your eyes” in letters large enough for the patient to see clearly. Ask him/her to read it and do what it says. Score 1 point only if s/he actually closes his eyes.

Writing: Give the patient a blank piece of paper, and ask him to write a sentence for you. Do not dictate a sentence; it is to be written spontaneously. It must contain a subject and verb to be sensible. Correct grammar and punctuation are not necessary.

Copying: On a clean piece of paper, draw intersecting pentagons, each side measuring about 1 inch, and ask the patient to copy it exactly as it is. All ten angles must be present and two must intersect to score 1 point. Tremor and rotation are ignored.

Estimate the patient’s level of consciousness along a continuum, from alert on the left to coma on the right.

Assessment of Decision-Making Capacity

Decision-making capacity is the capacity to 1) understand one's medical condition; 2) appreciate the consequences (benefits and burdens) of various treatment options including nontreatment; 3) judge the relationship between the treatment options and one's personal values, preferences, and goals; 4) reason and deliberate about one's options; and 5) communicate one's decisions in a meaningful manner. Lack of decision-making capacity is different from cognitive impairment. It is possible for someone to be mildly demented and have decision-making capacity. Traditionally, decision-making capacity has been assessed by clinical interview. In the last several years a number of standardized instruments have become available. An example of one of these instruments is presented below.

Example: Aid to Capacity Evaluation (ACE)²⁸⁰

Record observations that support your score in each domain, including exact responses of the patient. Indicate your score for each domain with a checkmark.

1. Able to understand medical problem. Observations: _____ _____	YES <input type="radio"/> UNSURE <input type="radio"/> NO <input type="radio"/>
2. Able to understand proposed treatment. Observations: _____ _____	YES <input type="radio"/> UNSURE <input type="radio"/> NO <input type="radio"/>
3. Able to understand alternative to proposed treatment (if any). Observations: _____ _____	YES <input type="radio"/> UNSURE <input type="radio"/> NO <input type="radio"/>
4. Able to understand option of refusing proposed treatment (including withholding or withdrawing proposed treatment). Observations: _____ _____	YES <input type="radio"/> UNSURE <input type="radio"/> NO <input type="radio"/>
5. Able to appreciate reasonably foreseeable consequences of accepting proposed treatment. Observations: _____ _____	YES <input type="radio"/> UNSURE <input type="radio"/> NO <input type="radio"/>
6. Able to appreciate reasonably foreseeable consequences of refusing proposed treatment (including withholding or withdrawing proposed treatment). Observations: _____ _____	YES <input type="radio"/> UNSURE <input type="radio"/> NO <input type="radio"/>
NOTE: For questions 7a and b, a "Yes" answer means the person's decision is affected by major depression or psychosis.	
7a. The person's decision is affected by major depression. Observations: _____ _____	YES <input type="radio"/> UNSURE <input type="radio"/> NO <input type="radio"/>
7b. The person's decision is affected by delusion/psychosis. Observations: _____ _____	YES <input type="radio"/> UNSURE <input type="radio"/> NO <input type="radio"/>

Overall Impression

Definitely Capable	<input type="radio"/>
Probably Capable	<input type="radio"/>
Probably Incapable	<input type="radio"/>
Definitely Incapable	<input type="radio"/>

Comments

(For example; need for psychiatric assessment, further disclosure and discussion with patient, or consultation with family)

The initial ACE assessment is the first step in the capacity assessment process. If the ACE is definitely or probably incapable, consider treatable or reversible causes of incapacity (e.g., drug toxicity). Repeat the capacity assessment once these factors have been addressed. If the ACE result is probably incapable or probably capable, then take further steps to clarify the situation. For example, if you are unsure about the person’s ability to understand the proposed treatment, then a further interview that specifically focuses on this area would be helpful. Similarly, consultation with family, cultural, and religious figures and/or a psychiatrist, may clarify some areas of uncertainty.

Never base a finding of incapacity solely on your interpretation of domain 7a and 7b. Even if you are sure that the decision is based on a delusion or major depression, we suggest that you always get an independent assessment.

Time taken to administer ACE: _____ minutes

Date: Day: _____ Month: _____ Year: _____ Hour: _____

Assessor: _____

Examples of Questions to Help Discuss End-of-Life Issues

The following table provides examples of questions that may be helping in discussing end-of-life issues with patients.²⁸¹

Table 16. Questions to Guide Discussions of End-of-Life Issues.

Potentially Useful Open-Ended Questions About End-of-Life Care
<ul style="list-style-type: none"> ▪ What concerns you most about your illness? ▪ How is treatment going for you (your family)? ▪ As you think about your illness, what is the best and the worst that might happen? ▪ What has been most difficult about this illness for you? ▪ What are your hopes (your expectations, your fears) for the future? ▪ As you think about the future, what is most important to you (what matters the most to you)?
Potentially Useful Questions With Which to Explore Spiritual and Existential Issues
<ul style="list-style-type: none"> ▪ Is faith (religion, spirituality) important to you in this illness? ▪ Has faith (religion, spirituality) been important to you at other times in your life? ▪ Do you have someone to talk to about religious matters? ▪ Would you like to explore religious matters with someone?
More Direct Questions That May Be Useful with Patients Who Want to Discuss Spiritual and Existential Issues
<ul style="list-style-type: none"> ▪ What do you still want to accomplish during your life? ▪ What thoughts have you had about why you got this illness at this time? ▪ What might be left undone if you were to die today? ▪ What is your understanding about what happens after you die? ▪ Given that your time is limited, what legacy do you want to leave your family? ▪ What do you want your children and grandchildren to remember about you?

Advance Directives

Advance directives are oral or written statements by a patient with decision-making capacity expressing his/her preferences for a surrogate and for future medical care in the event he/she becomes unable to participate in medical decision-making. All 50 states have one or more laws recognizing written advance directives. There are two types of advance directives, a living will and a health care proxy. The health care proxy is known in some states as a medical power of attorney or a durable power of attorney for health care. The living will, also known as an instruction directive, indicates a patient's wishes to be followed if he loses decision-making capacity. Wishes may refer to care in the event of particular medical conditions such as a terminal illness or a persistent vegetative state. The health care proxy designates a person to make decisions for a patient when the patient loses decision-making capacity. In some states, both of these functions are combined in the living will.

The U.S. Congress enacted the Patient Self-Determination Act ²¹⁵ to require that information concerning written directives be provided to all adults at the time of admission as a hospital inpatient, at the time of admission as a skilled nursing facility resident, in advance of coming under the care of a home health agency, or at the time of initial receipt of hospice care. State law may vary with regard to written directives. Information on advance directives can be obtained from Choice in Dying, a nonprofit organization that provides advance directives, counsels patients and families, trains professionals, advocates for improved laws, and offers a range of publications and services. State-specific advance directives can be ordered from them by phone or mail at 1-800-989-WILL (9455), or downloaded from their website (www.choices.org).

Prognostic Tables

Following are prognostic tables for ARF and ESRD.

Tables for Acute Renal Failure

The first table below gives gross ranges of mortality synthesized from the literature review. The second table below gives examples of multivariate predictive models of mortality that can be used in acute renal failure. Four of these models are available as part of an ICU ARF Severity Score tool at a “living” web-based ARF database (www.bio.ri.ccf.org/arf). The web site uses these models to generate readily available prognostic measures of mortality (e.g., give the probability of mortality of a particular patient when compared to groups of patients with similar scores). A provider enters characteristics of their particular patient and the probability of their hospital mortality is calculated (see Table 19 for a sample print-out).

Table 17. Expected Intensive Care Unit and Hospital Mortality for Dialysis Patients with Acute Renal Failure.

	Heterogeneous Patient Populations	Bone Marrow Transplant Patients	Post-Surgical Patients	Post-Trauma Patients
ICU Mortality	≈ 50 – 65%		≈ 60%	
Hospital Mortality	≈50 – 85%	≈85% ^a	45 – 65%	50 – 80%

^aBased on one small (n < 100) retrospective study.

Table 18. Predictive Models of Mortality for Dialysis Patients with Acute Renal Failure.

APACHE II ¹²² : Acute physiologic score based on 12 physiologic measures, age, and the presence of severe chronic health problems.
APACHE III : Refinement in APACHE II regarding scoring of physiologic measures plus adds location prior to ICU as variable.
*Brivet ¹²⁰ : Includes age, health status, initial or delayed renal failure, oliguria, sepsis, and physiologic severity of illness.
Bullock ¹²³ : Includes 6 variables: Age, jaundice, cardiovascular complications, hypercatabolism, pulmonary complications, and clinical presentation in terms of urine output.
*Chertow ⁷⁷ : Includes mechanical ventilation, malignancy, and nonrespiratory organ system failure.
Cioffi ¹²⁴ : Produces a prognostic index based on age, number of blood transfusions, cardiac surgery, the interval between the onset of ARF and dialysis and preoperative hypotension.
*Liano ¹¹⁸ : Includes metabolic, cardiovascular, respiratory, renal(2), neurological(2), and personal(2) variables.
Lohr ¹²⁵ : Includes five significant variables: Systolic blood pressure, assisted ventilation, CHF, sepsis, and gastrointestinal dysfunction.
Mortality Prediction Model (modified) ¹²⁷ : Seven variables: cardiovascular, neurological, hematology/malignancy, infection, CPR. Replaces the number of organ system in failure with information about use of CPR before ICU admission.

Table 18 Continued.

*Paganini¹²¹ : Includes gender, respiratory failure requiring intubation, hematologic dysfunction, bilirubin, surgery, creatinine, BUN, and number of failed organ systems.
Rasmussen¹²⁸ : Variables included not clear.
Simplified Acute Physiologic Score¹²⁹ : Consists of a selection of measurements of the original APACHE, without an adjustment for chronic health problems,
Simplified Acute Physiologic Score-Extended¹³⁰ : As above plus 8 more physiologic measures.
Simplified Acute Physiologic Score-Reduced¹³⁰ : Uses five physiologic variables only.
Schaefer⁸⁰ : Uses six metabolic, cardiovascular (2), respiratory, infection, and chronic disease variables.
SS¹³¹ : Modification of the APACHE II containing additional physiological measures but not including the reason for ICU admission.

*Indicates models available on website.

Table 19. Acute Renal Failure Severity Score Validation Probabilities for Sample Patient.²⁸²

Patient No.	Subjective Prediction (0-9)	Difference (in Days) between Prediction and First Day of Dialysis	SCORES: Probability of Hospital Mortality				Hospital Death
			Cleveland Clinic Foundation	Chertow (pseudo)	French Study Group (pseudo)	Liano (pseudo, outcome = ATN)	
26,934	5		0.969	0.724	I/E*	1	Yes

*I/E – indicates patient did not meet inclusion criteria

Tables for End-Stage Renal Disease

Table 20. Expected Remaining Years of Life For 1996 U.S. Prevalent Hemo- and Peritoneal Dialysis Populations by Age, Race, and Sex (USRDS, 1998 ADR, p.76)³

Age	Black Male	Black Female	White Male	White Female
20-24	16.8	15.9	14	13
25-29	14.5	14.1	11.3	11
30-34	12.7	12.5	9.4	9.3
35-39	11.3	11.4	8	7.9
40-44	10	9.8	6.9	7.1
45-49	8.6	8.5	6.1	6.3
50-54	7.3	7.1	5.2	5.2
55-59	6.3	6.3	4.4	4.5
60-64	5.2	5.3	3.7	3.9
65-69	4.2	4.4	3.1	3.3
70-74	3.5	3.7	2.7	2.9
75-79	2.9	3.0	2.4	2.5
80-84	2.5	2.5	2.1	2.1
85+	2.1	2.0	1.7	1.7

Table 21. One (from Day 91-One Year +90 Days), Two-, Five-, and Ten-Year Survival Probabilities by Age in All USRDS Patients (from USRDS, 1998 ADR, Reference Tables E14-20).³

Age	1 year (1995) ^a	2 year (1994)	5 year (1991)	10 year (1986)
20-24	95.54	94.41	83.73	71.26
25-29	91.5	88.2	76.17	61.28
30-34	89.43	83.66	70.85	53.92
35-39	89.77	83	63.19	45.17
40-44	89.89	81.67	60.91	40.06
45-49	89.25	79.05	53.23	32.33
50-54	87.73	77.69	47.01	22.54
55-59	84.63	71.01	39.43	14.13
60-64	80.51	65.63	30.31	8.89
65-69	75.70	58.44	22.55	4.81
70-74	71.88	51.63	17.67	2.61
75-79	66.05	46.07	13.69	1.4
80-84	61.61	39.74	8.6	0.81
85+	53.91	32.26	5.2	0

^aNumber in parentheses denotes year of incidence.

Table 22. 1-Year and 2-Year Survival by Albumin for HD Patients Starting Dialysis between 1987 and 1991 (Goldwasser, 1993).¹³⁶

Albumin (g/dL)	1-Year	2-Year
≥3.5	86%	76%
<3.5	50%	17%

Table 23. 18-Month Survival for Prevalent Patients by Albumin (Lowrie, 1990).¹⁵⁵

Average Albumin Concentration (g/dL)	N exposed	N Died	Risk of Death	RR to Index of 4.01-4.5
>4.5	124	10	0.0806	0.83
4.01-4.5	3,931	382	0.0972	1.00
3.51-4.0	6,517	1399	0.2147	2.21
3.01-3.5	1,266	598	0.4724	4.86
2.51-3.0	157	107	0.6815	7.01
≤2.5	29	21	0.7241	7.45

Table 24. Patient Functional Status and Mortality Among 10,355 Incident HD and PD Patients, Network 6, 1989 to 199 (McCellan, 1994).¹⁶⁸

Functional Status	N	Mortality		
		%	Rate*	RR(95% CI)
Normal*	1,128	13.1	8.3	
Mildly Impaired	3,215	37.3	10.6	1.28(1.08-1.52)
Moderately Impaired	2,748	31.8	19.0	2.29(1.94-2.70)
Severely Impaired	1,538	17.8	28.7	3.46(2.93-4.10)

*Unadjusted mortality rate expressed as deaths per 100 dialysis years

†Reference Group

Table 25. Diabetic versus Non-Diabetic Survival Rates for All Canadian Patients 1981-1992 (Fenton, 1995).¹⁸⁷

	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
DM	78 %	60%	48%	40%	32%	28%	25%	21%
Non-DM	83%	74%	67%	60%	55%	50%	48%	44%

Table 26. Cardiac Mortality (%) After Acute Myocardial Infarction by Year Myocardial Infarction Occurred (Herzog, 1998).¹⁸⁵

Year of AMI	1 Year	2 Year	3 Year	5 Year
1985-1989	39.3	51.3	60.0	71.7
1990-1995	42.2	52.0	59.3	65.4

Table 27. All Cause Mortality (%) After Acute Myocardial Infarction by Etiology of ESRD: 1977-1995 Incident Patients with a Myocardial Infarction ESRD (Herzog, 1998).¹⁸⁵

Year of AMI	1 Year	2 Year	3 Year	5 Year
1985-1989	56.0	71.3	80.7	90.0
1990-1995	61.7	74.2	82.0	89.1

Table 28. All Cause Mortality (%) After Acute Myocardial Infarction by Etiology of End-Stage Renal Disease (Herzog, 1998).¹⁸⁵

Etiology	1 Year	2 Year	3 Year	5 Year	10 Year
Diabetes	62.3	77.2	86.1	93.3	99.1
Hypertension	60.79	73.5	81.3	90.4	97.9
Other	55.4	68.9	77.5	86.9	95.8

Table 29. Cumulative Survival Following First Amputation After Renal Failure For Medicare End-Stage Renal Disease HD and PD Prevalent Patients 1991 through 1994 (Eggers, 1999).¹⁶²

Sub-Group	Days Post Amputation						
	N	30	60	90	180	365	730
Total							
Age	24877	88.9	80.1	74.2	62.8	49.3	32.7
25-34	419	96.4	93.2	89.7	83	73.8	61.3
35-44	2342	95.8	91.3	88	78.6	67.3	53.3
45-54	4038	93.8	88	84	74.1	60.7	44
55-64	6365	90.2	82	76.5	65.1	51.3	33.1
65-74	7956	86	75.7	68.7	56.5	41.7	24.5
≥75	3324	80.4	66.3	57	43.9	30.9	15.8
Diagnosis							
Diabetes	16970	90.5	82.4	76.7	65.7	51.7	34.8
GMN	892	83.7	74.3	66.8	54.6	41.3	27.8
HTN	4059	84.7	73.7	66.6	55.3	42.3	26.2
Level of Amputation							
Toe	7806	95.2	89.8	85.4	75.8	63	44.8
Below Knee	12380	89.6	81	75.2	63.2	49	31.7
Above Knee	4691	76.3	61.6	52.7	40.3	27.1	15.2

Assessment of Quality of Life or Functional Status

Patients and their providers may find it helpful to monitor patient-centered outcomes such as functional status or quality of life. The terms generally refer to functioning or well-being in one or more domains (e.g., physical, psychological, social, occupational, sexual, etc.). Poor functional status is highly predictive of early death in dialysis patients (for a discussion of this evidence, see Recommendation #3 of this guideline). Both generic and disease-specific instruments have been used to assess quality of life or functional status in hemodialysis patients. Of the studies reviewed for this guideline, 97 reported quality of life data from 72 unique studies. The 72 studies used over 150 different assessment instruments and strategies to assess quality of life, functional status, psychosocial adjustment, and related constructs. An accurate account of the instruments is difficult because several studies used instruments that were poorly described or poorly referenced. Several studies used unstandardized and/or single-item instruments with unknown or questionable reliability and validity. The most frequently used standardized and well-known instruments included variations of the Karnofsky Performance Status Scale²⁸³ (n=23), the Medical Outcomes Study 36-item Short Form (SF-36)²⁸⁴ or the Medical Outcomes Study 20-item Short Form (SF-20)²⁸⁵ (n=14), the Beck Depression Inventory²⁸⁶ (n=9), and the Sickness Impact Profile²⁸⁷ (n=8). Disease-specific instruments, such as the Kidney Disease Quality of Life (KDQOL) instrument,²⁸⁸ were also used less frequently. Quality of life and functional status can be assessed by a variety of methods: patient self-report, interviewer administered, and provider or significant other ratings. It is not clear to what extent provider or patient reports of quality of life for a particular patient are comparable. Only three studies reviewed for this guideline examined differences between providers and patients' ratings of QOL. One study compared patients', nurses', and nephrologists' ratings in 119 dialysis patients;²⁸⁹ the second compared patients' and nurses or dietitians' ratings of 49 patients;^{290,291} and a third study compared patients self-ratings to nurses' ratings in 256 patients.²⁹² Although these studies suggest that patients' and providers' ratings are significantly different, these results should be interpreted with caution because of multiple methodological problems.

Quality of life measurement in dialysis has developed rapidly in the past several years. Readers wishing to implement a program to monitor quality of life may wish to consult two recent reviews of quality of life measures used in dialysis settings.^{293,294} These developments include the modifications of the Dartmouth COOP Functional Health Assessment Charts for dialysis use and the creation by the Johns Hopkins Patient Outcome Research Team CHOICE study of the CHOICE Health Experience Questionnaire.^{295,296} In addition, one of the studies reviewed for this guideline reported on a clinic's experience in using the SF-36 as an outcome measure over a three-year period.²⁹⁷

The Working Group felt that patients are the best judges of their quality of life and that patients' views should be respected. The most commonly used self-report instrument to assess quality of life or functional status in our systematic review of the literature was the SF-36.²⁸⁴ A few patients, however, are incapable or unwilling to rate their quality of life.^{297,298} An example of an instrument that is provider rated, the Karnofsky Performance Status Scale,²⁸³ is provided on the following page.

Karnofsky Performance Status Scale

The Karnofsky Performance Status Scale (KPS) is an older and widely used method of quantifying the functional status of cancer patients and was the most commonly used instrument to assess functional status in our systematic review of the renal literature.²⁸³ As originally conceived, the KPS has three alphabetic groups for classifying patients' ability to work, to carry on normal activity, and to care for themselves.²⁸³ These alphabetic groups are further divided into 11 categories, which cover all possible levels of functioning from completely normal (100) to dead (0). Modifications of the scale have also been used, including a 4-point version¹⁶⁸ Although originally designed as a clinician rating scale, patient self-report versions are also available.^{61,292,299-301}

Performance Status

Condition	Percentage	Comments
A. Able to carry on normal activity and to work. No special care is needed.	100	Normal, no complaints, no evidence of disease.
	90	Able to carry on normal activity, minor signs or symptoms of disease.
	80	Normal activity with effort, some signs or symptoms of disease.
B. Unable to work. Able to live at home, care for most personal needs. A varying degree of assistance is needed.	70	Cares for self. Unable to carry on normal activity or to so active work.
	60	Requires occasional assistance, but is able to care for most of his needs.
	50	Requires considerable assistance and frequent medical care.
C. Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly.	40	Disabled, requires special care and assistance.
	30	Severely disabled, hospitalization is indicated although death not imminent.
	20	Hospitalization necessary, very sick, active supportive treatment necessary.
	10	Moribund, fatal processes progressing rapidly.
	0	Dead.

Dealing with Difficult Patients

Readers interested in developing local strategies to deal with difficult patients may wish to review the following exemplative set of recommendations developed by the Southeastern Kidney Council to reduce the incidence of disruptive/ abusive patient behavior in their facilities. The recommendations were designed to guide staff in dealing with difficult behavior appropriately and consistently. The recommendations are reproduced below with the permission of Network 6. The recommendations are also available on the web at the following address:

www.esrdnetworks.org/networks/net6/policies/po-recom.html

Purpose and Recommendations for Dealing with Disruptive and/or Abusive Behavior

Purpose

The purpose of these recommendations is to reduce the incidence of disruptive/abusive patient behavior that occurs in dialysis facilities and to guide staff in dealing with it appropriately and consistently. These recommendations are not a standard or regulation. They are advisory in nature, informational in content, and are intended for use by facility staff seeking to provide a safe and therapeutic environment. This document is not intended as a substitute for a specific policy tailored to a particular facility. The Southeastern Kidney Council assumes no liability for any use of this document. Nothing in this document shall be construed to supersede, or in any manner affect, and/or interrupt any federal, state, or local civil or criminal law. The content of this document is strictly the opinion of the Southeastern Kidney Council itself, and is not representative of any individual member.

Background Information

The Network often receives calls from facility staff for guidance in dealing with disruptive and/or abusive patient behavior. The Network is also often contacted by patients to complain about their rights, their care, and to report being kicked out of their facility. A Network survey of patient grievances and requests for assistance in dealing with disruptive and/or abusive behavior revealed that the number has risen dramatically over the last several years. Other Networks have expressed a similar trend. What is the reason for this increase?

- Are patients not as cooperative in following their treatment plan as they used to be?
- Are more patients being dialyzed who have a history of verbally or physically abusing others? Are patients less willing to take responsibility for their own health as before?
- Are more patients being dialyzed who just don't care about living?

OR

- Are renal professionals not educating their patients about the expectations and realities of dialysis as much as before?
- Is less time taken to individualize care?
- Are renal professionals assessing their patients' education needs less accurately or communicating with their patients less than they used to?
- Are renal professionals busier with more patients with a higher number of co-morbid conditions resulting in increased stress and less time to focus on their patients' needs and problems?

The reason for this trend is most likely a combination of many factors. Whatever the reasons, it is an unfortunate reality that dialysis staff are often called upon to treat patients whose behavior is threatening and potentially dangerous. It is also unfortunate that patients are often notified that they must correct certain problematic behaviors or obtain dialysis services elsewhere.

By the time the Network is contacted by facility staff, most psychosocial interventions have already been exhausted. Callers are interested in the Network policy regarding disruptive and/or abusive behavior and the legalities involved in terminating the professional relationship.

In response to the increase in this type of grievance activity in Network 6, the Southeastern Kidney Council Board of Directors asked the Southeastern Kidney Council Consumer Committee to develop recommendations for facility staff regarding these situations. All eighteen ESRD Networks were surveyed. They were asked if they had developed similar recommendations and if so, a copy was requested. A subcommittee was formed to review the information. These written recommendations were developed and approved by the Consumer Committee, Medical Review Board and Board of Directors. The Southeastern Kidney Council would like to express its appreciation to the ESRD Networks for sharing their materials with the members of the subcommittee.

The Southeastern Kidney Council has no formal policy regarding the handling or termination of disruptive and/or abusive patients. Providers are guided by Federal Regulation Section 405.2138[b][2], which requires that patients be transferred or discharged only for the following reasons:

- Medical reasons,
- The patient's welfare or that of other patients, or
- Nonpayment of fees (except as prohibited by Title XVIII of the Social Security Act), and that patients be given advance notice to ensure orderly transfer or discharge. The Federal Regulations leave much interpretation to the discretion of individuals. The terms “medical reasons,” “patient welfare,” and “advance notice” are not defined. The regulations clearly allow for the transfer or discharge of patients in some instances. It is also clear that the law requires advance notice and assistance with transfer. However, **the ultimate goal for renal professionals should be to avoid termination.**

The Network will continue to provide education to facility staff and patients, develop resource materials, and serve as a consultant to facility staff regarding specific cases.

Recommendations

The following steps are recommended by the Southeastern Kidney Council in order to prevent and resolve disruptive and abusive behavior:

Step 1: Policy Regarding Disruptive/Abusive Patients

The Network strongly recommends that each dialysis facility have a written policy that addresses disruptive and abusive patient behavior. It is important that this policy be developed before a response to a particular incident is required. Once a policy is developed, the staff should be educated to ensure that these situations are handled appropriately and consistently. The policy should address the behavior of patients on the entire premises of the facility, not just inside the building. The policy should include steps to be taken in the event of threatening or violent behavior. The Network recommends that all threats or acts of violence be taken seriously and reported to the police. The intensity of the threat may require that the police or security guards be present during each treatment until transfer takes place. In order to prevent weapons from being

brought into the facility, it is recommended that the policy prohibit patients and staff from carrying weapons and that the facility posts “No Weapons Allowed” signs on its doors.

It is recommended that the unit policy regarding disruptive/abusive patients be reviewed by an attorney before being implemented.

Step 2: Agreement of Expectations

Clearly defined expectations between the patient and the facility can help to prevent conflicts from occurring. The intent of such documents should be to state, in objective and measurable terms, the responsibilities of facility staff and the responsibilities of patients. Each patient at the facility should be required to enter into this agreement upon initiation of dialysis services as a part of patient orientation to the facility. It is recommended that the Agreement of Expectations be reviewed annually and as needed with each patient and/or a family member. If the patient's behavior becomes disruptive, a more specific behavior contract may be developed for the patient. The Network has examples of Agreement of Expectations forms. If you would like assistance in developing one, please contact the Network office.

Step 3: Rules of Conduct

Written rules of conduct for patients and staff should be established in each facility. When establishing these rules, it is important to keep in mind that:

- These rules apply to all patients at all times.
- Staff must be willing to enforce the rules with all patients in the same equitable manner.
- Staff should be able to justify the establishment of all rules to patients and family members.
- Rules of conduct should indicate a zero-tolerance for violence and threats of violence. This means that violence of any type which can range from intimidation, threats, and harassment to assault, rape and homicide, will not be tolerated and that any and all violators of this policy will be dealt with in a swift, judicious, and definitive manner.
- Inform patients that verbally abusive or threatening behavior is unacceptable and could lead to termination.

Step 4: Develop an Action Plan

Even with an Agreement of Expectations in place, problems may occur. The members of the healthcare team (MD, RN, SW, and RD) should arrange a conference with the patient to discuss the situation and develop a plan to resolve it. Family members and the patient representative should also be included, if possible. During this meeting, the staff and patient should identify the specific problems, contributing factors, and possible solutions. The staff should counsel the patient regarding specific behaviors. The staff should inform the patient of the consequences of inappropriate behaviors. A written plan to correct the problem should be developed and signed by the patient and staff. The patient care staff should be informed of the planned approach to be used in dealing with specific behaviors. Thorough documentation of the specific behaviors that are being addressed and the steps taken to correct the problem is essential. The staff may want to ask the patient representative to assist in carrying out the plan. The patient should be made aware of the Southeastern Kidney Council and his right to file a grievance. Facilities may want to consider forming a committee of individuals who are skilled at dealing with these types of situations to be responsible for developing the action plan. This committee should have additional training on dealing with behavioral problems, and should also be responsible for educating staff and assisting when a crisis develops.

Step 5: Behavior Contract

If the problem continues, the treatment team should meet again with the patient. Family members and the patient representative should also be included, if possible. The team and the patient should again identify possible reasons for the problem and potential solutions. A behavior contract should be developed which outlines specific patient and staff responsibilities related to the problem identified and consequences for violation of this contract. Consider including a psychiatric evaluation (or alternate care from an appropriate mental health care professional) in the contract. The patient and staff should develop mutually agreed upon consequences for violation of the agreement. The contract should be signed by the patient and each member of the treatment team. If the patient refuses to sign the contract, a witness should co-sign with documentation that the patient refused. Some facilities have been successful at involving both a legal representative as well as a member from the law enforcement community at these meetings. Thorough documentation of all steps taken to resolve the situation must be completed. Keep in mind that termination of dialysis services should be the last resort in resolving the situation. It is imperative that all possible interventions have been explored before the facility takes steps towards discharging the patient. If either the staff or the patient feels that the expectations of the contract are unreasonable or that the contract has not been honored, additional meetings can be called to discuss the contract further. The Network has sample Behavior Contract forms. If you would like assistance in developing one, please contact the Network office.

Step 6: Termination

If all forms of intervention have been exhausted, the facility staff may decide to terminate the facility-patient relationship. Facility and/or physician-initiated termination is a serious event, especially if the patient is acutely ill, and should be undertaken only after genuine attempts are made to understand and resolve differences (American College of Physicians, 1998). Before proceeding, the facility should have the following documentation in the patient's medical record:

- Specific problem behaviors.
- The impact of the patient's behavior on other patients and the staff.
- All steps taken by the facility to resolve the problem.
- The patient's response to the steps taken.

It is recommended that the facility contact legal counsel before making the decision to terminate.

If a decision is made to terminate the relationship, the facility must notify the patient in writing and include the following information:

- Date of termination. The patient must be given reasonable notice. Thirty days is usually recommended. More time may be necessary to make alternate arrangements; i.e., in rural areas.
- The reason for termination including specific examples.
- Assure the patient that the facility will provide all dialysis care for the patient during the thirty day period.
- A list of facilities with phone numbers for the patient to contact.
- Inform the patient that the facility will assist the patient with placement and will transfer medical records to other facilities.
- Emphasize to the patient the importance of finding another facility for continued care.

Send copies of the letter to the patient via certified mail, return receipt requested, and via regular mail. Also send a copy of the letter to the patient representative (if desired), physician, the facility's legal counsel, and the Network.

If an orderly transfer cannot be arranged, the facility should try to arrange an alternative such as:

- Sharing the patient on a rotating basis among several local facilities, or
- Offering another facility the opportunity to accept the patient on a trial basis. They may agree to provide dialysis for a period of time (30-60 days) at which time if the patient's behavior has not been considered acceptable, the patient would return to the transferring facility until another suitable placement can be found.

Cooperation between dialysis facilities will assist all providers in dealing with difficult patients. This may include an exchange system with other community ESRD facilities. Providers may want to consider “switching” patients indefinitely, or for a predetermined period of time.

Once a facility decides to terminate a patient, the physician may or may not decide to terminate the patient from his services, assuming that the physician has admitting privileges at another facility. Differences in state laws may add another dimension to termination of the doctor-patient relationship and should be examined carefully by the physician involved. If the physician decides to terminate the relationship, a separate letter should be written to inform the patient. This letter should include the date of termination, specific reasons for termination, and a list of other nephrologists with phone numbers for the patient to contact. The patient should be given adequate notice and should be informed that he will be assisted in finding another nephrologist for continued care.

Grievance Procedures

Subpart U of the Federal Regulations requires all ESRD facilities to have both a written statement of patient rights and responsibilities and a written grievance procedure. ESRD Network organizations have been charged by the Health Care Financing Administration to evaluate and resolve patient grievances. Information about the facility and Network grievance procedures must be available to patients, family members, and facility staff. The Network has advised all facilities to post the Network grievance procedure where all patients can read it. If the patient decides to file a grievance with the Network, they will be required to submit it in writing. The Network will then request the following documentation from the facility:

- A copy of the facility's Policy on Abusive/Disruptive Behavior.
- Signed Agreement of Expectations.
- Specific documentation from the patient's medical record describing the inappropriate behavior.
- Minutes of multidisciplinary meetings with the patient. This should include the Action Plan that was developed.
- Results of psychiatric evaluation.
- Signed Behavior Contract.
- A copy of the termination letter.
- The Network staff will evaluate the grievance based upon the patient's complaint and the facility's documentation. If necessary, the co-chairs of the Grievance Committee will be contacted for assistance.

Education

The Southeastern Kidney Council recommends the following related educational programs:

Education of Patients

The following education is recommended for ALL patients and/or family members at initiation of dialysis, annually, and as needed:

- Patient rights and responsibilities.
- The nature and consequences of uncooperative and abusive behavior.
- The facility's policy for handling disruptive/abusive patients.
- The facility's policy for zero-tolerance of violence and threats of violence.

Education of Facility Staff

The following education is recommended for ALL new hires and as an annual required inservice program for ALL staff:

- The nature of disruptive or abusive behavior in individuals with a chronic disease.
- Strategies for dealing with the uncooperative or abusive patient and strategies to prevent the escalation of aggressive behavior.
- Therapeutic communication techniques and aggression management.
- Professional behavior and the responsibility to treat all patients with respect no matter what their personal feelings.
- Patient rights and responsibilities.
- The facility's policy for handling disruptive/abusive patients.
- Related federal regulations.

Workplace Violence Prevention Program

The Occupational Safety and Health Act (OSHA) of 1970 mandates that all employers have a legal duty to provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm (U.S. Department of Labor, 1996). Employers can be cited for violating the General Duty Clause if there is a recognized hazard of workplace violence in their establishments and they do nothing to prevent or abate it. It is suggested that workplace policies indicate a zero-tolerance for violence of any kind.

The Network recommends that each facility establish, implement, and maintain a written Workplace Violence Prevention Program in order to focus on the prevention of any incidents before they occur. Employees should receive specific training concerning its content and implementation. This program should include a written policy that indicates a zero-tolerance for workplace violence or threats of violence. A procedure for reporting violent incidents should be developed. The prevention program should also consist of:

- Staff education.
- Developing a liaison with law enforcement representatives and others who can help identify ways to prevent or reduce incidents and assist if an incident does occur. This partnership may also assist in identifying potentially dangerous or unsafe conditions at the facility.
- Reporting all incidents in order to identify program improvements.
- Using staff screening tools to identify concerns staff may have for their safety.

- Adopting measures to decrease waiting time and reduce the emotional stress to patients.
- Assessing the behavioral history of new patients and establish a system to identify patients at high-risk for violence.
- Using Case Management conferences which include direct patient care staff to discuss techniques for dealing with patient behavior.
- Making arrangements to share the potentially violent patient among several facilities before an incident occurs.
- When an incident does occur, providing staff with post-incident support to reduce feelings of fear and trauma.

OSHA provides a free consultative service in selected states to assist employers who would like assistance in implementing a Workplace Violence Prevention Program. For information contact:

SC Onsite Consultative Program Licensing and Regulation, SCDOL
3600 Forest Drive
P.O. Box 11329
Columbia, SC 29211
(803) 734-9614

Georgia Onsite Consultation Program
Georgia Institute of Technology
O’Keefe Building - Room 23
Atlanta, GA 30332
(404) 894-2643

North Carolina Consultative Services
NC Dept of Labor
319 Chapanoke Road, Suite 105
Raleigh, NC 27603-3432
(919) 662-4644

Providers are encouraged to read “Guidelines for Preventing Workplace Violence for Health Care and Social Service Workers.” Copies can be obtained from the OSHA Publications Office, P.O. Box 37535, Washington, DC, 20013-7535 or from the Network office.

References

American College of Physicians. (1998). Ethics manual (4th ed.). *Annals of Internal Medicine*, 128, 576-594.

U.S. Department of Labor-Occupational Safety and Health Administration. (1996). *Guidelines for preventing workplace violence for health care and social service workers*. Washington, D.C.: U.S. Department of Labor.

The Southeastern Kidney Council would like to thank the following Networks for sharing their publications and allowing us to expand on their well-written documents:

- ESRD Network of Texas
- Mid-Atlantic Renal Coalition
- ESRD Network of New England
- ESRD Network Organization #13
- The Renal Network

- TransPacific Renal Network
- Northwest Renal Network
- ESRD Network of New York
- Intermountain ESRD Network
- ESRD Network of Florida

Also, special thanks to the members of the subcommittee as well as the members of the Medical Review Board, Consumer Committee, and the Board of Directors who contributed to this project.

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Checklist for Facility Staff

Policy Regarding Disruptive/Abusive Patients

- Develop written policy.
- Educate staff regarding policy.

Agreement of Expectations

- Have all patients sign Agreement of Expectations forms upon initiation of dialysis services, annually, and as needed.

Rules of Conduct

- Develop written rules of conduct for patients and staff.
- Educate patients and staff regarding rules of conduct.

Education

- Implement plan for staff and patient education as recommended by Network.

Workplace Violence Prevention Program

- Establish, implement, and maintain a written program
- Educate staff concerning the content and implementation of the program

When Dealing with an Abusive/Disruptive Patient

Develop an Action Plan

- Hold multi-disciplinary conference with patient (MD, RN, SW, RD). Also include family members and patient representative, if possible.
- Develop written Action Plan to be signed by patient and staff.
- Document specific patient behaviors and steps taken to correct problem.
- Notify patient of right to file grievance.

Behavior Contract

- Hold multi-disciplinary conference held with patient (MD, RN, SW, RD). Include family members and patient representative, if possible. Also consider including legal representative and/or law enforcement.

- Develop written Behavior Contract. Consider including psychiatric evaluation in the Contract.
- Hold additional conferences with patient to discuss Behavior Contract, if necessary.

Termination

- Explore all possible interventions before taking steps toward discharge.
- Ensure that specific problem behaviors, the impact of the behaviors on other patients and staff, all steps taken to resolve the problem, and the patient's response to steps taken are thoroughly documented.
- Contact legal counsel.
- Contact Network office.
- Notify patient in writing.
- Assist patient with placement.
- Consider alternate arrangements if permanent placement not possible.

National Kidney Foundation Checklists

The National Kidney Foundation's *Initiation or Withdrawal of Dialysis in End-stage renal disease: Guidelines for the Health Care Team*³⁰² included helpful checklists to follow in initiating dialysis, withdrawing dialysis, and in helping patients to prepare for dying.

Initiation of Dialysis Checklist

Patient's name, address, and telephone number:

Name, address, and telephone number of surrogate designated by advance directive, if applicable:

Names, addresses, and telephone numbers of significant other and family members (contact only with the consent of the patient if competent, or otherwise, the surrogate):

1. Pre-evaluation information:

- a. If applicable, attach a copy of the patient's advance directive(s) or other statement(s) of the patient's wishes and decisions regarding life sustaining medical treatment. State the type of directive executed.

- b. Materials should be reviewed for familiarization. The patient/surrogate should be asked to clarify any matters which may be unclear, incomplete or not in compliance with applicable state law. If the advance directive is only a treatment directive, ask if the patient wishes to designate a surrogate. If there is only a surrogate designation, ask if a treatment directive is considered appropriate.

- c. Assess whether the patient has the capacity to make medical decisions concerning initiation of dialysis and/or regarding other matters likely to require decisions in the foreseeable future (i.e. circumstances that would warrant a DNR order or discontinuation of dialysis). Document the methods used to determine capacity.
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- d. If the patient lacks capacity, assess whether it is temporary or permanent or related only to one of more medical decisions. Document the methods used to determine capacity.
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- e. If the patient lacks capacity and does not have an advance directive designating a surrogate, the physician or health care team treating the patient should consult with legal counsel to determine who can make medical decisions for the patient and what, if any, restrictions apply to such authority. The person who can act, the legal basis for that person's authority (i.e. health care power of attorney, health care proxy, court appointed guardianship, parent of minor) and the limitations on her/his authority are as follows:
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- f. Date, time and place of the discussion and decision to initiate or withhold dialysis, including the name of the person(s) making the decision and who else was present.
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- g. If there was a decision to withhold dialysis, identify any close family members/others who might object to withholding dialysis, and determine if the patient/surrogate has discussed not initiating dialysis with them. Explain why they might object to the decision to withhold dialysis.
-
-

2. Evaluation of Patient:

- a. Determine the reasons or conditions underlying the patient's/surrogate's desires regarding initiation of dialysis. Such assessment should include specific medical, physical, spiritual and psychological issues, as well as interventions which could be appropriate.

Some of the potentially treatable factors that might be identified by the assessment are:

- Fear of dialysis, possibly due to a lack of information about treatment;
- Underlying medical disorders, including the prognosis for short- or long-term survival on dialysis;

- The patient’s assessment of quality of life and ability to function prior to initiation of dialysis and preconceptions of anticipated quality of life and ability to function after initiation of dialysis;
 - The patient’s short- and long-terms goals;
 - The burden that cost of treatment/medications/diet/transportation may have on the patient/family/others;
 - The patient’s psychological condition, including conditions/symptoms that may be caused by uremia;
 - Undue influence or pressure from outside sources, including the patient’s family;
 - Conflict between the patient and others.
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b. If the patient/surrogate does not want dialysis initiated, consideration might be given to the use of psychometric tools, such as the Beck Depression Inventory, the Karnofsky Scale, the SF 36 Health Survey or similar measurement instruments. They could aid in identifying specific problems which could impact the decision. Identify any such tools used and the results.

c. 1. Have the patient/others received education about various ESRD treatment modalities and settings and the possibility of a trial period on dialysis to permit them to make an informed and knowledgeable decision on whether to initiate dialysis? Describe.

2. Have the patient/others spoken to dialysis patients with similar illnesses and/or cultural and socioeconomic backgrounds to learn the patient’s/ other’s perspective of the quality of life on dialysis?

d. If the patient/surrogate does not want dialysis initiated, did he/she consent to referral to a counseling professional? (e.g. social worker, pastoral care, psychologist or psychiatrist) If yes, identify and describe any findings or recommendations.

- e. 1. If the patient/surrogate does not want dialysis initiated, are there interventions that could alter the patient's circumstances which might result in him/her considering it reasonable to initiate dialysis? Describe possible interventions.

2. Does the patient/surrogate desire the proposed intervention(s)?

3. A determination has been made that the following intervention(s) will be undertaken.

- f. In cases where the surrogate has made the decision to either initiate or withhold dialysis, has it been determined that the judgment of the surrogate is consistent with the stated desires of the patient? Describe.

3. The Dying Process if ESRD Treatment is Withheld:

- a. Have the patient/others been given advice and information on the clinical course of the patient dying of uremia or an underlying illness? Describe.

- b. Have the patient/others been provided with counseling and information on bereavement issues? Describe.

- c. Have the patient/others been advised that the health care team will attempt to provide them with all necessary emotional, spiritual, social and medical assistance and support possible? The following assistance and support have been offered:

- d. Has the question of where the patient desires death to occur been discussed with the patient/surrogate? The patient/surrogate has made the following decision:

- e. 1. If the patient desires to die at home, have the patient/care givers been offered assistance in obtaining supportive services from agencies and providers, including hospice and home health care? (List services offered and those that were accepted.)
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2. Has there been discussion about whether emergency medical services in the community will honor DNR orders or an advance directive?
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- f. If the patient/surrogate has decided not to initiate dialysis at this time, has he/she advised that the decision can be reconsidered at a later date and given serious consideration by the physician?
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Withdrawal of Dialysis Checklist

Patient's name, address, and telephone number:

Name, address, and telephone number of surrogate designated by advance directive, if applicable:

Names, addresses, and telephone numbers of significant other and family members (contact only with the consent of the patient if competent, or otherwise, the surrogate):

1. Pre-evaluation Information:

- a. If applicable, attach a copy of the patient's advance directive(s) or other statement(s) of the patient's wishes and decisions regarding life sustaining medical treatment. State the type of directive executed.

- b. Materials should be reviewed for familiarization. The patient/surrogate should be asked to clarify any matters which may be unclear, incomplete or not in compliance with applicable state law. If the advance directive is only a treatment directive, ask if the patient wishes to designate a surrogate. If there is only a surrogate designation, ask if a treatment directive is considered appropriate.

- c. Assess whether the patient has the capacity to make medical decisions concerning withdrawal of dialysis. Document the methods used to determine capacity.

- d. If the patient lacks capacity, assess whether it is temporary or permanent or related only to one or more medical decisions. Document the methods used to determine capacity.
-
-

- e. If the patient lacks capacity and does not have an advance directive designating a surrogate, the physician or health care team treating the patient should consult with legal counsel to determine who can make medical decisions for the patient and what, if any, restrictions apply to such authority. The person who can act, the legal basis for that person's authority (i.e. health care power of attorney, health care proxy, court appointed guardianship, parent of minor) and the limitations on her/his authority are as follows:
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- f. If there was a decision to withdraw dialysis, indicate the date, time and place of the discussion and decision to withdraw dialysis, including the name of the person(s) making the decision and who else was present.
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- g. If there was a decision to withdraw dialysis, identify close family members/others who might object to withdrawal of dialysis, and determine if the patient/surrogate has discussed withdrawing dialysis with them. Explain why they might object to the decision to withdraw dialysis therapy.
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2. Evaluation of Patient:

- a. Determine the reasons or conditions underlying the patient/surrogate desires regarding withdrawal of dialysis. Such assessment should include specific medical, physical, spiritual and psychological issues, as well as interventions which could be appropriate.

Some of the potentially treatable factors that might be included in the assessment are:

- Underlying medical disorders, including the prognosis for short- or long-term survival on dialysis;
- Difficulties with dialysis treatments;
- The patient's assessment of his/her quality of life and ability to function;
- The patient's short- and long-terms goals;
- The burden that costs of continued treatment/medications/diet/transportation may have on the patient/family/others;
- The patient's psychological condition, including conditions/symptoms that may be caused by uremia;
- Undue influence or pressure from outside sources, including the patient's family;
- Conflict between the patient and others;

- Dissatisfaction with the dialysis modality, the time or the setting of treatment.
-
-

b. If the patient/surrogate wishes to withdraw from dialysis, consideration might be given to the use of psychometric tools, such as the Beck Depression Inventory, the Karnofsky Scale, the SF 36 Health Survey or similar measurement instruments. They could aid in identifying specific issues which could impact the decision. Identify any such tools used and the results.

c. If the patient/surrogate wishes to withdraw dialysis, did he/she consent to referral to a counseling professional? (e.g. social worker, pastoral care, psychologist or psychiatrist) If yes, identify and describe any findings or recommendations.

d. 1. If the patient/surrogate wishes to withdraw dialysis, are there interventions that could alter the patient's circumstances which might result in him/her considering it reasonable to continue dialysis? Describe possible interventions.

2. Does the patient/surrogate desire the proposed intervention(s)?

3. A determination has been made that the following intervention(s) will be undertaken.

e. In cases where the surrogate has made the decision to either continue or withdraw dialysis, has it been determined that the judgment of the surrogate is consistent with the stated desires of the patient? Describe.

3. The Dying Process if ESRD Treatment is Withdrawn:

a. Have the patient/others been given advice and information on the clinical course of the patient dying of uremia or of the patient's underlying illness? Describe.

- b. Have the patient/others been provided with counseling and information on bereavement issues? Describe.

- c. Have the patient/others been advised that the health care team will attempt to provide them with all necessary emotional, spiritual, social and medical assistance and support possible? The following assistance and support have been offered:

- d. Has the question of where the patient desires death to occur been discussed with the patient/surrogate? The patient/surrogate has made the following decision:

- e. 1. If the patient desires to die at home, have the patient/care givers been offered assistance in obtaining supportive services from agencies and providers, including hospice and home health care? (List services offered and those that were accepted.)

2. Has there been discussion about whether emergency medical services in the community will honor DNR orders or an advance directive?

- f. If the patient/surrogate has decided to withdraw dialysis, has he/she been advised that the decision can be reconsidered at a later date and given serious consideration by the physician?

Preparation for Dying Checklist

(The physician might consider discussing and providing this checklist to the patient/surrogate after a determination has been made not to initiate or to withdraw dialysis.)

The patient/surrogate may wish to consult with an attorney, accountant, spiritual advisor or others to discuss these or other matters that may be important given the patient's particular circumstances. Consideration should be given to providing copies of the relevant documents, such as an advance directive, to the patient's surrogate, the patient's family/significant other, primary physician and/or attorney.

A patient who has decided not to initiate or to withdraw dialysis should have or consider preparing the following documents:

- A will.
- Signed advance directive (living will, durable health care power of attorney or health care proxy, DNR order) complying with applicable state law.
- A durable power of attorney complying with applicable state law designating someone to act on the patient's behalf on all matters other than medical, including legal, financial, banking and business transactions. (A power of attorney must be "durable" if it is to remain in effect even if the individual becomes unable to make his or her own decisions or dies.)
- An inventory, including the location of her/his bank, brokerage and other financial accounts, stock and bond holdings not in brokerage accounts, real estate and business records and documents, medical and other insurance policies, pension plans and other legal documents.
- Names, addresses and telephone numbers of attorney, accountant, family members/significant other, friends and business associates who should be notified of the death or may have information that will be helpful in dealing with estate affairs.
- Documentation concerning preferences for funeral/memorial services, burial or cremation instructions and decisions about organ, tissue or body donation.
- Written or video or audio taped message to family/significant other, business associates and friends.

SECTION 8: ACKNOWLEDGEMENTS

The RPA and ASN wish to acknowledge the following individuals who have contributed significantly to this project.

Steering Panel

The Steering Panel was comprised of RPA and ASN representatives who possessed expertise in clinical practice guideline development.

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SECTION 9: GLOSSARY

Advance Care Planning: A process of communication among the patient, his/her family and friends, and the health care team in which the patient's preferences for a surrogate and for future medical care are determined prospectively (sometimes including the completion of a written advance directive), updated periodically, and respected when the patient no longer has the capacity to participate in medical decision-making.

Advance Directive: An oral or written statement by a patient with decision-making capacity expressing his/her preferences for a surrogate and/or for future medical care in the event he/she becomes unable to participate in medical decision-making. All 50 states have one or more laws recognizing written advance directives. There are two types of advance directives, a living will and a health care proxy. The health care proxy is known in some states as a medical power of attorney or a durable power of attorney for health care. The living will, also known as an instruction directive, indicates a patient's wishes to be followed if he loses decision-making capacity. Wishes may refer to care in the event of particular medical conditions such as a terminal illness or a persistent vegetative state. The health care proxy designates a person to make decisions for a patient when the patient loses decision-making capacity. In some states, both of these functions are combined in the living will.

Beneficence: Ethical principle that obliges persons to benefit or help others. This principle requires positive action: to prevent what is bad or harmful; to remove what is bad or harmful; and to do or promote what is good or beneficial.

CPR (Cardiopulmonary Resuscitation): Clinical interventions initiated at the time of cardiac or respiratory arrest aimed at maintaining life. These include chest compression, artificial ventilation, and electrical shock.

Decision-Making Capacity: The capacity to 1) understand one's medical condition; 2) appreciate the consequences (benefits and burdens) of various treatment options including nontreatment; 3) judge the relationship between the treatment options and one's personal values, preferences, and goals; 4) reason and deliberate about one's options; and 5) communicate one's decisions in a meaningful manner.

DNR (Do Not Resuscitate) Order: Medical record order including that a patient should not receive CPR.

End of Life Care: A subset of palliative care that is provided to dialysis patients who are terminally ill.

Forgo: to do without, abstain from, give up, withdraw, or withhold dialysis.

Guideline: A systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They are a set of statements, directions, or principles presenting current clinical rules or policy concerning proper indications for performing a procedure or treatment or for the proper management of specific clinical problems.

Hospice: A team approach to treatment of the terminally ill patient, usually in the home, that uses the principles of palliative care to help meet the physical, psychological, social, and spiritual needs of the patient and family. Hospice treats the person, not the disease; considers the entire family the unit of care; and provides bereavement counseling for the family after the patient's death.

Justice: An ethical principle that requires a fair distribution of benefits and burdens. Justice requires that persons receive that which they deserve and to which they are entitled. This principle is involved in decisions to allocate scarce health care resources. The specifics of how to implement this principle remain controversial in many situations.

Legal Agent: An individual named by the patient in an advance directive (variously named in different states a health care proxy, a durable power of attorney for health care, a medical power of attorney, or a living will) to make medical decisions for the patient in the event of the patient's loss of decision-making capacity or, if the patient has not completed an advance directive, the person selected to be the surrogate decision maker for the patient according to state law.

Medically Appropriate: Diagnostic or therapeutic intervention in which the expected benefits justify the risks.

Nonmaleficence: An ethical principle that obliges persons to refrain from harming others, including to refrain from killing them or treating them cruelly. It is one of non-intervention. It also requires persons to exercise due care so that they do not unintentionally harm others through actions such as reckless driving or careless surgical procedures.

Palliative Care: Active total treatment of the patient whose disease is not responsive to curative treatment. It affirms life and regards dying as a normal process. It neither hastens nor postpones death. It includes relief from pain and other distressing physical symptoms, integrates the psychological and spiritual aspects of patient care, and offers a support system to help the family cope during the patient's illness and in their own bereavement. Palliative care should be provided to ESRD patients throughout their course.

Professional Integrity: The ethical principle that requires physicians and other health care professionals to act in a manner consistent with the shared values of their profession. For example, physicians and other health care professionals are guided by values that require them to be of benefit and do no harm.

Renal Care Team: A group of health care professionals that provides dialysis care to dialysis patients and which usually includes one or more of the following: nephrologist, physician's assistant, advanced practice nurse, nephrology registered nurse, nephrology social worker, renal dietitian, and dialysis technician. The renal care team often works in conjunction with a primary care physician to insure comprehensive care for the ESRD patient.

Respect for Autonomy : An ethical principle based on the concept that people should be autonomous to the extent that they are able to understand and make decisions for themselves that are intentional and voluntary. The principle of respect for autonomy places importance on allowing persons to make important decisions for themselves. The legal right of patient self-determination is based on this principle.

Shared Decision-Making: Process by which physicians and patients come to agreement on a specific course of action, based on a common understanding of the goals of treatment and the risks and benefits of the chosen course compared with any reasonable alternatives.

Surrogate: A person who has the legal authority to make decisions for a patient who lacks decision-making capacity. A surrogate is usually a family member, but may be a close friend. A surrogate should make treatment decisions for a patient based on either the patient's expressed wishes, or upon the patient's known values and beliefs (a process known as "substituted judgment"), or when these are unknown, the patient's best interests.

Terminal Illness: Illness in which death is expected within six months.

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