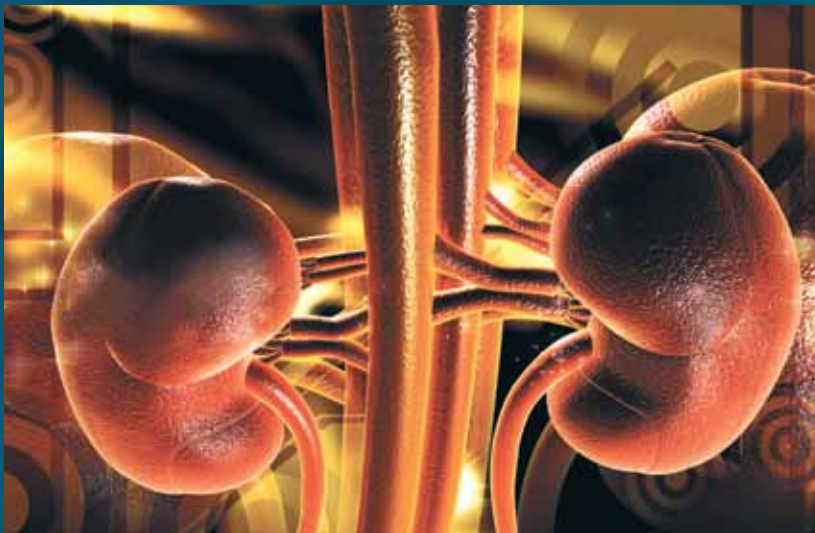


Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis

Clinical Practice Guideline

Second Edition



RPA

Renal Physicians Association

Rockville, Maryland
October 2010

About the Renal Physicians Association

www.renalmd.org

Since 1973 the Renal Physicians Association (RPA) has been dedicated to representing and serving nephrology practitioners in their pursuit and delivery of quality renal health care. RPA is a non-profit 501c6 national nephrology specialty medical association with over 4,000 members serving kidney patients. Our programs focus in the areas of practice management, public policy and quality patient care. We are the voice of nephrology practice and a committed advocate to the renal community, payers and federal policy makers. Our membership is comprised of physicians, physician assistants, advanced nurse practitioners and practice managers. These nephrology healthcare providers are engaged in diverse activities, including the practice of medicine, teaching, research, administration and they are devoted to improving the care of patients with kidney disease and related disorders. We provide timely and relevant programs along with current nephrology tools and resources to make certain our members maintain their highest level of professional satisfaction. To obtain more information about RPA or to become a member please contact us at (301) 468-3515 or by email at rpa@renalmd.org.

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RPA Clinical Practice Guideline on Shared Decision-Making in the Initiation of and Withdrawal from Dialysis, 2nd Edition.

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This guideline is intended to provide a framework for clinical practice and is not intended to be used as a substitute for clinical judgment or as a basis for legal action.

The American Society of Nephrology (ASN) is a not-for-profit organization that is dedicated to the advancement of nephrology and the improvement of patient care.

This guideline is a product of the ASN's Clinical Practice Guidelines Committee, which is composed of experts in the field of nephrology.

The ASN is committed to the highest standards of quality and integrity in the development and dissemination of its clinical practice guidelines.

This guideline is intended to be used in conjunction with the ASN's other clinical practice guidelines and other resources available to its members.

The ASN is committed to the ongoing evaluation and revision of its clinical practice guidelines to ensure that they remain current and relevant.

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Rockville, Maryland
October 2010

Dedication

The Renal Physicians Association dedicates this
clinical practice guideline to
Belding R. Scribner, MD,
the father of chronic dialysis, 1921-2003
on the 50th anniversary year of the first chronic
dialysis treatment,
March 9, 1960, Seattle, WA

At the 2010 Renal Physicians Association
annual meeting, his colleague, Christopher R. Blagg, MD,
spoke on “The University of Washington Hospital
Chronic Dialysis Program in 1960: Where It All Began”
and shared this quote,

*“If the treatment of chronic uremia cannot fully rehabilitate
the patient, the treatment is inadequate.”*

~ Belding R. Scribner, MD, 1963

Since the first publication of this clinical practice guideline, researchers have extensively investigated dialysis decision-making. To develop this second edition, the Renal Physicians Association conducted a literature search for studies published since 2000 addressing questions derived from the guideline's analytic framework. This revision provides the following new and expanded topic areas that build upon the original guideline:

- The poor prognosis of some elderly stage 4 & stage 5 chronic kidney disease patients, many of whom are likely to die prior to initiation of dialysis or for whom dialysis may not provide a survival advantage over medical management without dialysis.
- An online calculator to estimate prognosis in ESRD patients using an integrated model that incorporates the patient's age, serum albumin, comorbidities, and clinician assessment of the patient's likelihood of being dead within a year "Would I be surprised if this patient died in the next year?" available at <http://touchcalc.com/calculators/sq>.
- The identification of distinctly different treatment goals for ESRD patients based on their overall condition and preferences: 1) patients who choose aggressive therapy with dialysis without limitations on other treatments; 2) patients with a poor prognosis who choose dialysis but with limitations on other treatments such as cardiopulmonary resuscitation, intubation, and mechanical ventilation because they want to balance life prolongation and comfort; and 3) patients who decline dialysis and prefer that the primary goal of care be their comfort.
- The frequent prevalence of cognitive impairment in dialysis patients and the need to periodically assess dialysis patients for decision-making capacity.
- The failure of advance directives to impact patient care and the recognition that advance care planning with completion of Physician Orders for Life-Sustaining Treatment (POLST) forms (the name of the form may vary depending upon the state) is the preferred approach for decision-making for patients who lose decision-making capacity.
- The under recognition and under treatment of pain and other symptoms in dialysis patients.
- The underutilization of hospice in dialysis patients.
- An understanding of the communication challenges in discussing prognosis and treatment options with CKD and ESRD patients and their families and a presentation of strategies to assist nephrologists in this communication.
- An appreciation that pediatric dialysis decision-making is distinct from that for adults and that sufficient evidence and ethical policy statements exist to make recommendations with regard to pediatric dialysis decision-making.

To revise this clinical practice guideline, the Renal Physicians Association coordinated a large voluntary effort by a number of individuals within and outside the nephrology and dialysis communities. Section 8 acknowledges those who participated in the guideline revision development including those who reviewed and abstracted articles identified in the systematic literature search, those who incorporated the new evidence into the revision of the guideline recommendations and rationales, those who reviewed working drafts of the guideline recommendations and rationales and made suggestions for improvement, and the organizations who reviewed the final draft of this second guideline for consideration for

Preface

endorsement. The following people chaired workgroups that were tasked with article review and abstraction and revision of previous recommendations: Susan Bray, MD (Shared-Decision Making, Informed Consent, Conflict Resolution, and Time-limited Trials), Steven Weisbord, MD (Estimating prognosis in acute kidney injury), Michael Germain, MD (Estimating prognosis in end-stage renal disease), Jean Holley, MD (Advance directives and advance care planning), Richard Swartz, MD (Withholding or withdrawing dialysis including special patient groups), Sara Davison, MD (Palliative care), Jane Schell, MD, James Tulskey, MD, and Robert Arnold, MD (Communication), and Barbara Fivush, MD and Arlene Gerson, PhD (Pediatric decision-making for acute kidney injury and end-stage renal disease). The guideline revision project was directed by the Renal Physicians Association's Quality, Safety, and Accountability Committee chaired by Paul M. Palevsky, MD.

This guideline revision was the result of a team effort. Participants shared a commitment to improving the process of decision-making about dialysis initiation and withdrawal. Their goal was to provide clinicians, patients, and families with 1) the most current evidence about the benefits and burdens of dialysis for patients with diverse conditions, 2) recommendations for quality in decision-making and treatment of patients with acute kidney injury, chronic kidney disease, and end-stage renal disease, and 3) practical strategies to help clinicians implement the guideline recommendations. This goal is consistent with the Institute of Medicine definition of a clinical practice guideline: to provide systematically developed statements to assist practitioner and patient decisions about appropriate healthcare (in this case dialysis) for specific clinical circumstances. The true worth of this guideline will be determined by the extent to which it is used and found helpful by clinicians, patients, and families in making decisions to start or stop dialysis.

Alvin H. Moss, MD, Chair

Renal Physicians Association Clinical Practice Guideline Revision Working Group

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Acronyms and Abbreviations

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
ACP	advance care planning
ADR	adjusted death rate
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AKA	above the knee amputation
AKI	acute kidney injury
AMI	acute myocardial infarction
ASN	American Society of Nephrology
ASPN	American Society of Pediatric Nephrology
ATN	acute tubular necrosis
CAD	coronary artery disease
CHF	congestive heart failure
CKD	chronic kidney disease
COPD	congestive obstructive pulmonary disease
CPR	cardiopulmonary resuscitation
CQI	continuous quality improvement
DOPPS	Dialysis Outcomes and Practice Patterns Study
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 Administration
PD	peritoneal dialysis
POLST	Physician Orders for Life-Sustaining Treatment

Acronyms and Abbreviations

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 clinical practice guideline, *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis*, addresses recommendations concerning withholding or withdrawing dialysis in adult and pediatric patients with acute kidney injury (AKI), stage 4 or 5 chronic kidney disease (CKD), or end-stage renal disease (ESRD). The guideline was developed by the Renal Physicians Association (RPA) in conjunction with representatives from multiple disciplines and organizations and kidney patients. A list of the members who served on the Working Group and individuals who served as peer reviewers appears in Section 8.

The document is organized to allow readers to quickly access the following key pieces of information:

- **Guideline recommendation summary:** A brief summary of recommendations is provided on pages 1 through 10.
- **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 the methodology that was used to develop the guideline. Analytic frameworks and questions that were used to guide the entire process are presented. Literature searches, selection criteria, and methods of evidence critique and ratings are explained. Peer review processes and mechanisms for formulating final guideline recommendations are explicated.
- **Guideline recommendations and their rationales for adult and pediatric patients:** Sections 4 and 5 present the guideline recommendations, the principles, laws, and systematic reviews of evidence on which they were based. Ratings of the quality of evidence are provided.
- **Suggestion boxes:** Along with most guideline recommendations are boxes that specify action items health care providers can initiate to implement the recommendation in their own practices.
- **Prognostic data:** Figures and tables with prognostic data for Recommendation No. 3 are presented in the **Appendix**. They provide evidence-based information that may help health care professionals estimate prognosis for individual patients.
- **Research directions:** Throughout this guideline development, 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:** Section 7 offers suggestions for educating providers about the guideline and ideas for encouraging local implementation.
- **Acknowledgements:** A number of individuals and organizations who made significant contributions to this guideline are recognized in Section 8.

A Guide to This Document

- **Toolkit-Useful instruments for implementing the guideline recommendations:**
Section 9 provides numerous validated tools that clinicians may use to implement the guideline recommendations.
- **Glossary:** Key terms are defined in the glossary at the end of the document in Section 10.

Recommendation Summary

To develop their recommendations, the RPA Working Group used a priori analytic frameworks regarding decisions to withhold or withdraw dialysis in adult and pediatric patients with AKI, CKD, and ESRD. Systematic literature reviews were conducted to address pre-specified questions derived from the frameworks. The research evidence, case and statutory law, and ethical principles were used by the Working Group in the formulation of their recommendations.

Adult Patients

Establishing a Shared Decision-Making Relationship

Recommendation No. 1

Develop a physician-patient relationship for shared decision-making.

Shared decision-making is the recognized preferred model for medical decision-making because it addresses the ethical need to fully inform patients about the risks and benefits of treatments, as well as the need to ensure that patients' values and preferences play a prominent role. Because of the number and complexity of decisions involved in treating kidney failure, a shared decision-making relationship is particularly important for patients with acute kidney injury (AKI); stage 4 and 5 chronic kidney disease (CKD); and stage 5 CKD requiring dialysis end-stage renal disease (ESRD). Participants in shared decision-making should involve at a minimum the patient and the physician. In addition, patients should identify and include a person who could serve as their decision-maker in the event they lose decision-making capacity. If a patient lacks decision-making capacity, decisions should involve the person legally authorized to make health care decisions on behalf of the incapacitated patient. This person is often (though not always) a family member and will be called "the legal agent" in the remainder of this document (see **Section 10: Glossary** for a full description). With the patient's consent, shared decision-making may include family members or friends and other members of the health care team.



Informing Patients

Recommendation No. 2

Fully inform AKI, stage 4 and 5 CKD, and ESRD patients about their diagnosis, prognosis, and all treatment options.

In the setting of critical illness many patients with CKD will require urgent dialysis and the vast majority of patients with AKI will have multiple medical problems, in addition to kidney failure. The concept of shared decision-making necessitates a multidisciplinary approach including nephrologists, intensivists, and others as appropriate and decisions about acute renal replacement therapy should be made in the context of other life-sustaining treatments. For example, a decision to withhold dialysis in a patient agreeing to and receiving multiple other forms of life-sustaining therapy could represent discordant treatment in the same way that offering dialysis to a patient who has decided to forgo other forms of life-sustaining therapy might be inappropriate. Intensive care physicians need to be included in shared decision-making for kidney patients in the intensive care unit (ICU).

Recommendation Summary

For ESRD patients, the shared decision-making options include: 1) available dialysis modalities and kidney transplantation if applicable; 2) not starting dialysis and continuing medical management; 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 benefits and burdens of dialysis and the consequences of not starting or stopping dialysis. Research studies have identified a population of chronic kidney disease patients for whom the prognosis is particularly poor. This population has been found to include patients with two or more of the following characteristics: 1) elderly (defined by research studies identifying poor outcomes in patients who are age 75 years and older); 2) patients with high comorbidity scores (e.g., modified Charlson Comorbidity Index score of 8 or greater); 3) marked functional impairment (e.g., Karnofsky Performance Status Scale score of less than 40); and 4) severe chronic malnutrition (e.g., serum albumin level less than 2.5 g/dL using the bromocresol green method). Patients in this population should be informed that dialysis may not confer a survival advantage or improve functional status over medical management without dialysis and that dialysis entails significant burdens that may detract from their quality of life.

Recommendation No. 3

Give all patients with AKI, stage 5 CKD, or ESRD an estimate of prognosis specific to their overall condition.

To facilitate informed decisions about starting dialysis for AKI, stage 5 CKD, or ESRD, all patients should have their prognosis estimated and discussed, with the realization that the ability to predict survival in the individual patient is limited. Depending on the setting, a primary care physician, intensivist, or nephrologist who is familiar with estimating and communicating prognosis should conduct these discussions (see **Recommendation No. 10** for communication strategies). For patients with ESRD, the “surprise” question “Would I be surprised if this patient died in the next year?” can be used together with known risk factors for poor prognosis: age, comorbidities, severe malnutrition, and poor functional status. For patients with stage 5 CKD pre-dialysis, the estimate of prognosis should be discussed with the patient or legal agent, patient’s family, and among the medical team members to develop a consensus on the goals of care and whether dialysis or active medical management without dialysis should be used to best achieve these goals. These discussions should occur as early as possible in the course of the patient’s kidney disease and continue as the kidney disease progresses. For ESRD patients on dialysis who experience major complications that may substantially reduce survival or quality of life, it is appropriate to reassess treatment goals, including consideration of withdrawal from dialysis.

Facilitating Advance Care Planning

Recommendation No. 4

Institute advance care planning.

The purpose of advance care planning is to help the patient understand his/her condition, identify his/her goals for care, and prepare for the decisions that may have to be made as the condition progresses over time. For chronic dialysis patients, the interdisciplinary renal care team should encourage patient-family discussion and advance care planning and include advance care planning in the overall plan of care for each individual patient (see **Section 10: Glossary** for definition of renal care team). The renal care team should designate a person to be primarily responsible for ensuring that advance care planning is offered to each patient. Patients with decision-making capacity should be strongly encouraged while they have capacity to talk to their legal agents to ensure that the legal agent knows the patient's wishes and agrees to make decisions according to these wishes.

The renal care team should attempt to obtain written advance directives from all dialysis patients. Where legally accepted, Physician Orders for Life-Sustaining Treatment (POLST) or similar state-specific forms, also should be completed as part of the advance care planning process. At a minimum, each dialysis patient should be asked to designate a legal agent in a state-specific advance directive. Advance directives should be honored by dialysis centers, nephrologists, and other nephrology clinicians except possibly in situations in which the advance directive requests treatment contrary to the standard of care (see **Recommendation No. 8** on conflict resolution).



Making a Decision to Not Initiate or to Discontinue Dialysis

Recommendation No. 5*

If appropriate, forgo (withhold initiating or withdraw ongoing) dialysis for patients with AKI, CKD, or ESRD in certain, well-defined situations.

These situations include the following:

- Patients with decision-making capacity, who being fully informed and making voluntary choices, refuse dialysis or request that dialysis be discontinued.
- Patients who no longer possess decision-making capacity who have previously indicated refusal of dialysis in an oral or written advance directive.
- Patients who no longer possess decision-making capacity and whose properly appointed legal agents/surrogates 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.

*Medical management incorporating palliative care is an integral part of the decision to forgo dialysis in AKI, CKD, or ESRD, and attention to patient comfort and quality of life while dying should be addressed directly or managed by palliative care consultation and referral to a hospice program (see **Recommendation No. 9** on palliative care services).

Recommendation Summary

Recommendation No. 6

Consider forgoing dialysis for AKI, CKD, or ESRD patients who have a very poor prognosis or for whom dialysis cannot be provided safely.

Included in these categories of patients are the following:

- Those whose medical condition precludes the technical process of dialysis because the patient is unable to cooperate (e.g., advanced dementia patient who pulls out dialysis needles) or because the patient's condition is too unstable (e.g., profound hypotension).
- Those who have a terminal illness from non-renal causes (acknowledging that some in this condition may perceive benefit from and choose to undergo dialysis).
- Those with stage 5 CKD older than age 75 years who meet two or more of the following statistically significant very poor prognosis criteria (see **Recommendations No. 2 and 3**): 1) clinicians' response of "No, I would not be surprised" to the surprise question; 2) high comorbidity score; 3) significantly impaired functional status (e.g., Karnofsky Performance Status score less than 40); and 4) severe chronic malnutrition (i.e., serum albumin less than 2.5 g/dL using the bromocresol green method).

Resolving Conflicts about What Dialysis Decisions to Make

Recommendation No. 7

Consider a time-limited trial of dialysis for patients requiring dialysis, but who have an uncertain prognosis, or for whom a consensus cannot be reached about providing dialysis.

If a time-limited trial of dialysis is conducted, the nephrologist, the patient, the patient's legal agent, and the patient's family (with the patient's permission to participate in decision-making) should agree in advance on the length of the trial and parameters to be assessed during and at the completion of the time-limited trial to determine whether dialysis has benefited the patient and whether dialysis should be continued.

Recommendation No. 8

Establish a systematic due process approach for conflict resolution if there is disagreement about what decision should be made with regard to dialysis.

Conflicts may occur between the patient/legal agent and the renal care team about whether dialysis will benefit the patient. Conflicts also may occur within the renal care team or between the renal care team and other health care providers. In sitting down and talking with the patient/legal agent, the nephrologist should try to understand their views, provide data to support his/her recommendation, and correct misunderstandings. In the process of shared decision-making, the following potential sources of conflict have been recognized: 1) miscommunication or misunderstanding about prognosis; 2) intrapersonal or interpersonal issues; or 3) special values. If dialysis is indicated emergently, it should be provided while pursuing conflict resolution, provided the patient or legal agent requests it.

Recommendation Summary

Providing Effective Palliative Care

Recommendation No. 9

To improve patient-centered outcomes, offer palliative care services and interventions to all AKI, CKD, and ESRD patients who suffer from burdens of their disease.

Palliative care services are appropriate for people who chose to undergo or remain on dialysis and for those who choose not to start or to discontinue dialysis. With the patient's consent, a multi-professional team with expertise in renal palliative care, including nephrology professionals, family or community-based professionals, and specialist hospice or palliative care providers, should be involved in managing the physical, psychological, social, and spiritual aspects of treatment for these patients, including end-of-life care. Physical and psychological symptoms should be routinely and regularly assessed and actively managed. The professionals providing treatment should be trained in assessing and managing symptoms and in advanced communication skills. Patients should be offered the option of dying where they prefer, including at home with hospice care, provided there is sufficient and appropriate support to enable this option. Support also should be offered to patients' families, including bereavement support where appropriate. Dialysis patients for whom the goals of care are primarily comfort should have quality measures distinct from patients for whom the goals are aggressive therapy with optimization of functional capacity.

Recommendation No. 10

Use a systematic approach to communicate about diagnosis, prognosis, treatment options, and goals of care.

Good communication improves patients' adjustment to illness, increases adherence to treatment, and results in higher patient and family satisfaction with care. Patients appreciate sensitive delivery of information about their prognosis and the ability to balance reality while maintaining hope. In communicating with patients, the critical task for clinicians is to integrate complicated biomedical facts and conditions with emotional, social, and spiritual realities that are equally complex but not well described in the language of medicine. This information must be communicated in a way that patients, legal agents, and families can understand and use to reach informed decisions about dialysis and transplantation options. Patients' decisions should be based on an accurate understanding of their condition and the pros and cons of treatment options. To facilitate effective communication, reliance upon a multidisciplinary approach including nephrologists, intensivists, and others as appropriate is warranted. Decisions about acute renal replacement therapy in AKI should be made in the context of other life-sustaining treatments. Intensive care physicians should be included in shared decision-making for kidney patients in the ICU to facilitate discussions on global disease or injury prognosis. Fellowship programs should incorporate training to help nephrologists develop effective, empathetic communication skills, which are essential in caring for this patient population.

Recommendation Summary

Pediatric Patients

Establishing Family-centered Shared Decision-Making

Recommendation No. 1

Develop a patient-physician relationship that promotes family-centered shared decision-making for all pediatric patients with AKI, CKD, and ESRD.

In addition to involving pediatric patients to the extent that their decision-making capacity allows, the nephrologist should involve parents in determining health care decisions. If the parents request to involve other family members in shared decision-making, this request should be honored. If the treating nephrologist believes that a pediatric patient's parents are making decisions inconsistent with the best interest of their child, the nephrologist should involve medical ethics consultants or hospital ethics committees, mental health professionals, pediatricians specializing in child abuse and neglect, mediators, or conflict resolution specialists. These experts can assist in determining the reason for the parents' treatment choice and in determining an appropriate course of action. It is imperative that the nephrologist take steps to ensure that the pediatric patient has an adult advocate who is capable of participating in health care decision-making. Court involvement to order medical interventions over parental objections should be a last resort.

Family-centered shared decision-making process is recommended for all advance care planning discussions in which treatment options are discussed and treatment decisions are made. Education geared to the cognitive abilities of the parent and pediatric patient about the medical condition, prognosis, and available treatment options is an important component of the family-centered shared decision-making process. The pediatric patient's primary care physician, and in the case of the critically ill pediatric patient, their intensivist should be encouraged to participate in coordinating care related to treatment decisions made by the pediatric patient and his/her family. In the intensive care setting, patients with AKI will usually have multiple medical problems and the concept of shared decision-making necessitates a multidisciplinary approach including nephrologists, intensivists, and others as appropriate, and decisions about acute renal replacement therapy should be made in the context of other life-sustaining treatments.

Informing Patients and Parents

Recommendation No. 2

Fully inform patients with AKI, stage 4 or stage 5 CKD, or ESRD and their parents about the diagnosis, prognosis, and all appropriate treatment options. Inform children and adolescents in a developmentally appropriate manner, and if feasible, seek their assent about treatment decisions.

Treatment options include: 1) initiating or continuing dialysis; 2) transplantation for ESRD; 3) not starting dialysis and continuing optimal medical management; and 4) stopping dialysis and continuing to receive palliative treatment. The nephrologist and the medical team should make every effort to inform parents about the potential benefits and burdens of dialysis initiation

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or dialysis withdrawal before providing or withdrawing treatment. In the rare circumstances when this is not possible, parents should be informed as soon as possible about the rationale for emergent initiation or withdrawal of dialysis and the efforts that were made to contact the parents before changing the medical plan. As a component of informed permission/informed assent, and in keeping with the on-going process of both shared decision-making and advance care planning, the treating nephrologist may determine that dialysis is no longer providing net benefit (i.e., the risks or burdens outweigh the benefits, the underlying condition is progressive and dialysis is only prolonging the dying process without improving the quality of life during the dying process). In this case, the nephrologist and the medical team should approach the family and discuss the undue burden of dialysis given the patient's medical condition and recommend stopping dialysis and intensifying palliative treatment. This will typically occur in the intensive care setting and intensivists should coordinate the shared decision making in the context of other aspects of supportive care. Children and adolescents should be given the opportunity to communicate their feelings and perceptions regarding the benefits and burdens of dialysis to the extent they desire to do so and their developmental abilities and health status permits. When seeking informed permission/informed assent for discontinuing dialysis, the medical team should explicitly describe comfort measures and other components of palliative treatment that will be offered.

Recommendation No. 3

Facilitate informed decisions about dialysis for pediatric patients with AKI, CKD or ESRD, discuss prognosis, potential complications, and quality of life with the patient, parents, and/or legal guardian.

Nephrologists should rely on population-based survival data, using adjustments for confounders, to discuss prognosis, potential complications, and quality of life with patients, parents, and/or legal guardians. During these discussions, the nephrologist should acknowledge that the ability to predict survival in the individual patient is difficult and should reassure the patient and family that there will be ongoing opportunities for additional discussions regarding prognosis over time. Given the likelihood that health status changes for the better or worse are likely to occur in pediatric patients with AKI, CKD, and ESRD, discussions about survival odds and physical and psychosocial outcomes should be repeated when dramatic changes in health status occur. Each discussion regarding prognostic outcomes and patient/parent decisions regarding treatment should be documented in detail and dated. This documentation should be easily identified and accessible in the medical record. In the event of questionable understanding of the prognostic data, it is recommended that additional resources be offered to the pediatric patient and his or her family to ensure a reasonable understanding of likely outcomes and to allow for informed decision-making regarding treatment (see Recommendation No. 8).

Resolving Conflicts about What Dialysis Decisions to Make

Recommendation No. 4

Establish a systematic due process approach for conflict resolution if disagreements occur about dialysis decisions. Use conflict resolution interventions when family members disagree with one another, when children disagree with their parents, when families disagree with the health

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care team, or when the health care team disagrees about initiating, not initiating, or withdrawing dialysis.

The following types of interventions are recommended to resolve conflicts: additional medical consultation(s); involvement of pastoral care; palliative care consultation; a multidisciplinary conference including sources of support for the patient/family from within or outside the institution; short-term counseling or psychiatric consultation for the child and/or family and/or consultation with a hospital-based ethics committee. When the health care team believes that non-initiation of dialysis would constitute medical neglect, consultation with available child protection specialists would be appropriate to help determine next steps. Court involvement should be used as an intervention of last resort.

Facilitating Advance Care Planning

Recommendation No. 5

Institute family-centered advance care planning for children and adolescents with AKI, CKD, and ESRD. The plan should establish treatment goals based on a child's medical condition and prognosis.

Family-centered advance care planning is recommended for infants with poorly functioning or nonfunctioning kidneys due to genetic conditions and those with a non-reversible urological or kidney abnormality. In the event that the health care team has information that the viability of a fetus with suspected multisystem organ involvement is questionable, family-centered advance care planning should occur before the birth of the baby. This will allow the health care team to be able to act decisively in light of the neonate's health status and prognosis at the time of delivery.

Advance care planning should be an ongoing process in which treatment goals are determined and revised based on observed benefits and burdens of dialysis and the values of the pediatric patient and the family. The renal care team should designate a person to be primarily responsible for ensuring that advance care planning is offered to each patient. Patients with decision-making capacity should be *strongly* encouraged to talk to their parents to ensure that they know the patient's wishes and agrees to make decisions according to these wishes. Ongoing discussions that include reestablishing goals of care based on the child's response to medical treatment and optimal quality of life is the mechanism by which advance care planning occurs. Discussions should include the pros and cons of dialysis as well as potential morbidity associated with dialysis. Kidney transplantation should be discussed if appropriate.

Children and adolescents should be allowed to participate in advance care planning commensurate with their preference and developmental status. Parent or pediatric patient questions regarding discontinuation of dialysis if the patient's medical condition becomes irreversible and non-responsive to currently available treatments should be addressed frankly. Such questions can be used as a springboard for obtaining information about parent and child wishes regarding end-of-life care. Assurance should be given that the pediatric patient's comfort is paramount in the event that dialysis is discontinued. In addition, such questions should be used as an opportunity to explicitly describe comfort measures and other components of palliative care.

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Making a Decision to Not Initiate or to Discontinue Dialysis

Recommendation No. 6

Forgo dialysis if initiating or continuing dialysis is deemed to be harmful, of no benefit, or merely prolongs a child's dying process. The decision to forgo dialysis must be made in consultation with the child's parents. Give children and adolescents the opportunity to participate in the decision to forgo dialysis to the extent that their developmental abilities and health status allow.

An example of a clinical situation in which forgoing dialysis is often considered is an infant with multisystem organ failure for whom dialysis would be burdensome and would serve only to prolong dying. Forgoing dialysis should also be considered for a pediatric patient whose kidney failure is a consequence of a primary health condition that is non-reversible, non-treatable, and terminal and for whom dialysis would cause undue suffering. Infants or children who would otherwise be expected to survive for years with conditions causing severe neurologic impairment and who develop ESRD should ordinarily not undergo dialysis or transplant. Examples might be an infant with anencephaly or severe porencephaly, or a child with a severe progressive demyelinating condition. In children with severe developmental disabilities, clinicians will need to discuss with parents the balance of the benefits to burdens of prolonging life with dialysis. An intensification of palliative care treatment should occur in conjunction with any decision to forgo dialysis.

Recommendation No. 7

Consider forgoing dialysis in a patient with a terminal illness whose long-term prognosis is poor if the patient and the family are in agreement with the physician that dialysis would not be of benefit or the burdens would outweigh the benefit.

In pediatric patients who experience major complications from dialysis that may substantially reduce survival or quality of life, it is appropriate to discuss and/or reassess treatment goals, including considering forgoing dialysis or withdrawing dialysis and initiating or increasing the emphasis on goals commensurate with palliative care. Alternatively, it is reasonable to initiate dialysis for patients with AKI or ESRD who have chronic illness from a non-kidney cause in whom outcome studies have been favorable. For example in HIV-associated nephropathy, dialysis has the potential to improve the quality of life in children.

Recommendation No. 8

Consider the use of a time-limited trial of dialysis in neonates, infants, children, and adolescents with AKI or ESRD to allow for the assessment of extent of recovery from an underlying disorder.

In an intensive care setting, neonates, infants, children and adolescents with AKI or ESRD as a result of an underlying disorder may be candidates for initiating time-limited trials of dialysis. The purpose of such a trial would be to establish the extent of recovery from the underlying disorder and/or to determine the balance of benefits to burdens that continued life enabled by dialysis provides to the child. The initiation of dialysis in conjunction with extra-corporeal

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membrane oxygenation (ECMO) is an example of a time-limited trial. It is considered time-limited in that the dialysis is most often discontinued when ECMO is withdrawn due to patient non-viability.

Providing Effective Palliative Care

Recommendation No. 9

Develop a palliative care plan for all pediatric patients with ESRD from the time of diagnosis and for children with AKI who forgo dialysis. The development of a palliative care plan is a continuation of the process of advance care planning and should be family-centered.

The terminally ill child, family and child's physician(s) should be involved in developing and executing a palliative care plan, based on their preferences concerning goals of care and decisions regarding testing, monitoring, and treatment. With the patient and family's permission, health care professionals with expertise in hospice and palliative medicine should be involved in co-managing the medical, psychosocial, and spiritual aspects of end-of-life care for the child and family. The nephrology team along with the child's pediatrician and other medical providers should offer bereavement support to the patient's family. In the case of a long-standing relationship with the pediatric patient, nephrology team members are encouraged to send a condolence card to the patient's family. Nephrology team members should be given complete autonomy regarding attendance at a pediatric patient's funeral or memorial service. Nephrologists and the child's health care team are strongly encouraged to seek support, in dealing with the child's dying process and death in the event that that the situation causes significant stress that interferes with baseline functioning at work or home.

Endorsements and Commendations

The following organizations have endorsed the guideline:

Renal Physicians Association

American Academy of Hospice and Palliative Medicine

American Academy of Pediatrics

American Association of Critical Care Nurses

American Association of Kidney Patients

American College of Nurse Practitioners

American Geriatrics Society

American Society of Pediatric Nephrology

Center to Advance Palliative Care

Forum of End-Stage Renal Disease Networks

Kidney End-of-Life Coalition

National Hospice and Palliative Care Organization

National Renal Administrators Association

Society of Critical Care Medicine

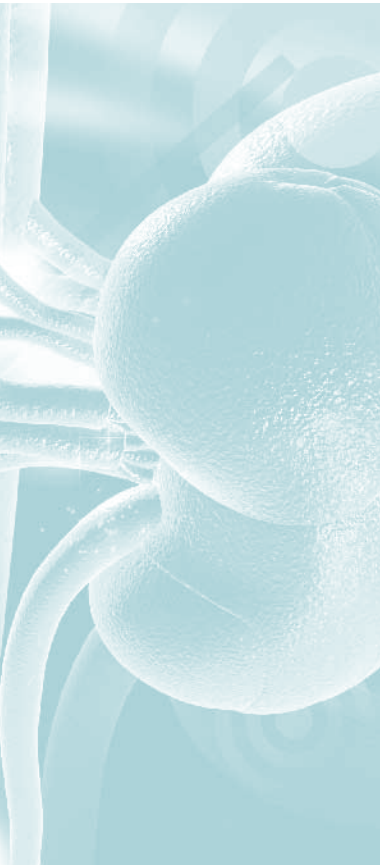
The following organizations have commended the value of the second edition of the guideline:

American Nephrology Nurses Association

National Kidney Foundation

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Foreword and Rationale



Process of Topic Selection

In 1997, the Renal Physicians Association (RPA) and the American Society of Nephrology (ASN) surveyed their leadership to select a topic for a second evidence-based clinical practice guideline (dialysis adequacy was the first). Topic selection was based on criteria similar to those recommended by the Agency for Health Care Policy and Research (AHCPR; now known as the Agency for Healthcare Research and Quality [AHRQ]) and the Institute of Medicine (IOM). These criteria included:

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

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The selected topic for the second RPA clinical practice guideline, published in 2000 by RPA and ASN, was *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis*.

Why the 2000 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 increasingly reported being asked to dialyze patients for whom they perceived dialysis to be of marginal benefit. During the 1990s, external forces raised the renal community’s awareness of the need to address the issues of starting and stopping dialysis. There was 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, a growing number of patients and their care providers developed advance directives.

In the latter half of the 1990s, this topic was given highest priority for guideline development also because the renal professional community recognized that the incident and prevalent ESRD population had changed substantially. An increasing number of patients who were initiating renal replacement therapy were elderly and suffered from substantial numbers of comorbid conditions. These in turn adversely affected 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. The USRDS 2008 annual report showed this trend

continuing, with the highest counts of incident patients for patients aged 45 to 64 years, followed by patients aged 75 years and older (Figure 1). The highest incident treatment rates were for patients aged 75 years and older, followed by those aged 65 to 74 years. Older patients have the most comorbid conditions and are at the greatest risk for developing illnesses during their subsequent course on dialysis.

Furthermore, voluntary withdrawal from dialysis became an increasingly common occurrence. USRDS data show approximately 1 of 5 patients voluntarily withdraw from dialysis.^{3,4} When categorized by age, older

Figure 1. Incident counts and adjusted rates by age.⁵

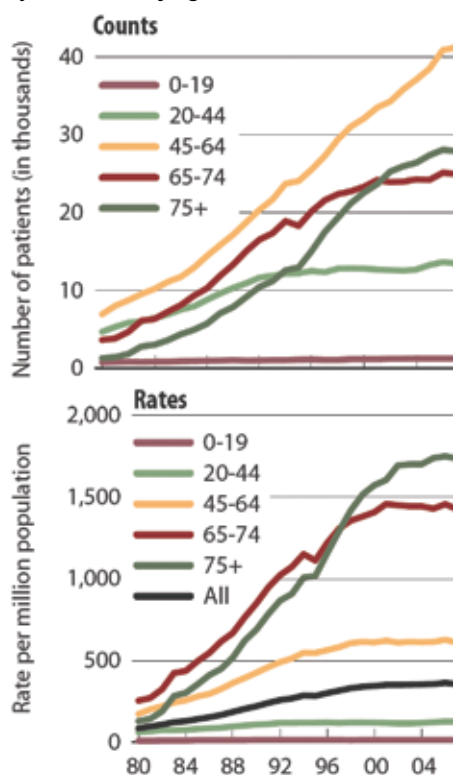
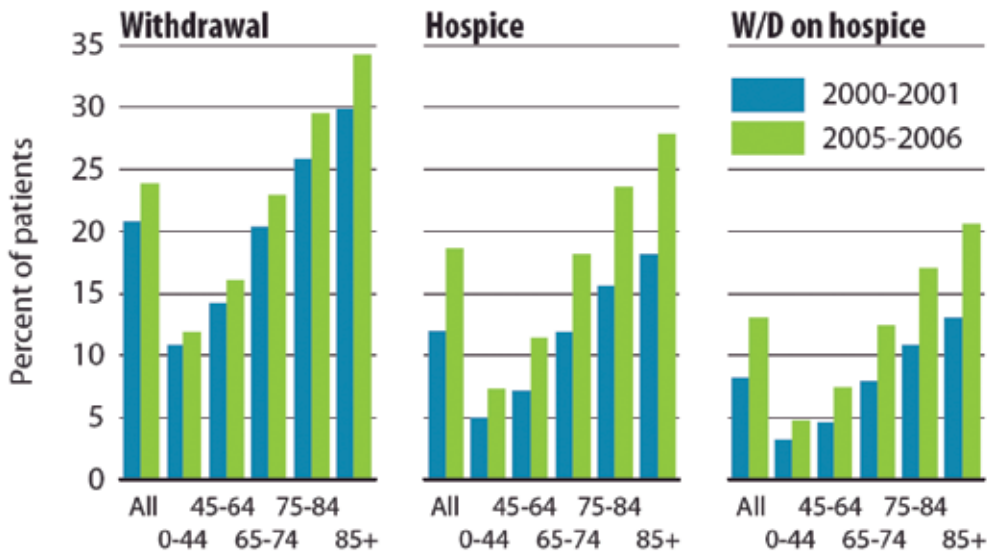


Figure 2. Withdrawal (W/D) and hospice status, by age, ESRD patients.⁶



patients are the most likely to stop their dialysis treatments and enroll in hospice (Figure 2).

As a result of these trends, the RPA and ASN published *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis* in 2000. Today, in the context of an expanding American dialysis program with an increase in the number of elderly patients who have substantial comorbid conditions, the RPA leadership believes that a revision of their evidence-based clinical practice guideline is timely and will be quite beneficial. RPA believes that such a revision will assist patients, families, and the nephrology team in making decisions about initiating, continuing, and stopping dialysis. This new guideline will benefit patients and families by presenting more information about various options for treatment of ESRD, including palliative care and conservative management without dialysis 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 kidney injury 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 injury 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

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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.⁷

Rationing occurred in this way: Beginning in 1962, prospective patients were thoroughly evaluated for treatment in clinical terms, including psychological assessment.⁸ 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.^{9,10}

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?"¹¹ 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.¹² 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.^{13,14} At the level of the public reaction to rationing, Seattle was subjected to very substantial critical publicity.¹⁵ 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 1960s¹⁶ He was not alone among commentators who were appalled by rationing in the wealthy United States.^{17,18}

When Congress enacted Sec. 299I of the Social Security Amendments of 1972,¹⁹ 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."¹⁹

No legislative history existed 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;²⁰ medical review regulations proposed in 1975²⁰ and adopted in 1976²¹ 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 disruptive 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.

Several other features of the IOM ethics chapter are worth noting. 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 RPA Working Group, be a profound ethical mistake. Any discussion of patient acceptance and patient withdrawal from

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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?” or more to the point in recent years with older and sicker patients starting dialysis, “Who should *not* 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 evidence about the values of that community to the clinical data about medical indications and outcomes of dialysis. 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 of looking at the ethical issues raised by this guideline and 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 (i.e., 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

appropriate to evaluating and treating 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 non-maleficence because the decisions based on medical indications must be guided by the ethical duty to benefit patients and do them no harm. Professional integrity requires physicians to refrain from providing dialysis when the burdens of treatment substantially outweigh the benefits. In circumstances in which dialysis is not medically indicated, a patient or family preference to receive dialysis does not justify its provision.

Patient Preferences

For all medically indicated 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 because providers of care, family members, and others have an ethical duty to accept the decisions regarding medically indicated treatment 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 respect for 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

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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 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 7-Step Process of Ethical Decision-Making in Patient Care

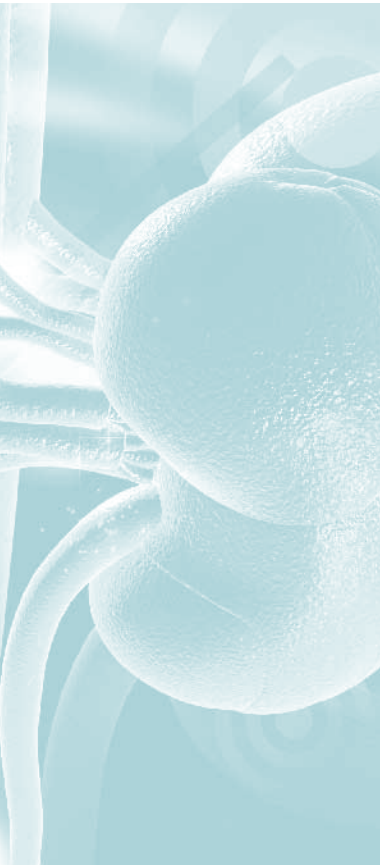
1. **What are the ethical questions?**
2. **What are the clinically relevant facts?**
3. **What are the values at stake?**
4. **List options.** What *could* you do?
5. **What *should* you do?** Choose the best option from the ethical point of view.
6. **Justify your choice.** Refer back to the values and give reasons why some values are more important in this case than others.
7. **How could this ethical issue have been prevented?** Would any policies/guidelines/practices be useful in changing any problems with the system?

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Section 2

Background



Scope and Intended Use

This guideline addresses withholding and withdrawing dialysis in adult and pediatric patients with AKI, CKD, 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.

Section 2

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.¹ 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.

Section 5 of this guideline specifically addresses dialysis decision-making for pediatric patients. Like Section 4, which covers dialysis decision-making for adults, Section 5 contains evidence-based recommendations with rationales, to the extent that evidence is available. Also as in Section 4, the pediatric workgroup used case and statutory law and ethical principles and ethics policy statements and guidelines of the American Academy of Pediatrics to formulate their recommendations.

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 have previously been addressed by the RPA, the National Kidney Foundation, and the American Society of Transplantation, respectively.²⁻⁸

Guideline Objectives

- Synthesize available research evidence on patients with AKI, CKD, and ESRD as a basis for making recommendations about starting, withholding, continuing, 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 AKI, CKD, or ESRD.
- Offer a publicly understandable and acceptable ethical framework for shared decision-making among health care providers, patients, and their families.

Target Audience

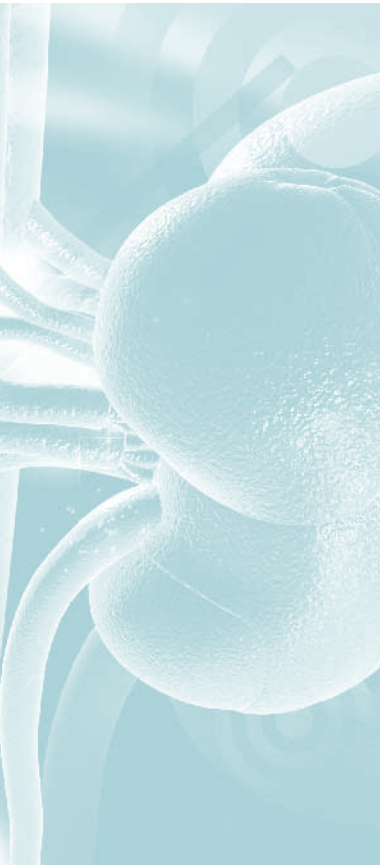
The primary target audience of this guideline is health care providers involved in the care of patients with AKI, CKD, or ESRD: adult and pediatric nephrologists, intensivists, primary care physicians, palliative care clinicians, psychologists, physician assistants, nephrology nurses, advanced practice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

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Section 3

Guideline Development Process



Original Guideline

Sponsorship

In developing the original guideline, the RPA and the ASN selected the topic, 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.

Section 3

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 AKI 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 had 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

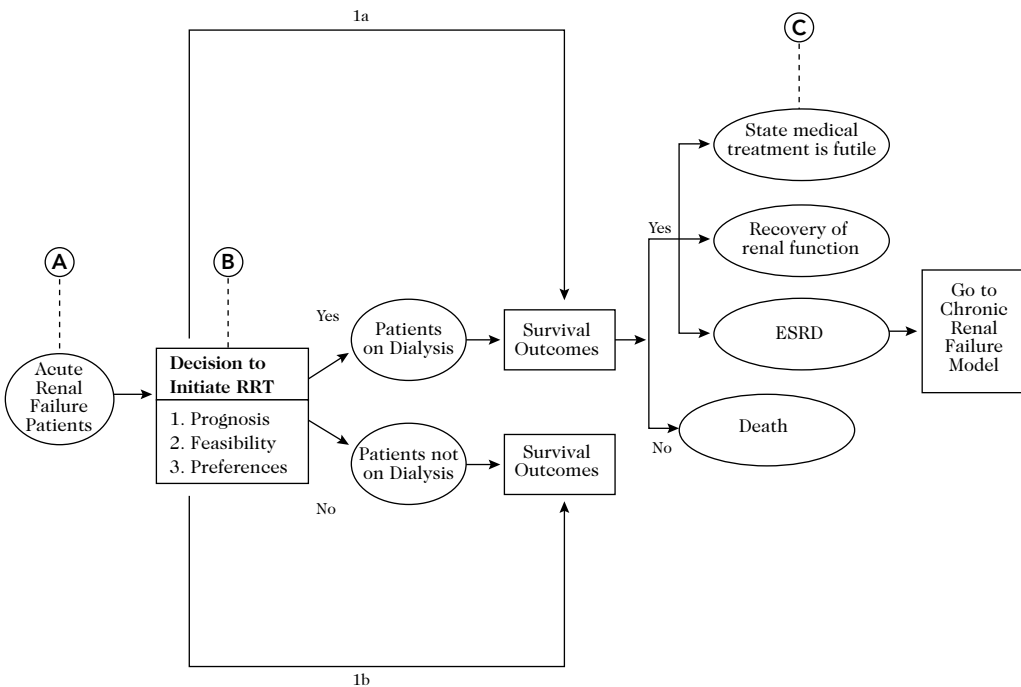
and withdrawal, preferences, prognosis, or quality of life, did not adequately capture the array of literature of interest to the Working Group. Thus, the Working Group used a very broad search strategy that included terms for dialysis, end-stage renal disease, and acute renal failure, and that excluded unpublished studies, case reports, editorials, and letters. The adult and pediatric literature was searched.

Selection of Relevant Research Evidence

Selection criteria guided the selection of several types of information that were deemed relevant to the key questions (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 AKI, 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.

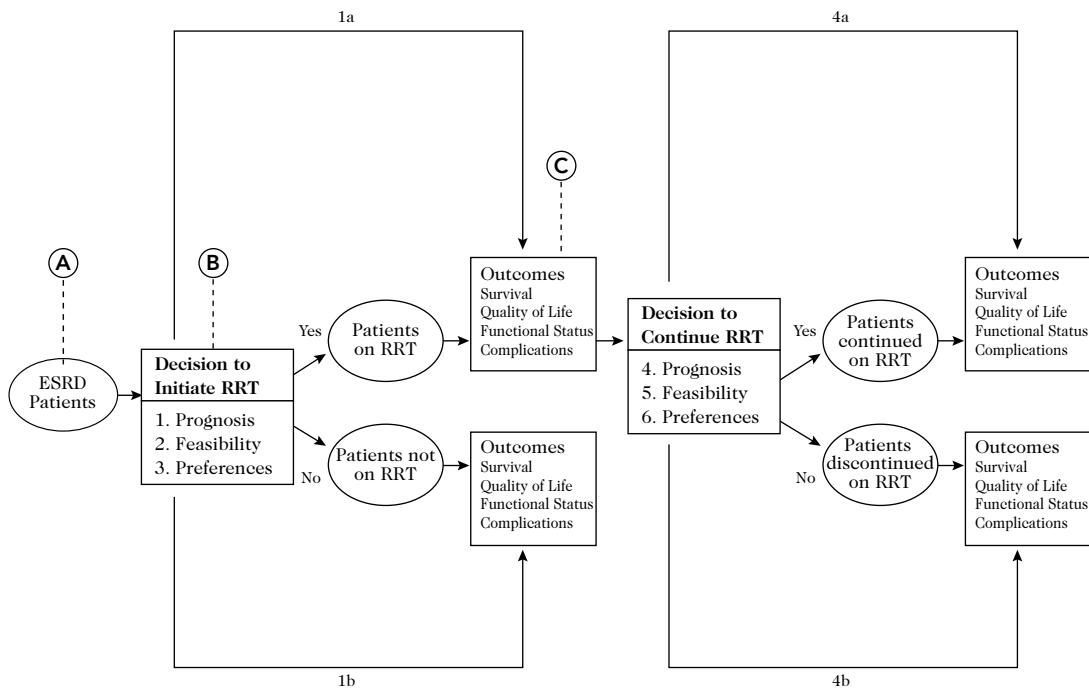
Figure 3. Analytic Framework for Decision-Making about Dialysis in Acute Renal Failure



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

Section 3

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

Selection Criteria for Prognosis Studies: <ul style="list-style-type: none">■ Original data from Western industrialized country such as US, 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 dialysis or hemodialysis (not hemoperfusion or hemopheresis).
Selection Criteria for Chronic Renal Failure Studies: <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, sample size: $n > 100$.■ If selected population, such as HIV or myeloma, sample size: $n > 20$; may be retrospective or prospective.■ Multivariate analysis unless special population.

Table 2. Selection Criteria (continued)

<p>Selection Criteria for Acute Renal Failure Studies:</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. ■ Sample size: $n > 20$.
<p>Selection Criteria for Predicting Withdrawal/Withholding Studies:</p> <ul style="list-style-type: none"> ■ Original data from Western industrialized country such as US, 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.
<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 US, 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 Studies of Patients who Do and Do Not Get Referred for Dialysis and When:</p> <ul style="list-style-type: none"> ■ Original data from Western industrialized country such as US, 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 before dialysis). ■ Sample size: $n > 20$.

Table 2. Selection Criteria (continued)

Selection Criteria for Functional Status/Quality of Life Studies:	
■	Original data from Western industrialized country such as US, 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: patient.
■	Sample size: n > 20.

Results of the article selection process were as follows. 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. An insufficient number of pediatric articles addressing the analytic framework questions were found to explicitly include pediatric recommendations in the original guideline.

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 three 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 AKI, 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: 1) ethical principles; 2) legal statutes; 3) shared decision-making; 4) the amount, type, quality, and consistency of supporting research evidence; and 5) 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 grading evidence addressing therapy, prevention, and prognosis were adapted from those of the Centre for Evidence-based Medicine at Oxford (www.cebm.net/index.aspx?o=1025). Criteria for rating observational evidence were developed by the San Antonio Evidence-based Practice Center. 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% 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% to 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 finding 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.

Section 3

The Working Group obtained background information about principles of ethical decision-making. They also were 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: 1) any major oversights in formulation of the evidence model, and 2) 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](#)).

Piloting and Plans for Updating

Although this guideline was not piloted before 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 in 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 was identified, the Working Group recommended updating the guideline.

Pertinent Questions for the Analytic Framework

Specific Evidence Questions for Decision-Making about Dialysis in AKI

1. **Expected outcome/prognosis for patients with AKI**
 - a. What are survival rates of dialyzed patients with AKI? Do survival rates vary by different etiologies of AKI, 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 AKI?
2. **Feasibility of initiating dialysis**
 - a. 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?

- 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 a 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?

4. 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?
- 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?

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- g. What are patient/family and nephrology team preferences and associated factors regarding initiating, withholding, or choosing a 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?
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) different dialysis modalities?
 - 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. What types of psychosocial situations (e.g., abusive patient, patient unable or unwilling to comply with dialysis procedures) make continued dialysis difficult?
6. **Preferences/shared decision-making/advanced directives related to withdrawal of dialysis**
- a. What are patients' knowledge, preferences, and level of involvement in making decisions relevant to initiating or withholding dialysis?
 - 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 a 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?

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 AKI 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 do not resuscitate (DNR) instructions or advance directives ignored?
- d. How many and what types of patients are withdrawn from dialysis?
- e. How many and what types of patents 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?

recently, found sufficient new evidence, and the RPA Quality, Safety, and Accountability Committee oversaw this guideline revision. For this revision, pertinent adult and pediatric English language literature published from January 2003 to October 2009 was identified from the following:

- PubMed
- References from articles
- Experts
- Hand searches of medical and nephrology journals

In addition to the search terms used in the original guideline development, palliative care and end-of-life care were also included. Figure 5 presents the article selection process. Under the direction of the RPA's Quality, Safety, and Accountability Committee, adult and pediatric nephrologists, nephrology nurse practitioners, intensivists, a pediatric psychologist, and a bioethicist participated in the literature review and revision of the guideline recommendations and rationales. The participants were divided into seven workgroups based on the topics of the original guideline recommendations plus a pediatric workgroup and were led by a chair or co-chairs.

The analytic frameworks for acute kidney injury and ESRD, selection of relevant research evidence, article selection criteria, data abstraction process, levels of evidence, and formulation of recommendations were the same as in the original guideline development. More than 35 nephrology health care providers and intensivists participated in the data abstraction process with each article reviewed by two persons. To aid standardization of abstraction, workgroup members were assigned articles related to specific thematic areas, such as shared decision-making and informed consent, prognosis of AKI, prognosis of ESRD, withholding and withdrawal of dialysis, advance directives and advance care planning, and palliative care.

Second Edition

Sponsorship and Methodology

The RPA sponsored the development of the second edition of this guideline using essentially the same methodology as the original guideline. In late 2002, the RPA considered doing a revision but found insufficient new information to warrant it at that time. The RPA revisited the issue more

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The pediatric workgroup used the same methodology as the adult workgroups and considered recommendations for pediatric dialysis decision-making for acute kidney injury, chronic kidney disease, and end-stage renal disease. The literature search identified 218 pediatric articles and 20 met selection criteria for inclusion. The pediatric workgroup added an additional 18 articles.

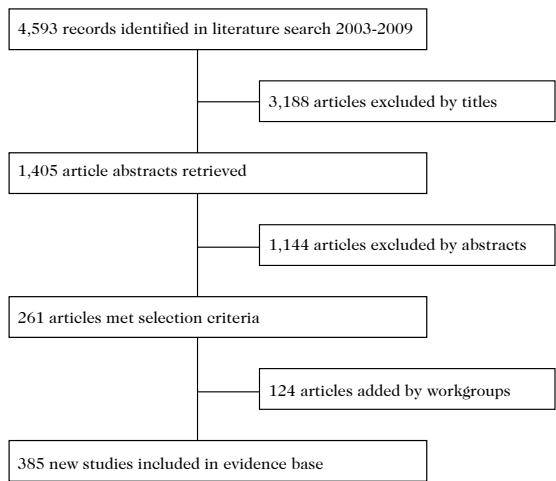
Peer Review and Endorsement

Peer review of the guideline was solicited at multiple points. First, for the adult patient recommendations and rationales, peer review of the revisions suggested by each workgroup was performed within the workgroups. Second, the seven workgroup chairs for the adult recommendations reviewed all seven workgroups' suggested changes. Each workgroup chair had previously been involved only in the literature review and revision of his or her assigned original guideline recommendation/s and rationale/s. Third, the adult recommendations and rationales were reviewed by a wide array of nephrologists, palliative care physicians, members of the Kidney End-of-Life Coalition, representatives

from the ASN, American Nephrology Nurses Association, American Association of Kidney Patients, and National Renal Administrators Association, and a health economist. The pediatrics recommendations were reviewed formally by the American Society of Pediatric Nephrology and the American Academy of Pediatrics. This peer review was done to identify any seminal research evidence that was missed in the literature search and any major omissions in recommendations and rationales. Peer reviewers included persons selected by the RPA Quality, Safety, and Accountability Committee and nominated by stakeholder organizations. Volunteers from the nephrology community also reviewed the revision (see **Section 8: Acknowledgements**).

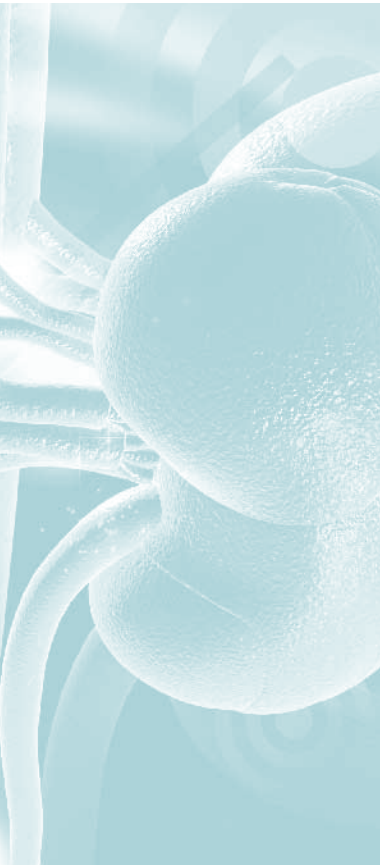
Endorsement was sought from all the organizations that endorsed the original guideline plus additional organizations whose members care for patients with AKI, CKD, or ESRD.

Figure 5. Diagram of Article Selection Process for the Guideline Revision



Section 4

Guideline Recommendations and Their Rationales for the Treatment of Adult Patients



Establishing a Shared Decision-Making Relationship

Recommendation No. 1

Develop a physician-patient relationship for shared decision-making.

Shared decision-making is the recognized preferred model for medical decision-making because it addresses the ethical need to fully inform patients about the risks and benefits of treatments, as well as the need to ensure that patients' values and preferences play a prominent role. Because of the number and complexity of decisions involved in treating kidney failure, a shared decision-making relationship is particularly important for patients with acute kidney injury (AKI); stage 4 and 5 chronic kidney disease (CKD); and stage 5 CKD requiring dialysis end-stage renal disease (ESRD). Participants in shared decision-making should involve at a minimum the patient and the physician. In addition, patients should identify and include a person who could serve as their decision-maker in the event they lose decision-making capacity. If a patient lacks decision-making capacity, decisions should involve the person legally authorized to make health care decisions on behalf of the incapacitated patient. This person is often (though not always) a family member and will be called "the legal agent" in the remainder of

Section 4



this document (see **Section 10: Glossary** for a full description). With the patient's consent, shared decision-making may include family members or friends and other members of the health care team.

Rationale

The recommended process by which health care professionals 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.¹ 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.²⁻⁶ (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 progressive CKD where the prognosis is known well before the actual need for dialysis arises.^{2,6-11} (Level B Observational Evidence)

A factor that could limit patients' understanding of information presented to them and their participation in shared decision-making is cognitive impairment that is severe enough to cause dialysis patients to lose decision-making capacity. Studies have found a high prevalence of cognitive impairment in certain populations of dialysis patients. In two studies in which the dialysis patients were randomly selected, cognitive impairment was found in 30 and 35 percent respectively.^{12,13} In a study of dialysis patients aged 55 years and older, cognitive impairment was found in 87 percent. It was mild in 14 percent, moderate in 36 percent, and severe in 37 percent.¹⁴ The authors of these

studies recommend cognitive testing before dialysis initiation and periodically thereafter. The toolkit in this guideline contains three instruments for assessing dialysis patients for cognitive impairment: the Montreal Cognitive Assessment Test (Tool 3-1), the Trail Making Part B test (Tool 3-2) and the Short Memory Questionnaire (does not require manual skills on the part of the patient and uses reliable informant to assess cognitive ability) (Tool 3-3).

It is important for physicians treating patients with CKD to identify cognitive impairment because patients with moderate to severe impairment are likely to lack decision-making capacity and be unable to meaningfully participate in shared decision-making. For those patients without decision-making capacity, the physician should identify the patient's legal agent and involve him or her in decision-making, including advance care planning. Because of the progression of cognitive impairment over time, earlier and more frequent advance care planning is recommended for the dialysis population.¹⁵ See **Recommendation No. 4** for additional discussion of the process of ensuring that each patient has a legal agent who can make health care decisions if the patient is unable to do so.

The majority of patients with AKI severe enough to be treated with renal replacement therapy have critical illness and are cared for in an ICU. In addition, they may have multiple-organ failure and receive multiple forms of organ support (e.g. mechanical ventilation, vasopressor therapy, etc.). This may also be true for some patients with stage 4-5 CKD who develop acute illness with rapid clinical deterioration. Thus, the concept of shared decision-making in this context necessitates a multidisciplinary approach including nephrologists, intensivists, and others as appropriate. Decisions about acute renal replacement therapy should be made in the context of other life-sustaining treatments.

In general it is appropriate to consider all life-sustaining therapy together when decisions about withdrawal or withholding of treatment are considered. However, the burdens of each individual treatment may differ and the values and preferences of an individual patient may lead to discordant decisions about therapies. The consequences of these decisions should be discussed openly with the patients and members of the health care team. An ethical framework for decision-making in the context of critical illness has been well established in the intensive care literature¹ and shared decision-making forms the backbone of this framework.

Informing Patients

Recommendation No. 2

Fully inform AKI, stage 4 and 5 CKD, and ESRD patients about their diagnosis, prognosis, and all treatment options.

In the setting of critical illness many patients with CKD will require urgent dialysis and the vast majority of patients with AKI will have multiple medical problems, in addition to kidney failure. The concept of shared decision-making necessitates a multidisciplinary approach including nephrologists, intensivists, and others as appropriate and decisions about acute renal replacement therapy should be made in the context of other life-sustaining treatments. For example, a decision to withhold dialysis in a patient agreeing to and receiving multiple other forms of life-sustaining therapy could represent discordant treatment in the same way that offering dialysis to a patient who has decided to forgo other forms of life-sustaining therapy might be inappropriate. Intensive care physicians need to be included in shared decision-making for kidney patients in the intensive care unit (ICU).

For ESRD patients, these options in shared decision-making include: 1) available dialysis modalities and kidney transplantation if applicable; 2) not starting dialysis and continuing medical management; 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 benefits and burdens of dialysis and the consequences of not starting or stopping dialysis. Research studies have identified a population of chronic kidney disease patients for whom the prognosis is particularly poor. This population has been found to include patients with two or more of the following characteristics: 1) elderly (defined by research studies identifying poor outcomes in patients who are age 75 years and older); 2) patients with high comorbidity scores (e.g., modified Charlson Comorbidity Index score of 8 or greater); 3) marked functional impairment (e.g., Karnofsky Performance Status Scale score of less than 40); and 4) severe chronic malnutrition (e.g., serum albumin level less than 2.5 g/dL using the bromocresol green method). Patients in this population should be informed that dialysis may not confer a survival advantage or improve functional status over medical management without dialysis and that dialysis entails significant burdens that may detract from their quality of life.

Rationale

There is widespread consensus that patients with decision-making capacity should participate in medical decisions if they so choose.¹⁶⁻²³ Competent patients have an absolute right to accept or refuse medically indicated treatment. This recommendation is supported by the ethical principle of respect

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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.^{3-5,7,24-29} (Level B Observational Evidence) Dialysis patients may discuss advance directives more with their families than with physicians, but 50% to 90% report no or inadequate discussions with health care professionals about therapeutic options including forgoing dialysis.^{2-11,20,30,31} (Level B Observational Evidence) Observational studies show most patients want information about their medical conditions and many (75% to 90%), though not all, desire to participate in care decisions.^{2,5,7,8,20,25,32-37} (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.³⁸

Elderly (aged 75 years and older) patients with stage 4 or 5 CKD constitute a group for whom the informed consent process regarding initiation of dialysis requires special consideration of the risk:benefit ratio. Because of the severe comorbidities, functional impairment, and malnutrition of

some elderly CKD patients, research shows that nephrologists should not take an “age neutral” approach to the management of CKD patients.³⁹ On the other hand, age alone should not constitute a contraindication to starting dialysis because comorbidity is the single most important determinant of outcome in dialysis patients.⁴⁰⁻⁴³ Age and comorbidity are additive in predicting dialysis patient survival. Thus, before placement of an arteriovenous access or peritoneal dialysis catheter, elderly patients with stage 4 or 5 CKD and severe comorbidities should be specifically informed that:

- Dialysis may not confer a survival advantage.
- Patients with their level of illness are more likely to die than live long enough to progress to ESRD.
- Life on dialysis entails significant burdens that may detract from their quality of life.
- It is likely that they may not experience any functional improvement with dialysis and that they may undergo significant functional decline during the first year after dialysis initiation.⁴⁴⁻⁴⁶
- The burdens of dialysis include surgery for vascular or peritoneal access placement and complications from the vascular access or peritoneal dialysis catheter.
- They may experience adverse physical symptoms on dialysis such as dizziness, fatigue, and cramping, and a feeling of “unwellness” after dialysis.

Further, patients need to be informed that there will be travel time and expense to and from dialysis, long hours spent on dialysis, and a reduction in the time available for physical activity.^{46,47} Dialysis may entail an “unnecessary medicalization of death” resulting in invasive tests, procedures, and hospitalizations.⁴⁸

In one study, elderly patients with significant comorbidity treated with dialysis as opposed to medical management without dialysis were more than four times as likely to die in the hospital as at home and spent 47.5% of the days they survived either in the hospital or at the dialysis clinic.⁴⁹ Such patients should be informed that medical management without dialysis is an acceptable alternative that may

better achieve patients' goals of care. It is active treatment that entails advance care planning, implementation of patients' goals, and management of anemia, bone disease, fluid balance, acidosis, and blood pressure. Multiple studies report a median survival ranging from 6.3 to 23.4 months for patients managed medically without dialysis.⁴⁹⁻⁵²

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 AKI).
 - Assess patient decision-making capacity and whether it is diminished by major depression, encephalopathy, or other disorder (see Tool 4 in **Section 9: Toolkit** 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, comorbidities, functional status, and age (see Tools 6-1 to 6.3 in **Section 9: Toolkit** for tools for assessing functional status and quality of life, and estimating prognosis).
 - Identify the patient's wishes.
 - Communicate options, taking advantage of educational resources, such as other patients or videotapes and brochures.
 - 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 is 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 Tool 8-2 in **Section 9: 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 Tool 5-1 in **Section 9: Toolkit** for helpful questions to use).
 - Refer for palliative care and hospice as appropriate.

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Recommendation No. 3

Give all patients with AKI, stage 5 CKD, or ESRD an estimate of prognosis specific to their overall condition.

To facilitate informed decisions about starting dialysis for AKI, stage 5 CKD, or ESRD, all patients should have their prognosis estimated and discussed, with the realization that the ability to predict survival in the individual patient is limited. Depending on the setting, a primary care physician, intensivist, or nephrologist who is familiar with estimating and communicating prognosis should conduct these discussions (see **Recommendation No. 10** for communication strategies). For patients with ESRD, the “surprise” question “Would I be surprised if this patient died in the next year?” can be used together with known risk factors for poor prognosis: age, comorbidities, severe malnutrition, and poor functional status. For patients with stage 5 CKD pre-dialysis, the estimate of prognosis should be discussed with the patient or legal agent, patient’s family, and among the medical team members to develop a consensus on the goals of care and whether dialysis or active medical management without dialysis should be used to best achieve these goals. These discussions should occur as early as possible in the course of the patient’s kidney disease and continue as the kidney disease progresses. For ESRD patients on dialysis who experience major complications that may substantially reduce survival or quality of life, it is appropriate to reassess treatment goals, including consideration of withdrawal from dialysis.

Rationale

Acute Kidney Injury (AKI)

Effect of AKI on Prognosis and Decision-making

The nephrologist can play a critical role in determining the aggressiveness of care for patients with AKI. AKI requiring renal replacement therapy provides a natural break

point in the escalation of care. Discussions regarding the patient’s ability to withstand dialytic therapy can give family members a feeling that “everything” reasonable has been done to provide for the recovery of the patient. Multiple prospective and retrospective studies have documented intensive care unit and in-hospital mortality rates of approximately 50% to 75% for patients with AKI receiving dialysis.⁵³⁻¹⁰² (Level A Prognostic Evidence) Medical and surgical patients had roughly similar mortality rates in these studies. A recent meta-analysis demonstrated the long-term morbidity and mortality after AKI.¹⁰³ The one retrospective study in bone marrow transplant patients showed a mortality rate of 85% with AKI-requiring dialysis and variable mortality risks depending on the type of bone marrow transplant.¹⁰⁴ In a prospective study of AKI cases requiring dialysis in an intensive care unit, deaths following life support withdrawal occurred in many more AKI patients (72%) than in intensive care unit patients who did not have AKI (40%).¹⁰⁵ In one large intensive care unit study, AKI requiring dialysis was found often to reflect the severity of underlying illness, affect overall survival negatively, and be associated with more frequent withdrawal from life support.¹⁰⁶ Recovery from AKI is low in patients discharged to a long-term care hospital while still requiring dialysis. In a study of 110 patients with AKI requiring dialysis who were admitted to a long-term care hospital, only 30 percent regained kidney function and were able to stop dialysis. Patients who did not recover renal function were significantly older and had higher baseline creatinine levels.¹⁰⁷

Prognosis Tools for Patients with AKI

Mortality prognosis can be quantified using routinely available measurement tools and scoring systems.^{60,98,100,101,108-131} Development of such measurement tools and prognostic scores has involved various multivariate modeling techniques and testing of more than 75

potential prognostic variables. Variables most often independently associated with increased mortality have been liver failure, mechanical ventilation, and multiorgan failure.^{53,54,56-58,61,101,132} 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.^{54-57,60}

In dialysis-dependent patients with AKI, general scoring systems may underestimate mortality risk.¹³³⁻¹³⁵ Recognizing the inability to precisely predict individual prognosis, the Working Group supported the provision of gross estimates of prognosis based on the belief that this information facilitates realistic patient and family expectations and promotes informed decision-making. Time-limited trials of dialysis for AKI with goals and parameters to be assessed, which are agreed upon in advance, allow the physicians and family to determine whether dialysis has benefited the patient and whether dialysis should be continued.

Recovery Rate from AKI

Collective studies are inconclusive regarding the rate of recovery from AKI. Several studies report dialysis-free rates of approximately 70% to 90% among survivors of AKI that required renal replacement therapy.^{53,57,58,61,62,67,71,78-81,85,86,99,136,137} (Level B Prognostic and Observational Evidence) Most of these studies were small, retrospective, and only followed patients to hospital discharge. Two recent clinical trials have shown widely disparate rates of recovery of kidney function, ranging from 75% to 95% at 2 to 3 months of follow up.^{137,138} Complete recovery of kidney function to within 0.5 mg/dL of baseline serum creatinine concentration at 28 days after the initiation of renal replacement therapy was observed in fewer than 30% of patients surviving an episode of severe AKI in one

clinical trial.¹⁰⁴ Adequate evidence regarding how many patients recover normal function and how long it takes for them to recover function was not found. In a study by Wald and colleagues, the risk of developing ESRD after an episode of AKI requiring dialysis was 2.63/100 person years, nearly triple that of the control group (0.91/100 person years) who did not have AKI.¹³⁹ (Figure 6 and Table 4). The Working Group recommends that patients with AKI who no longer require dialysis but who still have significant kidney 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 AKI 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 and asked to repeat back this information to ensure their understanding.

Chronic Kidney Disease

Although it is difficult to predict whether CKD will progress to ESRD in some patients, the majority of patients have relatively slow disease progression, which allows sufficient time for counseling about treatment options. These counseling sessions should occur before the time that dialysis is absolutely necessary. Furthermore, late referral to nephrology may prevent the nephrologist from developing the therapeutic relationship needed to achieve a consensus regarding the goals of care until after the patient starts dialysis. Several studies suggest that 40% to 70% of patients with ESRD are either not referred to nephrologists before beginning dialysis or have emergent first dialysis sessions (rather than electively planned first sessions) and/or are using a venous catheter for dialysis access.^{37,140-144} Data from USRDS patients beginning dialysis

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in 1996 showed 33% and 21% of patients were first seen by a nephrologist less than 3 months and less than 1 month, respectively, of beginning dialysis.¹⁴⁵ Recent Dialysis Outcomes and Practice Patterns Study (DOPPS) data demonstrated a mortality hazard ratio of 0.65 for patients seen by a nephrologist less than 1 month before starting dialysis.¹⁴⁴ The French Renal Epidemiology and Information Network study¹⁴³ and others found negative consequences of an unplanned start for dialysis.¹⁴⁶⁻¹⁴⁸ (Level B Prognostic Evidence) If the patient has already begun dialysis, a discussion about prognosis during the Comprehensive Assessment Process and development of the Plan of Care should begin as soon as the nephrologist and the other members of the renal care team determine the patient and/or legal agent can engage in meaningful conversation. With the patient's consent, the family should be encouraged to participate in the Plan of Care discussion. The occurrence of sentinel events (see the end of the ESRD section below) should also prompt further discussion of prognosis, values, preferences, and treatment goals.

Special Prognostic Considerations for Stage 4 and 5 CKD

Recent studies have shed light on the poor prognosis of many CKD patients. Studies have demonstrated that CKD patients are more likely to die than to reach dialysis, due to increasing cardiovascular mortality with higher stages of CKD.^{39,149,150} In one study, patients older than age 85 years had no baseline glomerular filtration rate at which they were more likely to progress to dialysis than die.³⁹ Studies of selected sicker CKD patients have usually demonstrated a small survival benefit to dialysis versus active medical management without dialysis but not uniformly so.^{41,48,49,51,52,151,152} (Table 5) In a study by Murtagh, patients older than age 75 years with ischemic heart disease or more than one comorbidity had no survival benefit

from dialysis.⁵² (Figure 7) Likewise, a study of patients with more comorbidities and lower functional status who had been recommended a non-dialytic approach to management but chose dialysis instead, showed no significant survival advantage.⁴⁸ (Level B Observational Evidence)

ESRD

Estimating Prognosis for Survival

Many studies report the effect of prognostic factors on survival for patients with ESRD on dialysis, but most of these studies in large databases (USRDS, DOPPS) are investigating variables that may point to potentially treatable causes of increased mortality. Furthermore the survival time frame is often more than 1 year. The Working Group was interested in identifying patients with an estimated prognosis of 12 or fewer months for the purpose of distinguishing patients who want to continue dialysis but have a poor prognosis and who are more likely to benefit from a predominantly comfort and symptom management approach to care as opposed to patients who want an aggressive treatment approach that focuses on prolonging life and optimizing function. This is not to say that pain and symptom management and advance care planning are not important to patients receiving an aggressive approach to treatment, but the point of the distinction is to identify patients for whom the goals of care are focused on reducing suffering more than on prolonging life. Eventual referral to hospice would be an appropriate near-term consideration for dialysis patients with a poor prognosis. It is assumed that all potentially treatable conditions have been addressed in these patients, and that the factors causing the poor prognosis are not reversible.

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 fewer than 20 to 150,000), and wide variation in data sources (single dialysis facilities, multicenter studies, commercial dialysis chains, and regional and national registries).

Other sources of variation include the type of population enrolled in each study, length of follow-up, and how deaths are designated. In the United States 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 before the start of the study) and incident patients. Length of follow-up can be as short as 6 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 CMS 2746 Death Notification form (revised in 2004), “withdrawal yes/no” is a separate item from cause of death. In addition, uremia/withdrawal is listed as a cause of death. In the United States, about 25% of patients annually withdraw from dialysis before death, and this number has been increasing over the past 10 years.¹⁵³ The rate of withdrawal varies by age (higher in the elderly), race (lower in Blacks) and geographic region.^{145,153,154} In a recent DOPPS analysis, in which withdrawal from dialysis was assessed in the first 120 days of starting dialysis (when the majority of withdrawals occur), the predictors of early mortality were no longer valid after dialysis withdrawal deaths were censored.¹⁴⁴ This suggests that the very high early mortality in incident dialysis patients is not “caused” by

withdrawal, and that it is likely that many patients who die in the first few months of dialysis had limited prospects for survival or quality of life benefit from dialysis.

Age is a powerful and consistent risk factor for death. For 1-year increments in age beginning at age 18, there is a remarkable consistency of risk ratios between 1.03 and 1.04 or a 3% to 4% increase in death rate per additional year of age.¹⁵³⁻¹⁶⁸ (Level A Prognostic Evidence) The effect of age is illustrated in Tables 6 and 7.¹⁶⁹ In comparison to the US population as a whole, dialysis patients have remaining lifetimes that are on average only one-fourth as long as non-dialysis patients of the same age and sex. Survival is significantly better in ESRD patients of all age groups after renal transplantation.

Although a small but consistent decrease in mortality (in particular from cardiovascular causes) has occurred in prevalent hemodialysis patients over the past 20 years (Figure 8 and Figure 9) the survival of incident patients in the first 6 to 12 months of dialysis has improved little.¹⁶⁹ The 30 to 120 day mortality rates remain extraordinarily high, particularly in the elderly.¹⁶⁹ (Figure 10) From 1993 to 2005, mortality rates in the first 3 months after starting dialysis have risen.

Serum albumin level, both at baseline and during the course of dialysis treatment, is a consistent and strong predictor of death with multiple studies showing a statistically significant relationship.^{153,155-158,160,161,168,170-181} (Level A Prognostic Evidence) The lower the serum albumin level, the higher the risk of death.¹⁸² (Figure 11) For example, an albumin of less than 3.0 grams per deciliter (g/dL) versus more than 4.0 g/dL confers a 4.4 times greater risk of early death.¹⁷⁰ An albumin level of less than 3.5 g/dL is associated with 1-year mortality of approximately 50%.^{156,170,172,176,183,184} (Level A Prognostic Evidence) A recent large study from 2008 that examined 1995 to 2004

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data on incident dialysis patients with CMS 2728 forms completed supports the prognostic value of serum albumin. It demonstrates that serum albumin levels have declined over time in the incident US ESRD population and confirms the previously reported strong association with the first value after starting dialysis and mortality. With case-mix adjustment, incident dialysis patients with an initial serum albumin less than 2.5 g/dL have an odds ratio of dying in 1 year more than three times greater than patients with a serum albumin equal to or greater than 4 g/dL.¹⁸⁵

Apart from the serum albumin, other nutritional status markers also are powerful predictors 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 1 month before the onset of ESRD to 6 weeks after the first treatment), body mass index, subjective global assessment of nutritional status (per the method of Baker and Detsky),^{186,187} protein catabolic rate, skinfold thickness, and creatinine level. Cachexia, poor subjective global assessment of nutritional status, and “undernourished” all convey a significantly elevated risk of death.^{160,164,165,168,181,188} (Level B Prognostic Evidence)

Recently the malnutrition inflammatory complex syndrome (MICS) has been shown to predict short-term mortality.¹⁸⁹ (Table 8 and Table 9) In one study, the MIS (malnutrition inflammation score), Charlson Comorbidity Index, and C-reactive protein (CRP) level were superior to serum albumin in predicting 12-month mortality.¹⁸⁹ The MIS takes into account dry weight change in the past 3 to 6 months, gastrointestinal symptoms/appetite, functional capacity, years on dialysis and severe comorbidities (congestive heart failure, AIDS, severe coronary artery disease,

moderate to severe chronic obstructive pulmonary disease, metastatic cancer, and major neurologic conditions), muscle wasting, loss of fat stores, body mass index, serum albumin, and total iron binding capacity. Interleukin 6 and tumor necrosis factor also were measured, and although correlated with mortality, in the multivariate analysis they did not add prognostic value to the above factors.¹⁸⁹

Other laboratory values that correlate with malnutrition-inflammation and are predictors of short-term mortality are low serum cholesterol and low serum low phosphorus.^{144,189} Vitamin D levels and use of Vitamin D also have shown an association with mortality.¹⁹⁰

High serum troponin,^{191,192} beta-natriuretic peptide (BNP),¹⁹³⁻¹⁹⁵ low blood pressure, use of a venous catheter for dialysis access,¹⁹⁶ and unplanned start of dialysis¹⁴⁴ also are short-term mortality predictors.

Poor functional status is highly predictive of early death (relative risk ranges of 1.5 to 3).^{153,158,160,170,171,174,177,179,180,197-203} (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)^{160,165,171,204} mild-severe mobility impairment,¹⁷⁰ Karnofsky or modified Karnofsky scale (see Tool 7 in **Section 9: Toolkit**),^{153,174,177,180,198-200,205,206}



Gutman functional status,¹⁹⁸ Activities of Daily Living,^{297,201} and the Medical Outcomes Study 36-item Short Form (SF-36).²⁰³ Frailty scores also correlate with increased mortality.²⁰⁷ In most studies, functional status was assessed by the health care providers rather than the patients, who may rate their quality of life higher. In particular, an inability to transfer and falls are indicators of a poor prognosis.²⁰⁸ Dialysis in nursing home residents is associated with a marked decline in functional status at 1 year (only 13% maintained baseline function) and a 58% mortality.⁴⁶ In another study of dialysis patients age 80 years or older, the initiation of dialysis was found to be marked by functional loss requiring community or private caregiver support or transfer to a nursing home in 30% of patients by 6 months. At the end of a year, 22% of patients remained independent, 31% were supported, and 44% had died.⁴⁵

Comorbidity is the single most important determinant of outcome in ESRD patients on dialysis.⁴⁰ Multiple 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, ischemic heart disease, cardiovascular disease, and other comorbidities 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,^{163,209,210} to grading the comorbidity burden,¹⁵⁴ to using aggregations of ICD-9 codes from hospitalizations.²¹¹ One study specifically developed a severity of illness index for patients with ESRD.²¹¹ In all of these studies, having comorbid illness conferred higher risk although the magnitude of relative risk varied widely, from 1.11 to 12.8 (Level A Prognostic Evidence) The Charlson Comorbidity Index

and modification of the Charlson Comorbidity Index for ESRD have good predictive value. (Level A Prognostic Evidence)²¹²⁻²¹⁴ In chronic dialysis patients, a Charlson Comorbidity Index score of equal to or greater than 8 has been shown to be associated with about a 50% 1-year mortality.²¹⁵

Numerous comorbid conditions have been studied for their effect on survival: diabetes, congestive heart failure (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.^{153,155,160,162,164,167,173,176,178,188,198,199,202,216-221}

(Level A Prognostic Evidence) Some studies find diabetes' significance diminishes when laboratory abnormalities are included in multivariate models.^{161,176} 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 diabetes confers a significantly higher risk of death.^{165,166,222}

Most studies found CHF to be predictive of poorer survival, with a relative risk anywhere from 14% to 84% higher than those without CHF.^{153,155,167,168,170,223} (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^{153,155,165,168,171,202,217,219} and 14 studies showed an increased risk of anywhere from 26% up to 780%.^{160,162,164-166,168,170,171,179,181,183,188,198,220,224}

(Level A Prognostic Evidence) In 6 of 7 studies, PVD conveyed an increased risk of death between 11 and 862%.^{153,155,160,168,171,181,223} (Level A Prognostic Evidence) Cancer confers anywhere from 30% to 250% increased risk of

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death.^{153,162,164,170,171,202,203} (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%.^{153,155,161,167-171,173,223} (Level A Prognostic Evidence)

The most consistent comorbid factors that predict less than 12-month survival are New York Heart Association class 4 heart failure, moderate to severe COPD, severe PVD, dementia, severe behavioral conditions, acquired immunodeficiency syndrome, and metastatic cancer. Quality of life scores, depression, pruritus, and restless leg syndrome also correlate with poor outcomes.²²⁵⁻²³⁴

Predicting Who Will Die Within the First Year on Dialysis. Eleven articles^{41,42,144,170,235-240} 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, Barrett²³⁹ 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. Barrett and Chandna⁴² 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)²²³ and above the knee amputation (AKA)^{184,241,242} (Level A Prognostic Evidence). For both of these events survival at 1 year is less than 50% (38% to 44% for AMI and 27% for AKA). 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. A 2009 study demonstrates the poor prognosis after strokes

and pneumonia.^{243,244} Survival after coronary artery bypass surgery in ESRD is much worse than an aged-matched cohort, especially when associated with PVD and CVA.^{245,246} Falls (and the number of falls) in the elderly is associated with increased mortality.²⁰⁸ Table 10 displays the ranges of risk estimates from these studies.

In the DOPPS database a number of sentinel events were associated with withdrawal from dialysis: failure to thrive, gangrene, cancer, dementia, stroke, amputation, pneumonia, CHF, myocardial infarction, and gastrointestinal bleed.²⁴⁷

Summary Risks and Mathematical Models. Recently, investigators have attempted to develop and test mathematical models for identifying ESRD patients with a poor short-term prognosis.²³⁵ An integrated prognostic model takes into account the clinician's estimate of prognosis, laboratory values, comorbidities,^{41,143,212,236,248-250} changes in comorbidity score over time,²³⁶ functional status/fragility, quality of life,²²⁵⁻²²⁹ and possibly the patient's prediction of prognosis.²⁵¹ Two recent studies have supported the value of this approach. The simple "surprise question" is a strong indicator of 6 to 12 month mortality²⁵¹ (Figure 12). Cohen and colleagues developed and validated a mathematical model for estimating patient survival at 6 months that used the surprise question, serum albumin, age, and presence or absence of two comorbidities: dementia and peripheral vascular disease. This model had a receiver operating curve (ROC) of .82.²⁵² Use of large databases²⁵³ and results from multivariate analyses of various prognostic studies allow comparison of the magnitude of effect between risk factors. Newer statistical methods, such as time-variate and additive damage models,²⁵⁴⁻²⁵⁶ have the potential to improve mortality risk prediction. Couchoud and colleagues developed and validated a model and scoring system from the French database in incident dialysis patients to predict 6-month mortality.⁴¹ Independent risk factors were

BMI less than 18.5, diabetes, CHF (stage 3,4), PVD (stage 3,4), unplanned dialysis, inability to transfer, active malignancy, and severe behavioral disorder. A point score was developed that predicted 6-month mortality with the intention to provide guidance for recommending a palliative approach to care.⁴¹ (Table 11 and Table 12)

Using the Catalan database Mauri and colleagues developed and validated a 12-month mortality model in incident patients based on age, sex, cause of kidney disease, physical function, COPD, liver disease, cardiovascular disease, dialysis vascular access, malnutrition, and malignancy.¹⁵² (Table 13)

Additional approaches to improving prognostic modeling include changes to comorbidities and severity of comorbidities over time,²³⁶ and a self-learning rules-based model.²³⁷

These data and other studies suggest that it may be possible with further research to identify a subset of elderly patients who will not benefit from starting dialysis. Dialysis in these patients may be associated with significant morbidity, deterioration in functional capacity and quality of life, and the shortest survival. A prognosis prediction tool that incorporates the surprise question, age, comorbidities, and functional status is likely to be able to help identify these patients. Once identified, the renal care team should

Box 2. Suggested Steps for Implementing Recommendation No. 3

- For ESRD patients, estimate prognosis based upon patient's age, functional status, medical condition, including comorbidity and recent sentinel events, and the "surprise" question. The website <http://touchcalc.com/calculators/sq> provides a calculator for use of the surprise question response and other variables to estimate prognosis in dialysis patients. The same degree of precision does not exist for tools that estimate prognosis for patients with AKI.
- Present the prognosis in a manner that is considerate of the patient's emotional condition. Balance the patient's desire for quality and quantity of life and provide reassurance that the physician has kept the patient's best interest in mind. With the patient's permission, strongly encourage the patient's legal agent/family to participate in the discussion of prognosis and treatment options. See **Recommendation No. 10** for suggested approaches to discussing prognosis, treatment options, and goals of care with AKI, CKD, and ESRD patients.
- Identify patient's wishes and goals for treatment at onset of dialysis and again after any irreversible change in medical condition.
- For ESRD patients, reassess and communicate prognosis on at least an annual basis, and more often as indicated by any major change in status.
- For CKD and ESRD patients, during each annual Comprehensive Assessment and Plan of Care discussion, communicate appropriate options based on the patient's condition, prognosis, and goals for care. Regardless of choice, palliative care should be offered for pain and symptom management and advance care planning. Hospice referral is appropriate for ESRD patients stopping dialysis.
- Provide recommendation to withhold/stop dialysis in patients who are not likely to benefit.
- If conflicts arise in shared decision-making, consider palliative care or ethics consultation (see **Recommendation No. 8**).

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engage these patients and family/legal agents in discussions of goals of care and end-of-life treatment preferences.

Facilitating Advance Care Planning

Recommendation No. 4

Institute advance care planning.

The purpose of advance care planning is to help the patient understand his/her condition, identify his/her goals for care, and prepare for the decisions that may have to be made as the condition progresses over time. For chronic dialysis patients, the interdisciplinary renal care team should encourage patient-family discussion and advance care planning and include advance care planning in the overall plan of care for each individual patient (see **Section 10: Glossary** for definition of renal care team). The renal care team should designate a person to be primarily responsible for ensuring that advance care planning is offered to each patient. Patients with decision-making capacity should be *strongly* encouraged to talk to their legal agents while they still have capacity to ensure that the legal agent knows the patient's wishes and agrees to make decisions according to these wishes.

The renal care team should attempt to obtain written advance directives from all dialysis patients. Where legally accepted, Physician Orders for Life-Sustaining Treatment (POLST) or similar state-specific forms, also should be completed as part of the advance care planning process. At a minimum, each dialysis patient should be asked to designate a legal agent in a state-specific advance directive. Advance directives should be honored by dialysis centers, nephrologists, and other nephrology clinicians except possibly in situations in which the advance directive

requests treatment contrary to the standard of care (see **Recommendation No. 8** on conflict resolution).

Rationale

Goals of care discussions are an inherent part of advance care planning and necessary before completing advance directives. Goals of care discussions for the AKI, CKD, and ESRD patient, broadly defined, should be explicit about: 1) whether cure is feasible (where the main aim will be achieving that cure); 2) whether life can realistically be extended with acceptable functional capacity; 3) whether the principal goals of care in a patient who wants to start or continue dialysis are life prolongation and comfort; and 4) whether the patient prefers a natural death without life-sustaining treatment (active medical management without dialysis; see **Section 10: Glossary** for an expanded explanation). The key times of transition are likely to include: 1) when active medical management without dialysis is being considered in stage 5 CKD; 2) preparation for and transition onto dialysis; 3) clinical physical and/or cognitive deterioration despite dialysis, associated with increasing dependency; and 4) consideration of withdrawal from dialysis and likely referral to hospice.

Advance care planning is a patient-centered, comprehensive, ongoing discussion among care providers and their patients and families (or the patient's designated legal agent) about values, treatment preferences, decision-makers in the event of the patient's incapacity, and goals of care.²⁵⁷⁻²⁶⁰ The advance care planning process includes communicating information to the patient and family about the current clinical condition, prognosis, and treatment options within the context of the patient's values and goals, which will ultimately guide medical decision-making. Because one's medical condition is a primary factor influencing treatment choices,^{7,261} advance care planning interactive discussions

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must be re-visited at critical points in a patient's care or whenever a patient or a legal agent wishes to revisit these issues.

Advance care planning is grounded in the ethical principle of respect for patient autonomy. Multiple observational studies demonstrate many, though not all, patients want to communicate about their future medical care and discuss their preferences for care in the event they lose decision-making capacity.^{5,7,8,23,25,32-37,262,263} (Level A Observational Evidence) 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 presume them.^{21-23,91,264,265} (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.^{266,267} (Level C Observational Evidence). Patients and families generally assume physicians will introduce advance care planning discussions and usually want these discussion to occur earlier in the course of CKD than they typically do.^{5,268-270}

Advance care planning can facilitate the completion of written advance directives, but the advance care planning process itself can increase congruence between patient, family, and physician understanding and therefore improve satisfaction and compliance with patient preferences.²⁷¹ Key components of advance care planning (See Boxes 3 and 4) can provide a structure for the process.^{268,272}

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 directives flow from advance care planning and are an integral part of the process.

Proxy directives (formally naming a person to make decisions in the event the patient is unable to make his or her own decisions) and instruction directives (e.g., living wills or Do Not Resuscitate [DNR] documents) are examples of advance directives. Written advance directives are always preferable to oral directives because they provide better legal protection. Some patients may not prefer or refuse written directives. In such instances, it is acceptable to obtain an oral statement with two witnesses present and to document the oral advance directive in the chart.

Patients who decide to forgo dialysis should be questioned to be sure their reasons are understood and informed of the implications of their decision. Because death from cardiac arrest as a late complication of uremia is likely, patient agreement to a DNR/Do Not Intubate order should be obtained in advance, and the patient's legal agent should be part of the discussion. Such directives and discussions will help to avoid situations in which patients lacking written advance directives have their wishes overridden by a legal agent later in their disease course.

Studies show variability in how well patients understand and trust advance care documents.^{273,274} (Level C Observational Evidence) Several observational studies show that while most patients support the concept of advance directives, a minority actually complete them.^{3,5,26-29,261,266,275,276} (Level A Observational Evidence) and certain groups of patients and families (e.g., ethnic minorities) are less likely than others to complete advance directives.²⁷⁷

Several attempts have been made to increase the use of advance directives. The Patient Self-Determination Act (PSDA),²⁵⁷ effective in 1991, mandated that health care providers

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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. In 2008, in the updated Conditions for Coverage for End-Stage Renal Disease Facilities, dialysis units are required to inform dialysis patients about their right to complete advance directives and the facility's policy with regard to advance directives. 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%.²⁵⁸ (Level C Observational Evidence) Having advance directives has been correlated with having discussions with health care providers about life-sustaining therapies.^{5,258} (Level C Observational Evidence) Providing patients educational material about advance directives has had variable impact on completion rates.^{262,263,273,274} (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.²⁷⁸ (Level C Observational Evidence) Efforts to increase the completion of advance directives have generally failed, making encouragement of advance care planning discussions among patients and families even more important. Patient-centered advance care planning can be effective in promoting shared decision-making between patients and their surrogates.²⁷¹

Surveys show physicians in general are willing to honor advance directives,^{9,21,22} but that approximately a quarter express difficulty honoring directives when the directives conflict with what they personally

think is best for patients.²⁶⁵ (Level C Observational Evidence) A scenario-based study of physicians at one academic center found that more specific preferences listed in advance directives were more likely to be followed.²⁷⁹ (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.²⁸⁰ (Level C Observational Evidence) Use of the Physician Orders for Life-Sustaining Treatment (POLST) has been adopted by multiple states and regions (www.polst.org) in response to inadequacies in general written advance directives.²⁸¹ Unlike living wills (instruction directives) or documents naming legal agents (proxy directives), POLST forms are signed physician (in some states nurse practitioners are authorized to sign) orders directing treatments based on patient choice. POLST forms are especially appropriate for patients for whom the nephrologist would not be surprised if the patient died in the next year. They have shown to be effective in honoring patients' end-of-life treatment preferences in part because they ensure continuity of orders for the patient across treatment settings.²⁸² Where available, such documents are particularly applicable to many, if not most, CKD and dialysis patients and should be offered, completed, and honored.

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.²⁷⁸ (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.²⁸³ (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.²⁸⁴ (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.³⁸⁵ (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 cardiopulmonary resuscitation; nearly half of DNR orders were written within 2 days of death; approximately a third of patients who died spent at least 10 days in an intensive care unit; and half of conscious patients who died reported moderate to severe pain at least half of the time before 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.²⁸⁶ 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.²⁸⁷ (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. A retrospective study of advance care planning in peritoneal dialysis patients in long-term care found that age and functional status strongly influenced plans not to hospitalize and not to attempt resuscitation but such plans did not affect patient survival.²⁸⁸ Plans were established for nearly all the 109 patients in this study, and no patient with a do not attempt resuscitation order underwent unwanted cardiopulmonary resuscitation.²⁸⁸ Taken together these studies show many aspects of end-of-life care, especially advance care planning, need to be improved.

Several 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.^{259,273,289} The five key components in advance care planning with ESRD patients include: facilitated advance care planning,²⁷² documentation of the process and the patient's preferences, timing of the discussion, involving the optimal systems and processes for success, and assessing the process through quality improvement.²⁷² Patient participation is essential, as is the involvement of individuals identified by the patient as central to the process. Although patients and families expect physicians to raise the issues involved

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Box 3. Suggested Steps for Implementing Recommendation No. 4



- Assess decision-making capacity (see Tool 4-1 in **Section 9: Toolkit**).
- Include advance care planning in the Comprehensive Assessment and Plan of Care for each individual patient.
- Inform dialysis patient of his/her right to complete an advance directive and of the dialysis facility's policy with regard to advance directives as required by the 2008 Conditions for Coverage.
- Encourage patient-centered advance care planning among patients and families; raise the issue of advance care planning with each patient at the initiation of dialysis (earlier is preferred) and on at least a yearly basis. Hospitalizations and/or significant changes in medical, physical, or functional status should prompt reconsideration of advance care planning.
- Discuss advance care planning 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 which would you choose?
 - Under what circumstances, if any, would you want to stop dialysis?
 - If your heart stops beating or you stop breathing, would you want to allow a natural death?
 - 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 who do you wish to be with you when you die?
- 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 appointing a surrogate according to state law.
- Encourage patients to be specific about their preferences with legal agent, family, friends, and providers.
- 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. Where available, complete a Physician Orders for Life-Sustaining Treatment (POLST) or similar form to translate patients' wishes into medical orders (see www.polst.org).
- Place a copy of advance directives, DNR order card, and/or POLST form in multiple medical records as appropriate, including dialysis facility, commonly attended clinics, hospital, nursing home, and home.
- Encourage the patient, family and/or legal agent to carry a current copy of the patient's advance directive, do not resuscitate order card, and/or POLST form whenever traveling or being admitted for overnight medical care.

Box 4. Desired Outcomes for Advance Care Planning for CKD and ESRD Patients^{259,260,270,272,282}

- Enhance patient and family understanding about their illness and end-of-life issues, including prognosis and likely outcomes of alternative plans of care
- Define the particular patient's key priorities in end-of-life care and develop a care plan that address these issues and identifies the patient's overall goals of care
- Enhance patient autonomy by shaping future clinical care to fit the patients preferences and values
- Improve the process of health care decision-making generally, including 1) patient and family satisfaction with the advance care planning process; 2) health care provider understanding of advance care planning and advance directives; and 3) provider comfort in participating in advance care planning
- Help patients find hope and meaning in life and achieve a sense of spiritual peace
- Explore ways to ease the emotional and financial burdens borne by patients and families
- Strengthen relationships with loved ones
- Complete written advance directives, particularly those identifying a legal agent, do not resuscitate documents, and POLST documents where available
- Honor advance directives, do not resuscitate orders, and POLST orders at the end of life

in advance care planning,^{5,268,270,272} other dialysis unit personnel such as social workers, nurses, or peer counselors, may be integral to the process.

Making a Decision to Not Initiate or to Discontinue Dialysis

Recommendation No. 5*

If appropriate, forgo (withhold initiation or withdraw ongoing) dialysis for patients with AKI, CKD, or ESRD in certain, well-defined situations.

These situations include the following:

- Patients with decision-making capacity, who being fully informed and making voluntary choices, refuse dialysis or request that dialysis be discontinued.
- Patients who no longer possess decision-making capacity who have previously indicated refusal of dialysis in an oral or written advance directive.
- Patients who no longer possess decision-making capacity and whose properly appointed legal agents/surrogates 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.

*Medical management incorporating palliative care is an integral part of the decision to forgo dialysis in AKI, CKD, or ESRD, and attention to patient comfort and quality of life while dying should be addressed directly or managed by palliative care consultation and referral to a hospice program (see Recommendation No. 9 on palliative care services).

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Rationale

The legal and ethical principles supporting this recommendation include informed refusal, respect for patient autonomy, beneficence, non-maleficence, 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. Authoritative psychiatry and nephrology opinion supports the notion that patients in the general nephrology setting who choose to forgo dialysis are neither psychopathological nor suicidal even though depression may be present.²⁹⁰ Relevant observational evidence is limited but suggests that withdrawal is common, with rates ranging from 17% to 50% of deaths in different dialysis populations.²⁹¹⁻²⁹⁴ (Level C Observational Evidence) However, often patients have neither discussed their preferences with family or renal care team members nor completed written advance directives.^{3-5,7,25-29} (Level B Observational Evidence) A few studies suggest that patients with decision-making capacity most often initiate the discussion of withdrawal of dialysis themselves and that physicians most often raise the issue for patients without decision-making capacity.^{291-293,295} (Level C Observational Evidence) Evidence also indicates that patients often expect medical staff to initiate these discussions and that staff are reluctant often because of a lack of experience, either professional or personal, with end-of-life discussion.^{26,29,276,296}

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.^{7,261,297,298}

(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 they have reported that affect their withdrawal decisions include patient's neurological and physical functional status, comorbidities, family wishes, and age.^{21-23,263,265,295,299} (Level C Observational Evidence) More recent evidence suggests that depression, as measured using survey and questionnaire methods, is associated with forgoing dialysis, although it is uncertain whether this depression is causative or a concomitant phenomenon.^{300,301} Previous studies have found that diabetes, severe pain, lack of a significant partner, Caucasian race, female gender, nursing home residence, and terminal illness are associated with withdrawal from dialysis.^{22,265,276,291-293,295,297,299,302,303} (Level C Observational Evidence) More recent evidence suggests that inadequately treated pain may be an important concomitant of depression and independently predict withdrawal decisions.³⁰⁰ (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 AKI is substantial (29%) and that increasing age and dementia were independent predictors of withholding in multivariate analyses adjusting for confounders.⁹¹ (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 years to more than 70 years), and may be higher in women.^{264,275,304,305} (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.³⁰⁶ (Level C Observational Evidence) More than 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.

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.^{307,308}

The request for dialysis by patients with a poor prognosis or their legal agents should be considered within the framework of goals for care. Dialysis might allow additional time deemed of acceptable quality by the patient while at the same time there is agreement that aggressive end-of-life therapy will not be pursued. However this consideration must be balanced against continuing treatment that violates the ethical principle of professional integrity when the burdens of dialysis substantially outweigh the benefits.³⁰⁷⁻³¹¹

The renal care 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) or to participate in ongoing family life in a way which is personally meaningful and in which the family participates directly in the care of the patient (e.g., home peritoneal dialysis). There are some anecdotal examples in which dialysis enables unexpected survival with subjectively acceptable quality of life for some functionally dependent elderly patients, patients with chronic cardiac or liver disease, or patients with terminal illness. An innovative alternative, a “No Dialysis Clinic,” has been described in Great Britain in which patients with CKD who so chose are managed for

the duration of their survival. Even in this setting, some patients still ultimately opt for a short course of dialysis before they die.⁵⁰ In the acute hospital setting, review of hospital death experience suggests that advance directives often do not focus sufficiently on palliative measures when treatment is withdrawn.³¹² Nonetheless, family satisfaction can be favorably influenced by more discussion concerning general prognosis and comfort measures, even if these discussions prolong the process and even when terminal extubation is ultimately chosen.^{107,313}

Generally, “terminal illness” for the purposes of hospice referral is defined as a life expectancy of less than or equal to 6 months if the disease process takes its normal course. AKI, CKD, or ESRD patients with non-kidney terminal illness include those with end-stage liver, heart, or lung disease who are deemed inappropriate organ transplantation candidates. Non-kidney terminal illnesses which AKI, CKD, or ESRD patients may have include end-stage cirrhosis with hepatorenal syndrome, severe congestive heart failure, 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.^{64,65,67-71,123} (Level A Prognostic Evidence) The survival for patients with intact kidney function and such selected terminal comorbid conditions may be estimated. When the expected survival for patients with a specific terminal illness but intact kidney function is estimated to be less than 6 months, it is logical to conclude that dialysis for patients with AKI, CKD, or ESRD and one or more of the above conditions is unlikely to extend survival beyond 6 months.

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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 permanent vegetative states fulfill this definition.

Recommendation No. 6

Consider forgoing dialysis for AKI, CKD, or ESRD patients who have a very poor prognosis or for whom dialysis cannot be provided safely.

Included in these categories of patients are the following:

- Those whose medical condition precludes the technical process of dialysis because the patient is unable to cooperate (e.g., advanced dementia patient who pulls out dialysis needles) or because the patient's condition is too unstable (e.g., profound hypotension).
- Those who have a terminal illness from non-renal causes (acknowledging that some in this condition may perceive benefit from and choose to undergo dialysis).
- Those with stage 5 CKD older than age 75 years who meet two or more of the following statistically significant very poor prognosis criteria (see **Recommendations No. 2 and 3**): 1) clinicians' response of "No, I would not be surprised" to the surprise question; 2) high comorbidity score; 3) significantly impaired functional status (e.g., Karnofsky Performance Status score less than 40); and 4) severe chronic malnutrition (i.e., serum albumin less than 2.5 g/dL using the bromocresol green method).

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.^{307,308} Patients with advanced cognitive impairment who are unable to cooperate with the dialysis process may be harmful to themselves, other patients, and personnel in the dialysis unit and may create an unsafe working environment.²¹⁴ Examples of patients who might be in this category include those who are unsafe despite physical or chemical restraints or a sitter during dialysis. 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). If there is conflict with regard to the appropriateness of dialysis of a patient described by **Recommendation No. 7**, then conflict resolution is recommended (see **Recommendation No. 9**).

Evidence is increasing that elderly patients with stage 5 CKD and high comorbidity scores, significant functional impairment, and severe malnutrition may not benefit from dialysis in terms of increased survival or improved quality of life. See "Special Considerations for Stage 4 and 5 CKD" in the rationale for **Recommendation No. 3** for a discussion of these studies and findings. Palliative care consultation for such patients may assist with comprehensive goals of care discussions and explicit expressions of the patients' treatment preferences for their present condition and in the future when there are changes in their condition.

Resolving Conflicts about What Dialysis Decisions to Make

Recommendation No. 7

Consider a time-limited trial of dialysis for patients requiring dialysis, but who have an uncertain prognosis, or for whom a consensus cannot be reached about providing dialysis.

If a time-limited trial of dialysis is conducted, the nephrologist, the patient, the patient's legal agent, and the patient's family (with the patient's permission to participate in decision-making) should agree in advance on the length of the trial and parameters to be assessed during and at the completion of the time-limited trial to determine whether dialysis has benefited the patient and whether dialysis should be continued.

Rationale

Experts recommend time-limited trials of life-sustaining treatment such as dialysis in situations when the benefit to the patient is uncertain. 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. In this way, time-limited trials may promote informed shared decision-making.^{16,314-316} For example, a patient who is uncertain about his/her quality of life on dialysis may benefit from a time-limited trial. The Working Group found no research data about outcomes of time-limited trials of dialysis.

The exact time period for the trial may be made on a case-by-case basis. For patients with AKI, time periods of several days to 2 weeks may be reasonable. For patients with

ESRD, time periods of 1 to 3 months are reasonable. If there is uncertainty about the ability of a patient to cooperate with dialysis, the patient should be considered for a time-limited trial of dialysis before it is withheld. In one study, nephrologists who reported they were very well prepared to participate in end-of-life decision-making with dialysis patients were more likely to use time-limited trials than those who reported a lower level of preparedness.³¹⁷ In addition, nephrologists who reported they were very well prepared to participate in end-of-life dialysis decision-making were more likely to be aware of the first edition of this clinical practice guideline.

Recommendation No. 8

Establish a systematic due process approach for conflict resolution if there is disagreement about what decision should be made with regard to dialysis.

Conflicts may occur between the patient/legal agent and the renal care team about whether dialysis will benefit the patient. Conflicts also may occur within the renal care team or between the renal care team and other health care providers. In talking with patients/legal agents, the nephrologist should try to understand their views, provide data to support his/her recommendation, and correct misunderstandings. In the process of shared decision-making, the following potential sources of conflict have been recognized: 1) miscommunication or misunderstanding about prognosis; 2) intrapersonal or interpersonal issues; or 3) special 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

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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.^{21-33,275,318} (Level C Observational Evidence)

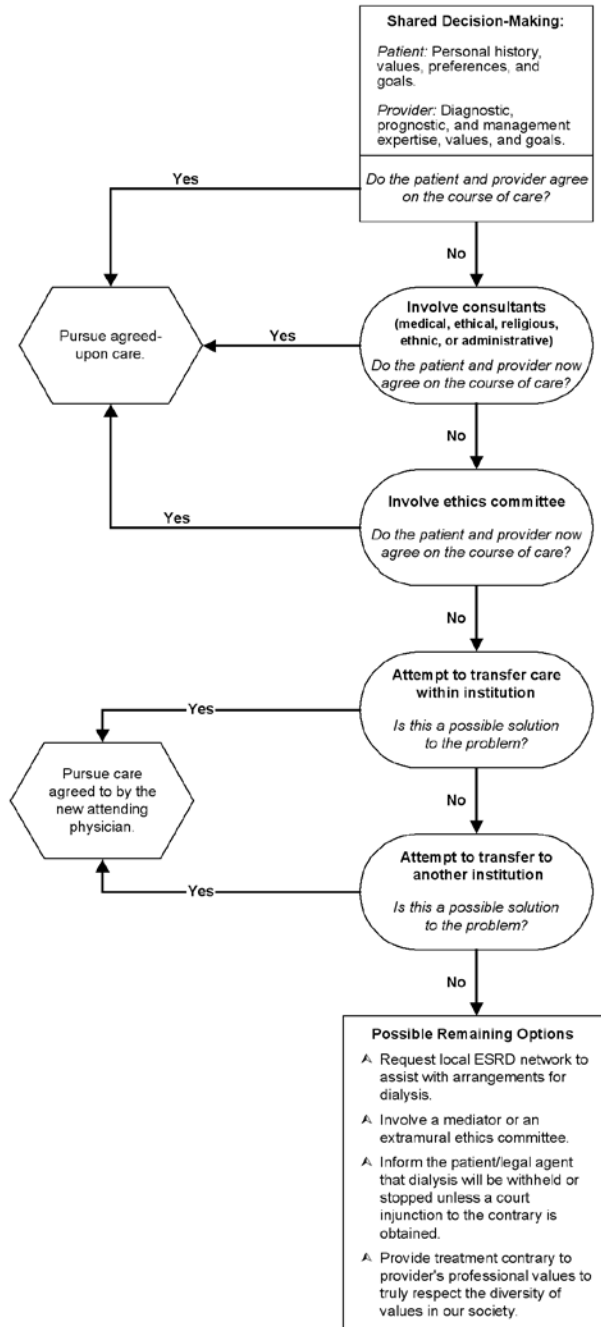
When the clinician determines that, based on the medical evidence, the burdens of dialysis substantially outweigh the benefits, he/she should meet with patient/legal agent and present the factors that indicate a poor outcome with dialysis. The aim is to reach agreement about the goals of care. If agreement is not reached on the course of care, then conflict resolution using the due process approach in Figure 13 should be initiated, and an ethics consultation should be considered.³¹⁹ 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.³²⁰ (Level C Observational Evidence) 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 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 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.³²⁰⁻³²⁶ (Level B Observational Evidence) In contrast to a 1990 survey, a survey of nephrologists in 2005 indicated that a majority of nephrologists use ethics committees to assist with decision-making in challenging situations.³²⁷

Conflict also may occur when a patient with decision-making capacity refuses to start or continue dialysis that the physician believes is or will be beneficial. In such circumstances it is important to ensure that the decision to refuse recommended dialysis is based on good information and consistent with the patient's values and goals. Nephrologists are required by ethics and the law to respect the informed decision of a patient with decision-making capacity who chooses to refuse dialysis. (See **Recommendation No. 5** for further discussion of this issue.) If a nephrologist is unwilling to respect such a decision, then he or she should transfer the patient's care to another physician or institution.

Guideline Recommendations and Their Rationales for the Treatment of Adult Patients

Figure 13: Systematic Approach to Resolving Conflict between Patient and Kidney Care Team



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Box 5. Suggested Steps for Implementing Recommendation No. 8

Engage in extended conversation for either request for dialysis when not recommended or refusal of dialysis when recommended:

- Why does the patient or legal agent desire dialysis when it is not recommended by the renal care team?
- Does the nephrologist misunderstand the patient's or legal agent's reasons for requesting dialysis?
- Does the patient or legal agent misunderstand the diagnosis, prognosis, and treatment alternatives and why dialysis is not recommended?
- Why does the patient or legal agent refuse dialysis when it is recommended by the renal care team?
- Is the patient's refusal of recommended dialysis based on an accurate understanding of the likely benefits of dialysis?
- Is the patient's refusal of recommended dialysis consistent with the patient's values and goals?
- Does the nephrologist understand the psychosocial, cultural, or spiritual concerns and values the patient or legal agent has?
- Has the nephrologist consulted a psychologist, social worker, or chaplain for assistance in fully understanding the concerns of the patient or legal agent/family? Have strategies in the Decreasing Provider Patient Conflict project been used as appropriate? (http://esrd.aclark.net/special-projects/copy_of_DPPCProviderManual.pdf)

For circumstances in which the patient/legal agent requests dialysis when it is not recommended, the following process may be helpful to resolve the conflict:

- Consult 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?
- Consult with an ethics committee or ethics consultants
 - Has the patient or legal agent been informed that the purpose of the ethics consult is 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, mediation, or a time-limited trial of dialysis?

- Document
 - 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 also should document their assessment of the patient's diagnosis, prognosis, and their recommendations in the chart.
- 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 may ethically and legally 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
- Request regional ESRD network to assist with arranging dialysis
- Notify 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 may 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.
- Communicate options
 - 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.

Providing Effective Palliative Care

Recommendation No. 9

To improve patient-centered outcomes, offer palliative care services and interventions to all AKI, CKD, and ESRD patients who suffer from burdens of their disease.

Palliative care services are appropriate for people who chose to undergo or remain on dialysis and for those who choose not to start or to discontinue dialysis. With the patient's consent, a multi-professional team with expertise in renal palliative care, including nephrology professionals, family or community-based professionals, and specialist hospice or palliative care providers, should be involved in managing the physical, psychological, social, and spiritual aspects of

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treatment for these patients, including end-of-life care. Physical and psychological symptoms should be routinely and regularly assessed and actively managed. The professionals providing treatment should be trained in assessing and managing symptoms and in advanced communication skills. Patients should be offered the option of dying where they prefer, including at home with hospice care, provided there is sufficient and appropriate support to enable this option. Support also should be offered to patients' families, including bereavement support where appropriate. Dialysis patients for whom the goals of care are primarily comfort should have quality measures distinct from patients for whom the goals are aggressive therapy with optimization of functional capacity.

Rationale

The evidence shows that although patients and families place a high priority on good symptom control and preparation for death, both patients and professionals find it difficult to address these concerns, including end-of-life issues. Nephrologists' identification, assessment and management of symptoms is poor,³²⁸ and many symptoms (such as pain) are under-recognised and under-treated.^{329,330} Nephrology professionals also find it challenging to help patients engage with end-of-life issues.³³¹ In addition, patients doing less well on dialysis often find it difficult to make sense of what they perceive as "not quite living" while on dialysis and struggle with issues raised by the use of dialysis and the prolongation of poorer quality life.³³¹ To some extent, nephrology staff recognize the need for symptom control and the importance of psychosocial aspects of care, but implementation of these aspects of care are perceived to be difficult.³³²

Kidney patients have considerable and complex health care needs toward the end of life. There is growing evidence of a high

physical and psychological symptom burden among dialysis patients,^{329,333-337} especially among those with multiple comorbidities.³²⁸ Those who opt for active medical management without dialysis³³⁸ or dialysis withdrawal³³⁹ have similarly high symptom burden, and need pro-active management.³⁴⁰ While dying is peaceful and symptom-free for some, others experience considerable uncontrolled symptoms.³⁴¹

Some early evidence indicates how these needs are best addressed. In general, the complex needs of those dialysis patients with palliative goals of care are best addressed through the collaboration of nephrology professionals with family/community-based professionals and hospice or palliative care providers.^{342,343} The actual care provider may be determined by the strengths of local service programs, but the approach is characterized by:

- Holistic and patient-centered care.
- Multidisciplinary professional collaboration to provide this care.
- High-quality, skilled communication, and sensitive advance care planning.
- Attention to needs across the physical, psychological, social and spiritual domains of care.
- Consideration of family needs, including bereavement support.

There is evidence that hospice is underused for dialysis patients, especially for those who withdraw from dialysis. In addition, those dialysis patients who use hospice are more likely to die at home and spend less time in an acute hospital care.³⁴⁴ At home, symptoms may be more easily recognized and communicated.³³⁹

Specific interventions can be used for CKD and ESRD patients. Tools have been developed that can effectively measure symptoms³⁴⁵⁻³⁴⁸ and quality of life³⁴⁹ toward the end of life,

although validation in populations with ESRD is still limited. Pharmacological interventions for pain^{334,350} and depression³³⁶ have been identified as useful.³⁵¹ In particular, using the WHO analgesic ladder to treat pain has been shown to be effective for kidney patients.^{334,352,353}

Although evidence relating to those on dialysis is growing, there is an urgent need for further research to clarify which stage 5 CKD patients will do best with active medical management without dialysis. In the United Kingdom, older age, higher comorbidity, and poorer functional status are associated with the recommendation for active medical management without dialysis.⁴⁸

Appropriate quality measures for patients whose main goal for dialysis is comfort as opposed to rehabilitation and optimization of function need to be defined. Care delivered to dialysis patients whose goals of care are focused on minimizing the burdens of treatment should be evaluated by quality measures. These measures include documented discussion of patient's prognosis,

designation of a legal agent, pain and symptom assessment and management, documentation of an end-of-life care plan (including patients' preferences regarding life-sustaining treatments and preferred site of death), and timely referral to hospice.

Quality care measures used for dialysis patients in whom the goals of care are aggressive therapy with optimization of function such as dialysis adequacy, anemia and bone disease management, patient survival, and vascular access type and function (for hemodialysis patients only) are inappropriate for dialysis patients for whom the goals are maximizing comfort and minimizing procedures and hospitalizations. Furthermore, to avoid misrepresenting the quality of dialysis unit care on public reporting sites, dialysis patients with a poor prognosis who have chosen dialysis with a goal of maximizing comfort should not be included in the calculations of dialysis unit-specific standardized mortality ratios and quality measures for dialysis patients seeking aggressive therapy and rehabilitation. Current practices of aggregating all dialysis patients regardless of their goals of care in quality

Box 6: Recommendations for end-of-life care practices in chronic kidney disease³⁵⁴

1. Identify patients who would benefit from palliative care interventions.
 - a. Those who are being managed medically, i.e., a GFR \leq 15ml/min/1.73m² with no dialysis.
 - b. High risk of death within the next year. Consider using an integrated prognostic model and/or the surprise question, "Would I be surprised if this patient died in the next year?"
2. Screen for and manage pain and other physical symptoms routinely.
 - a. A simple tool such as the Edmonton Symptom Assessment Scale (ESAS) is appropriate and has been validated in CKD.
3. Screen for and manage emotional, psychosocial and spiritual distress; refer to allied health professionals as appropriate.
 - a. The ESAS is also appropriate for screening for anxiety and depression.
 - b. A simple question such as "Do you have any spiritual needs or concerns that your health care providers may help address?" may be appropriate for screening for spiritual distress.
4. Assess patients' desire for prognostic information.

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5. Enhance pre-dialysis education
 - a. Educate regarding active medical management without dialysis option as appropriate.
 - b. Education should include available palliative care and hospice services.
6. Provide routine advance care planning (ACP) as described in **Recommendation No. 5**
 - a. Ensure patients and families are aware of the relevance of these discussions (i.e., have an understanding of their overall health state and prognosis).
 - b. Consider initiating ACP at the time that patients are being educated with respect to renal replacement options.
 - c. Include discussions of patients' goals of care, health states that the patient would no longer want dialysis, and preferred location of death.
 - d. Establish a surrogate decision-maker.
 - e. Ensure that family and other important people (as identified by the patient) are present for these discussions, especially the surrogate decision-maker.
7. Increase access to specialist palliative care including hospice.
8. Develop relationships with hospice providers that focus on transition of care from dialysis to hospice, bridging patients into hospice by decreasing frequency of dialysis treatments, and having the patient be in control of when they are ready to stop palliative dialysis.
9. Provide bereavement support to patients' families where necessary.
10. Incorporate palliative care training for all nephrology fellows with an emphasis on symptom management, advance care planning, and communication about prognosis and treatment options.

measures discourage the appropriate setting and honoring of different expectations and goals of dialysis patients.

Recommendation No. 10

Use a systematic approach to communicate about diagnosis, prognosis, treatment options, and goals of care.

Good communication improves patients' adjustment to illness, increases adherence to treatment, and results in higher patient and family satisfaction with care. Patients appreciate sensitive delivery of information about their prognosis and the ability to balance reality while maintaining hope. In communicating with patients, the critical task for clinicians is to integrate complicated biomedical facts and conditions with emotional, social, and spiritual realities that

are equally complex but not well described in the language of medicine. This information must be communicated in a way that patients, legal agents, and families can understand and use to reach informed decisions about dialysis and transplantation options. Patients' decisions should be based on an accurate understanding of their condition and the pros and cons of treatment options. To facilitate effective communication, reliance upon a multidisciplinary approach including nephrologists, intensivists, and others as appropriate is warranted. Decisions about acute renal replacement therapy in AKI should be made in the context of other life-sustaining treatments. Intensive care physicians should be included in shared decision-making for kidney patients in the ICU to facilitate discussions on global disease or injury prognosis. Fellowship programs should

incorporate training to help nephrologists develop effective, empathetic communication skills, which are essential in caring for this patient population.

Rationale

Nephrologists care for a patient population with significant comorbidities and a yearly mortality rate that surpasses most cancers. Patients with chronic disease, such as advanced CKD, face a number of challenges. They deal with the emotional aspect of having a life-limiting illness and, concurrently, must participate in difficult decisions regarding the management of their disease. The quality of physician communication affects how patients respond to these challenges and plan for the future. Although limited data exists describing how nephrologists communicate serious news such as prognosis, the nephrology literature has shown effective communication results in increased patient satisfaction, understanding, and hope.^{269,355} Research also shows that empathic communication decreases patient anxiety and improves patient trust at end of life.²⁴⁹

Despite these data, discussions about prognosis are difficult, and physicians frequently feel stressed approaching these conversations. This anxiety is understandable and not surprising as communication skills are often not specifically taught or reinforced. Barriers to these conversations include time constraints and concern that discussing such topics may take away patient hope.³⁵⁶⁻³⁵⁸ These concerns are shared by all specialists and nephrologists appear to be no exception.³⁵⁹ The lack of conversations between nephrologists and patients influences their disease and treatment decisions. Data suggests patients report lacking knowledge regarding specific treatment options, such as hemodialysis, peritoneal dialysis, and transplantation.³⁶⁰ They also tend to have increased anxiety regarding their treatment and prognosis.³⁶¹ Most importantly, patients

want to hear information about their disease and its prognosis. A survey of CKD and ESRD patients found almost all respondents felt information regarding their diagnosis, including prognosis, was important. Yet only 10% reported having had a discussion about of end-of-life care with their nephrologists.³⁵⁴ As patients' comorbidities and care become more complex, the role of effective communication becomes essential in patient care and decision-making. A focus group of patients with life-limiting illness and their caregivers identified communication components most important to them, including talking in an honest and straightforward way with understandable language. Patients appreciated sensitive delivery of the news and the ability to balance reality while maintaining hope. Patients also expressed better understanding and comfort when physicians encourage and are open to conversations.³⁶²

Core communication skills

A growing body of literature is focused on good communication techniques with seriously ill patients. Good communication involves the ability to recognize and respond to patients' informational and emotional concerns regarding their disease. A core set of communication skills are described briefly below, and examples of this communication strategy are described in Tool 11 in **Section 9: Toolkit**.³⁶³

Identifying concerns: Elicit and recognize concerns

The ability to respond to patients' concerns and needs begins with the ability to effectively elicit and recognize these concerns. Open-ended questions elicit patient concerns and allow patients time to speak. Continuing to probe until the patient has nothing else to add is important because the patient may not bring up concerns the first time a physician asks.^{364,365}



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Respond to informational concerns: Ask-Tell-Ask

As physicians approach discussions, such as prognosis or treatment options, it is helpful to learn how patients want to hear this information. This includes both the timing and content of the information disclosed. For example, while studies show that most patients want prognostic information, a significant minority do not. There is no way to predict this, and data from focus groups suggest that patients want the doctor to negotiate about whether and when to discuss prognostic information. By eliciting these patients' needs, physicians can ensure that patients get the information they need but are not forced to talk about things that they are not ready to hear. This can best be accomplished with the Ask-Tell-Ask communication skill.

The first “Ask” involves eliciting what the patient understands about their disease. This helps the physician understand what the patient knows and allows misperceptions to be identified and correct. Asking before giving prognostic information also means ensuring that the patient wants to know about prognosis (*“Are you the kind of person who wants to know what might happen next or would you rather that be something I talk with your wife about?”*). It also ensures that it is an appropriate time to have the conversation (*“Is it ok that we talk about your prognosis now? Is there anyone else you want there?”*).

Having established the patient's interest in talking about prognosis, the physician can then “Tell” the news in a way that addresses the patient's concerns. Given that people can only retain three to seven pieces of information at a time, it is important to focus on the key information. Giving all the medical details is likely to overwhelm the patient and may lead them

to focus on details that are not critical. Experts thus recommend that information be given in small chunks and frequently checking in to ensure that the information was understood (*“Any questions about what I said?”*). In addition, it is important, particularly in the beginning to start at a literacy level that most patients will understand, typically fifth or sixth grade.

The second “Ask” provides an opportunity to ensure that the patient understands what has been said. The only way to ensure adequate understanding is to ask the patient. An indirect way to do this is to ask about the questions or concerns they have about the information you provided. Another way is to ask what they will tell their loved one about the conversation when they go home (*“To make sure I have done a good job explaining what is going on, can you tell me what you will tell your husband about our conversation?”*).

Respond to emotional concerns: Demonstrate empathy

Patients respond to discussions of prognosis with emotions such as sadness, anger, or disbelief. When their physicians identify these emotions, patients feel more supported. Emotional support includes listening and using specific language that expresses empathy. By responding to these emotions, physicians improve the likelihood the patient will be receptive to the information. For example, in one study, patients with breast cancer were more likely to believe their physician cared about them and were less anxious when the physician expressed empathy.³⁶⁶

Physicians can respond to patients' emotions both verbally and nonverbally. Use of the N-U-R-S-E acronym (see Tool 11 in **Section 9: Toolkit**) and “wish” statements assists physicians to express verbal empathy.³⁶⁷ The former includes naming the patient's emotion



and attending to it in an empathic manner. The latter tool allows physicians to walk in the shoes of the patient and respond as human beings faced with overwhelming circumstances that are not of their choosing.³⁶⁷ The acronym S-O-L-E-R employs nonverbal expressions such as body posture and facial expressions to convey empathy (See Tool 11 in **Section 9: Toolkit**).



A Six-Step Approach for Talking about Serious Illness

Patients report the manner in which news is delivered is more important than the actual content of the discussion.³⁶⁸ A frequently used model for delivering serious news includes six steps, originally called “SPIKES” (Setup, Perception, Invitation, Knowledge, Emotion, Summarize). These steps are presented in Box 7 and facilitate the development of a treatment plan that includes the involvement and cooperation of the patient.³⁶⁹

Communicating with Patients Whose Health Is Declining

For many patients who decide to undergo dialysis, the disease trajectory is often marked by decline from new illnesses (e.g., heart attack or stroke) or loss of function resulting from hospitalizations. The events triggering these setbacks serve as a prompt to discuss whether the present treatment plan remains consistent with the patient’s goals (“*I wanted to check in with you to see how our treatment plan was going. You had said that dialysis was worth it, because it allowed you to stay at home and have more time with your grandchildren. How has that been going for you?*”) For a patient on dialysis, the transition may occur when the burdens of dialysis outweigh the benefits of life prolongation. (“*Is being on dialysis still worth it for you? I worry that for some people, dialysis may no longer be a benefit to them as they may be unable to do what they like to do. Can we talk about this?*”).

Box 7. A Six-Step Approach to Talking about Serious Illness

1. **Set up the conversation.** This includes making the environment private and quiet. Also have a nurse or social worker available for further discussion after you leave.
2. **Assess the patient’s perception.** Asking what the patient understands or expects can be helpful in determining how you approach and plan the conversation.
3. **Ask for an invitation to talk about the news.** By asking the patient if you can discuss the news gives them some control and emphasizes your goal to work cooperatively.
4. **Disclose the news straightforwardly to improve the patient’s knowledge.** It is best to start with a warning statement to let the patient brace themselves for bad news. The news should be straightforward and be delivered in comprehensible language.
5. **Respond to the patient’s emotions.** The physician must be aware of the patient’s emotion and be able to respond to it in an empathic way.
6. **Summarize the plan.** At the close of the visit, the physician should summarize what has been discussed and describe the next steps the patient will need to take.

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These deteriorations can be challenging for physicians as they involve giving bad news, or directly confronting the dying process. However, patients and caregivers report these are important conversations that they want to have and that they want the doctor to raise the topic. By avoiding conversations about whether continued dialysis is meeting the patient's goals, physicians risk missing opportunities to address concerns and fears, focusing the treatment plan in a way that meets the patient's goals, and exploring issues related to life closure.

This approach of balancing discussions of hope with preparation for future outcomes respects the patient's hopes and fears while still allowing for opportunities to reassess and redefine the patient's goals of care over time. The treatment plan can be modified to focus on what can be achieved given the patient's values, and treatments that are

no longer beneficial can be discontinued. After such discussions, patients may decide to switch from a more aggressive approach to dialysis to one in which the focus on dialysis is on a reduction in suffering with concerted attention to pain and symptom management and advance care planning. Thus, these conversations may allow for timely involvement of palliative care services and hospice referral.³⁷⁰

Nephrologists are faced with the challenge of caring for a complex patient population with multiple comorbidities. How physicians communicate with patients impacts their experience with their disease and their treatment decisions. This recommendation provides tools to gather and effectively deliver information and to respond to patient's emotional concerns. Through practice and close attention to how communication is delivered, physicians can effectively communicate and negotiate a plan of care consistent with the patient's own values and needs.

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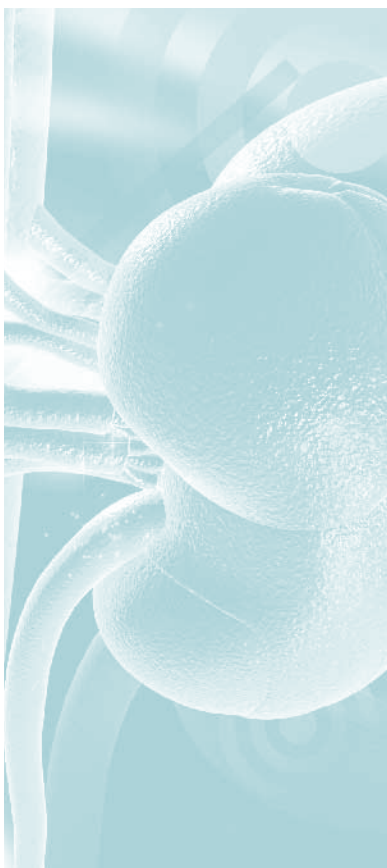
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Section 5

Guideline Recommendations and Their Rationales for the Treatment of Neonates, Infants, Children, and Adolescents



Introduction

Dialysis has been used in adults to treat acute kidney injury (AKI) since the 1940s and end-stage kidney disease (ESRD) since the early 1960s. Due to technical issues and ethical concerns, dialysis did not become commonly available to children in the United States until the late 1960s¹ and controversies regarding the use of dialysis in neonates and infants persist.²⁻⁵

Four distinct groups of children who could potentially benefit from dialysis have been identified: 1) infants with poorly functioning or nonfunctioning kidneys due to genetic conditions or a urological or kidney abnormality that is non-reversible; 2) infants with acute kidney injury without prior evidence of intrinsic kidney disease or urological abnormality; 3) children with acute kidney injury with or without prior evidence of kidney problems; and 4) children with chronic kidney disease whose kidney function over time becomes progressively worse. As an outgrowth of increased provision of dialysis for each of these pediatric groups over the past three decades, evidence about its feasibility, tolerability and efficacy has led to continued improvements in dialysis techniques. In addition, longer-term experience with pediatric dialysis has allowed the accumulation of data regarding risk factors for poor short-term and long-term health and quality of life outcomes.

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Developing a clinical practice guideline that addresses initiating and withdrawing dialysis in this patient population has not occurred before this effort in part because of the limited research on which to base recommendations, and the research that has been conducted has been population-based. Additionally, pediatric nephrologists have hesitated to produce guidelines because of risks associated with basing clinical decisions about individual patients on population-based research. In spite of the challenges to developing this clinical practice guideline, this effort has multiple benefits. A clinical practice guideline can:

- Assist pediatric nephrologists in communicating their recommendations to medical colleagues and families in an objective and systematic manner (i.e., presenting age and disease-specific research, clinical experience, and information about the patient as the basis for recommending a particular course of action).
- Be a catalyst for establishing pediatric-specific resources for patients and their families in end-of-life planning.
- Provide health-care providers who have limited expertise in pediatric kidney disorders with additional information to help them formulate realistic expectations about dialysis interventions.
- Provide a decision-making framework for initiating and withdrawing dialysis for neonates, infants, children and adolescents.
- Provide information to primary care providers, who are charged with providing a medical home for children with these complex medical problems.

Guideline Development Process

The pediatric workgroup was comprised of five pediatric nephrologists, a child psychologist and a pediatric ethicist. The workgroup used the same methodology as the adult workgroups and considered recommendations for pediatric dialysis decision-making for acute kidney injury, chronic kidney disease, and end-stage renal disease. In developing their recommendations, the pediatric workgroup reviewed the following: 1) the pediatric recommendations contained in the RPA/ASN 2000 *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis* clinical practice guideline; 2) clinical practice guidelines from non-US pediatric nephrology groups; 3) the policy statements, clinical reports, and clinical practice guidelines written by the American Academy of Pediatrics (AAP) and cited on the AAP web site as of October 2009 and specifically those containing recommended “best practices” regarding the provision of medical care to pediatric patients with AKI, CKD or ESRD; and 4) a draft of the second RPA 2010 adult *Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis* clinical practice guideline. A summary of the pediatric clinical practice guideline recommendations can be found in Table 14.

Establishing Family-Centered Shared Decision-Making

Recommendation No. 1

Develop a patient-physician relationship that promotes family-centered shared decision-making for all pediatric patients with AKI, CKD, and ESRD.

In addition to involving pediatric patients to the extent that their decision-making capacity allows, the nephrologist should involve parents in determining health care decisions. If the parents request to involve other family members in shared decision-making, this request should be honored. If the treating nephrologist believes that a pediatric patient's parents are making decisions inconsistent with the best interest of their child, the nephrologist should involve medical ethics consultants or hospital ethics committees, mental health professionals, pediatricians specializing in child abuse and neglect, mediators, or conflict resolution specialists. These experts can assist in determining the reason for the parents' treatment choice and in determining an appropriate course of action. It is imperative that the nephrologist take steps to ensure that the pediatric patient has an adult advocate who is capable of participating in health care decision-making. Court involvement to order medical interventions over parental objections should be a last resort.

Family-centered shared decision-making process is recommended for all advance care planning discussions in which treatment options are discussed and treatment decisions are made. Education geared to the cognitive abilities of the parent and pediatric patient about the medical condition, prognosis, and available treatment options is an important component of the family-centered shared decision-making process. The pediatric patient's primary care physician, and in the case of the critically ill pediatric patient, their intensivist should be encouraged to participate in coordinating care related to treatment decisions made by the pediatric patient and his/her family. In the intensive care

setting, patients with AKI will usually have multiple medical problems and the concept of shared decision-making necessitates a multidisciplinary approach including nephrologists, intensivists, and others as appropriate, and decisions about acute renal replacement therapy should be made in the context of other life-sustaining treatments.

Rationale

Family-centered decision-making is supported by the ethical principles of beneficence, nonmaleficence, and respect for autonomy. The AAP has published numerous policy statements that support the use of shared decision-making in pediatric patients (Table 15). The AAP policy statements and guidelines endorse family-centered decision-making in which provider-family partnerships are established to allow for evaluation of treatment options and choice of treatment interventions. Pediatricians who embrace the medical home concept should be encouraged to participate in coordinating care related to treatment decisions made by the pediatric patient and his/her family.⁶⁻⁸

The AAP policy statements and guidelines not only support children's participation in decision-making commensurate with their preference, development, and health status, but also state that children should not be excluded from health care decision-making without "persuasive reasons." A prospective study evaluating influences on parental decisions to limit or withdraw no longer beneficial or unduly burdensome medical interventions provides some evidence that shared decision-making is beneficial for parents, too.⁹

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Informing Patients and Parents

Recommendation No. 2

Fully inform patients with AKI, stage 4 or stage 5 CKD, or ESRD and their parents about the diagnosis, prognosis, and all appropriate treatment options. Inform children and adolescents in a developmentally appropriate manner, and if feasible, seek their assent about treatment decisions.

Treatment options include: 1) initiating or continuing dialysis; 2) transplantation for ESRD; 3) not starting dialysis and continuing optimal medical management; and 4) stopping dialysis and continuing to receive palliative treatment. The nephrologist and the medical team should make every effort to inform parents about the potential benefits and burdens of dialysis initiation or dialysis withdrawal before providing or withdrawing treatment. In the rare circumstances when this is not possible, parents should be informed as soon as possible about the rationale for emergent initiation and the efforts that were made to contact the parents before changing the medical plan.

As a component of informed permission/informed assent, and in keeping with the on-going process of both shared decision-making and advance care planning, the treating nephrologist may determine that dialysis is no longer providing net benefit (i.e., the risks or burdens outweigh the benefits, the underlying condition is progressive and dialysis is only prolonging the dying process without improving the quality of life during the dying process). In this case, the nephrologist and the medical team should approach the family and discuss the undue burden of dialysis given the patient's medical condition and recommend stopping dialysis and intensifying palliative treatment. This

will typically occur in the intensive care setting and intensivists should coordinate the shared decision-making in the context of other aspects of supportive care. Children and adolescents should be given the opportunity to communicate their feelings and perceptions regarding the benefits and burdens of dialysis to the extent they desire to do so and their developmental abilities and health status permits. When seeking informed permission/informed assent for discontinuing dialysis, the medical team should explicitly describe comfort measures and other components of palliative treatment that will be offered.

Rationale

The AAP Committee on Bioethics' policy statement on informed consent, parental permission, and assent provides support for this recommendation.^{10,11} The policy statement recommends use of the term "informed permission" (rather than the term informed consent) to describe the ethically and legally mandated process of assisting parents in developing a comprehensive understanding of their child's clinical situation in order for timely and informed decisions to be made among treatment alternatives.¹⁰ The process of informed permission is similar to that of informed consent and involves the following 4 elements: 1) provision of information; 2) assessment of a surrogate's understanding of information; 3) assessment of capacity of the surrogate to make a decision; and 4) assurance of freedom of the surrogate to assist in the choice between treatment alternatives.¹⁰ The policy statement also points out that although pediatric patients do not generally have legal authority to make independent health care decisions unless they have been determined to be "mature or emancipated minors," some children may, in fact, have decision-making capacity. In such cases, their opinions should be particularly taken into account.¹⁰ Adolescents should be given the opportunity to talk with medical providers independently

of their parents so they have the opportunity to ask questions and voice their preferences in privacy. This guideline encourages physicians to obtain pediatric assent and parental “informed permission” in such a manner that there is a shared responsibility between the physician, the pediatric patient, and the parents for collaborative treatment decisions.¹⁰ Furthermore, the guideline recommends that medical personnel should, if possible, respect the wishes of a pediatric patient who withholds or refuses assent until such time that a better understanding of his/her situation occurs or the patient comes to terms with the fears or other concerns regarding the proposed care.¹⁰ In the unfortunate situation that the child or adolescent becomes more neurologically impaired as a consequence of their injury or as a consequence of their progressive kidney failure, this may not be possible and the parents will have to be involved in decision-making without their child’s ongoing participation.

The AAP Committee on Bioethics’ guideline regarding non-initiation or withdrawal of intensive care treatment for high-risk newborns provides specific guidance regarding informed consent discussions with families of newborn infants who have a very poor prognosis.¹¹ The guideline acknowledges that determining what is in the best interest of a severely ill newborn is very difficult and points out that there is no ethical distinction between not initiating and withdrawing life-sustaining treatment in pediatric patients with anticipated poor prognosis.¹¹ As in other AAP policy statements pertaining to pediatric medical care, shared decision-making between the parents and physicians, based on ongoing evaluation of the benefits and burdens of continuing intensive care treatments, is encouraged.¹¹ The guideline cautions that parents’ views of their child’s health status are influenced by how information is presented to them and that care should be taken to

present information in a “frank and balanced” manner.¹¹ The guideline also stipulates however, that “the physician is not obligated to provide inappropriate treatment or to withhold beneficial treatment at the request of the parents.”¹¹ The AAP policy statement on religious objections to medical care strongly supports the importance of physicians’ safeguarding children’s rights to receive medically indicated care notwithstanding parents’ religious beliefs to the contrary.¹²

The AAP Committee on Bioethics’ guideline regarding forgoing life-sustaining medical treatment provides advice to physicians both about how and what information should be provided to families of seriously ill children.^{13,14} The guideline advises that during the course of obtaining informed permission, in addition to providing information regarding the risks, discomforts, side effects, and benefits of treatment alternatives, physicians should provide their opinion regarding the best option for the patient, citing their reasons for their recommendations based on medical, experiential, and moral factors.⁹ Furthermore, the guideline advises that when a physician believes that a currently offered treatment is no longer providing benefit and should be ended, that families should be informed of this opinion without delay.¹³ The guideline also states that young children, “deserve to hear the general conclusions of decisions that will affect their continued survival” even though they may not necessarily be able to understand the details of the gravity of their medical condition. Such communication has many potential benefits, including allowing them to say goodbye to their loved ones.¹³

A multi-center study evaluated the extent to which health care providers who were currently treating children with life-threatening conditions were aware of published guidelines regarding initiating and withdrawal of life-sustaining medical

treatments, were in agreement with the guidelines, and behaved in accordance with the guidelines.¹⁵ Surprisingly, 53% of the respondents were not aware of the ethical concordance of not starting and discontinuing a life-sustaining treatment (e.g., dialysis).¹⁵ Furthermore, 57% of the respondents acknowledged that sometimes they felt that they were saving children who should not be saved and 46% acknowledged feeling that the treatments they have offered children are overly burdensome.¹⁵

Recommendation No. 3

Facilitate informed decisions about dialysis for pediatric patients with AKI, CKD or ESRD, discuss prognosis, potential complications, and quality of life with the patient, parents, and/or legal guardian.

Nephrologists should rely on population-based survival data, using adjustments for confounders, to discuss prognosis, potential complications, and quality of life with patients, parents, and/or legal guardians. During these discussions, the nephrologist should acknowledge that the ability to predict survival in the individual patient is difficult and should reassure the patient and family that there will be ongoing opportunities for additional discussions regarding prognosis over time. Given the likelihood that health status changes for the better or worse are likely to occur in pediatric patients with AKI, CKD, and ESRD, discussions about survival odds and physical and psychosocial outcomes should be repeated when dramatic changes in health status occur. Each discussion regarding prognostic outcomes and patient/parent decisions regarding treatment should be documented in detail and dated. This documentation should be easily identified and accessible in the medical record. In the event of questionable understanding of the prognostic data, it is recommended that additional resources be offered to the pediatric patient and his or her

family to ensure a reasonable understanding of likely outcomes and to allow for informed decision-making regarding treatment (see **Recommendation No. 8**).

Rationale

Multiple studies support the initiation of dialysis for neonates, infants, children, and adolescents with AKI without prior evidence of kidney problems, although survival in these groups is highly variable.¹⁶⁻²⁵ (Level B Observational Evidence) Although some studies suggest that mortality is particularly high in neonates who require dialysis post-operatively for cardiac abnormalities, it should, nevertheless, be considered in children for whom survival is possible.²⁶⁻²⁸ (Level A Prognostic Evidence)

Neonates, infants, children and adolescents who have higher disease severity scores and more significant life-threatening illness in the intensive care unit have been shown to have higher mortality rates.^{16-18,20-23,26-34} (Level A Observational Evidence) Generally, children with multi-system organ involvement tend to have a worse prognosis.⁵ Prediction of who will survive, however, is not possible and, in fact, many neonates, infants, children and adolescents who receive dialysis for AKI recover kidney function with no apparent kidney dysfunction. An AAP policy statement opposes the use of population-based survival formulas as the exclusive determinant of whether critically ill pediatric patients should receive life-sustaining medical technology such as dialysis. The AAP's rationale rests on the current inability to make accurate predictions for individual patients based on such data.³⁵

In regard to offering dialysis to children with ESRD, the literature suggests that outcomes and survival in infants and children on dialysis is at least as good as in adults who are maintained on chronic dialysis therapy.^{3,5,36-41} (Level A Observational Evidence) In fact, survival likelihood is so high in children

receiving maintenance dialysis that quality of life, rather than survival, has become a major outcome of interest for health care providers.⁴²⁻⁴⁶ (Level B Observational Evidence) In addition, even though survival in neonates and infants with ESRD (e.g., neonates and infants with poorly functioning or nonfunctioning kidneys due to genetic conditions or a non-reversible urological or kidney abnormality) is highly variable, studies support the initiation of dialysis.^{3,4,47,48} (Level C Observational Evidence) Mortality in this group is often attributed to comorbidities rather than dialysis failure.

Conversations with patients and/or parents should include a discussion of the goals of care and how dialysis treatment is consistent with the goals. Three differing goals have been identified. One group of dialysis patients includes those who choose (or their parents choose for them) aggressive therapy without limitations. All attempts to optimize functional status are made. If their condition deteriorates, they may move into the second group.

The second group of dialysis patients is one in which the patients have a poor prognosis and the patient (or his/her parents) chooses therapy reasonable for their prognosis, but not aggressive therapy (e.g., no intubation, no pressors, and no intensive care unit admission). In such cases, it is best if the patients, parents and nephrologist arrive together at a determination that the calculus of benefits and burdens favors discontinuation of dialysis.

The third group of patients are those stage 5 CKD or ESRD patients or their parents who decline dialysis and prefer that the goal of the patient's care be primarily oriented towards comfort. These patients receive as desired active medical management of their anemia, bone disease, and fluid balance in addition to pain and symptom management to promote

their comfort. They do not receive dialysis. They do not have a dialysis access placed.

Resolving Conflicts about What Dialysis Decisions to Make

Recommendation No. 4

Establish a systematic due process approach for conflict resolution if disagreements occur about dialysis decisions. Use conflict resolution interventions when family members disagree with one another, when children disagree with their parents, when families disagree with the health care team, or when the health care team disagrees about initiating, not initiating, or withdrawing dialysis.

The following types of interventions are recommended to resolve conflicts: additional medical consultation(s); involvement of pastoral care; palliative care consultation; a multidisciplinary conference including sources of support for the patient/family from within or outside the institution; short-term counseling or psychiatric consultation for the child and/or family and/or consultation with a hospital-based ethics committee. When the health care team believes that non-initiation of dialysis would constitute medical neglect, consultation with available child protection specialists would be appropriate to help determine next steps. Court involvement should be used as an intervention of last resort.

Rationale

The AAP has published several policy statements that provide advice about the resolution of disagreements relating to treatment decisions for seriously ill children. First and foremost the AAP endorses preventing conflict through the on-going use of shared decision-making.^{10,13,49,50} When

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disagreements cannot be resolved through courteous communication efforts, the AAP encourages physicians to use mediators and conflict resolution specialists to negotiate a resolution. Conflict resolution resources include: medical consultation with colleagues not currently on the treatment team, multidisciplinary conferences and consultation with a hospital ethics committee. Consultation with child protection specialists also is recommended by AAP in the case where not initiating dialysis would constitute medical neglect. In addition, counseling or psychiatric consultation for the child and/or family may be of benefit under certain circumstances, especially when the parent and child disagree about treatment options. Mental health consultation may be sought for assistance if needed if the decision-making capacity of a parent or legal guardian is questioned.

The AAP cautions that court system involvement should be used as a last resort and reserved for situations in which unresolved differences of opinion continue in spite of attempts to resolve conflicts using less adversarial processes.^{10,13,49,50} Health care providers should seek to contest parental authority only if the parents' decision is contrary to the child's best interest (see Figure 8 and Box 5).

Facilitating Advance Care Planning

Recommendation No. 5

Institute family-centered advance care planning for children and adolescents with AKI, CKD, and ESRD. The plan should establish treatment goals based on a child's medical condition and prognosis.

Family-centered advance care planning is recommended for infants with poorly functioning or nonfunctioning kidneys due to genetic conditions and those with a non-reversible urological or kidney abnormality. In the event that the health care team has information that the viability of a fetus with suspected multisystem organ involvement is questionable, family-centered advance care planning should occur before the birth of the baby. This will allow the health care team to be able to act decisively in light of the neonate's health status and prognosis at the time of delivery.

Advance care planning should be an ongoing process in which treatment goals are determined and revised based on observed benefits and burdens of dialysis and the values of the pediatric patient and the family. The renal care team should designate a person to be primarily responsible for ensuring that advance care planning is offered to each patient. Patients with decision-making capacity should be *strongly* encouraged to talk to their parents to ensure that they know the patient's wishes and agrees to make decisions according to these wishes. Ongoing discussions that include reestablishing goals of care based on the child's response to medical treatment and optimal quality of life is the mechanism by which advance care planning occurs. Discussions should include the pros and cons of dialysis as well as potential morbidity associated with dialysis. Kidney transplantation should also be discussed if appropriate.

Children and adolescents should be allowed to participate in advance care planning commensurate with their preference and developmental status. Parent or pediatric patient questions regarding discontinuation of dialysis if the patient's medical condition becomes irreversible and non-responsive to currently available treatments should

be addressed frankly. Such questions can be used as a springboard for obtaining information about parent and child wishes regarding end-of-life care. Assurance should be given that the pediatric patient's comfort is paramount in the event that dialysis is discontinued. In addition, such questions should be used as an opportunity to explicitly describe comfort measures and other components of palliative care.

Rationale

Advance care planning is a clinical practice approach that has been endorsed as beneficial for adults and children with life-limiting medical conditions. Advance care planning is described as a family-centered and culturally sensitive process that is initiated at diagnosis of a potentially life threatening condition, is continued throughout the course of care, and involves an ongoing discussion about a child's medical status, response to treatment, and treatment goals.⁵¹ The advance care planning approach differs from routine clinical practice in its explicit recommendation to solicit patient/family communication about medical concerns to enable the pediatric patient to have an optimal quality of life. Advance care planning discussions should occur well before the end-of-life period and can be used as a springboard for discussions about patient/family values and wishes for endoflife care should this be needed.⁵² This practice approach is an extension of patient-centered care and shared decision-making. It enhances the opportunity to improve communication and thus the quality of life for the child living with a life-threatening condition. It has been influenced by the recognition that the end-of-life period is often difficult to identify and, as such, important information about patient/family treatment preferences in light of patient/family values may not be able to be used most effectively if it is obtained in

the midst of a medical crisis. Advance care planning also has been shown to enhance patient satisfaction with health care services in both adult and pediatric patients.

Procedures for implementing advance care planning for pediatric patients vary widely, and are dictated by a variety of factors, including physician comfort in having such discussions.⁵³ In pediatric patients whose CKD is of long duration and relatively mild morbidity, advance care planning discussions are often postponed until a medical crisis necessitates such a discussion. However, both an AAP policy statement and a research study that evaluated parents' attitudes about medical care of their critically ill child recommend that such discussions occur well in advance of the need for decisions regarding the use of dialysis and other life-sustaining medical treatments.^{9,13} Similarly, two AAP policy statements support the value of prenatal counseling that includes discussion of care planning when severe fetal abnormalities are detected prenatally.^{35,49}

The Patient Self-Determination Act (PSDA), which took effect in 1991, requires Medicare and Medicaid institutional providers to provide adults receiving inpatient medical treatment or enrollment into a federally subsidized health care program with information regarding their rights to establish advance directives, such as living wills or durable powers of attorney for healthcare. The PSDA does not apply to children and adolescents as most states do not authorize them to complete advance directives. Several AAP policy statements and a research study strongly advocate for physicians and others to accord considerable weight to the expressed preferences of children and adolescents to forgo life-sustaining medical treatment when such treatment preserves their biological existence only.^{9,13,35}

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Making a Decision to Not Initiate or to Discontinue Dialysis

Recommendation No. 6

Forgo dialysis if initiating or continuing dialysis is deemed to be harmful, of no benefit, or merely prolongs a child's dying process. The decision to forgo dialysis must be made in consultation with the child's parents. Give children and adolescents the opportunity to participate in the decision to forgo dialysis to the extent that their developmental abilities and health status allow.

An example of a clinical situation in which forgoing dialysis is often considered is an infant with multisystem organ failure for whom dialysis would be burdensome and would serve only to prolong dying. Forgoing dialysis should also be considered for a pediatric patient whose kidney failure is a consequence of a primary health condition that is non-reversible, non-treatable, and terminal and for whom dialysis would cause undue suffering. Infants or children who would otherwise be expected to survive for years with conditions causing severe neurologic impairment and who develop ESRD should ordinarily not undergo dialysis or transplant. Examples might be an infant with anencephaly or severe porencephaly, or a child with a severe progressive demyelinating condition. In children with severe developmental disabilities, clinicians will need to discuss with parents the balance of the benefits to burdens of prolonging life with dialysis. An intensification of palliative care treatment should occur in conjunction with any decision to forgo dialysis.

Rationale

The ethical principles and concepts supporting this recommendation include beneficence, nonmaleficence, respect for autonomy, professional integrity, and the best interest standard. From an ethics perspective, if initiating or continuing dialysis is deemed to be harmful, of no benefit, or merely prolonging dying and not in the best interest of the child, it should be forgone. An AAP guideline acknowledges the stress physicians incur when they recommend forgoing the use of life-sustaining medical technology and encourages physicians to obtain support from a variety of resources during the process of communicating their recommendation to families.¹³ Furthermore, the AAP guideline recommends that those who “generally decline” to participate in the limitation or withdrawal of medical intervention communicate their position to patients and families as soon as their disinclination becomes relevant and arrange for transfer of care as necessary.⁹ In addition, transfer of care to another medical facility would be indicated in instances where parents’ desire for treatment is against physicians’ recommendations or not consistent with institutional policies. With regard to the recommendation to take the children’s preferences into account, while pediatric patients do not have the legal authority to decide to forgo dialysis, several recently published AAP policy statements strongly advocate for physicians and others to accord considerable weight to the feelings and opinions of children and adolescents regarding this issue.^{13,35} Options for talking with parents about not initiating or withdrawing from dialysis are presented in Table 16.⁵⁴

Recommendation No. 7

Consider forgoing dialysis in a patient with a terminal illness whose long-term prognosis is poor if the patient and the family are in agreement with the physician that dialysis would not be of benefit or the burdens would outweigh the benefit.

In pediatric patients who experience major complications from dialysis that may substantially reduce survival or quality of life, it is appropriate to discuss and/or reassess treatment goals, including considering forgoing dialysis or withdrawing dialysis and initiating or increasing the emphasis on goals commensurate with palliative care. Alternatively, it is reasonable to initiate dialysis for patients with AKI or ESRD who have chronic illness from a non-kidney cause in whom outcome studies have been favorable. For example in HIV-associated nephropathy, dialysis has the potential to improve the quality of life in children.

Rationale

It has been shown in recent studies that pediatric patients who have secondary kidney failure due to their underlying disease may do better than their adult counterparts with dialysis.⁵⁵ Based on the ethical principles of beneficence and nonmaleficence, it is reasonable to initiate dialysis when a potential benefit of dialysis is anticipated, and it is reasonable to not initiate dialysis in a pediatric patient with a non-kidney terminal illness when it can be predicted that there will be no survival benefit or the child will likely experience increased suffering with dialysis. Similarly, it is justifiable to stop dialysis for pediatric patients for whom the burdens of dialysis have been shown to substantially outweigh the benefits.

Recommendation No. 8

Consider the use of a time-limited trial of dialysis in neonates, infants, children, and adolescents with AKI or ESRD to allow for the assessment of extent of recovery from an underlying disorder.

In an intensive care setting, neonates, infants, children and adolescents with AKI or ESRD as a result of an underlying disorder may be candidates for initiating time-limited trials of dialysis. The purpose of such a trial would be to establish the extent of recovery from the underlying disorder and/or to determine the balance of benefits to burdens that continued life enabled by dialysis provides to the child. The initiation of dialysis in conjunction with extra-corporeal membrane oxygenation (ECMO) is an example of a time-limited trial. It is considered time-limited in that the dialysis is most often discontinued when ECMO is withdrawn due to patient non-viability.

Rationale

Rather than initiating time-limited trials, in which dialysis is begun for a predetermined amount of time, dialysis is generally initiated if potential benefit is anticipated and withdrawn if dialysis causes harm or if no net benefit is derived. In this regard, time-limited trials are used less often in children than in adults. When they are used in neonates, infants, children and adolescents with AKI or ESRD, the reason most frequently is to allow time for the assessment of extent of recovery from an underlying disorder.

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Providing Effective Palliative Care

Recommendation No. 9

Develop a palliative care plan for all pediatric patients with ESRD from the time of diagnosis and for children with AKI who forgo dialysis. The development of a palliative care plan is a continuation of the process of advance care planning and should be family-centered.

The terminally ill child, family and child's physician(s) should be involved in developing and executing a palliative care plan, based on their preferences concerning goals of care and decisions regarding testing, monitoring, and treatment. With the patient and family's permission, health care professionals with expertise in hospice and palliative medicine should be involved in co-managing the medical, psychosocial, and spiritual aspects of end-of-life care for the child and family. The nephrology team along with the child's pediatrician and other medical providers should offer bereavement support to the patient's family. In the case of a long-standing relationship with the pediatric patient, nephrology team members are encouraged to send a condolence card to the patient's family. Nephrology team members should be given complete autonomy regarding attendance at a pediatric patient's funeral or memorial service. Nephrologists and the child's health care team are strongly encouraged to seek support, in dealing with the child's dying process and death in the event that the situation causes significant stress that interferes with baseline functioning at work or home.

Rationale

Palliative care seeks to enhance quality of life in the face of a life-limiting or life-threatening condition by proactively addressing physical, emotional, psychosocial and spiritual/

existential distress associated with severe illness.⁵⁶ An AAP policy statement stresses the importance of ongoing communication with pediatric patients and their families in this setting.⁵⁶ Furthermore, communication between the various members of a pediatric patient's health-care team, including the child's pediatrician, is essential. The AAP policy statement also acknowledges that significant barriers exist with regard to the provision of pediatric palliative care and recommends continued advocacy on behalf of children to alter existing reimbursement and regulatory policies that interfere with children receiving appropriate end-of-life services.⁵⁶

Conclusion

Neonates, infants, children, and adolescents with reversible and non-reversible kidney injury are potential candidates for dialysis (Level A and B Observational Evidence). Clinical experience and research has led to improvements in dialysis techniques and outcomes in children over the past three decades. Such experience and research also has allowed for the identification of risk factors for increased morbidity and mortality and decreased quality of life in children receiving dialysis for AKI and/or ESRD. This clinical practice guideline regarding shared decision-making in the initiation and withdrawal from dialysis for neonates, infants, children, and adolescents is meant to provide a framework for addressing the difficult situations that arise when a child is gravely ill. The recommendations in this clinical practice guideline do not indicate specific procedures to be followed. Rather, in keeping with the goal of the guideline, it provides guidance about the process by which decisions should be made, including the importance of considering the individual circumstances of the pediatric patient.

Guideline Recommendations and Their Rationales for the Treatment of Neonates, Infants, Children, and Adolescents

Table 14: Summary of pediatric clinical practice guideline recommendations

Recommendation Number	
1	Develop a patient-physician relationship that promotes family-centered shared decision-making for all pediatric patients with AKI, CKD, and ESRD.
2	Fully inform patients with AKI, stage 4 or stage 5 CKD, or ESRD and their parents about the diagnosis, prognosis, and all appropriate treatment options. Inform children and adolescents in a developmentally appropriate manner, and if feasible, seek their assent about treatment decisions.
3	Facilitate informed decisions about dialysis for pediatric patients with AKI, CKD or ESRD, discuss prognosis, potential complications, and quality of life with the patient, parents, and/or legal guardian.
4	Establish a systematic due process approach for conflict resolution if disagreements occur about dialysis decisions. Use conflict resolution interventions when family members disagree with one another, when children disagree with their parents, when families disagree with the health care team, or when the health care team disagrees about initiating, not initiating, or withdrawing dialysis.
5	Institute family-centered advance care planning for children and adolescents with AKI, CKD, and ESRD. The plan should establish treatment goals based on a child's medical condition and prognosis.
6	Forgo dialysis if initiating or continuing dialysis is deemed to be harmful, of no benefit, or merely prolongs a child's dying process. The decision to forgo dialysis must be made in consultation with the child's parents. Give children and adolescents the opportunity to participate in the decision to forgo dialysis to the extent that their developmental abilities and health status allow.
7	Consider forgoing dialysis in a patient with a terminal illness whose long-term prognosis is poor if the patient and the family are in agreement with the physician that dialysis would not be of benefit or the burdens would outweigh the benefit.
8	Consider the use of a time-limited trial of dialysis in neonates, infants, children, and adolescents with AKI or ESRD to allow for the assessment of extent of recovery from an underlying disorder.
9	Develop a palliative care plan for all pediatric patients with ESRD from the time of diagnosis and for children with AKI who forgo dialysis. The development of a palliative care plan is a continuation of the process of advance care planning and should be family-centered.

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Table 15. Cited American Academy of Pediatrics policy statements and guidelines

Title	AAP Committee	Most recent update or reaffirmation	Original Publication
Noninitiation or withdrawal of intensive care for high-risk newborns	AAP: Committee on Fetus and Newborn	Pediatrics, 2007; 119(2); 401-403	Revision of: Pediatrics 1995; 96(2):362-363. The initiation or withdrawal of treatment for high-risk newborns
Ethics and the care of critically ill infants and children	AAP Committee on Bioethics	Pediatrics, 1996; 98(1), 149-152	
Religious objections to medical care	AAP Committee on Bioethics	A statement for reaffirmation of this policy was published on Feb 1, 2007 and August 1, 2009	Pediatrics 1997; 99(2): 279-281
Guidelines for forgoing life-sustaining medical treatment	AAP Committee on Bioethics	A statement for reaffirmation of this policy was published on Oct 1, 2004 and May 1, 2009	Pediatrics 1994; 93(3): 532-536
Institutional Ethics Committees	AAP Committee on Bioethics	A statement for reaffirmation of this policy was published on Oct 1, 2004 and May 1, 2009	Pediatrics 2001, 107(1): 205-209
Informed consent, parental permission, and assent in pediatric practice	AAP Committee on Bioethics	A statement of reaffirmation for this policy was published on Feb 1, 2007	Pediatrics 1995, 95(2): 314-317
Palliative care for children	AAP Committee on Bioethics and Committee on Hospital Care	A statement of reaffirmation for this policy was published on Feb 7, 2007	Pediatrics 2000, 106(2): 351-357

Guideline Recommendations and Their Rationales for the Treatment of Neonates, Infants, Children, and Adolescents

Table 16. Options for communicating information to parents about non-initiation or withdrawal from dialysis⁵⁴

<p>Clinical Judgment: “The dialytic treatment is no longer providing benefit”</p> <p>Rationale: (a) the risks outweigh the benefit; (b) the underlying condition is progressive; and (3) dialysis is prolonging the dying process.</p>
<p>“Usual” Method of Communicating Message: “Let’s stop heroic treatment.”</p> <p>Alternative Method of Communicating Message: “At this time, I think the wisest thing we can do is to understand how sick Sarah is and stop treatments that are not working for her. I think we should do all we can to ensure her comfort and yours, make sure there are no missed opportunities, and ensure we properly celebrate her life. I will follow your lead on this. Some ideas that have helped other families include getting her home with help for you if you wish, or you may choose to have her friends and your family come here instead and have a party; you can bring her clothes so that she will look like herself, bring in her music or a photo album and relive some of your best memories of her, make a mold of her hand so that you will always have her hand to hold, or anything else that would be a proper celebration of her life.”</p>
<p>“Usual” Method of Communicating Message: “Let’s stop aggressive treatment.”</p> <p>Alternative Method of Communicating Message: “We will do all we can to ensure he is as comfortable as possible.”</p>
<p>“Usual” Method of Communicating Message: “We are recommending withdrawal of care for Marisa.”</p> <p>Alternative Method of Communicating Message: “Marisa is too ill to get better. We need to refocus our efforts on making the most of the time she has left.”</p>
<p>“Usual” Method of Communicating Message: “There is nothing more we can do for Adam.”</p> <p>Alternative Method of Communicating Message: “We need to change the goals of our care for Adam. At this point we clearly cannot cure him, but that does not mean we can’t help him and your family.”</p>
<p>“Usual” Method of Communicating Message: “Johnny is not strong enough to keep going.”</p> <p>Alternative Method of Communicating Message: “Johnny is a strong boy and has fought hard with us to beat his disease. Unfortunately, as much as we wish we could, we cannot cure Johnny. At this point we are hurting him rather than helping, giving him side effects, and keeping him from being at home or taking a trip, or whatever he really wants to do in the time he has left.”</p>
<p>“Usual” Method of Communicating Message: “We need to stop active treatment for Dwayne.”</p> <p>Alternative Method of Communicating Message: “The goal of curing Dwayne’s disease, despite the best efforts of a lot of smart and hard-working people, is no longer possible. We are so sorry and wish that that were different. I have cared for many children who are as sick as your son. It is very hard on all of us, especially you, his parents and family when the treatments do not work as we had hoped. Many parents like you have agreed to stop efforts to cure when they are not working, as difficult as that is. Would you like me to put you in touch with some of the other parents who have been through this too?”</p>

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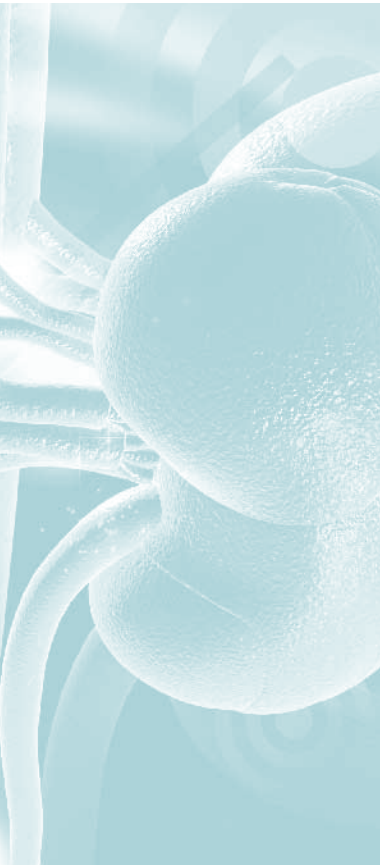
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Section 6

Future Research Directions



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

Pre-dialysis Chronic Kidney Disease

- Develop an accurate prognostic tool for the pre-dialysis population so that the subset of CKD patients who are not likely to benefit from dialysis can be identified.
- Study the frequency and outcomes of communication about prognosis and disease progression among patients with CKD and their nephrologists. Determine what communication interventions improve understanding and result in changes in treatment in patients with advanced CKD who may not benefit from dialysis.
- Study the impact of health literacy on decision-making about dialysis initiation.
- Evaluate outcomes of patients with active medical management without dialysis versus comparably matched patients who choose to undergo dialysis: long-term survival, progression of CKD, functional decline, quality of life, uremic and other symptoms assessment and management, percent of patients

Section 6

who die from uremia as opposed to other causes, and quality of death.

- Determine the true incidence of decisions to not initiate dialysis.

Acute Kidney Injury

- Continue to refine and prospectively validate prognostic models for AKI 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 who recover from AKI.
- Study the communication of poor prognosis and recommendation to withhold or withdraw dialysis in AKI. How are other physicians and caregivers (intensivist, primary care physician, residents, intensive care unit nurses) communicating prognosis? How is this communication understood by families? What are the factors associated with “effective” communication and concordance in understanding of prognosis between physicians and families?
- Elucidate how decisions regarding dialysis for AKI are being made in the intensive care unit. Are they shared decisions or, if the family wants dialysis for the patient, is it usually done regardless of prognosis?
- Describe the experience of withholding dialysis in patients with very poor prognosis, including prognostic markers associated with withholding dialysis. Describe patient and caregiver factors involved in the decision-making process.
- Determine whether time-limited trials of dialysis are being used in the intensive care unit. What are the outcomes?
- Identify how the transition to permanent dialysis is made in AKI patients. Does a new discussion take place allowing for a decision to continue dialysis or not?

End-Stage Renal Disease

- Identify predictors of deaths that occur within the first 90 days of dialysis.
- Evaluate whether time-limited trials of dialysis are used as a viable option. Are they being done? Are patients being reassessed? Do the trials make a difference in regard to future decisions and quality of life? Evaluate the bereaved family/caregiver experience of patients who have undergone time-limited trials. Did it positively affect outcomes, such as quality of life, symptoms, and patient/family ability to cope with decision about continued dialysis?
- Assess the benefits and costs of periodic measurement of cognitive and functional status and/or quality of life in patients on dialysis. Assess the impact of interventions, such as outpatient rehabilitation therapy, on functional status and outcomes.
- Determine when and how often it is appropriate to review with the patients their wishes regarding end-of-life care.
- Identify successful approaches to incorporating palliative care into dialysis units.
- Determine how to achieve earlier access to hospice services for terminally ill ESRD patients.
- Determine how to improve access to palliative care services for ESRD patients for symptom management and advance care planning, including end-of-life care.
- Study the functional status and symptom trajectory among ESRD patients before death so that palliative services can be appropriately timed and targeted.

Acute Kidney Injury and End-Stage Renal Disease

- Study content and benefits/burdens of palliative care and who delivers it for patients who never initiate or withdraw from dialysis.
- Use a prospective controlled design to study the use of palliative care consultation in treating pain and other symptoms, conducting advance care planning discussions, and achieving consensus on goals of care for patient with family.
- Study whether patients really have informed consent and make informed decisions.
- Continue to 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 to stop dialysis.
- Study emotional reactions and job satisfaction of involved health care professionals when patients decide to initiate dialysis against the physician's recommendation.
- Study emotional reactions and job satisfaction of involved health care professionals when incapacitated patients are started on dialysis or are kept on dialysis against the health care professionals' wishes.
- Explore patients' preferences for life-sustaining treatment over time and over the disease course.
- 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.
- Develop and assess methods to ensure timely referral to nephrologists for patients with AKI or ESRD.
- Develop and assess methods to ensure 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 6 months.
- Study methods to improve communication about prognosis and treatment preferences.
- Identify most effective methods of educating patients and families to enhance advance care planning, including completion of advance directives and a Physician Orders for Life-Sustaining Treatment (POLST) Paradigm form. Study other best practices for advance care planning, such as use of videos for instruction.
- Analyze different methods for diagnosing depression and anxiety and examine their role in patient decisions to discontinue treatment.
- Continue to describe and measure how dialysis patients die.
- Develop standards regarding "quality of dying" and assess their utility in monitoring quality of care.
- Study families' perspective of dialysis discontinuation, their satisfaction with end-of-life care, and their bereavement and adaptation to patients' deaths.
- Study methods to implement this guideline and others relevant to dialysis and associated outcomes.
- Continue to study attitude of patients and professionals toward respecting do-not-resuscitate orders in dialysis units.

Section 6

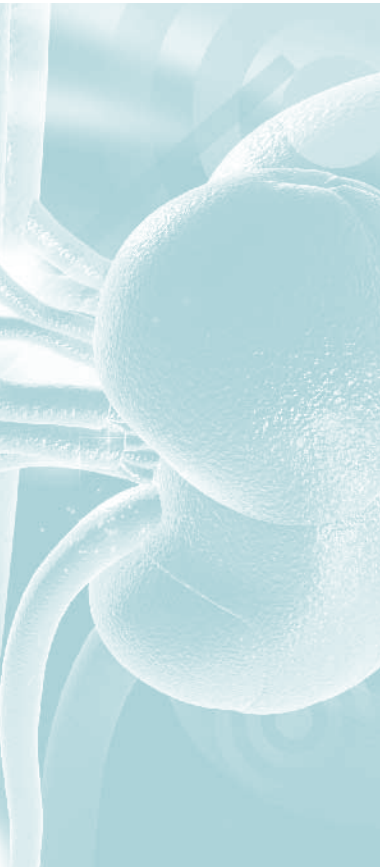
- Develop and test specific clinical performance measures to study how nephrology clinicians and facilities implement the guideline recommendations.
- Determine whether and how the new guideline changes nephrologists' attitudes and practices.
- Determine the practicality and effectiveness of structured discussions of poor prognosis with CKD (stage 1-6) and AKI patients.
- Determine practicality and effectiveness of training nephrologists and fellows in end-of-life communication skills.

Pediatric Patients

- Study long-term outcomes and quality of life in pediatric patients undergoing dialysis for AKI and ESRD.
- Study long-term outcomes 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, and why.
- Determine how often dialysis is initiated for a time-limited trial in pediatric patients.
- Determine whether and how the new guideline changes pediatric nephrologists' attitudes and practices.

Section 7

Implementation of Guideline Recommendations



Dissemination and Educational Initiatives

A first step in guideline implementation is dissemination and education. The Working Group recommends that the guideline document be disseminated throughout the ESRD Networks, as well as to individual providers. They also recommended incorporating the guideline into nephrology and critical care fellowship 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 advance care planning, palliative care, and communication.

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 prognosis and treatment options (including the right

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to refuse dialysis). One of the fundamental principles of Quality Improvement (QI) is that opportunities for improvement exist whenever there is variability in process and outcomes. Chronic kidney disease clinics and dialysis facilities and their patients could benefit from QI activities that seek to increase communication and shared decision-making between providers and patients (or their legal agents) about dialysis 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 remeasuring performance. Choosing reliable, specific, valid, reproducible, and interpretable quality indicators will help ensure successful implementation and desired improvements in care. Under the 2008 Conditions for Coverage, dialysis facilities are required to have a Quality Assessment and Performance Improvement (QAPI) program (CFR 42, Section 494.110) in place.

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

- Increase number of patients with advance care plans in place.
- Increase number of patients who have a designated legal decision-maker in the event of incapacity.
- Decrease number of patients reporting pain.

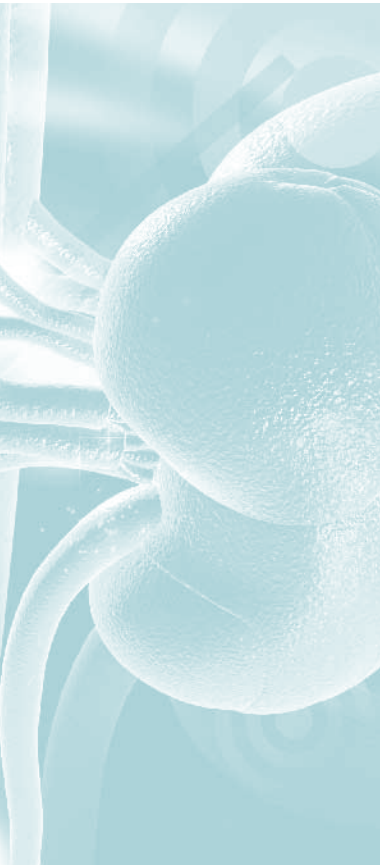
- Increase number of patients with symptom assessments done.
- Increase number of patients for whom nephrology clinicians have answered the “surprise” question.
- Increase number of terminally ill patients who are referred to hospice.

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 Tool 4 in **Section 9: Toolkit**.



Section 8

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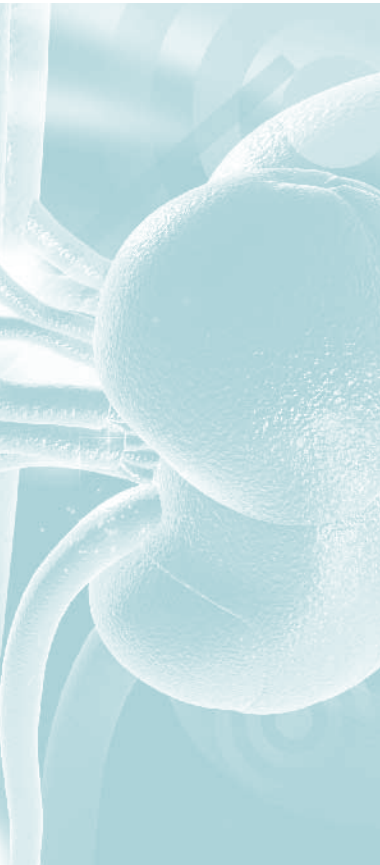
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Section 9

Toolkit



Many validated tools can be used to assess depression, cognitive capacity, decision-making capacity, quality of life, and prognosis. Choice of a particular tool depends upon issues such as preferences, resources, and provider familiarity and training. The Working Group especially recommends the following instruments because they have been used and validated in dialysis patients or in patients with comparable age and cognitive disorders.

Section 9

1. General Checklist for Implementing Shared Decision-Making Recommendations

The Working Group developed the following checklist with examples of items that could be added to the Comprehensive Assessment and Plan of Care 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 given information on advance directives.
Date: _____ Staff: _____
- ☐ yes ☐ no Patient has a signed durable power of attorney for health care in chart.
- ☐ yes ☐ no Patient has a signed living will in chart.
- ☐ yes ☐ no Patient has completed a Physicians Orders for Life-Sustaining Treatment (POLST) Paradigm form.
- ☐ yes ☐ no Circumstances, if any, under which patient would desire discontinuation of dialysis have been documented in chart.
- ☐ yes ☐ no Circumstances, if any, under which patient would not want cardiopulmonary resuscitation, mechanical ventilation, or tube feeding documented in chart.
- ☐ yes ☐ no Patient or designated legal agent has been given prognostic information. Estimated survival prognosis is a range of _____ to _____ (state months or years) based on: _____ (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 ☐ N/A Has an intervention been planned to improve quality of life or functional status?

2. Depression Assessment Tools

Many validated instruments 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.¹ Below is an example of a validated and easy-to-use depression screening instrument: the *Patient Health Questionnaire (PHQ-9)*.² Anyone who screens positive should have his or her diagnosis confirmed through a diagnostic interview.

Tool 2. Patient Health Questionnaire (PHQ-9)

Patient Health Questionnaire (PHQ-9)

Name: _____ Date: _____

Over the *last 2 weeks*, how often have you been bothered by any of the following problems?
(use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or hurting yourself in some way	0	1	2	3

add columns:

+

+

(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card.)

TOTAL:

10. If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all

Somewhat difficult

Very difficult

Extremely difficult

PHQ-9 is adapted from PRIME MD TODAY, developed by Drs Robert L. Spitzer, Janet B.W. Williams, Kirt Kroenke, and colleagues, with an educational grant from Pfizer Inc. For research information, contact Dr. Spitzer at rfs8@columbia.edu. Use of the PHQ-9 may only be made in accordance with the Terms of Use available at <http://www.pfizer.com>. Copyright ©1999 Pfizer Inc. All rights reserved. PRIME MD TODAY is a trademark of Pfizer Inc.

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Section 9

Fold back this page before administering this questionnaire

INSTRUCTIONS FOR USE

for doctor or healthcare professional use only

PHQ-9 QUICK DEPRESSION ASSESSMENT

For initial diagnosis:

1. Patient completes PHQ-9 Quick Depression Assessment on accompanying tear-off pad.
2. If there are at least 4 ✓s in the blue highlighted section (including Questions #1 and #2), consider a depressive disorder. Add score to determine severity.
3. **Consider Major Depressive Disorder**
—if there are at least 5 ✓s in the blue highlighted section (one of which corresponds to Question #1 or #2)
Consider Other Depressive Disorder
—if there are 2 to 4 ✓s in the blue highlighted section (one of which corresponds to Question #1 or #2)

Note: Since the questionnaire relies on patient self-report, all responses should be verified by the clinician and a definitive diagnosis made on clinical grounds, taking into account how well the patient understood the questionnaire, as well as other relevant information from the patient. Diagnoses of Major Depressive Disorder or Other Depressive Disorder also require impairment of social, occupational, or other important areas of functioning (Question #10) and ruling out normal bereavement, a history of a Manic Episode (Bipolar Disorder), and a physical disorder, medication, or other drug as the biological cause of the depressive symptoms.

To monitor severity over time for newly diagnosed patients or patients in current treatment for depression:

1. Patients may complete questionnaires at baseline and at regular intervals (eg, every 2 weeks) at home and bring them in at their next appointment for scoring or they may complete the questionnaire during each scheduled appointment.
2. Add up ✓s by column. For every ✓: Several days = 1 More than half the days = 2 Nearly every day = 3
3. Add together column scores to get a TOTAL score.
4. Refer to the accompanying PHQ-9 Scoring Card to interpret the TOTAL score.
5. Results may be included in patients' files to assist you in setting up a treatment goal, determining degree of response, as well as guiding treatment intervention.

PHQ-9 SCORING CARD FOR SEVERITY DETERMINATION

for healthcare professional use only

Scoring—add up all checked boxes on PHQ-9

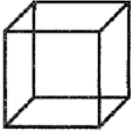
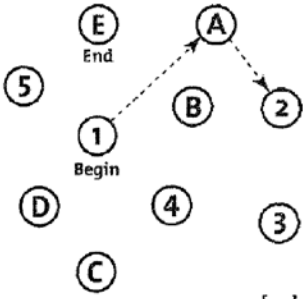

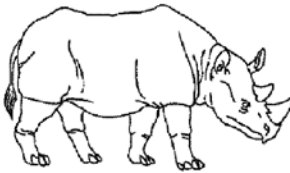

For every ✓: Not at all = 0; Several days = 1;
More than half the days = 2; Nearly every day = 3

Interpretation of Total Score

Total Score	Depression Severity
1-4	Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

3. Cognitive Capacity Assessment Tools

Tool 3-1. The Montreal Cognitive Assessment (MOCA)³

MONTREAL COGNITIVE ASSESSMENT (MOCA)						NAME : Education : Sex : Date of birth : DATE :
VISUOSPATIAL / EXECUTIVE		 <div style="display: flex; justify-content: space-between;"> Copy cube Draw CLOCK (Ten past eleven) (3 points) </div>		POINTS		
 <div style="display: flex; justify-content: space-around; margin-top: 10px;"> [] [] </div>		<div style="display: flex; justify-content: space-around;"> [] [] [] </div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> Contour Numbers Hands </div>		___/5		
NAMING						
						
[]		[]		[]		
___/3						
MEMORY		Read list of words, subject must repeat them. Do 2 trials. Do a recall after 5 minutes.				
		FACE	VELVET	CHURCH	DAISY	RED
		1st trial				
		2nd trial				
		No points				
ATTENTION		Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order [] 2 1 8 5 4 Subject has to repeat them in the backward order [] 7 4 2				
		___/2				
ATTENTION		Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors [] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B				
		___/1				
ATTENTION		Serial 7 subtraction starting at 100 [] 93 [] 86 [] 79 [] 72 [] 65 4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt				
		___/3				
LANGUAGE		Repeat : I only know that John is the one to help today. [] The cat always hid under the couch when dogs were in the room. []				
		___/2				
LANGUAGE		Fluency / Name maximum number of words in one minute that begin with the letter F [] ____ (N ≥ 11 words)				
		___/1				
ABSTRACTION		Similarity between e.g. banana - orange = fruit [] train - bicycle [] watch - ruler				
		___/2				
DELAYED RECALL		Has to recall words WITH NO CUE				
		FACE	VELVET	CHURCH	DAISY	RED
		[]	[]	[]	[]	[]
Optional		Category cue Multiple choice cue				
		Points for UNCUE recall only				
ORIENTATION		[] Date [] Month [] Year [] Day [] Place [] City				
		___/6				
TOTAL		Add 1 point if ≤ 12 yr edu				
		___/30				

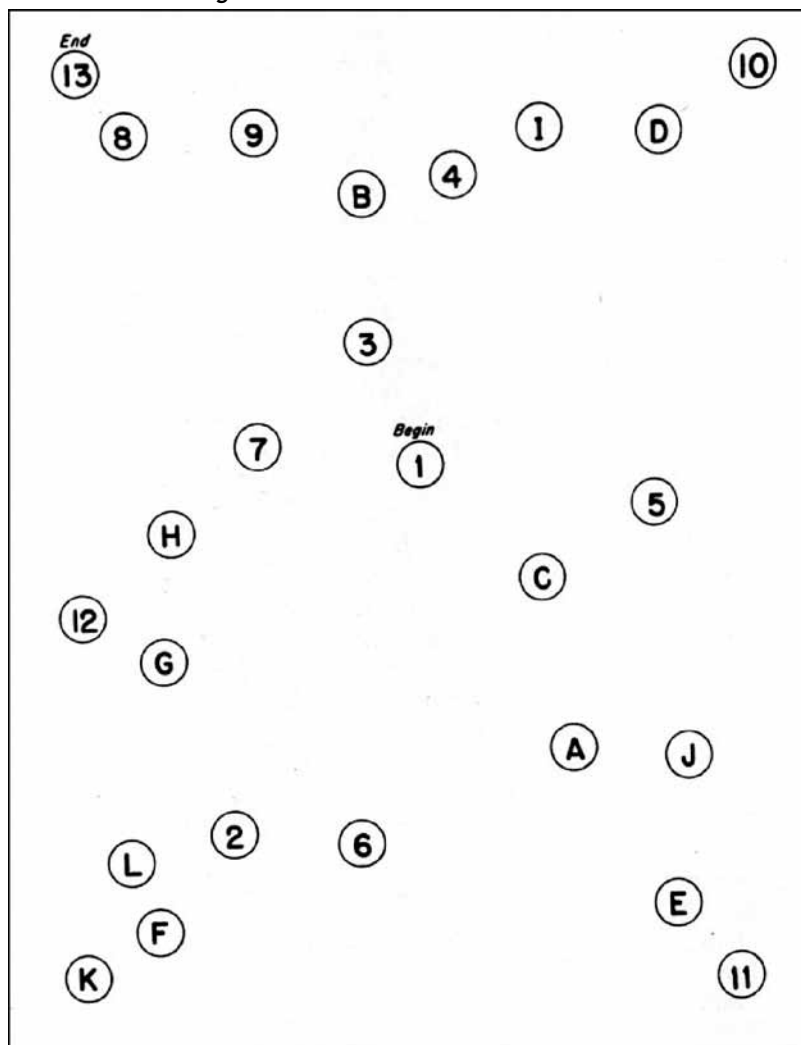
© Z.Nasreddine MD Version 7.0 www.mocatest.org Normal ≥ 26 / 30

Administered by: _____

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In research to study the Montreal Cognitive Assessment test on 90 normal controls, 93 patients with previously diagnosed mild cognitive impairment, and 94 patients with Alzheimer's disease, the mean scores for the three groups were as follows: normal controls 29, patients with mild cognitive impairment 22, and patients with Alzheimer's disease 16.³

Tool 3-2. The Trail Making Test Part B^{4,5}



In a study analyzing cognitive impairment in chronic kidney disease patients, normal individuals completed the Trail Making Test Part B in a mean of 92.7 ± 32.5 seconds; individuals with chronic kidney disease completed the test in a mean of 158.8 ± 74.1 seconds; and individuals with end-stage renal disease completed the test in a mean of 218.4 ± 83.9 seconds ($P < 0.001$).⁵

Tool 3-3. Short-Memory Questionnaire^{*6}

Questions	Almost Never	Sometimes	Often	Almost Always
1. Can he/she remember what clothes he/she wore yesterday?	1	2	3	4
7. Can he/she remember where his/her ride will meet him/her?	1	2	3	4
8a. Can he/she recall his/her telephone number?	1	2	3	4
11. Can he/she shop for groceries without a list and not forget any items (5 items)?	1	2	3	4
12a. Does he/she usually remember where he/she put his/her glasses?	1	2	3	4
12b. Does he/she usually remember where he/she put his/her keys?	1	2	3	4
15. Does he/she forget birthdays in his/her family?	1	2	3	4
16. If someone calls him/her, can he/she give that person directions to his/her home?	1	2	3	4
17. After leaving, can he/she remember whether he/she locked his/her house?	1	2	3	4
20. When he/she leaves the supermarket, can he/she remember how much change he/she received?	1	2	3	4
21. Can he/she describe what he/she did last Sunday afternoon?	1	2	3	4
22. Does he/she have to be reminded of things that his/her spouse or someone else has asked him/her to do?	1	2	3	4
26. Is it difficult for him/her to find the words that he/she wants to use?	1	2	3	4
27. Can he/she recall all his/her financial obligations (bills, bank accounts, savings)?	1	2	3	4

^{*}Item numbers are those of the original scale.⁷ Scoring key: almost never=1; sometimes=2; often=3; almost always=4. Scores on items 15 and 26 should be subtracted from the total because they have a reverse meaning. A total score of less than 40 is suggestive of disproportionate cognitive difficulties.

The Short-Memory Questionnaire has excellent specificity and sensitivity for identifying dementia in patients with Alzheimer's disease.⁶ It has not been validated for dialysis patients, but reviewers have suggested that this questionnaire would be helpful for patients with limited visual capacity or limited manual skills who cannot write or draw.

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4. Decision-Making Capacity Assessment Tools

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 non-treatment; 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 past several years, a number of standardized instruments have become available. An example of one of these instruments is presented below.

Tool 4. Aid to Capacity Evaluation (ACE)⁸

Record the 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="checkbox"/> UNSURE <input type="checkbox"/> NO <input type="checkbox"/>
2. Able to understand proposed treatment. Observations: _____ _____	YES <input type="checkbox"/> UNSURE <input type="checkbox"/> NO <input type="checkbox"/>
3. Able to understand alternative to proposed treatment (if any). Observations: _____ _____	YES <input type="checkbox"/> UNSURE <input type="checkbox"/> NO <input type="checkbox"/>
4. Able to understand option of refusing proposed treatment (including withholding or withdrawing proposed treatment). Observations: _____ _____	YES <input type="checkbox"/> UNSURE <input type="checkbox"/> NO <input type="checkbox"/>
5. Able to appreciate reasonably foreseeable consequences of accepting proposed treatment. Observations: _____ _____	YES <input type="checkbox"/> UNSURE <input type="checkbox"/> NO <input type="checkbox"/>
6. Able to appreciate reasonably foreseeable consequences of refusing proposed treatment (including withholding or withdrawing proposed treatment). Observations: _____ _____	YES <input type="checkbox"/> UNSURE <input type="checkbox"/> NO <input type="checkbox"/>

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 UNSURE NO	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7b. The person’s decision is affected by delusion/psychosis. Observations: _____ _____	YES UNSURE NO	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Overall Impression

- Definitely Capable ☐
- Probably Capable ☐
- Probably Incapable ☐
- Definitely Incapable ☐

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 definitely or probably indicates incapacity, the clinician should 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 indicates probable incapacity or probable capacity, then take further steps to clarify the situation. For example, if the clinician is 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 an interpretation of domain 7a and 7b. Even if the clinician is sure that the decision is based on a delusion or major depression, it is always valuable to get an independent assessment.

Time taken to administer ACE: _____ minutes

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

Assessor: _____

5. Advance Care Planning Including Advance Directives

Tool 5-1. Advance Care Planning Questions

The following table provides examples of questions that may be helpful in discussing end-of-life issues with patients.⁹

Potentially Useful Open-Ended Questions About End-of-Life Care
■ 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?
Potentially Useful Questions With Which to Explore Spiritual and Existential Issues
■ 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
■ 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?

Tool 5-2. Explanation of Advance Directives

Advance directives are oral or written statements by a patient with decision-making capacity, which express 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 health care proxy and a living will. The health care proxy designates a person to make decisions for a patient when the patient loses decision-making capacity. 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 that are to be followed if he/she 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. In some states, both of these functions are combined in the living will.

The US Congress enacted the Patient Self-Determination Act¹⁰ 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 laws vary with regard to written directives.

Tool 5-3. Website Resources for Advance Care Planning and Advance Directives

The Kidney End-of-Life Coalition provides information and resources to help dialysis professionals, facilities, and patients complete advance care planning and advance directive completion. See <http://www.kidneyeol.org/>.

The Caring Connections website offers information about advance care planning and free downloads of state-specific, legal advance directives. See <http://www.caringinfo.org/stateadownload>.

The Physician Orders for Life-Sustaining Treatment (POLST) Paradigm program to convert patients' end-of-life wishes into easily identifiable, portable, and reviewable medical orders that are honored throughout the health care system is recognized as a preferred practice by the National Quality Forum in its *A National Framework and Preferred Practices for Palliative Care and Hospice Care Quality* (2006). The POLST Paradigm program was also recognized as a model practice for implementing advance care planning by RAND Health in their *Advance Directives and Advance Care Planning: A Report to Congress* (2009). The website link for the POLST Paradigm Program is www.polst.org.

Below is a model advance care planning policy that dialysis facilities may find helpful as they develop their advance directive policies and procedures to comply with the Conditions for Coverage published by the Centers for Medicare and Medicaid Services in 2008. Subpart C. Patient Care, Section § 494.70 Condition: Patients' Rights requires dialysis facilities to have advance directives policies.

Tool 5-4. Model Dialysis Unit Advance Care Planning Policy¹

I. Policy

It is the policy of (*name of the dialysis facility*) to respect the right of patients with decision-making capacity to execute advance directives documents and to have these documents respected by personnel of the dialysis facility.

II. Rationale for the Policy

Adoption of these policies and procedures enhances the dialysis facility's ability to provide the medical care sought by patients. Their implementation is a major step in assuring respect for patient autonomy and the patient's ability to exercise his or her right to self-determination concerning medical treatment.

1 Adapted in part with permission from the Robert Wood Johnson Foundation's End-Stage Renal Disease Workgroup's Recommendations to the Field, Model Policy and Procedure for DNR Orders in Dialysis Facility. Refer to www.promotingexcellence.org/esrd for the Robert Wood Johnson Foundation's End- Stage Renal Disease Workgroup's final product.

This policy and procedure represents the work of the Kidney End-of-Life Coalition and does not necessarily represent the views of the above Foundations. It is reprinted here with permission of the Mid-Atlantic Renal Coalition and the Kidney End-of-Life Care Coalition.

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III. Definitions

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 health care proxy and for future medical care 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: A statement by a patient with decision-making capacity expressing his/her preference for a health care proxy 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 or regulations recognizing written advance directives and the rights of patients to have their wishes respected. There are two types of written advance directives: a living will (an instruction directive in which the patient gives directions for future medical care in the event of particular medical conditions, such as terminal illness or a persistent vegetative state); and a health care proxy (a proxy directive in which the patient designates a person to make decisions for him/her when the patient loses decision-making capacity). In some states the health care proxy is referred to as a medical power of attorney or durable power of attorney for health care. In some states both instruction and proxy directives may be combined into one advance directive form. Some patients may want to state their preferences verbally to their family and to dialysis staff and not put them into writing. Any expressed preferences should be documented in the patient's dialysis medical record. Such verbal statements constitute oral advance directives. (Since written advance directives are preferable from a legal perspective, the remainder of this policy and procedure refers to written advance directives.)

Attending Physician: A licensed physician with staff privileges in the dialysis facility who has primary responsibility for treatment of the patient. (In the case of dialysis patients, this physician is likely to be the nephrologist primarily assigned to the supervision of the patient's dialysis and related care.) If more than one physician shares the responsibility for care of the patient, any of those physicians may act as the attending physician under this policy.

Decision-Making Capacity: The capacity of a patient to 1) understand his/her medical condition; 2) appreciate the consequences (benefits and burdens) of various treatment options including non-treatment; 3) judge the relationship between the treatment options and his/her personal values, preferences and goals; 4) reason and deliberate about his/her options; and 5) communicate his/her decision in a meaningful manner. Assessment of decision-making capacity is a clinical judgment made by the patient's attending physician.

Health Care Agent, Proxy, Surrogate, Guardian, Medical Power of Attorney, or Durable Power of Attorney for Health Care: A person, who in accordance with applicable state laws, has been selected by a patient or who, in accordance with applicable state laws, has been appointed, and has been given the authority to make informed health care decisions for the patient in the event the patient loses decision-making capacity. The appropriate terminology may vary from state to state, but the intent to allow an individual to pre-assign decision-making authority to another person is common among all such instruments. To the extent permitted by applicable state law, the health care agent may have the opportunity to be guided in his/her decision-making by prior knowledge of the patient's wishes through conversations and/or the stipulations in a written advance directive.

Living Will: The living will, also known as an instruction directive, indicates a patient's wishes to be followed if he/she 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 patient may indicate that he/she wishes under certain circumstances to have or continue treatments such as dialysis or CPR or to discontinue or refrain from such treatments.

Patient Without Decision-Making Capacity: A patient who in accordance with the clinical judgment of the attending physician, clinical practice guidelines, and applicable state laws, has been declared to lack the capacity to: 1) understand his/her medical condition; 2) appreciate the consequences (benefits and burdens) of various treatment options including non-treatment; 3) judge the relationship between the treatment options and his/her personal values, preference and goals; 4) reason and deliberate about his/her own options; and 5) communicate his/her decision in a meaningful manner.

IV. Procedures

- A. _____ (facility should designate a specific individual, committee or category of health professionals, i.e. social worker, nurse, clinician) will assume ultimate responsibility for assuring compliance with the advance directive policies and procedures and assuring that each patient is advised of his/her rights under the policies. The responsible individual(s) will be well informed about advance directives and relevant state laws and will be comfortable with and capable of discussing issues related to death and dying. The individual(s) will also have an awareness of how cultural diversity affects the views and concerns of persons of different ethnic and religious groups towards death and dying. Designated staff should assure that their personal beliefs and values about death and dying are not imposed onto the patient and family.
- B. All clinical staff will be made familiar with advance directives and will be oriented with the facility's written policies and procedures.
- C. Upon adoption of these policies and procedures, a determination of decision-making capacity will be made by the patient's attending or rounding physician or other licensed professional as allowed by state law on the patient's admission to the dialysis unit, yearly, and whenever there is a change in the patient's neurological status.
- D. A determination will be made if each patient has previously signed any type of advance directive authorized by state law. Upon adoption of these policies and procedures, existing patients will be asked. A new patient will be asked upon admission to a dialysis facility for the initiation of dialysis treatment.
- E. If the patient has existing advance directives, he/she will be requested to provide a copy to the facility for placement in the patient's dialysis medical record.
- F. If the patient, either new or existing, is unable to participate in discussions with staff of the facility, an effort will be made through discussion with the patient's legal guardian or authorized health care proxy according to state law to determine if the patient has previously signed any type of advance directive. An effort will be made to obtain a copy of any such advance directive for placement in the patient's dialysis medical record.

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- G. Any existing advance directive document(s) will be reviewed and discussed with the patient if he/she is able to participate in such discussions. The patient will also be asked if he/she is comfortable with the existing advance directive or desires to execute a new one.
- H. If the patient has not signed advance directives, the responsible staff member(s) will have a discussion with and provide written information to the patient about advance directives and applicable state laws regarding advance directives.
 - a. If the patient does elect to complete an advance directive document, the following are helpful questions to ask during the advance care planning process:
- I. 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 and why?
- J. Under what circumstances, if any, would you want to stop dialysis?
- K. 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?
- L. Where do you prefer to die and who do you wish to be with you when you die?
 - a. (Applicable state forms for advance care planning can be obtained through Caring Connections, www.caringinfo.org)
 - b. Patients new to dialysis who have not signed advance directives will be approached within one month of initiation of dialysis therapy. Since the prospect of beginning dialysis is overwhelming to most individuals, patients who have not previously signed advance directives may not wish to discuss or sign advance directives at the time of admission. If at all possible, however, patients will be encouraged to complete a medical power of attorney to allow for a decision-maker in the event of an emergency.
- M. If it is determined that the patient has not signed advance directives and the patient's decision-making capacity is temporarily impaired due to a medical condition, e.g. uremia, the initial discussion of advance directives will be delayed until the patient can participate in the process.
- N. If the patient does not have advance directives and does not wish to discuss or sign advance directives the first time he/she is approached, the topic will be approached again within three months. However, regardless of whether the patient completes an advance directive, he/she will be asked to provide the name of a person he/she would want to make decisions for him/her in the event of incapacity. This person's name shall be documented in the advance directive section of the patient's dialysis medical record.
- O. If the patient still does not elect to complete advance directives, his/her decision will be respected. However, in conjunction with Comprehensive Assessment and Plan of Care completion, or if the patient's physical condition deteriorates, appropriate staff will once again offer to discuss advance care planning if the patient so desires.
- P. When a discussion regarding advance directives occurs with the patient, the discussion, as well as the patient's decision whether or not to sign advance directives, will be noted in the progress notes of the dialysis medical record. The patient's Comprehensive Assessment and Plan of Care will include pertinent information on advance directives that will be regularly updated as needed.

- Q. If the patient chooses to complete advance directives, the dialysis medical record will be marked in a manner that makes it readily apparent to staff that an advance directive exists. There will be a standardized section of the patient's dialysis medical record that is devoted to documenting end-of-life preferences. A copy of the advance directives document(s) will also be maintained in the dialysis medical record in a form that complies with applicable state law, if any.
- R. The patient's advance directives, if any, will be reported at periodic patient care meetings to ensure that staff members are familiar with the existence of that patient's advance directives.
- S. Staff assigned to deal with advance directives in the facility will promptly notify any third party designated to act under the advance directives if circumstances arise which are addressed by the patient's advance directive.
- T. The patient will be advised to discuss his/her advance directives and provide a copy of them to any person designated as a health care proxy or authorized to act under a health care power of attorney or similar advance directives. The patient will also be advised to discuss his/her advance directives and provide a copy of the advance directives to one or more of the following groups of people: his/her personal physician, significant other, family, friend, attorney or religious adviser. If the patient desires, a facility staff person will facilitate discussions with these individuals.
- U. Advance directives will be reviewed with the patient on a semi-annual basis, at approximately the time of the patient's Comprehensive Assessment and Plan of Care meeting, or more frequently if there is significant change in the patient's physical condition, to determine if changes in the advance directives are necessary. The facility will periodically review any health care proxy to ensure that the designated person can still act as proxy and that the contact information is current.
 - a. If the patient alters his/her advance directives, the facility should document that the superseded advance directive was revoked. If a copy of the revoked advance directive is maintained, it should be clearly marked to distinguish that it has been revoked. (Facilities should determine if applicable state law mandates how revocation is documented.)
- V. The dialysis patient or his/her health care proxy is responsible for giving a copy of his/her advance directive to health care professionals treating the patient. With a signed release from the patient or proxy, the dialysis facility will provide a copy of the advance directives to the following:
 - a. A hospital at the time of any future admission;
 - b. Another dialysis facility upon permanent transfer or transient treatments;
 - c. Any treating physician, home health agency, hospice, nursing home or health maintenance organization which provide service to the patient; or
 - d. Any ambulance service, transportation provider or EMT, which provides transport to the patient.

6. Prognosis Tools

Tool 6-1. Integrated Prognostic Model for Dialysis Patients

Nephrology clinicians and other staff can use an Internet-based integrated prognostic model for dialysis patients to estimate 6-, 12-, and 18-month survival.¹¹ The model requires the user to enter patient age, serum albumin level, response to the surprise question, and presence or absence of dementia and peripheral vascular disease. The model is accessible at <http://touchealc.com/calculators/sq>.

Tool 6-2. Modified Charlson Comorbidity Index¹²

Completed by _____

Date of completion _____ Time _____

Assigned Weights of diseases

Conditions

1	Myocardial Infarction (any form of coronary artery disease) Congestive Heart Failure Peripheral Vascular Disease Cerebrovascular disease Dementia Chronic obstructive pulmonary disease Connective tissue Disease Ulcer Disease Mild Liver Disease Diabetes
2	Hemiplegia Moderate or severe renal disease Diabetes with end-organ damage Any tumor Leukemia Lymphoma
3	Moderate or Severe Liver Disease
6	Metastatic solid tumor AIDS

For each decade over the age of 40 years, add a score of 1. Non-diabetic dialysis patients receive a minimum score of 2 for moderate to severe renal disease, and diabetic patients receive a minimum score of 4 (2 for diabetic end-organ damage and 2 for end-stage renal disease).

Total score of the patient ____/____.

Tool 6-3. Malnutrition Inflammation Score (M.I.S.)¹³

MALNUTRITION INFLAMMATION SCORE (M.I.S.)			
(A) Patients' related medical history:			
1- Change in end dialysis dry weight (overall change in past 3-6 months):			
0	1	2	3
No decrease in dry weight or weight loss <0.5 kg	Minor weight loss (>0.5 kg but <1 kg)	Weight loss more than one kg but <5%	Weight loss >5%
2- Dietary intake:			
0	1	2	3
Good appetite and no deterioration of the dietary intake pattern	Somewhat sub-optimal solid diet intake	Moderate overall decrease to full liquid diet	Hypo-caloric liquid to starvation
3- Gastrointestinal (GI) symptoms:			
0	1	2	3
No symptoms with good appetite	Mild symptoms, poor appetite or nauseated occasionally	Occasional vomiting or moderate GI symptoms	Frequent diarrhea or vomiting or severe anorexia
4- Functional capacity (nutritionally related functional impairment):			
0	1	2	3
Normal to improved functional capacity, feeling fine	Occasional difficulty with baseline ambulation, or feeling tired frequently	Difficulty with otherwise independent activities (e.g. going to bathroom)	Bed/chair-ridden, or little to no physical activity
5- Co-morbidity including number of years on Dialysis:			
0	1	2	3
On dialysis less than one year and healthy otherwise	Dialyzed for 1-4 years, or mild co-morbidity (excluding MCC*)	Dialyzed >4 years, or moderate co-morbidity (including one MCC*)	Any severe, multiple co-morbidity (2 or more MCC*)
(B) Physical Exam (according to SGA criteria):			
6- Decreased fat stores or loss of subcutaneous fat (below eyes, triceps, biceps, chest):			
0	1	2	3
Normal (no change)	mild	moderate	Severe
7- Signs of muscle wasting (temple, clavicle, scapula, ribs, quadriceps, knee, interosseous):			
0	1	2	3
Normal (no change)	mild	moderate	Severe
(C) Body mass index:			
8- Body mass index: BMI = Wt(kg) / Ht²(m)			
0	1	2	3
BMI>20 kg/m ²	BMI: 18-19.99 kg/m ²	BMI: 16-17.99 kg/m ²	BMI<16 kg/m ²
(D) Laboratory Parameters:			
9- Serum albumin:			
0	1	2	3
Albumin> 4.0 g/dL	Albumin: 3.5-3.9 g/dL	Albumin: 3.0-3.4 g/dL	Albumin: <3.0 g/dL
10- Serum TIBC (total Iron Binding Capacity): ♣			
0	1	2	3
TIBC> 250 mg/dL	TIBC: 200-249 mg/dL	TIBC: 150-199 mg/dL	TIBC: <150 mg/dL
Total Score = sum of above 10 components (0-30):			

* MCC (Major Comorbid Conditions) include CHF class III or IV, full blown AIDS, severe CAD, moderate to severe COPD, major neurological sequelae, and metastatic malignancies of s/p recent chemotherapy.

♣ Suggested equivalent increments for serum transferrin are: >200 (0), 170-200 (1), 140-170 (2), and <140 mg/dL (3).

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Tool 6-4. French Renal Epidemiology and Information Network Registry Clinical Score to Predict 6-month Prognosis¹⁴

Risk factors	Points
Body mass index (kg/m²)	
≥18.5	0
<18.5	2
Diabetes	
Absence	0
Presence	1
Congestive heart failure stage III or IV	
Absence	0
Presence	2
Peripheral vascular disease stage III or IV	
Absence	0
Presence	2
Dysrhythmia	
Absence	0
Presence	1
Active malignancy	
Absence	0
Presence	1
Severe behavioral disorder	
Absence	0
Presence	2
Totally dependent for transfers	
Absence	0
Presence	3
Initial context	
Planned dialysis	0
Unplanned dialysis (late referral)	2

The risk of death increases with the score. Patients with ≥9 points had a predicted 6-month mortality of 62% in the derivation sample (2,500 patients) and 70% in the validation sample (1,640 patients).

7. Quality of Life or Functional Status Assessment Tools

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). Poor functional

status is highly predictive of early death in dialysis patients (for a discussion of this evidence, see Recommendation No. 3 of this guideline).

Both generic and disease-specific instruments have been used to assess quality of life or functional status in hemodialysis patients. The most frequently used standardized and well-known instruments to assess dialysis patients include variations of the Karnofsky Performance Status Scale¹⁵, the Medical Outcomes Study 36-item Short Form (SF-36)¹⁶ or the Medical Outcomes Study 20-item Short Form (SF-20)¹⁷, the Beck Depression Inventory¹⁸, and the Sickness Impact Profile.¹⁹ Disease-specific instruments, such as the Kidney Disease Quality of Life (KDQOL) instrument,²⁰ have been used less frequently.

Tool 7. Karnofsky Performance Status Scale

The Karnofsky Performance Status Scale (KPS) is a well-established and widely used method of quantifying the functional status of cancer patients and was the most commonly used instrument to assess functional status in the Working Group's systematic review of the renal literature.¹⁴ As originally conceived, the KPS has three alphabetic groups (A, B, and C) for classifying patients' ability to work, carry on normal activity, and care for themselves.³³ These alphabetic groups are further divided into 11 categories, which cover all possible levels of functioning from completely normal (100) to dead (0).

Karnofsky Performance Status Scale Definitions Rating (%) Criteria²¹

A. Able to carry on normal activity and to work; no special care 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 and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal 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; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead.

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8. National Kidney Foundation Dialysis

Initiation and Withdrawal Tools

The National Kidney Foundation's *Initiation or Withdrawal of Dialysis in End-stage Renal Disease: Guidelines for the Health Care Team*²² included helpful checklists to follow in initiating dialysis, withdrawing dialysis, and in helping patients to prepare for dying.

Tool 8-1. 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.

- 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.

- 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:

- 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.

- 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 before initiation of dialysis and preconceptions of anticipated quality of life and ability to function after initiation of dialysis;

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The patient's short- and long-term 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.

- 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?

- 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?

Tool 8-2. 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:

- 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.

- 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.

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;

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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.

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- 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.

-
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- 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?

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Tool 8-3. 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.

9. Pain and Symptom Assessment and Management for Dialysis Patients

Tool 9-1. Clinical Algorithm & Preferred Medications to Treat Pain in Dialysis Patients

The Mid-Atlantic Renal Coalition and the Kidney End-of-Life Coalition supported, in part, under CMS Contract #HHSM-500-2006-NW005C, developed, *Clinical Algorithm & Preferred Medications to Treat Pain in Dialysis Patients*, an evidence-based algorithm for assessing and treating pain in dialysis patients.²³⁻³²

The algorithm can be accessed at <http://www.kidneyeol.org/painbrochure9.09.pdf>.

Tool 9-2. Dialysis Symptom Index

The Dialysis Symptom Index is a validated tool for dialysis patients to assess symptom frequency and severity.³³

Instructions

Below is a list of physical and emotional symptoms that people on dialysis may have. For each symptom, please indicate if you had the symptom **during the past week** by circling “yes” or “no.” **If “yes,”** please indicate how much that symptom bothered you by circling the appropriate number.

During the past week: Did you experience this symptom?		If “yes”: How much did it bother you?				
		Not at All	A Little Bit	Some-what	Quite a Bit	Very Much
1. Constipation	No Yes →	0	1	2	3	4
2. Nausea	No Yes →	0	1	2	3	4
3. Vomiting	No Yes →	0	1	2	3	4
4. Diarrhea	No Yes →	0	1	2	3	4
5. Decreased appetite	No Yes →	0	1	2	3	4
6. Muscle cramps	No Yes →	0	1	2	3	4
7. Swelling in legs	No Yes →	0	1	2	3	4
8. Shortness of breath	No Yes →	0	1	2	3	4

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During the past week: Did you experience this symptom?		If "yes": How much did it bother you?				
		Not at All	A Little Bit	Some-what	Quite a Bit	Very Much
9. Lightheadedness or dizziness	No Yes →	0	1	2	3	4
10. Restless legs or difficulty keeping legs still	No Yes →	0	1	2	3	4
11. Numbness or tingling in feet	No Yes →	0	1	2	3	4
12. Feeling tired or lack of energy	No Yes →	0	1	2	3	4
13. Cough	No Yes →	0	1	2	3	4
14. Dry mouth	No Yes →	0	1	2	3	4
15. Bone or joint pain	No Yes →	0	1	2	3	4
16. Chest pain	No Yes →	0	1	2	3	4
17. Headache	No Yes →	0	1	2	3	4
18. Muscle soreness	No Yes →	0	1	2	3	4
19. Difficulty concentrating	No Yes →	0	1	2	3	4
20. Dry skin	No Yes →	0	1	2	3	4
21. Itching	No Yes →	0	1	2	3	4
22. Worrying	No Yes →	0	1	2	3	4
23. Feeling nervous	No Yes →	0	1	2	3	4
24. Trouble falling asleep	No Yes →	0	1	2	3	4
25. Trouble staying asleep	No Yes →	0	1	2	3	4
26. Feeling irritable	No Yes →	0	1	2	3	4

During the past week: Did you experience this symptom?		If "yes": How much did it bother you?				
		Not at All	A Little Bit	Some-what	Quite a Bit	Very Much
27. Feeling sad	No Yes →	0	1	2	3	4
28. Feeling anxious	No Yes →	0	1	2	3	4
29. Decreased interest in sex	No Yes →	0	1	2	3	4
30. Difficulty in becoming sexually aroused	No Yes →	0	1	2	3	4

Are there any other symptoms not mentioned on this questionnaire that you have experienced during the past week? _____

The University of Pittsburgh Medical Center



VA Pittsburgh Healthcare System

10. ESRD End-of-Life Care Tool

In 2000 the Robert Wood Johnson Foundation National Program *Promoting Excellence in End-of-Life Care* assembled an interdisciplinary 23-person workgroup with expertise in nephrology and palliative care to assess the state of end-of-life care for dialysis patients and make recommendations to the field on ways to improve it.³⁴ This workgroup held a series of meetings, deliberated for 18 months, and issued a 96-page report.³⁵

The links below describe the findings of the workgroup and report the multiple recommendations they made to the Centers for Medicare and Medicaid Services, the NIH's National Institute of Diabetes and Digestive and Kidney Diseases, nephrology researchers, nephrology educators, nephrology clinicians, nephrology certifying boards, dialysis corporations, dialysis units, ESRD networks, public and private funders of nephrology research, and ESRD patient advocacy groups.

The Robert Wood Johnson Foundation National Program *Promoting Excellence in End-of-Life Care* ESRD workgroup webpage can be accessed at <http://www.promotingexcellence.org/esrd/>.

The specific reference for the workgroup report is http://www.promotingexcellence.org/downloads/esrd_full_report.pdf.

11. Communication Tools^{36,37}

Recommended Skill	Example
I. Identifying concerns:	
Eliciting concerns	
Open-ended questions	“What concerns you about your kidney disease?”
Active listening	Allowing patient to speak without interruption; allowing pauses to encourage patient to speak
Recognizing concerns	
Informational concerns	Patient: “I’m not sure about the treatment options”
Emotional concerns	Patient: “I’m worried about that”
II. Responding to informational concerns:	
“Ask-Tell-Ask”	Topic: communicating information about kidney disease
Ask	“What have others told you about what is going on with your illness?”
Tell	After learning what the patient knows, the physician can better tell the information in a way that addresses that patient’s concerns and needs.
Ask	“What questions do you have about what I just said?”

Recommended Skill	Example
III. Responding to emotional concerns: Nonverbal empathy: S-O-L-E-R	
S	Face the patient SQUARELY
O	Adopt an OPEN posture
L	LEAN toward the patient
E	Use EYE contact
R	Maintain a RELAXED body posture
Verbal empathy: N-U-R-S-E	
N	NAME the emotion: “You seem worried”
U	UNDERSTAND the emotion: “I see why you are concerned about this”
R	RESPECT the emotion: “You have shown a lot of strength”
S	SUPPORT the patient: “I want you to know that I will still be your doctor no matter what treatment plans we decide”
E	EXPLORE the emotion: “Tell me more about what is worrying you”

Clinical Scenarios in which expressions of wishes might be appropriate³⁸

Clinical Scenario	Sample Responses
Delivering very bad news	<i>I wish I had better news to give you.</i>
Responding to unrealistic hopes from patient or family	<i>I wish that were possible. It sounds like all of us would be a lot happier if that were so.</i>
Responding to expressions of loss, grief, and hopelessness	<i>It sounds like a terrible loss for you. I wish it hadn't turned out this way.</i>
Responding to disappointment in medicine or physician	<i>I can understand how disappointing this is for you. I too wish we had been able to do more for your loved one.</i>
Responding to demands or aggressive treatment when the prognosis is very poor	<i>It must be very hard to come to the intensive care unit every day and see so little change. I wish medicine had the power to turn things around.</i>
Responding to medical complications or errors	<i>This is so hard for you – just when our hopes were so high, for her to have this complication. I wish it had been otherwise.</i>

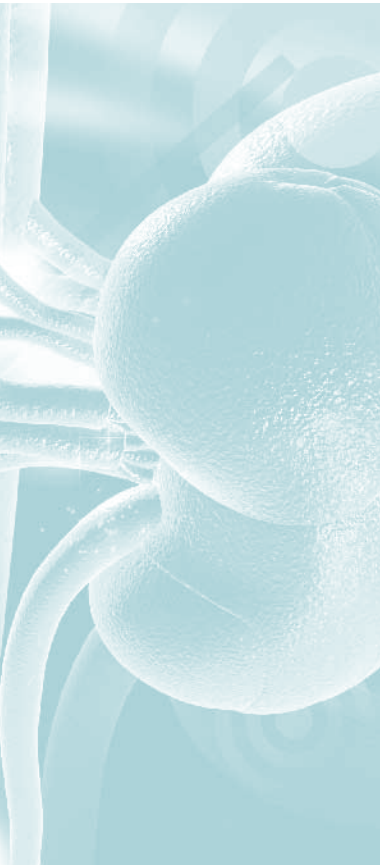
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Section 10

Glossary



Active Medical Management without Dialysis: Active treatment for a patient with stage 4 or 5 CKD who does not want dialysis. It includes management of acidosis, anemia, bone disease, fluid balance, hypertension, pain, and symptoms. The patient's goals for care should be established in advance care planning, and the renal care team should complete a do-not-resuscitate order and a Physician Order for Scope of Treatment (POLST) form (or comparable form depending on the state) for the patient. For patients estimated to have less than six months to live, physicians should present the option of a hospice referral to them. The surprise question—"Would I be surprised if this patient died in the next year?"—may be helpful to identify patients for whom a recommendation to consider active medical management without dialysis is reasonable.

Acute Kidney Injury: Acute kidney injury is defined as an abrupt and sustained decrease in kidney function associated with an absolute rise in serum creatinine of ≥ 0.3 mg/dl (≥ 26.4 mol/l) or percentage increase in serum creatinine $\geq 50\%$.

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Advance Care Planning: A process of communication among the patient, 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 health care proxy and a living will. The health care proxy designates a person to make decisions for a patient when the patient loses decision-making capacity. 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 that are to be followed if he/she 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. In some states, both of these functions are combined in the living will.

Beneficence: Ethical principle that obliges a person 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 no treatment; 3) judge the relationship between 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 patients who are terminally ill.

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

Guideline: A systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. It is 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 treating 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 as a health care proxy, a durable power of attorney for health care, a medical power of attorney, or a living will) who is legally authorized to make medical decisions for the patient in the event of the patient's loss of decision-making capacity. If the patient has not completed an advance directive, the legal agent is 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 stage 4 and 5 CKD and 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 that 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 agree 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 6 months.

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Appendix

Figures and Tables for Recommendation No. 3

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Figure 6. Risk of Chronic Kidney Disease Requiring Dialysis and Mortality in Association with Acute Kidney Injury and Dialysis During Index Hospitalization¹³⁹

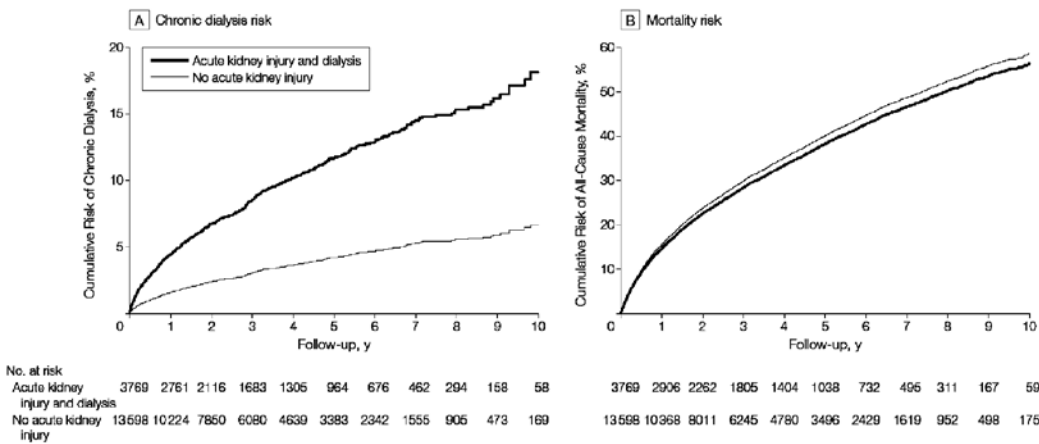


Table 4. Risk of Chronic Dialysis and All-Cause Mortality by Group¹³⁹

Outcome	Acute Kidney Injury and Dialysis at Index Hospitalization (n = 3769)		Without Acute Kidney Injury or Dialysis at Index Hospitalization (n = 13 598)		Hazard Ratio (95% Confidence Interval)	
	No. of Events (%)	Incidence Rate Per 100 Person-Years	No. of Events (%)	Incidence Rate Per 100 Person-Years	Crude ^a	Adjusted ^b
Chronic dialysis	322 (8.5)	2.63	403 (3.0)	0.91	3.26 (2.73-3.89)	3.23 (2.70-3.86)
All-cause mortality	1311 (34.8)	10.10	4884 (35.9)	10.83	0.95 (0.88-1.02)	0.95 (0.89-1.02)

^aReflects the effect of acute kidney injury and dialysis vs matched individuals without acute kidney injury.

^bFurther adjusted for age (continuous in years) and the propensity score for acute kidney injury and dialysis.

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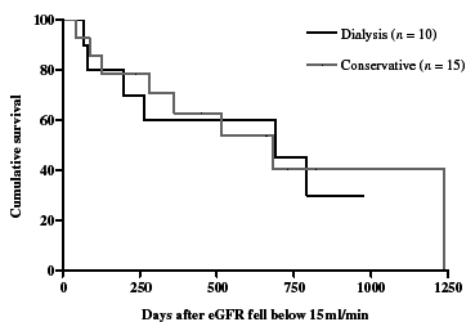
Table 5. Survival of Patients with Active Medical Management without Dialysis versus Dialysis*

Study	N	Dialysis	MM*	Median survival	Independent Predictors of Medical Management Recommendation	Age (yrs)	GFR (ml/min)
Smith 2003 ⁴⁸	321	258	63	RRT MM 8.3 vs. 6.3 months=NS (10 patients vs. 26 patients) RRT group 80% 4 yr survival	Age KPS Diabetes	Mean 61.5	
Joly 2003 ¹⁵⁰	144	107	37	RRT MM 28.9 vs. 8.9 months P<.001	KPS Social Isolation Late Referral Diabetes Low BMI	Mean 83 Cut off ≥ 80	<10 CG
Carson 2009 ⁴⁹	202	173	29	RRT MM 37.8 vs. 13.9 months P<.001	Age	≥70 Cut off	≤30
Murtagh 2007 ⁵²	129	52	77	RRT MM 84% vs. 68% at 1 yr (P<.001) MM 18 months No survival advantage for RRT patients with high comorbidity score or ischemic heart disease.	Age Comorbidity Ischemic Heart Disease (excluded Late Referrals and GFR <15)	>75 yrs	< 15 Stage 5
Wong 2007 ⁵⁰	73	--	73	MM 23.4 months 1-yr survival 65%	Comorbidity	Median 79 yrs	Median 12 Range (4-31)
Ellam 2009 ⁵¹	69	--	69	MM 21 months	Serum albumin ≤3.5 g/dL Late referral	Median 80	<15 MDRD Stage 5

*MM = active medical management without dialysis. Yrs = years. GFR = estimated glomerular filtration rate in milliliters per minute. RRT = renal replacement therapy. KPS = Karnofsky Performance Status score. CG = Cockcroft-Gault estimate. BMI = body mass index. MDRD = Modified Diet in Renal Disease study estimate.

In the Smith 2003 study, survival of 10 patients who chose dialysis over medical management was not statistically significantly better than that of the 26 patients who chose medical management without dialysis.

Figure 7. Comparative Survival of CKD Patients Older than 75 Years with High Comorbidity Score with and without Dialysis⁵²



Kaplan-Meier survival curves for those with high comorbidity (score=2), comparing dialysis and conservative groups ($P=0.98$).

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Table 6. Expected Remaining Lifetimes (Years) of the General US Population and of Prevalent Dialysis and Transplant Patients (General US Population, 2004; ESRD Patients, 2006)¹⁶⁹

U.S. 2004	All races			White			African American		
	All	M	F	All	M	F	All	M	F
0-14	71.4	68.8	73.9	71.8	69.2	74.3	67.2	63.7	70.3
15-19	61.6	59.1	64.1	62.0	59.5	64.4	57.5	54.0	60.6
20-24	56.9	54.4	59.2	57.2	54.8	59.5	52.7	49.4	55.7
25-29	52.1	49.7	54.4	52.5	50.1	54.7	48.1	44.9	50.9
30-34	47.4	45.1	49.5	47.7	45.4	49.8	43.5	40.5	46.2
35-39	42.7	40.4	44.7	42.9	40.7	45.0	39.0	36.0	41.5
40-44	38.0	35.8	40.0	38.3	36.1	40.2	34.5	31.6	37.0
45-49	33.5	31.4	35.4	33.7	31.7	35.6	30.3	27.5	32.6
50-54	29.2	27.2	30.9	29.3	27.4	31.1	26.3	23.7	28.5
55-59	25.0	23.1	26.5	25.1	23.3	26.6	22.6	20.1	24.5
60-64	21.0	19.3	22.4	21.0	19.4	22.4	19.1	16.9	20.7
65-69	17.2	15.7	18.5	17.3	15.8	18.5	15.9	14.0	17.2
70-74	13.8	12.5	14.8	13.8	12.5	14.8	13.0	11.4	14.0
75-79	10.8	9.7	11.5	10.7	9.6	11.5	10.4	9.1	11.2
80-84	8.2	7.3	8.7	8.1	7.2	8.6	8.3	7.3	8.7
85+	4.4	3.9	4.6	4.3	3.8	4.5	5.0	4.4	5.1
Overall	25.2	23.4	26.6	25.3	23.6	26.7	23.1	20.9	24.8

Dialysis 2006	All races			White			African American			Native American			Asian		
	All	Male	Female	All	Male	Female	All	Male	Female	All	Male	Female	All	Male	Female
0-14	19.8	20.5	19.1	20.5	21.2	19.6	17.2	17.7	16.6	22.0	22.3	21.7	33.3	34.5	32.1
15-19	17.6	18.5	16.6	17.8	18.5	16.9	16.7	17.8	15.5	19.1	19.8	18.6	26.6	27.1	25.9
20-24	14.9	15.8	13.9	14.9	15.6	14.0	14.2	15.3	13.2	16.1	16.6	15.6	23.0	23.5	22.4
25-29	13.2	13.9	12.3	12.9	13.5	12.1	12.9	13.8	11.9	14.0	14.5	13.6	20.2	20.6	19.8
30-34	11.4	11.8	10.8	10.9	11.3	10.4	11.5	12.1	10.7	12.0	12.2	11.9	17.4	17.6	17.2
35-39	9.9	10.3	9.5	9.4	9.6	9.1	10.2	10.7	9.6	10.4	10.4	10.4	14.9	15.0	14.9
40-44	8.6	8.8	8.4	8.0	8.2	7.8	9.0	9.3	8.7	9.1	8.9	9.2	12.6	12.7	12.6
45-49	7.4	7.5	7.3	6.9	6.9	6.8	7.9	8.0	7.6	7.8	7.6	8.0	10.5	10.5	10.6
50-54	6.5	6.6	6.4	6.0	6.0	5.9	7.0	7.1	6.8	6.9	6.6	7.2	9.0	8.9	9.1
55-59	5.6	5.7	5.6	5.2	5.2	5.1	6.2	6.3	6.0	6.0	5.9	6.2	7.6	7.5	7.7
60-64	4.8	4.8	4.9	4.4	4.4	4.5	5.3	5.4	5.3	5.3	5.1	5.5	6.5	6.4	6.5
65-69	4.1	4.0	4.1	3.8	3.7	3.8	4.6	4.6	4.6	4.5	4.2	4.8	5.3	5.2	5.5
70-74	3.4	3.4	3.5	3.2	3.2	3.2	3.9	3.8	3.9	4.0	3.7	4.1	4.6	4.4	4.7
75-79	2.9	2.8	2.9	2.7	2.7	2.7	3.2	3.1	3.3	3.2	3.0	3.4	3.7	3.6	3.8
80-84	2.4	2.3	2.5	2.3	2.2	2.3	2.7	2.6	2.7	2.7	2.4	2.9	3.0	2.9	3.1
85+	1.9	1.9	2.0	1.9	1.8	1.9	2.2	2.1	2.2	2.2	1.8	2.3	2.3	2.2	2.4
Overall	5.9	6.0	5.9	5.6	5.6	5.5	6.3	6.5	6.1	6.4	6.2	6.6	8.4	8.4	8.4

Transplant 2006	All races			White			African American			Native American			Asian		
	All	Male	Female	All	Male	Female	All	Male	Female	All	Male	Female	All	Male	Female
0-14	55.0	54.7	55.6	55.3	55.1	55.8	52.2	51.9	52.8	51.3	49.7	54.1	63.0	61.8	64.9
15-19	42.4	42.0	43.0	42.5	42.3	43.1	40.3	39.9	40.9	39.4	37.8	42.1	49.6	48.3	51.7
20-24	38.4	38.0	39.1	38.5	38.2	39.1	36.6	36.1	37.3	35.7	34.1	38.4	45.4	44.1	47.4
25-29	35.1	34.7	35.9	35.2	34.8	35.8	33.8	33.3	34.6	33.1	31.4	35.8	41.6	40.3	43.7
30-34	31.3	30.8	32.2	31.3	30.9	32.1	30.3	29.8	31.2	29.5	27.9	32.3	37.4	36.0	39.5
35-39	27.8	27.2	28.8	27.7	27.2	28.6	27.1	26.4	28.1	26.2	24.8	29.0	33.3	32.0	35.5
40-44	24.3	23.7	25.4	24.3	23.7	25.2	23.7	23.0	24.8	23.0	21.5	25.6	29.3	27.9	31.5
45-49	21.1	20.5	22.3	21.1	20.5	22.1	20.5	19.8	21.6	19.8	18.4	22.5	25.4	24.1	27.6
50-54	18.1	17.4	19.3	18.1	17.5	19.2	17.6	16.8	18.7	17.0	15.7	19.6	21.8	20.5	23.9
55-59	15.5	14.8	16.7	15.5	14.8	16.6	14.9	14.2	16.0	14.6	13.3	17.0	18.5	17.3	20.6
60-64	13.1	12.4	14.2	13.0	12.4	14.1	12.7	12.0	13.7	12.3	11.2	14.6	15.5	14.4	17.5
65-69	10.8	10.2	11.8	10.8	10.2	11.8	10.6	9.9	11.6	10.4	9.3	12.5	12.9	11.9	14.8
70-74	8.9	8.4	9.8	8.9	8.4	9.7	8.9	8.2	9.8	8.6	7.7	10.7	10.6	9.7	12.4
75-79	7.5	7.0	8.3	7.4	7.0	8.2	7.7	7.1	8.5	7.1	6.5	9.4	9.0	8.2	10.6
Overall	16.4	15.8	17.4	16.4	15.8	17.3	16.0	15.3	17.0	15.5	14.3	17.9	19.6	18.5	21.6

Table 7. One-Year Survival Probabilities: Incident ESRD Patients from Day 91 to 1 Year + 90 Days, by Age, Sex, Race, Ethnicity, and Primary Diagnosis¹⁶⁹

UNADJUSTED	1980	1985	1990	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
0-4	93.5	88.9	85.0	89.3	92.0	89.3	88.5	87.5	84.1	88.8	90.3	90.9	89.3	93.9	86.0
5-9	93.5	95.0	97.1	97.2	95.7	96.1	100.0	96.7	96.1	98.0	94.4	97.2	98.6	98.6	96.7
10-14	97.7	97.6	96.8	97.5	97.0	97.8	97.8	98.0	97.7	98.0	96.7	97.9	97.5	97.2	97.9
15-19	96.5	95.8	97.6	97.3	96.7	98.3	96.6	98.0	97.9	97.9	97.7	98.3	97.3	97.5	97.8
20-29	91.8	92.3	92.6	92.7	94.3	95.4	95.1	95.5	93.7	95.0	94.1	93.8	94.1	94.4	94.9
30-39	89.5	89.4	90.1	88.7	90.4	91.0	91.3	91.0	91.0	91.5	91.6	91.8	92.2	92.2	92.9
40-49	88.0	88.0	89.0	89.2	89.5	90.1	89.1	89.6	89.6	89.1	88.9	89.0	89.5	89.6	90.1
50-59	83.7	82.2	84.2	85.9	85.2	85.8	85.4	86.0	85.5	85.9	85.9	85.6	86.1	86.1	87.0
60-64	78.6	76.4	78.3	80.1	81.4	81.7	79.9	81.1	80.9	81.8	81.1	82.1	82.1	83.0	83.3
65-69	72.7	71.2	75.6	76.9	77.4	76.7	76.3	76.3	77.0	77.2	77.0	78.0	77.5	78.9	79.6
70-79	67.1	66.9	68.5	70.5	70.3	69.5	69.7	69.3	69.5	70.0	70.1	70.1	70.6	71.1	72.1
80-84	59.5	60.1	61.6	62.6	61.8	61.3	60.0	61.5	60.5	61.0	62.1	62.3	63.5	63.0	63.3
85+	52.8	51.1	54.0	55.8	53.6	54.1	52.9	52.6	53.1	53.7	53.6	54.3	55.3	55.4	56.1
Male	81.4	78.8	79.5	79.8	79.9	79.6	79.1	79.3	79.0	79.3	79.1	79.2	79.4	79.7	80.6
Female	82.1	79.3	79.5	79.9	79.3	78.8	78.0	78.1	77.7	78.0	77.7	78.0	78.7	79.0	79.6
White	80.3	77.1	77.1	77.7	77.2	76.6	76.2	76.5	76.2	76.2	76.2	76.5	76.9	77.3	78.2
African American	85.2	83.1	83.8	83.2	83.9	83.8	82.7	82.6	82.0	82.8	82.1	81.9	82.4	82.8	83.4
Other race	82.2	83.8	86.5	84.5	83.1	84.3	82.9	83.0	84.0	85.2	84.2	85.1	85.5	85.8	86.6
†Hispanic					83.8	83.1	83.3	82.9	83.7	84.0	83.2	83.8	84.6	84.8	85.9
†Non-Hispanic					79.1	78.7	78.0	78.1	77.6	77.9	77.7	77.9	78.2	78.6	79.2
Diabetes	76.1	74.3	77.1	78.9	78.7	78.2	77.4	78.1	78.1	78.4	78.3	78.7	79.2	79.7	80.6
Hypertension	84.5	79.0	78.1	79.0	78.4	77.4	76.9	76.9	76.6	76.8	76.9	76.9	77.1	76.9	78.0
Glomerulonephritis	91.5	88.1	87.4	87.8	88.3	88.3	88.5	87.6	88.3	88.4	88.2	88.6	89.1	89.8	89.8
Other cause	79.4	78.4	80.2	78.0	78.1	78.7	78.1	77.9	76.7	77.2	76.2	76.6	77.2	77.9	78.6
All	81.7	79.1	79.5	79.8	79.6	79.2	78.6	78.7	78.4	78.7	78.5	78.7	79.1	79.4	80.2
ADJUSTED															
0-19	93.4	91.6	92.9	93.7	93.3	94.3	93.6	94.1	92.5	94.1	93.3	95.0	93.6	95.0	93.3
20-44	87.9	88.9	89.7	89.1	90.5	91.1	90.7	90.9	90.7	90.9	90.8	90.9	91.4	91.6	92.3
45-64	80.2	80.0	82.9	85.0	85.1	85.7	84.8	85.6	85.3	85.7	85.4	85.4	85.8	86.1	86.7
65-74	69.7	69.0	73.2	75.2	75.4	74.7	74.7	74.7	75.0	75.4	75.2	75.8	76.1	76.9	78.1
75+	61.0	62.0	63.2	64.4	63.8	63.4	62.8	63.0	63.1	63.6	63.9	64.0	64.6	64.7	65.2
Male	72.3	72.1	75.4	77.1	77.8	78.1	77.8	78.2	78.2	78.6	78.5	78.8	79.0	79.3	80.2
Female	74.0	74.4	77.1	78.8	78.7	78.6	77.9	78.1	78.1	78.6	78.4	78.7	79.2	79.5	80.1
White	70.2	70.7	74.2	76.8	76.9	76.8	76.6	77.2	77.2	77.4	77.6	77.9	78.4	78.6	79.4
African American	79.6	77.8	79.7	79.8	80.9	81.0	80.0	79.8	79.4	80.4	79.7	79.4	79.9	80.3	81.0
Other race	72.2	77.7	83.2	82.9	81.9	83.3	81.6	82.2	83.1	84.2	83.3	84.5	84.7	85.2	85.9
Diabetes	68.1	68.4	73.9	77.1	77.3	77.2	76.5	77.3	77.6	78.1	78.0	78.4	79.0	79.4	80.3
Hypertension	80.5	78.2	79.1	80.5	80.3	79.8	79.6	79.6	79.5	79.8	80.1	79.9	80.1	80.0	80.8
Glomerulonephritis	83.6	81.8	82.0	83.3	84.3	84.4	84.6	83.9	84.6	84.3	84.5	84.8	85.1	86.0	86.1
Other cause	73.9	73.6	75.8	74.2	74.5	75.7	75.0	74.9	73.8	74.5	73.5	74.0	74.6	75.5	76.3
All	73.1	73.2	76.2	78.0	78.2	78.3	77.8	78.2	78.1	78.6	78.5	78.7	79.1	79.4	80.2

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Figure 8. Adjusted All-Cause and Cause-Specific Mortality in the First Year of Hemodialysis¹⁶⁹

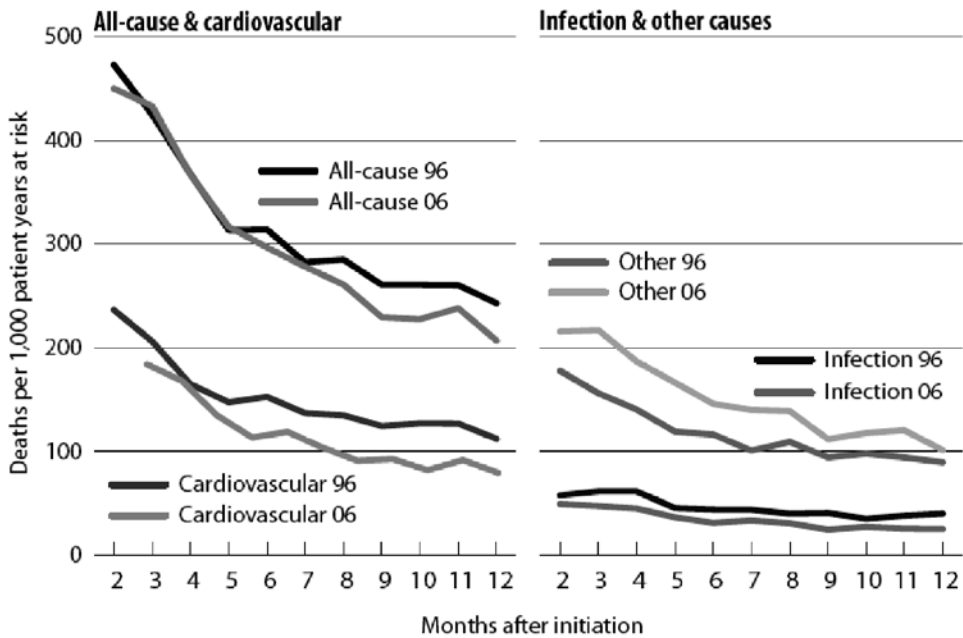


Figure 9. Adjusted All-Cause Mortality in the First Year of Hemodialysis, by Month and Age¹⁶⁹

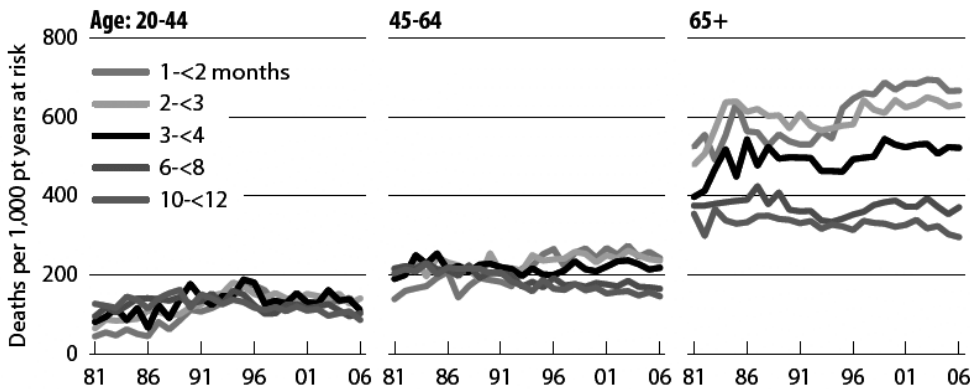
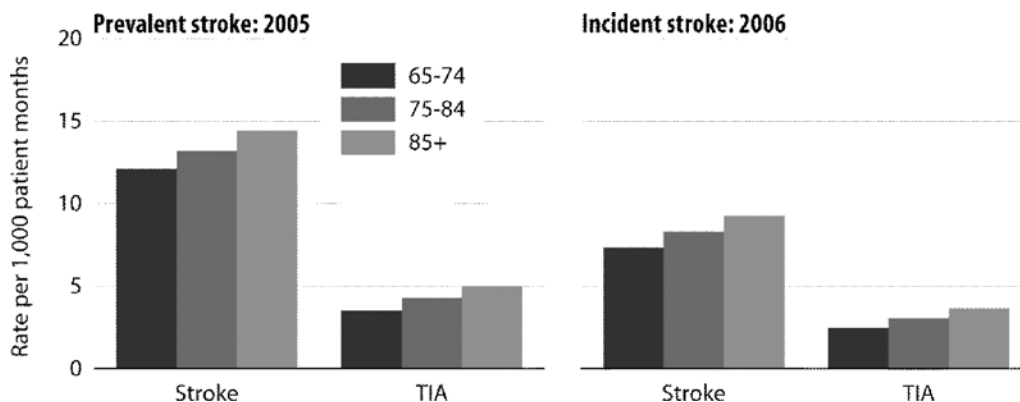
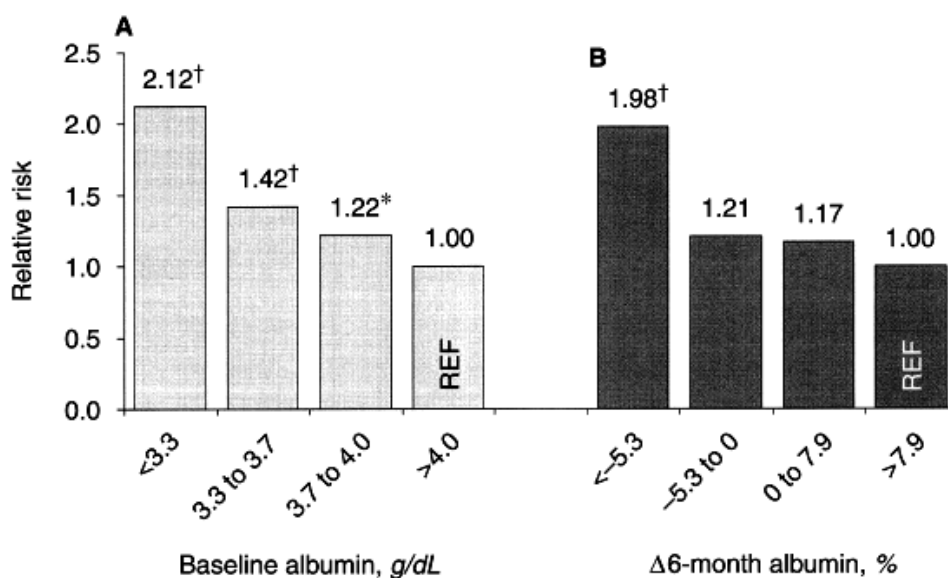


Figure 10. Rate of Stroke and TIA in Prevalent Hemodialysis Patients, by Age, 2005-2006¹⁶⁹Figure 11. Relative Risk of Mortality Based on Baseline Serum Albumin and Change at 6 Months¹⁸²

Relative risk of mortality and quartiles of serum albumin, adjusted for baseline albumin (A), Δalbumin (B), demographics, and 15 comorbid conditions. *P < 0.05 and †P < 0.001 vs. 4th quartile. Reprinted with permission.

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Table 8. Associations Between Baseline Nutritional and Inflammatory Markers and the Risk of Death Over the 12-Month Follow-Up Period, as Reflected by Mortality Hazard Ratios (Hrs) and 95% Confidence Intervals (CIs) in 378 Maintenance Hemodialysis Patients¹⁸⁹

Mortality	Status of the fourth quarter (lowest or highest)	HR across all four quartiles (first to fourth)	HR for the fourth vs the first quartile	HR for the fourth quartile vs the rest	Kaplan–Meier <i>P</i> for four quartiles
Albumin (g/dl) ^a	Lowest (<3.63 g/dl)	1.84 (1.27–2.68) <i>P</i> = 0.001	9.80 (1.93–49.70) <i>P</i> = 0.006	2.24 (1.13–4.44) <i>P</i> = 0.02	0.0002
Pre-albumin (mg/dl)	Lowest (<21 mg/dl)	1.17 (0.84–1.64) <i>P</i> = 0.4	2.18 (0.63–7.50) <i>P</i> = 0.2	1.79 (0.90–3.55) <i>P</i> = 0.09	0.04
Cholesterol (mg/dl)	Lowest (<115.5 mg/dl)	1.14 (0.84–1.56) <i>P</i> = 0.4	1.80 (0.65–4.96) <i>P</i> = 0.3	1.62 (0.78–3.37) <i>P</i> = 0.2	0.6
TIBC (mg/dl) ^a	Lowest (<174 mg/dl)	1.28 (0.94–1.74) <i>P</i> = 0.12	1.46 (0.56–3.85) <i>P</i> = 0.4	1.80 (0.93–3.51) <i>P</i> = 0.08	0.2
CRP (mg/l)	Highest (>8.4 mg/l)	1.81 (1.27–2.59) <i>P</i> = 0.001	6.31 (1.76–22.60) <i>P</i> = 0.005	3.27 (1.67–6.41) <i>P</i> = 0.001	0.005
IL-6 (pg/ml)	Highest (>17.9 pg/ml)	2.23 (1.52–3.26) <i>P</i> < 0.001	27.44 (3.52–213.74) <i>P</i> = 0.002	3.97 (2.02–7.79) <i>P</i> < 0.001	0.00003
TNF- α (pg/ml)	Highest (>9.26 pg/ml)	1.19 (0.88–1.62) <i>P</i> = 0.3	1.94 (0.73–5.13) <i>P</i> = 0.2	1.81 (0.89–3.70) <i>P</i> = 0.10	0.8
MIS (0–30)	Highest (>8)	1.64 (1.17–2.31) <i>P</i> = 0.005	4.91 (1.81–13.30) <i>P</i> = 0.002	3.83 (1.82–8.04) <i>P</i> < 0.001	0.0002

Multivariate HR values are based on Cox proportional hazard regression models and adjusted for age, gender, race (Blacks vs others), ethnicity (Hispanics vs others), insurance status (Medicaid vs others) diabetes mellitus, Charlson co-morbidity score, dialysis vintage, dialysis dose (single-pool Kt/V), BMI and history of cardiovascular disease. All models are based on Poisson regression analyses.

^aSerum albumin and TIBC concentrations are based on 3-month averaged values for each patient.

TIBC = total iron binding capacity.

Table 9. Mortality and Hospitalization Predictability of Markers of MICS Using Unifying Multivariate Models (Cox and Poisson) in 378 Maintenance Hemodialysis Patients¹⁸⁹

	Mortality (Cox)		First hospital admission (Cox)		Hospitalization frequency (Poisson)	
	z-Statistics	P-value	Z-Statistics	P-value	Z-Statistics	P-value
Markers of MICS						
MIS	3.13	0.002	2.54	0.01	4.23	<0.001
Serum CRP	3.3	0.001	3.43	0.001	8.02	<0.001
IL-6	−0.59	0.6	0.64	0.5	−0.18	0.9
TNF- α	0.37	0.7	−0.99	0.3	−1.55	0.12
Albumin	−1.07	0.3	−1.18	0.2	−5.14	<0.001
Pre-albumin	0.85	0.4	−0.46	0.6	1.36	0.2
Creatinine	0.65	0.5	0.39	0.7	0.77	0.4
Total iron binding capacity	0.86	0.4	0.57	0.6	1.03	0.3
Cholesterol	−0.27	0.8	0.25	0.8	−2.41	0.02
nPNA (nPCR)	−0.92	0.4	0.9	0.4	4.26	<0.001
Other covariates						
Charlson co-morbidity index	3.75	<0.001	4.94	<0.001	7.82	<0.001
Age	1.75	0.08	1.72	0.09	0.95	0.3
Gender	0.72	0.5	−1.13	0.3	−4.1	<0.001
Race (African Americans vs others)	1.72	0.09	−0.38	0.7	−2.58	0.01
Ethnicity (Hispanics vs others)	1.37	0.2	0.53	0.6	−1.13	0.3
Diabetes mellitus	−1.04	0.3	−3.38	<0.001	−4.59	<0.001
Dialysis vintage	−0.31	0.8	−0.06	0.9	−0.57	0.6
Insurance status (Medicaid)	0.72	0.5	−1.56	0.12	−3.68	<0.001
Body mass index	0.77	0.4	1.85	0.06	2.92	0.003
Kt/V (single pool)	0.66	0.5	−1.03	0.3	−1.46	0.2
History of cardiovascular disease	−1.79	0.07	−2.85	0.004	−0.94	0.3

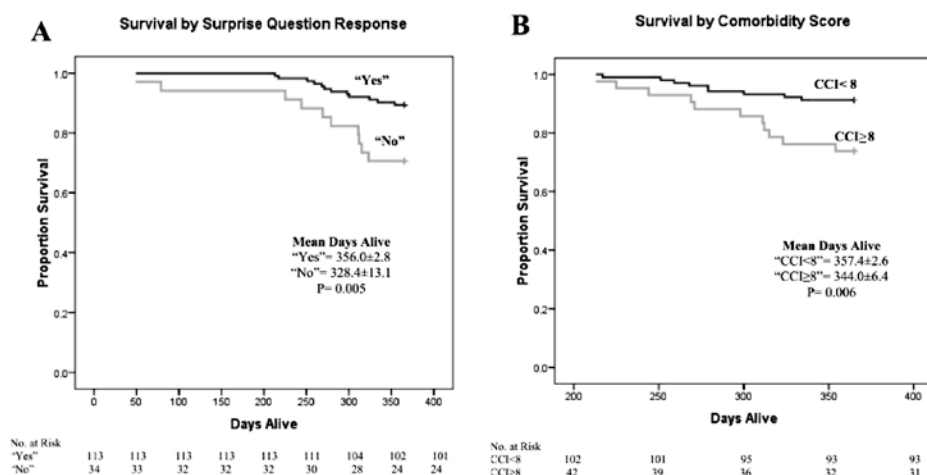
nPNA: normalized protein nitrogen appearance; nPCR: normalized protein catabolic rate.

Table 10. Comparative Percent of Increased or Decreased Risk for Death for Eight Factors Studied in \geq Two Studies with Multivariate Analyses

Risk Factor	Age	Race	Gender	Serum Albumin	Under-nourished/ Cachexia	Functional Status	Diabetes	CAD/ CHF/ Heart Disease
References	124,131,132,135,145,166,174,248	124,132,156,166,174,248	131,132,135,156,166,174,248	41,124,131,132,145,166,189,215	41,131,135	41,124,152	131,135,166,174,248	124,131,135,156
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	25-130 % increase	52-158% increase for moderate impairment and 100-383% increase for severe impairment	10-74% increase	11-41% increase

For references for the Appendix, please see the reference list at the end of **Section 4: Guideline Recommendations and their Rationales for the Treatment of Adult Patients**.

Figure 12. Survival of Dialysis Patients by “Surprise” Question Response and Comorbidity Score²⁵¹



Survival curves for “surprise” question response and comorbidity score in days alive at 12 months. Data are means \pm standard error of means. (A) Curves of “yes” and “no” response groups to the “surprise” question, “Would I be surprised if this patient died in the next year?” (B) Curves of the lower (<8) and higher (\geq 8) Charlson Comorbidity Index (CCI) score groups.

Section 11

Table 11. Adjusted Odds Ratios for 6-Month Mortality and Points Assigned to Each Risk Factor in the Training Sample⁴¹

Risk factors	Adjusted OR ^a (95% CI)	β-coefficient	Points ^b
Body mass index (kg/m ²)			
≥18.5	1		
<18.5	1.3 (1.1–1.6)	0.283	2
Diabetes			
Absence	1		
Presence	1.2 (1.1–1.3)	0.180	1
Congestive heart failure stage III or IV			
Absence	1		
Presence	1.3 (1.2–1.5)	0.289	2
Peripheral vascular disease stage III or IV			
Absence	1		
Presence	1.3 (1.1–1.5)	0.269	2
Dysrhythmia			
Absence	1		
Presence	1.2 (1.1–1.3)	0.170	1
Active malignancy			
Absence	1		
Presence	1.3 (1.1–1.5)	0.250	1
Severe behavioural disorder			
Absence	1		
Presence	1.5 (1.2–1.8)	0.391	2
Totally dependent for transfers			
Absence	1		
Presence	1.7 (1.4–2.0)	0.519	3
Initial context			
Planned	1		
Unplanned	1.5 (1.3–1.7)	0.395	2

^aMean odds ratio^a for the five imputed datasets (multiple imputation for missing data). OR (95% CI): odds ratio (95% confidence interval).

^bPoints were assigned to each risk factor using β-coefficients (parameter estimates) from the multivariate logistic regression model. The β-coefficient for each risk factor was divided by the lowest β-coefficient (dysrhythmia) and rounded to the nearest integer.

Table 12. Six-Month Mortality Rates by Risk Score in the Training and the Validation Samples⁴¹

Risk score	Training sample			Validation sample		
	Number of deaths ^a	Number at risk ^a	Percentage	Number of deaths ^a	Number at risk ^a	Percentage
0 Point	41	511	8	26	330	8
1 Point	39	508	8	33	339	10
2 Points	64	453	14	49	294	17
3–4 Points	160	628	26	82	399	21
5–6 Points	93	266	35	59	178	33
7–8 Points	50	98	51	32	64	50
≥9 Points	22	36	62	25	35	70
All	470	2500	19	306	1640	19

^aMean^a number of patients from the five imputed datasets (multiple imputation for missing data).

Table 13. Prognostic Model for Mortality at 1 Year Following Initiation of Hemodialysis Treatment^{†152}

	β	SE	OR	95% CI of OR
Sex	-0.095	0.115	0.92	0.73–1.14
Age_10 ^a	0.310	0.055	—	—
Primary renal disease	—	—	—	—
Standard	0	—	1	—
Diabetes	0.025	0.132	1.03	0.79–1.33
Systemic	0.971	0.210	2.64	1.75–3.99
Functional autonomy degree	—	—	—	—
Normal	0	—	1	—
Limited	0.632	0.131	1.88	1.45–2.43
Special care	1.343	0.152	3.83	2.84–5.16
Chronic obstructive pulmonary disease	0.250	0.129	1.28	0.99–1.65
Malignant processes ^a	3.535	0.886	—	—
Chronic liver disease	0.351	0.201	1.42	0.96–2.11
First vascular access by CV	—	—	—	—
AV fistula and no CV	0	—	1	—
AV fistula and CV	1.177	0.210	3.24	2.15–4.90
Catheter and no CV	1.345	0.204	3.84	2.57–5.72
Catheter and CV	1.728	0.138	5.63	4.30–7.37
First vascular access by malnutrition	—	—	—	—
AV Fistula and no malnutrition	0	—	1	—
AV Fistula and malnutrition	1.208	0.276	3.35	1.95–5.75
Catheter and no malnutrition	1.345	0.204	3.84	2.57–5.72
Catheter and malnutrition	1.697	0.181	5.46	3.83–7.78
Age_10 by Malignant processes ^a	-0.417	0.125	—	—
Constant	-5.799	0.401	0.003	—

^aThe OR and 95% confidence interval of the factors that intervene in an interaction cannot be calculated and analysed separately. Thus, interactions with dichotomous variables are expressed together. For non-dichotomous variables, only the β and the SE are presented in the table and the analysis of interactions is shown in Figure 2.

SE = standard error.



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