Renal Physicians Association Clinical Practice Guideline #3

Appropriate Patient Preparation for Renal Replacement Therapy

Executive Summary

October **2002**

Renal Physicians Association

Duke Evidence-based Practice Center
Center for Clinical Health Policy Research

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ABBREVIATIONS USED

%	Percent
ACE	Angiotensin converting enzyme
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
ARB	Angiotensin II Receptor Blocker
ACVD	Atherosclerotic cardiovascular disease
ASN	American Society of Nephrology
ATP-III	National Cholesterol Education Task Force Adult Treatment Panel - III
AV	Arteriovenous
BCG	Bromo-Cresol-Green
BP	Blood pressure
BUN	Blood urea nitrogen
Ca	Calcium
CHD	Coronary heart disease
C-HPTH	Carboxyl-terminal parathyroid hormone
CKD	Chronic kidney disease
CME	Continuing medical education
CMS	Centers for Medicare and Medicaid Services
CPG	Clinical practice guideline
CPM	Clinical performance measure
CPT	Current procedure terminology
CrCl	Creatinine clearance
CQI	Continuous quality improvement
CVD	Cardiovascular disease
dL	Deciliter
EDTA	Ethylenediaminetetraacetic acid
EPC	Evidence-based Practice Center
ESRD	End-stage renal disease
g	Gram
GAP	Guidelines Applied to Practice
GFR	Glomerular filtration rate
h	Hour
Hb	Hemoglobin
Hct	Hematocrit
HDL	High-density lipoprotein
HPTH	Hyperparathyroidism
ICD-9	International Classification of Diseases, Ninth Revision
iPTH	Immunoreactive parathyroid hormone
JNC VI	Sixth Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure
K/DOQI	Kidney Disease Outcomes Quality Initiative
L	Liter
LDL	Low-density lipoprotein
LPD	Low-protein diet
LVH	Left ventricular hypertrophy
m	Meter
mcg	Microgram
MDRD	Modification of Diet in Renal Disease
mEq	Milliequivalents
mg	Milligram
MedPAC	Medicare Payment Advisory Commission
min	Minute
mL	Milliliter
mm Hg	Millimeters of mercury
mmol	Millimoles
NHANES	National Health and Nutrition Examination Survey
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NKF	National Kidney Foundation
OCSQ	Office of Clinical Standards and Quality
PAERI	Prevalence of Anemia in Patients with Early Renal Insufficiency
PD	Peritoneal dialysis
PEAC	Practice Expense Advisory Committee
pg	Picogram
PTH	Parathyroid hormone
QALY	Quality Adjusted Life Year
RBC	Red blood cell
RCT	Randomized controlled trial
RPA	Renal Physicians Association
RRT	Renal replacement therapy
RUC	Relative Value Update Committee
SCr	Serum creatinine
SGA	Subjective Global Assessment
TIBC	Total iron binding capacity
TLC	Therapeutic lifestyle changes
TSAT	Transferrin saturation
UNOS	United Network for Organ Sharing
VLDL	Very low-density lipoprotein
WHO	World Health Organization

ABOUT RPA

RPA . . . the Advocate for Excellence in Nephrology Practice

Organized in 1973, the Renal Physicians Association (RPA) is a national medical specialty association with a membership comprised of healthcare providers in the subspecialty area of internal medicine known as nephrology. RPA represents and serves nephrologists, practice managers, advanced practice nurses and physician assistants in their pursuit of quality renal health care. RPA's members are engaged in diverse activities including the practice of medicine, teaching, research and all are committed to improving the care of patients with renal disease and related disorders.

RPA's Core Values:

1. Commitment to high quality, cost effective, ethical renal care
2. Promotion of the interests and professional status of the discipline of nephrology
3. Promotion of the leadership role of the nephrology profession in defining policy which influences renal care
4. Recognition of and respect for the multidisciplinary nature of renal care

RPA represents nephrologists and is recognized by national leaders as the organization that sets the standards for delivering value and accountability for quality renal patient care. The Association's long-standing advocacy program has fostered a close working relationship with federal agencies and other organizations involved in health care policy development and implementation. RPA regularly meets with and advises key government officials as well as decision makers in private sector organizations to stay apprised of legislative and regulatory issues and options in order to act on behalf of our members to protect their ability to practice medicine with minimal regulatory burdens and receive fair compensation.

RPA includes advanced practice nurses, physician assistants and practice managers who, as part of the renal care team, conduct important functions within the nephrology practice. Volunteers representing each of these group's special interests communicate with RPA leaders and staff about how to best address issues that arise.

RPA addresses Medicare, Medicaid and private sector health care financing issues. RPA leaders meet with representatives of the Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing Administration) and the carrier medical directors to address concerns about discrepancies in local carrier policies, documentation requirements, and trends in payment denials.

RPA monitors the Medicare Payment Advisory Commission (MedPAC) as well as Congressional health care financing activities and serves as a resource on renal-related issues. As an active participant on the American Medical Association (AMA) Relative Value Update Committee (RUC), Practice Expense Advisory Committee (PEAC) and Current Procedure Terminology (CPT) Editorial Panel, RPA works to assure that work values for nephrology services are appropriately determined and that CPT codes accurately reflect nephrology clinical practice.

RPA tracks problems related to reimbursement for nephrology services and payment denials experienced by members to determine trends and identify areas where the Association needs to take action.

RPA is committed to ensuring quality care for patients

with renal disease. The Association works closely with CMS' Office of Clinical Standards and Quality (OCSQ), the Forum of ESRD Networks and the Agency for Health Care Research and Quality (AHRQ) to develop policies and procedures that result in an effective quality assessment and improvement program.

RPA develops clinical practice guidelines and performance measures to promote physician accountability. RPA also works to develop documentation tools (e.g. Medical Director's checklist, ICD-9 coding cards, Evaluation and Management documentation charts) to help nephrologists appropriately track the services delivered to patients. The Association coordinates these efforts with other organized medicine groups as well as with AHRQ and CMS.

Patient safety is an important part of the RPA physician-patient equation. Through RPA's efforts in quality and accountability, patient safety has been highlighted an important program initiative.

RPA promotes funding for biomedical research on kidney disease by the National Institutes of Health, specifically the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). RPA supports medical treatment effectiveness and outcomes assessment research relating to kidney disease and advocates funding for these initiatives through AHRQ. RPA has been instrumental in garnering support for the creation, implementation and maintenance of the U.S. Renal Data System.

For more information about RPA, a list of RPA's publications and to obtain membership information visit www.renalmd.org or call the RPA office at 301-468-3515.

Acknowledgment

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ENDORSEMENTS

The following organizations have endorsed the guideline recommendations: Renal Physicians Association, American Nephrology Nurses Asociation, American Association of Kidney Patients, and the Forum of End-Stage Renal Disease Networks.

EXECUTIVE SUMMARY

This document is a summary of the Renal Physicians Association (RPA) Clinical Practice Guideline (CPG) on Appropriate Patient Preparation for Renal Replacement Therapy (RRT). This is RPA's third CPG.

To develop this document, the RPA convened a "Working Group" consisting of clinical experts and stakeholders. Participants were nominated by national organizations representing practitioners, patients, administrators, insurers, and Federal research funders. The Working Group was supported by a team of methodologists and nephrologists from the Duke Center for Clinical Health Policy Research. The foundation of the CPG and CPMs is a comprehensive review of the literature, "Evidence Report: Appropriate Preparation for Renal Replacement Therapy,"[1] as well as expert consensus on the most effective interventions. The evidence report may be viewed and downloaded from the RPA web site, www.renalmd.org.

The patient population at the center of the RPA's CPG is the patient subset referred to as "advanced CKD," a shorthand term for the more specific designation of those patients whose clinical condition is categorized as advanced chronic kidney disease (CKD) stages 4 and 5, but not on RRT[2]. This corresponds to a glomerular filtration rate (GFR) of less than or equal to 30 mL/min/1.73 m^2, when kidney function is at a high risk of progression.[3]

Natural history data indicate that when the vast majority of patients reach stage 4 they will likely progress and require RRT. Prior to stage 4, the focus of diagnosis and treatment of CKD is on slowing progression and identifying and managing comorbidities. As the patient progresses to stages 4 and 5, advanced CKD, the focus shifts to managing complex metabolic disturbances and preparing the patient for RRT (dialysis or transplantation). Proactive preparation for RRT is recommended to facilitate the transition and reduce the burden of clinical risk factors known to be associated with worse outcomes in end-stage renal disease patients.

The recommendations contained in the CPG are intended to provide clinicians with practical guidance for the care of individuals with advanced CKD not yet requiring RRT. Since these patients have complex needs, the CPG is targeted to nephrologists and generalists with a special interest in advanced CKD patients. The objective of this document is to enhance, but not substitute for, the provider's ability to care for patients based on the best available scientific evidence. The CPMs that have been developed on the basis of the recommendations in the CPG are not intended for physician comparison, survey or population purposes, instead, they are meant to facilitate individual physician quality improvement.

The guideline is applicable to the population of adult patients (18 years of age and older) with advanced CKD not yet on RRT who are expected to progress and require RRT within 6 to 18 months. This CPG is not intended for use in children and adolescents.

The RPA has identified seven particularly important goals of care to be addressed by this CPG:

- Optimal management of anemia
- Prevention of hyperparathyroidism, hyperphosphatemia, hypocalcemia, and metabolic bone disease
- Control of blood pressure
- Maintenance of adequate nutrition
- Managing qualitative and quantitative lipid disorders
- Timing of the initiation of RRT and vascular access
- Counseling for choices of RRT, patient rehabilitation, and psychosocial and economic preparation.

A summary of the guidelines is presented on the following pages. To obtain the complete guideline publication, please contact the RPA office.

ANEMIA GUIDELINES

Monitoring anemia regularly

If a patient has GFR ≤ 30 mL/min/1.73 m^2, then s/he should have his/her hemoglobin checked at least every three months. (Grade C)

Workup of anemia

If a patient has GFR ≤ 30 mL/min/1.73 m^2 and a hemoglobin < 12 g/dL if a woman, and < 13 g/dL if a man, then s/he should undergo a complete work-up for anemia including iron studies. (Grade B)

Treating iron deficiency

If a patient has GFR ≤ 30 mL/min/1.73 m^2, and if iron deficiency is identified, then s/he should be treated. (Grade C)

Treatment with erythropoietin or erythropoietin analogue

If a patient has GFR ≤ 30 mL/min/1.73 m^2, and remains anemic despite appropriate evaluation and iron therapy, then s/he should be treated with erythropoietin or analogue. (Grade B)

Monitoring blood pressure for those receiving erythropoietin or erythropoietin analogue

If a patient has GFR ≤ 30 mL/min/1.73 m^2, and is receiving erythropoietin or analogue, then s/he should have his/her blood pressure checked with each dose. (Grade C)

HYPERTENSION GUIDELINES

Monitoring blood pressure

If a patient has GFR ≤ 30 mL/min/1.73 m^2, then his/her blood pressure should be checked with every clinic visit (Grade A), which should be at least every three months. (Grade C)

Responding to elevated blood pressure

If a patient has GFR ≤ 30 mL/min/1.73 m^2, and if blood pressure is determined to be elevated (systolic > 130 mmHg OR diastolic > 80 mmHg), then s/he should receive encouragement and instruction to initiate therapeutic lifestyle changes (Grade C) and s/he should receive intensified antihypertensive therapy. (Grade B)

Treating with ACE inhibitors and ARBs

If a patient has GFR ≤ 30mL/min/1.73 m^2 and hypertension, then s/he should receive an ACE inhibitor or an ARB as a first-line agent. (Grade C)

BONE DISEASE GUIDELINES

Monitoring for metabolic acidosis

If a patient has GFR ≤ 30 mL/min/1.73 m^2 then s/he should be monitored for acidosis (serum bicarbonate concentration) at least every three months. (Grade C)

Correcting metabolic acidosis

If a patient has a GFR ≤ 30 mL/min/1.73 m^2 then his/her chronic metabolic acidosis should be corrected to a serum bicarbonate ≥ 22 mmol/L. (Grade C)

Monitoring calcium, phosphorus, and iPTH

If a patient has a GFR ≤ 30 mL/min/1.73 m^2, then s/he should have his/her serum calcium and phosphorus measured at least every three months, and iPTH levels measured at least once, (Grade B) AND if calcium and/or phosphorus levels are abnormal, iPTH should be monitored at least every three months. (Grade C)

Treating HPTH and/or hyperphosphatemia

If a patient has GFR ≤ 30 mL/min/1.73 m^2, and if iPTH > 100 pg/mL (or > 1.5 times the upper limit of normal for each assay used), OR serum phosphorus > 4.5 mg/dL then s/he should be placed on a low phosphorus diet (< 800-1000 mg/day) for one month, and phosphorus levels should be re-checked, regardless of phosphorus or iPTH levels. (Note: a low phosphorus diet implies a low protein diet.) If serum phosphorus is still > 4.5 mg/dL, then phosphate binder should be started (Grade B) AND iPTH levels should be monitored every three months following the initiation of therapy, whether phosphorus is controlled or not. (Grade B)

Managing decreased vitamin D levels (vitamin D insufficiency)

If a patient has GFR ≤ 30 mL/min/1.73 m^2 and if iPTH > 100 pg/mL (or 1.5 times the upper limit of normal for each assay used), then measure 25(OH) vitamin D; AND if 25(OH) vitamin D is decreased (serum levels < 30 ng/mL) then s/he should receive vitamin D_2 50,000 units orally every month for 6 months. (Grade C)

Managing hypocalcemia

If a patient has GFR ≤ 30 mL/min/1.73 m^2 and corrected serum calcium is < 8.5 mg/dL (using a normal reference range of 8.5-10.5 mg/dL) after phosphorus issues are addressed, then s/he should receive elemental calcium 1g/day between meals or at bedtime. (Grade C)

Treating refractory HPTH

If a patient has GFR ≤ 30 mL/min/1.73 m^2 and iPTH remains > 100 pg/mL (or > 1.5 times the upper limit of normal for each assay used) after 3 months of previously recommended interventions, then s/he should receive oral vitamin D therapy with 0.25 mcg/day of calcitriol[4,5] (Grade C) or alfacalcidol 0.25 mcg/day, to a maximum of 0.5 mcg/day.[6]

NUTRITION GUIDELINES

Monitoring nutritional status regularly

If a patient has GFR ≤ 30 mL/min/1.73 m^2, then his/her nutritional status should be monitored by measuring body weight and serum albumin every three months. (Grade B)

Managing malnutrition

If a patient has GFR ≤ 30 mL/min/1.73 m^2, and if body weight decreases unintentionally by more than 5% or serum albumin decreases by more than 0.3 g/dL or is < 4.0 g/dL (for Bromo-Cresol-Green assay, or 3.7 for Bromo-Cresol-Purple assay), then s/he should be evaluated for causes. If other causes are ruled out and cause is therefore determined to be CKD, then s/he should receive diet assessment and counseling by qualified and experienced personnel. (Grade C)

Dietary recommendations should include:

1. Energy intake > 30-35 kcal/kg body weight/day.
2. Protein intake ≥ 0.6 g/kg body weight/day.

Initiating RRT based on nutritional status

If a patient has GFR < 20 mL/min/1.73 m^2, with evidence of malnutrition that does not respond to nutritional intervention in the absence of other causes of malnutrition, then s/he should begin RRT. (Grade C)

DYSLIPIDEMIA GUIDELINES

Monitoring for dyslipidemias

If a patient has GFR ≤ 30 mL/min/1.73 m^2, then she/he should be monitored for dyslipidemias; measurements should include triglycerides, LDL, HDL, and total cholesterol. (Grade B)

Evaluation for secondary causes

If a patient has GFR ≤ 30 mL/min/1.73 m^2, and has dyslipidemia, then s/he should be evaluated for secondary causes including comorbid conditions and certain medications. (Grade C)

Treatment of dyslipidemias

If a patient has GFR ≤ 30 mL/min/1.73 m^2, LDL should be targeted to < 100 mg/dL; non-HDL cholesterol should be targeted to < 130 mg/dL; and fasting triglycerides ≥ 500 mg/dL should be treated. (Grade C)

COUNSELING AND REHABILITATION GUIDELINES

Exercise

If a patient has GFR ≤ 30 mL/min/1.73 m^2 and does not engage in regular physical activity, then s/he should receive counseling and encouragement to increase physical activity. If a patient is unable to walk or unable to increase fully mobile physical activity, then s/he should be referred to physical therapy or cardiac rehabilitation. (Grade B)

Evaluation, education and encouragement

If a patient has GFR ≤ 30 mL/min/1.73 m^2, then s/he should receive structured education regarding preparation for RRT. (Grade C)

Employment counseling

If a patient has GFR ≤ 30 mL/min/1.73 m^2 then s/he should be encouraged to maintain employment and be referred to vocational counseling per his/her preference. (Grade C)

TIMING GUIDELINES

Early counseling about modality of RRT.

If a patient has GFR ≤ 30 mL/min/1.73 m^2, modality of RRT should be discussed with him/her. (Grade B)

GFR as a guide to RRT timing

No recommendation can be made for initiating RRT based solely on a specific level of GFR. (Grade B)

Early referral for transplant evaluation

If a patient has GFR ≤ 30 mL/min/1.73 m^2 and is willing to have a renal transplant, then s/he should receive a transplant evaluation (Grade B), unless s/he has an unacceptable level of surgical risk or does not satisfy the United Network for Organ Sharing (UNOS) Ethics Committee criteria for transplant candidacy.

Preservation of veins for vascular access

If a patient has GFR ≤ 30 mL/min/1.73 m^2 and it has been determined that s/he will receive hemodialysis, veins suitable for placement of vascular access should be preserved. (Grade C)

Timing for vascular access placement

If a patient has GFR ≤ 30 mL/min/1.73 m^2, and it has been determined that s/he will receive hemodialysis, then s/he should be referred for surgery to attempt construction of a primary AV fistula. (Grade C)

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