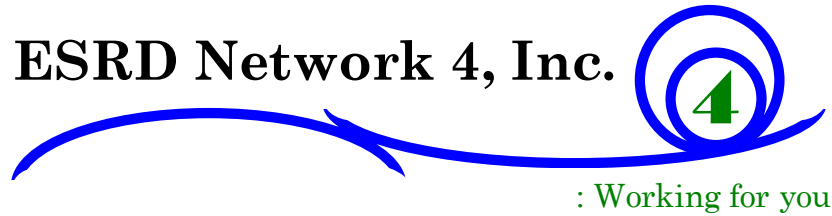


ESRD Network 4, Inc.



# **GUIDELINES FOR CARE OF ESRD PATIENTS**

Revised July 2004

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The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Centers for Medicare & Medicaid Services, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcome.

The guidelines presented in these chapters have been developed to ensure minimum levels of quality in dialysis facilities, dialysis centers and transplantation centers in Pennsylvania and Delaware.

These guidelines are not to be considered as licensure requirements. They are based on the current federal and state regulations for chronic renal dialysis and guidelines approved by renal professional organizations. Therefore, they provide a reference for areas of accountability.

## TABLE OF CONTENTS

<b>Chapter 1: Medical Director</b> .....	<b>4</b>
Qualifications of the Medical Director .....	5
<i>Federal Regulations</i> .....	5
<i>RPA/ASN</i> .....	5
Duties and Responsibilities of the Medical Director .....	5
<i>Medical</i> .....	5
<i>Technical</i> .....	6
<i>Administrative</i> .....	7
<b>Chapter 2: Physician</b> .....	<b>8</b>
Qualifications of the Physician .....	9
Responsibilities of the Physician .....	9
<b>Chapter 3: Transplant Surgeon</b> .....	<b>12</b>
Qualifications of the Transplant Surgeon .....	13
Responsibilities of the Transplant Surgeon .....	13
<b>Chapter 4: Transplant Physician</b> .....	<b>14</b>
Qualifications of the Transplant Physician.....	15
Responsibilities of the Transplant Physician .....	15
<b>Chapter 5: Nurse Responsible for Nursing Services</b> .....	<b>16</b>
Qualifications of the Nurse Responsible for Nursing Services .....	17
Responsibilities of the Nurse Responsible for Nursing Services .....	18
Guidelines for Staff RN/LPN.....	18
Guidelines for PCT .....	19
<b>Chapter 6: Social Work Services</b> .....	<b>21</b>
Qualifications of the Social Worker.....	22
<i>Standard: Social Services</i> .....	22
<i>Qualified Personnel: Social Worker</i> .....	22
Responsibilities of the Social Worker .....	22
Social Work Services References .....	24
<b>Chapter 7: Nutritional Services</b> .....	<b>25</b>
Qualifications of the Dietitian .....	26
<i>Standard: Dietetic Services</i> .....	26
<i>Qualified Personnel: Dietitian</i> .....	26
Responsibilities of the Dietitian.....	26
<i>Assessment</i> .....	26
<i>Care Plans</i> .....	27
<i>Monitoring and Education</i> .....	27
Role of the Renal Dietitian.....	28
<b>Chapter 8: Transplantation Documentation</b> .....	<b>29</b>
Evaluate and Classify Patients.....	30
Inform and Document Decision .....	30
Document Transplant Status .....	30

Annual Review .....	31
Network 4 Transplantation Goals and Objectives .....	31
<b>Chapter 9: Quality Improvement .....</b>	<b>32</b>
Goals of Quality Improvement.....	33
Quality Improvement Guidelines .....	33
<i>Special Note on Quality Projects and Research</i> .....	34
<i>Additional Materials Available</i> .....	34
<b>Chapter 10: Water Treatment.....</b>	<b>35</b>
New 2001 Dialysis Collection .....	36
AAMI Water Quality Standard .....	36
<i>Substances Normally Included in Dialysate</i> .....	36
<i>Substances Identified as Toxic in Hemodialysis</i> .....	36
<i>Substances Regulated by the Safe Drinking Water Act</i> .....	36
<i>Bacteriologic Standards</i> .....	37
<b>Chapter 11: Medical Records.....</b>	<b>38</b>
Medical Record Model.....	39
<i>Condition: Medical Records</i> .....	39
<i>Standard: Medical Records Supervisor</i> .....	39
<i>Qualified Personnel: Sec. 405.2102 Definitions</i> .....	40
<i>Recommendations: Content Of Active Records</i> .....	40
<i>Acknowledgments</i> .....	45
<b>Chapter 12: Pediatric Patients .....</b>	<b>46</b>
Caring for Pediatric Patients.....	47
Blood Pressure Control .....	47
Patient Care Ratio for Children on Hemodialysis .....	48
Growth and Nutrition .....	48
Metabolic Control .....	49
Renal Osteodystrophy .....	49
Anemia Control.....	50
Seizure Control.....	50
Patient/Family Education.....	50
Transplantation as a Modality Option .....	51
Infection Control .....	51
Articles.....	51
Daily Nutrient and Fluid Recommendations .....	52
Tanner Stages of Development of Secondary Sexual Characteristics .....	56
<b>Acknowledgements .....</b>	<b>57</b>
<b>Independent Submission of Quality Improvement Materials.....</b>	<b>58</b>

# Chapter 1: Medical Director

Source: RPA/ASN Position Paper  
Federal Regulations Governing Chronic Renal Dialysis

<b>QUALIFICATIONS OF THE MEDICAL DIRECTOR</b>
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Federal Regulations

From the outset of the ESRD program, federal regulators defined the Medical Director of a unit as "a physician who is board eligible or board certified in Internal Medicine or Pediatrics and has had at least 12 months of experience or training in the care of patients at ESRD facilities or who had served at least 12 months as director of a dialysis or transplantation program prior to 1976." In those areas where such a physician was not available to direct a dialysis facility, another physician was able to direct the facility, subject to approval of the Secretary of Health. [Federal Register, Vol. 41, No. 108, Thursday, June 3, 1976, Section 405.2102 (e) (1-3).]

RPA/ASN

The background, expertise and training make the practicing nephrologist the most appropriate physician to serve as Medical Director who coordinates the renal health care team in providing optimal, integrated care to the dialysis patient; although availability of an exception for established qualified Medical Directors not meeting these criteria should be maintained.

<b>DUTIES AND RESPONSIBILITIES OF THE MEDICAL DIRECTOR</b>
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Medical

Criteria	Exceptions	Data Source
1) Coordinates the comprehensive renal health care team to ensure quality of care. This would include the establishment and implementation of policies regarding subspecialty nephrologic care (dialysis prescription, EPO, hepatitis vaccines, frequency of physician visits, etc.) as well as policies addressing the general internal medicine or pediatric care of co-morbid conditions. For the latter, many attending nephrologists have assumed the role of primary care giver.	None	RPA/ASN
2) Assures that there are written policies which address a long-term patient care plan to select the appropriate ESRD modality.	None	CMS
3) Assures that there are written policies outlining the units' programs for in-center hemodialysis, home hemodialysis, and peritoneal dialysis modalities.	None	CMS
4) Assures that the ESRD patient has appropriate consultation with a renal dietitian, renal social worker, and other individuals as needed.	None	CMS
5) Assures the appropriate execution of the dialysis orders and day-to-day patient care policy by the nursing and technical staff.	None	CMS

<b>DUTIES AND RESPONSIBILITIES OF THE MEDICAL DIRECTOR</b>
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Medical, continued

Criteria	Exceptions	Data Source
6) Assures attending physician education and compliance with the unit policies on patient care and technical aspects.	None	RPA/ASN

Technical

Criteria	Exceptions	Data Source
1) Participates in the selection of treatment modalities and dialysis supplies to be offered by the facility, and advises attending physicians regarding the compatibility of their dialysis prescriptions with the options available at the facility. The selection process may include supplies for both hemodialysis (in-center, and home) and peritoneal dialysis.	None	RPA/ASN
2) Approves policies and procedures ensuring the adequate training of nurses and technicians in dialysis science and techniques. The Medical Director should provide continuous coverage for medical and technical questions to the patient care staff, including alternative physician coverage in the event that the Medical Director is not available.	None	RPA/ASN
3) Supervises the development of a dialysis water standards policy including implementation, monitoring, and enforcement.	None	RPA/ASN
4) Supervises the development of a unit-specific policy regarding dialyzer reuse/reprocessing including implementation, monitoring, and enforcement.	None	RPA/ASN
5) Supervises the development of a unit-specific policy on the administration of EPO and intra dialytic medications such as Vitamin D analogs and intravenous iron preparations.	None	RPA/ASN

<b>DUTIES AND RESPONSIBILITIES OF THE MEDICAL DIRECTOR</b>
--

Administrative

Criteria	Exceptions	Data Source
1) Assures written policies and guidelines including: <ul style="list-style-type: none"> <li>a) Medical records of the dialysis patient.</li> <li>b) Physical environment, fire and safety, and emergency preparedness of the dialysis facility.</li> <li>c) Communicable disease control within the unit.</li> <li>d) Patient care policy and procedures manual which is unit specific. This manual should represent a written plan of organization, responsibilities, and functions of each category of all personnel employed in the facility.</li> <li>e) Patient education program.</li> <li>f) Medical staff bylaws and physician credentialing, in conjunction with the unit's governing body.</li> <li>g) Unit specific policies for:               <ul style="list-style-type: none"> <li>i) Dialyzer reuse/reprocessing</li> <li>ii) Anemia evaluation and management including guidelines for erythropoietic agents and intravenous iron preparation</li> <li>iii) Adequacy of dialysis measures</li> <li>iv) Dialysis water standards</li> <li>v) Immunization guidelines for Hepatitis B, influenza and pneumococcal vaccines</li> <li>vi) Use of I.V. Vitamin D preparations and monitoring of renal osteodystrophy parameters</li> <li>vii) Infection Control</li> </ul> </li> </ul>	None	RPA/ASN
2) Assures Quality Improvement programs to monitor the policies listed under Administrative item (g), sub-items i through vii.	None	RPA/ASN
3) The Medical Director should participate actively in facility Quality Improvement programs and may initiate programs to measure performance outcomes.	None	RPA/ASN
4) The Medical Director assures that all attending physicians comply with all network, state, and federal mandates applicable to the dialysis facility.	None	RPA/ASN
5) The Medical Director establishes a documented practice goal within the facility to ensure optimal patient care.	None	RPA/ASN

# Chapter 2: Physician

Source: Federal Regulations Governing Chronic Renal Dialysis

<b>QUALIFICATIONS OF THE PHYSICIAN</b>
--

Criteria	Exceptions	Data Source
1) Hold a valid license to practice medicine in the State in which he/she practices.	1) Federal Hospital	CMS
2) Be an MD or DO who is board certified or eligible in Nephrology <b>or</b> Pediatric Nephrology <b>or</b> board certified or eligible in Internal Medicine <b>or</b> Pediatrics and have at least 12 months of supervised experience in the care of ESRD patients, <b>or</b> during the five-year period prior to the effective date of these guidelines served for at least 12 months as attending physician in an ESRD program.	2) None	
3) Have admitting privileges to at least one hospital in the areas where appropriate renal care can be provided.	3) Physician on initial provisional status. Have documented referral arrangement to nephrologist for inpatient care.	CMS

<b>RESPONSIBILITIES OF THE PHYSICIAN</b>
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Criteria	Exceptions	Data Source
1) Provides within 30 days of admission to a chronic program a complete data base on the new patient consisting of: a) A complete medical history and physical exam b) A listing of the patient's major diagnoses	1) May be provided by resident, fellow or mid-level practitioner under the documented supervision of the attending physician. History and physical, consult, discharge summary from recent hospitalization or office visit.	
2) Generate dialysis prescription, medications, therapies, diet and fluid regimen.	2) Resident, fellow, or mid-level practitioner under the documented supervision of the attending physician.	CMS
3) a) Monitor patient progress, condition and response to dialytic therapy as needed. b) Provide documented physician evaluation monthly, with reference to overall renal care. (Progress notes on treatment record are acceptable). Unstable diagnoses should be	3) May be performed by a resident, fellow or mid-level practitioner under the documented supervision of the attending physician.  Home Patients – both hemodialysis and peritoneal dialysis.	Network

<b>RESPONSIBILITIES OF THE PHYSICIAN</b>		
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Criteria	Exceptions	Data Source
appropriately addressed. c) Evaluate the patient at least once monthly while on dialysis.		
4) Active participation in periodic Patient Care Conferences to evaluate current therapy as required by CMS Standards (Subpart U of the Medicare Regulations; 42 CFR 405.2137).	4) None	CMS
5) Participation in an initial, as well as a yearly updated Long Term Progress Plan to include: a) Comments on current medical condition. b) Assurance that the patient receives adequate information on all therapeutic options and comments on the appropriateness of the current therapeutic modality.	5) None	CMS
6) Perform a periodic updated medical history and physical exam, as needed but at least yearly and including ordering appropriate diagnostic studies.	6) a) May be provided by resident, fellow or mid-level practitioner under the documented supervision of the attending physician. b) Patient refusal. c) Discharge summary with documented history and physical exam, office history and physical, or consult history and physical are acceptable by the above practitioners.	CMS
7) Obtain and evaluate appropriate monthly laboratory studies for in-center patients and <b>at least</b> quarterly for home patients.	7) Patient refusal	CMS
8) Provide continuous medical coverage for patient care needs, including adequate alternate physician coverage when not personally available.	8) None	CMS
9) Provide a note (within thirty days) summarizing hospitalization and note when a patient recovers, is	9) May be provided by resident, fellow or mid-level practitioner under the documented supervision of the	CMS

<b>RESPONSIBILITIES OF THE PHYSICIAN</b>		
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Criteria	Exceptions	Data Source
successfully transplanted or expires.	attending physician.	
10) Provide appropriate transfer information to the facility whenever a patient transfers.	10) May be provided by resident, fellow or mid-level practitioner under the documented supervision of the attending physician.	CMS
11) Be members of an organized medical staff with a Medical Director, having written objectives and policies to provide quality care and encourage cooperation among physicians, non-physician staff and administration.	11) None	CMS
12) Cooperate with dialysis facility staff in their responsibilities to carry out ESRD Network goals and objectives.	12) None	CMS
13) To be recredentialed every two years.	13) None	Network

# Chapter 3: Transplant Surgeon

Source: UNOS

<b>QUALIFICATIONS OF THE TRANSPLANT SURGEON</b>
---

Criteria	Exceptions	Data Source
1) Transplant Surgeon will be an MD or DO, who is board eligible or certified by the American Board of Surgery or American Board of Urology. <ul style="list-style-type: none"> <li>a) One year minimum of formal training in a renal transplant program sanctioned by the Education Committee of the American Society of Transplant Surgeons.</li> <li>b) In lieu of one year of formal training, a minimum of three years experience to include:               <ul style="list-style-type: none"> <li>i) Pre-operative assessment, operation as primary surgeon or first assistant, and post-operative management of renal transplants.</li> <li>ii) A minimum of ten renal transplants per year at a transplant program meeting United Network for Organ Sharing (UNOS) criteria for membership.</li> </ul> </li> <li>c) Maintain current knowledge in the care of transplant patients. Obtain twelve Continuing Medical Education credits in renal transplantation every three years.</li> </ul>	1) None	UNOS

<b>RESPONSIBILITIES OF THE TRANSPLANT SURGEON</b>
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Criteria	Exceptions	Data Source
1) Reporting on patient care: <ul style="list-style-type: none"> <li>a) Reporting and documentation which meets UNOS Criteria will be considered as adequate for Network 4.</li> </ul>	1) None	

# **Chapter 4: Transplant Physician**

Source: UNOS

<b>QUALIFICATIONS OF THE TRANSPLANT PHYSICIAN</b>
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Criteria	Exceptions	Data Source
1) The transplant physician will be an MD or DO, board certified or eligible in Internal Medicine or Pediatrics, and satisfy the requirement for physicians caring for ESRD patients as in Section I. <ul style="list-style-type: none"> <li>a) Additional training of one year formalized training in transplantation medicine or a minimum of two years documented experience in transplantation medicine with a transplant program that is approved by UNOS.</li> <li>b) Experience must include pre-operative and post-operative patient care responsibility for a minimum of ten renal transplants per year in a UNOS approved renal transplant program.</li> <li>c) Or a cumulative experience of at least 20 renal transplants over more than two years.</li> <li>d) The transplant physician must maintain a minimum of 12 Continuing Medical Education credits in transplantation every three years.</li> </ul>	1) a) Nephrology with transplantation experience	UNOS

<b>RESPONSIBILITIES OF THE TRANSPLANT PHYSICIAN</b>
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Criteria	Exceptions	Data Source
1) Reporting of activity and patient followup: <ul style="list-style-type: none"> <li>a) Shall be considered adequate if in compliance with UNOS reporting criteria.</li> </ul>	1) None	

# **Chapter 5: Nurse Responsible for Nursing Services**

Source: Federal Regulations Governing Chronic Renal Dialysis  
American Nephrology Nurses Association Core Curriculum

## QUALIFICATIONS OF THE NURSE RESPONSIBLE FOR NURSING SERVICES

Federal Regulations require that the Nurse responsible for Nursing Services "is licensed as a registered nurse by the state in which practicing, and (i) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation including training in and experience with the dialysis process; or (ii) has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process. (iii) If the nurse responsible for nursing services (qualified) is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care." [Federal Register, Vol. 41, No. 108, Thursday, June 3, 1976, Section 405.2102 (r) (4) (i).]

**Qualifications/Training** – Assures that documentation is available for the following:

- ❖ In the personnel files, that the person is a qualified nurse, with possession of a current valid license to practice nursing in the state
- ❖ In the personnel files, that nursing personnel have received needed supervised clinical experience according to facility policy to develop competency in their area of responsibility
- ❖ In the personnel file, resume, in-service record or staff training manual that shows person has received instructions in and/or demonstrated knowledge of:
  - Anatomy and physiology of normal kidney
  - Fluid and electrolyte and acid-base balance
  - Pathophysiology of renal disease
  - Acceptable laboratory values for the patient with renal disease
  - Theoretical aspects of hemodialysis and/or peritoneal dialysis, including vascular access and maintenance of blood flow or peritoneal access and maintenance of dialysate flow
  - Technical aspects of hemodialysis or peritoneal dialysis
  - Monitoring patients during treatment, treatment initiation and termination
  - Recognition of dialysis complications, emergency conditions, and institution of the appropriate corrective action; emergency equipment is available and staff is trained in its use
  - Psychological, social, financial and physical complications of long term dialysis
  - Care of the patient with acute renal failure
  - Dietary modifications and medications for the uremic patient
  - Understanding of referral pattern and when referrals should be made to the physician, social worker or dietician
- ❖ In the personnel files or inservice record that personnel are informed of new developments in the field and basic principles are reviewed
- ❖ Staff are updated in emergency procedures to include:
  - Certification in CPR
  - Annual updates on the following
  - Hemodialysis
  - Anaphylactic shock
  - Disaster (including power outage)
  - Cardiac and/or pulmonary arrest
  - Pyrogen reaction
  - Air embolism
  - Problems peculiar to central dialysate and/or water systems

## RESPONSIBILITIES OF THE NURSE RESPONSIBLE FOR NURSING SERVICES

### **CONDITION: Staff of a renal dialysis facility or renal dialysis center.**

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and non-medical emergencies.

#### ❖ **Standard: Registered Nurse**

- The dialysis facility employs at least one full time qualified nurse responsible for nursing service.

#### ❖ **Standard: On-duty personnel**

Whenever patients are undergoing dialysis:

- One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care
- An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients
- An adequate number of personnel are readily available to meet medical and non-medical needs

#### ❖ **Standard: Self-care dialysis training personnel**

- If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see Sec. 405.2102)

#### ❖ **Staffing – Assures that documentation is available for the following:**

- A licensed health professional (e.g., physician, RN or LPN) experienced in rendering ESRD care is on duty whenever a patient is dialyzing, i.e., professional signature must appear on flow sheet or elsewhere on chart

#### ❖ **Staff Health Policies – Assures that documentation is available for the following:**

- Any routine health screening required by state law and/or facility policy, i.e., Hepatitis screening, TB screening, health assessment.

## GUIDELINES FOR STAFF RN/LPN

- ❖ Individual is a qualified nurse, with possession of a current valid license to practice nursing in the state
- ❖ Has received needed supervised clinical experience according to facility policy to develop competency in their area of responsibility
- ❖ Has received instructions in and/or demonstrated knowledge of:
  - Anatomy and physiology of normal kidney
  - Fluid and electrolyte and acid-base balance
  - Pathophysiology of renal disease
  - Acceptable laboratory values for the patient with renal disease
  - Theoretical aspects of hemodialysis and/or peritoneal dialysis, including vascular access and maintenance of blood flow or peritoneal access and maintenance of dialysate flow
  - Technical aspects of hemodialysis or peritoneal dialysis
  - Monitoring patients during treatment, treatment initiation and termination

## GUIDELINES FOR STAFF RN/LPN, continued

- Recognition of dialysis complications, emergency conditions, and institution of the appropriate corrective action; emergency equipment is available and staff is trained in its use
- Psychological, social, financial and physical complications of long term dialysis
- Care of the patient with acute renal failure
- Dietary modifications and medications for the uremic patient
- Understanding of referral pattern and when referrals should be made to the physician, social worker or dietician
- ❖ Provide safe, effective delivery of patient care in compliance with standards outlined in patient care policies and procedures, as well as regulations set forth by state and federal agencies
- ❖ Promotes and assists in the maintenance of a safe and clean working environment
- ❖ Informed of new developments in the field and basic principles are reviewed. Acquires information and knowledge in current practice related to dialysis principles and techniques by participating in in-service classes.
- ❖ Coordinated the patient care plan with physician, dietician, and social worker
- ❖ Competency with all emergency operational procedures to include the following, in addition to the ability to respond appropriately in the event of an emergency:
  - Certification in CPR
  - Annual updates on the following
    - Hemodialysis
    - Anaphylactic shock
    - Disaster (including power outage)
    - Cardiac and/or pulmonary arrest
    - Pyrogen reaction
    - Air embolism
    - Problems peculiar to central dialysate and/or water systems

Differences between LPN scope of practice in Pennsylvania and Delaware include the following:

- ❖ Under the direction of an RN, Delaware LPNs are able to administer Hypertonic Saline, Mannitol and Sodium Bicarb, while LPNs in Pennsylvania are not.

## GUIDELINES FOR PCT

- ❖ Has received needed supervised clinical experience according to facility policy to develop competency in their area of responsibility
- ❖ Has received instructions in and/or demonstrated knowledge of:
  - Anatomy and physiology of normal kidney
  - Fluid and electrolyte and acid-base balance
  - Pathophysiology of renal disease
  - Acceptable laboratory values for the patient with renal disease
  - Theoretical aspects of hemodialysis and/or peritoneal dialysis, including vascular access and maintenance of blood flow or peritoneal access and maintenance of dialysate flow
  - Technical aspects of hemodialysis or peritoneal dialysis
  - Monitoring patients during treatment, treatment initiation and termination

## GUIDELINES FOR PCT, continued

- Recognition of dialysis complications, emergency conditions, and institution of the appropriate corrective action; emergency equipment is available and staff is trained in its use
- Psychological, social, financial and physical complications of long term dialysis
- Care of the patient with acute renal failure
- Dietary modifications and medications for the uremic patient
- Understanding of referral pattern and when referrals should be made to the physician, social worker or dietician
- ❖ Provides safe, effective delivery of patient care in compliance with standards outlined in patient care policies and procedures, as well as regulations set forth by state and federal agencies
- ❖ Assists in the maintenance of a safe and clean working environment
- ❖ Informed of new developments in the field and basic principles are reviewed. Acquires information and knowledge in current practice related to dialysis principles and techniques by participating in in-service classes.
- ❖ Competency with all emergency operational procedures to include the following, in addition to the ability to assist with all emergency operational procedures:
  - Certification in CPR
  - Annual updates on the following
    - Hemodialysis
    - Anaphylactic shock
    - Disaster (including power outage)
    - Cardiac and/or pulmonary arrest
    - Pyrogen reaction
    - Air embolism
    - Problems peculiar to central dialysate and/or water systems

Differences between Pennsylvania state regulations and Delaware state regulations for PCT's include the following:

- ❖ Heparin administration by a PCT under the direction of an RN is permitted in Pennsylvania, but not in Delaware

# **Chapter 6: Social Work Services**

Source: Federal Regulations Governing Chronic Renal Dialysis  
NKF – Council of Nephrology Social Workers  
ESRD Network 4, Inc.

<b>QUALIFICATIONS OF THE SOCIAL WORKER</b>
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Standard: Social Services

"Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of the patient's progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and group work services to patients and their families in dealing with special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them." [Federal Register, Vol. 41, No 108. Thursday, June 3, 1976, 405.2163 (b) and 405.2171 (b).]

Qualified Personnel: Social Worker

"A person who is licensed, if applicable, by the State in which practicing, and (i) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education or (ii) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to the effective date of these regulations, and has established a consultative relationship with a social worker who qualifies under (6) (i) of this section." [Federal Register, Vol. 41, No. 108, Thursday, June 3, 1976, Section 405.2102 (r) (6) (i).]

<b>RESPONSIBILITIES OF THE SOCIAL WORKER</b>
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Criteria	Exceptions	Data Source
1) Social worker holds masters degree from a graduate school of social work accredited by the Council on Social Work Education.	1) Social worker has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to the effective date of these regulations (9/1/76) and has established a consultative relationship with a social worker who is licensed.	CMS
2) Social worker is licensed by the state, if applicable, in which practicing.	2) Licensing not available in your state.	
3) There will be a written record of social work policies and procedures that include: a) Statement of program philosophy and objectives. b) A written job description of renal social work duties.	3) None	

<b>RESPONSIBILITIES OF THE SOCIAL WORKER, continued</b>		
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Criteria	Exceptions	Data Source
<p>4) Sufficient suitable space is available to the social worker so that patient/family/staff interviews and other activities can be conducted with privacy and confidentiality.</p>	<p>4) None</p>	
<p>5) There will be documentation in progress notes of initial intake interview on each patient <u>new</u> to the facility within 4 weeks (i.e., documentation that social worker has introduced self and explained role).</p>	<p>5)</p>	
<p>6) CMS-2728 Form (End State Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration) completed and submitted to Social Security and to the Network 4 office within 45 days of patient's first chronic treatment.</p>	<p>6) When patient initiates treatment at the chronic outpatient facility more than 45 days after the first treatment.</p>	
<p>7) Psychosocial assessment conducted for all new patients and documented in chart within one month of patient's first treatment at chronic outpatient facility.</p> <p>a) Assessment has been updated at least on a yearly basis.</p> <p>b) Psychosocial assessment should include:</p> <ul style="list-style-type: none"> <li>i) Family/support system</li> <li>ii) Education</li> <li>iii) Employment</li> <li>iv) Living arrangements</li> <li>v) Finances/insurance</li> <li>vi) Significant medical or psychosocial history</li> <li>vii) Psychosocial treatment plan and goal setting</li> </ul>	<p>7) Initial, less formal, brief psychosocial assessment done within two weeks with comprehensive psychosocial assessment within three months.</p> <p>a) Patient has not been in the facility for a year.</p> <p>b) None</p>	

<b>RESPONSIBILITIES OF THE SOCIAL WORKER, continued</b>		
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Criteria	Exceptions	Data Source
8) The medical record will contain dated entries of direct social work services to patients and their families as well as related activities on their behalf. <ul style="list-style-type: none"> <li>a) For dated entries:               <ul style="list-style-type: none"> <li>i) Problem is identified, situation assessed.</li> <li>ii) Plan for resolution formulated and implemented.</li> <li>iii) Problem resolved to extent possible or social worker or patient determine services are unavailable to or not utilized by patient.</li> </ul> </li> <li>b) Documentation in the medical record that the social worker has assisted in the development of the long term and short term care plan               <ul style="list-style-type: none"> <li>i) LTCP within 30 days of admission to facility and annually thereafter</li> <li>ii) STCP reviewed/updated a minimum of every six months</li> </ul> </li> </ul>	9) None	Network

<b>SOCIAL WORK SERVICES REFERENCES</b>
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To reference a “Position Statement” on social work staffing, go to pages 10 – 18 in the **Standards of Practice for Nephrology Social Work**, Fourth Edition, Council of Nephrology Social Workers, National Kidney Foundation.

# **Chapter 7: Nutritional Services**

Source: Federal Regulations Governing Chronic Renal Dialysis  
ESRD Network 4, Inc.

## QUALIFICATIONS OF THE DIETITIAN

### Standard: Dietetic Services

"Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (Sec. 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets." [Federal Register, Vol. 41, No. 108. Thursday, June 3, 1976, 405.2163(d) and 405.2102(b).]

### Qualified Personnel: Dietitian

- 1) "Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least one year of experience in clinical nutrition; or
- 2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least one year of experience in clinical nutrition."

## RESPONSIBILITIES OF THE DIETITIAN

### Target Population of Adult ESRD Patients Receiving Chronic Hemodialysis Treatments

### Assessment

Criteria	Data Source
1) Documentation in the medical records that a qualified Registered Dietitian (R.D.) has interviewed the patient within two weeks of admission to the facility.	Network
2) Documentation of the patient's nutritional assessment (Initial Assessment in the medical record by the qualified R.D. within one month of the admission to the facility (and recommended to be updated annually) to include: a) Height/Weight b) Patient's usual and present weight (% usual body weight and % of standard [NHANES II] body weight), stability of weight. c) Pertinent lab data d) Dietary interview and/or diary e) Assessment of adequacy of patient's caloric and protein intake. Address the need to modify other nutrients in patient's diet (i.e. potassium, phosphorus, sodium) and fluids. f) Documentation of nutrition education progress, level of understanding, and ability/willingness of the patient and/or caregiver to follow the nutrition information provided.	CMS PA Department of Health Network Forum of ESRD Networks (Annual Update)

**RESPONSIBILITIES OF THE DIETITIAN, continued**

Target Population of Adult ESRD Patients Receiving Chronic Hemodialysis Treatments

Care Plans

Criteria	Data Source
1) Documentation in the medical record that a qualified R.D. has assisted in the development of the Long Term Plan (LTCP) for each patient within 30 days of admission to the facility and annually thereafter.	CMS PA Department of Health Network Forum of ESRD Networks (Annual Update)
2) Documentation in the medical record that a qualified R.D. has participated in the development of the interdisciplinary patient Short Term Care Plan (STCP). A STCP is developed monthly on patients who are unstable. STCP's are reviewed/updated a minimum of every six months on stable patients to insure that the plan provides for the patient's on-going needs.	CMS PA Department of Health Network Forum of ESRD Networks (Annual Update)

Monitoring and Education

Criteria	Data Source
1) Progress notes are documented in the medical record by a qualified R.D. at regular intervals. Minimum required entries include: <ul style="list-style-type: none"> <li>a) Monthly progress notes on unstable patients</li> <li>b) Progress notes every six months on stable patients (though quarterly charting is recommended).</li> </ul>	CMS PA Department of Health Network Forum of ESRD Networks (for recommended quarterly progress notes)
2) Recommended routine measurements for monitoring nutritional status are (see NKF-K/DOQI Nutrition Guidelines for suggested frequency of measurements): <ul style="list-style-type: none"> <li>◆ Predialysis or stabilized serum albumin</li> <li>◆ Percent of usual post-dialysis or post-drain body weight</li> <li>◆ Percent of standard (NHANES II) body weight</li> <li>◆ nPNA</li> <li>◆ Subjective global assessment (SGA)</li> <li>◆ Dietary interview and/or diary</li> </ul>	NKF-K/DOQI Nutrition Guidelines (for recommended measures for routine monitoring)
3) Any specific nutrition related problems requiring assessment and referral for follow-up resources (i.e. community contacts, extended care facilities, nutrition supplement programs) should also be documented as needed.	
4) Document nutrition education provided to the patient/or adjustments in the diet that were made, along with the reasoning. Document patient adherence and response to diet counseling.	CMS
5) For patients receiving parenteral nutrition, document the monitoring of the patient's nutritional status and response to parenteral nutrition therapy.	PA Department of Health

## ROLE OF THE RENAL DIETITIAN

*Taken from the chapter on **Nutrition**, Appendix IV, Clinical Practice Guidelines for Nutrition in Chronic Renal Failure, National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI)*

Implicit in many of the guidelines in this document is the availability to the patient of an individual with expertise in renal dietetics. Implementation of many of the guidelines concerning nutritional assessment (anthropometry, subjective global assessment, dietary interviews and diaries, and integration of the results of nutritional measurements) and nutritional therapy (developing a plan for nutritional management, counseling the patient and his/her family on appropriate dietary protein and energy intake, monitoring nutrient intake, educational activities, and encouragement to maximize dietary compliance) is best performed by an individual who is trained and experienced in these tasks. Although occasionally a physician, nurse or other individual may possess the expertise and time to conduct such activities, a registered dietitian, trained and experienced in renal nutrition usually is best qualified to carry out these tasks. Such an individual not only has undergone all of the training required to become a registered dietitian, including, in many instances, a dietetic internship, but has also received formal or informal training in renal nutrition. Such a person, therefore, is particularly experienced in working with MD patients as well as individuals with CRF.

There appears to be a general sense among renal dietitians, based on experience, that an individual dietitian should be responsible for the care of approximately 100 MD patients but almost certainly no more than 150 patients to provide adequate nutritional services to these individuals. Because, in many dialysis facilities, the responsibilities of the renal dietitian are expanded beyond the basic care described in these guidelines (e.g. monitoring protocols and continuous quality improvement), these facilities should consider a higher ratio of dietitians to patients. Randomized prospective controlled clinical trials have not been conducted to examine whether this is the maximum number of patients at which dietitians are still highly effective.

# **Chapter 8: Transplantation Documentation**

Source: ESRD Network 4 Organ Procurement/Transplantation Committee

## EVALUATE AND CLASSIFY PATIENTS

The medical record will indicate the following:

- The patient has been medically and psychosocially evaluated by the professional care team (a multidisciplinary team including, but not limited to, a nephrologist, a nurse, a social worker and a dietitian. The review by the transplant center can be by a designated individual and accomplished by mail)

### AND

- The patient has been classified as a suitable or unsuitable candidate for transplantation. Patient classification should be completed within 90 days following initiation of dialysis.

Guidelines for referral are determined by the transplant center. Therefore, consultation with the transplant center may be necessary to determine unsuitability.

#### Suitable Patients Are Usually

- Psychologically stable
- Understand risks, hazards & benefits of transplant
- Free of uncorrectable medical conditions

#### Unsuitable Patients Are Usually

- Active infection

Advanced age and cardiac disease are no longer regarded as absolute contraindications to transplantation

## INFORM AND DOCUMENT DECISION

The medical record will indicate that:

- Patients determined not suitable for transplant referral were informed of this determination
- Suitable patients were presented the option of referral to a transplant center for evaluation, and received information on cadaveric and living donor transplant.
- The patient's signature on the form indicates the discussion of the above occurred.

The Nephrologist may wish to review: Criteria for Ratings of Appropriateness for Renal Transplantation: Epstein AM, et al: Racial disparities in access to renal transplantation. The New England Journal of Medicine (Volume 343:1537-1544, November 23, 2002.)

## DOCUMENT TRANSPLANT STATUS

For Patients Electing Evaluation for Transplantation:

- The medical record will document referral to a transplant center
- Process to evaluate patient for cadaveric or living donor transplant initiated
- Patient wait-listed for cadaveric transplant and/or scheduled for living donor transplant
- Patient deemed unsuitable candidate for transplant
- Patient refused the transplant option after further consideration

## ANNUAL REVIEW

CMS Subpart U Regulations mandate the generation of a written Patient Long-Term Program and Care Plan, updated yearly, representing the selection of a suitable treatment modality (i.e. dialysis or transplantation). Treatment modality must be reviewed with all patients annually, regardless of prior suitability or referral decision.

## NETWORK 4 TRANSPLANTATION GOALS AND OBJECTIVES

100% of dialysis facilities should have a written policy for delivery of transplant information to all patients, including: when transplant information will be presented to new patients, what tools (brochures, video, verbal) are used, and who conducts annual follow-up education with the patient.

**Each Network 4 patient will have documented transplant status that is updated annually.**

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For pediatric patients (<18 years of age) the term "patient" applies to the patient (if they are old enough to understand) and their identified responsible caretaker.

# Chapter 9: Quality Improvement

Source: JCAHO Quality Model  
ESRD Network 4 Medical Review Board

## **GOALS OF QUALITY IMPROVEMENT**

The ultimate goal of performance improvement is to improve patient outcomes. The facility must perform important functions in order to achieve desired outcomes, and to insure the internal and external customers of the value and quality of services. External customers may be CMS, Networks, Professional Organizations, Consultants, and most importantly, the patient. Internal customers include Network office staff, the Medical Review Board, committee members, etc. Performance improvement (PI) activities are most effective when they are planned, systematic, and organization wide and when all appropriate individuals and professions work collaboratively to implement them. The quality within the organization cannot be assured without a structure to plan, implement, measure and evaluate performance.

## **QUALITY IMPROVEMENT GUIDELINES**

- 1) All facilities will participate in Network continuous quality improvement (CQI) projects as identified and defined by the Medical Review Board (MRB).
- 2) All facilities will conduct ongoing monitoring, evaluations, and intervention resulting in improvement of CPM indicators, following guidelines established by the nephrology community including, but not limited to:
  - a) NKF-K/DOQI Guidelines
    - i) hemodialysis adequacy
    - ii) peritoneal dialysis adequacy
    - iii) vascular access
    - iv) anemia
    - v) nutrition
  - b) AAMI standard and guidelines
    - i) water treatment
    - ii) reuse
- 3) All facilities will collect data on important processes or outcomes related to patient care and organization functions. Suggestions to include, but not limited to:
  - a) Anemia management
  - b) Dialysis adequacy
  - c) Vascular access monitoring and management
  - d) Processes which put patients at risk
    - i) Water quality maintenance
    - ii) Medical equipment maintenance
    - iii) Reuse of dialyzers
    - iv) Infection control procedures
  - e) The needs, expectations, and satisfaction of patients
  - f) Staff views regarding performance and improvement opportunities
  - g) Risk-management activities
    - i) Adverse or sentinel events
    - ii) Mortality
    - iii) Hospitalization
    - iv) Staffing
  - h) Quality control activities
    - i) Safety/environmental
    - ii) Clinical outcomes including nutrition

- iii) Patient rehabilitation, including social service needs
  - iv) Medical records maintenance
  - v) Treatment morbidity
  - vi) Medication administration including antibiotics, Epogen, parenteral iron, immunization, etc.
  - vii) Blood use
- 4) When improvement activities reveal that a system or process is problematic, the facility modifies the system or process and takes appropriate action in the quality improvement cycle.

#### Special Note on Quality Projects and Research

*Currently there are issues over the relationship between quality projects and research that exist. When definitive definitions are issued, that information will be forwarded to each ESRD facility.*

The Medical Review Board of ESRD Network 4, Inc. identified two articles for review under this topic:

- “The Role of the Institutional Review Board in Quality Improvement: A Survey of Quality Officers, Institutional Review Board Chairs, and Journal Editors.” Am J Med. 2002; 113: 575-579.
- “Determining When Quality Improvement Initiatives Should Be Considered Research: Proposed Criteria and Potential Implications.” JAMA. 2000; 283: 2275-2280.

#### Additional Materials Available

Please refer to the “Independent Submission of Quality Improvement Materials” included with this document.

# Chapter 10: Water Treatment

Source: Recommended Practice for Water Quality Standards  
Developed by Association for the Advancement of Medical Instrumentation  
(AAMI)

**NEW 2001 DIALYSIS COLLECTION**

The new 2001 dialysis collection is available through AAMI's Customer Service Department:  
(800) 332 – 2264, extension 217

Order Code: DSBK01-PR  
Web Site: www.aami.org

**AAMI WATER QUALITY STANDARD**

Substances Normally Included in Dialysate

<b>Contaminant</b>	<b>AAMI Standard</b>
Calcium	2 mg/L (0.1 mEq/L)
Magnesium	4 mg/L (0.3 mEq/L)
Potassium	8 mg/L (0.2 mEq/L)
Sodium	70 mg/L (3.0 mEq/L)

Substances Identified as Toxic in Hemodialysis

<b>Contaminant</b>	<b>Lowest Concentration Associated with Dialysis Toxicity</b>	<b>AAMI Standard</b>
Aluminum	0.06 mg/L	0.01 mg/L
Chloramines	0.25 mg/L	0.10 mg/L
Free Chlorine		0.50 mg/L
Copper	0.49 mg/L	0.10 mg/L
Fluoride	1.0 mg/L	0.20 mg/L
Nitrate	21 mg/L	2.0 mg/L
Sulfate	200 mg/L	100 mg/L
Zinc	0.2 mg/L	0.10 mg/L

Substances Regulated by the Safe Drinking Water Act

<b>Contaminant</b>	<b>EPA Maximum for Drinking Water</b>	<b>AAMI Standard</b>
Antimony	0.006 mg/L	0.006 mg/L
Arsenic	0.01 mg/L	0.005 mg/L
Barium	2.0 mg/L	0.10 mg/L
Beryllium	0.004 mg/L	0.0004 mg/L
Cadmium	0.005 mg/L	0.001 mg/L
Chromium	0.10 mg/L	0.014 mg/L
Lead	0.015 mg/L	0.005 mg/L
Mercury	0.002 mg/L	0.0002 mg/L
Selenium	0.05 mg/L	0.09 mg/L
Silver	0.10 mg/L	0.005 mg/L
Thallium	0.002 mg/L	0.002 mg/L

Bacteriologic Standards

	<b>AAMI Limit</b>	<b>Action Level</b>
<b>Bacteria</b>		
Water	<200 cfu/mL	≥50 cfu/mL
Dialysate	<2,000 cfu/mL	
Concentrate	<200 cfu/mL	≥50 cfu/mL
<b>Endotoxin</b>		
Water	<2 EU/mL	≥1 EU/mL

# Chapter 11: Medical Records

Source: Federal Regulations Governing Chronic Renal Dialysis  
Forum of ESRD Networks  
ESRD Network 4, Inc.

## MEDICAL RECORD MODEL

From: Forum of ESRD Networks  
Developed: 4/1993  
Revised: 8/2001  
Approved by Forum's BOD: 10/2001

### NOTE:

The Forum of ESRD Networks, working through the Quality Improvement Directors, has developed and endorsed this Medical Record Model for use by all dialysis facilities. The goal of this Model is to enhance quality care by promoting consistent content for medical records. Although use of this Model is not mandatory, it is hoped that dialysis providers will voluntarily adopt the Model for use within their own programs.

The Medical Record Model defines the components necessary to achieve a consistent approach to ESRD medical records, thereby decreasing the fragmentation that frequently occurs in the medical records of ESRD patients.

It was developed using existing guidelines, standards and ideas regarding medical records, with input from the major nephrology professional organizations, the 18 ESRD networks, and dialysis facilities around the country.

All medical records should be completed in accordance with applicable state laws.



The following medical records guidelines represents what the Network and Forum of ESRD Networks believe comprises a comprehensive medical record. Requirements for the content of the records and the medical records supervisor are taken from the Federal Register - §405.2139 (41 CFR Ch. IV [10/1/90 Edition], Pages 142-143).

### Condition: Medical Records

"The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information."

### Standard: Medical Records Supervisor

"A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner."

## Qualified Personnel: Sec. 405.2102 Definitions

Medical record practitioner. A person who:

1. Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.
2. Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect Jun 3, 1976, or
3. Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American Medical Record Association under its requirements in effect June 3, 1976.

## Recommendations: Content Of Active Records

### **Identifying Information**

- Name
- Address
- Telephone number
- Date of birth
- Sex
- Race
- Ethnicity
- Primary/secondary ESRD diagnosis
- Current comorbid conditions
- Primary/attending physician and phone number
- Facility patient registration number
- Date/type of first renal therapy (first acute, chronic location)
- Date of admission to current facility
- Next of kin/significant other
- Emergency contact person and phone number
- Social Security number
- HIC (Medicare) number
- Copy of patient's driver's license and Medicare or insurance card
- Allergy stickers/information

### **Computerized Records**

Acceptable, if meets all requirements of paper records (i.e. confidentiality and retention laws)

## **Consents and Notifications**

- Informed consent for treatment
- Informed consent for reprocessed dialyzer (if applicable)
- Informed consent for blood transfusion
- Receipt of “Patient Rights and Responsibilities”
- Receipt of “Patient Grievance Form” and process information
- Receipt of ESRD Network grievance/contact information
- Release of records form
- Medical records request form
- Advance directives forms (e.g. DNR), or documentation that issues have been discussed and/or information received when applicable
- Hepatitis and other vaccination consent forms (if applicable)
- Informed consent of treatment options and modalities

## **History and Physical (done by physician extenders)**

- Initial H&P to include:
  1. Previous health history, including hospitalizations, procedures and other medical diagnoses.
  2. ESRD history, including predialysis laboratory data (BUN, creatinine, electrolytes, serum albumin, hemoglobin minimum), uremic symptoms, justification for need for renal replacement therapy.
- Annual exam by primary/attending physician, including review of systems and current problems.
- Current history and physical should be included within two weeks of initiation of renal replacement therapy and/or admission to the facility, and included in the patient’s record. (Also include amputations).

## **Assessments/Evaluations**

- Initial: within 30 days of admission to facility
- Nursing, social worker, dietitian
- Annual update

## **Transplantation Status**

- Treatment options discussed and documented
- If patient not candidate, reason/choice documented on record

## **Hospitalization Records**

- Admission history and physical
- Hospital discharge summary (if not obtained, a physician summary of each hospitalization should be completed).

## **Language Translation**

In some states/counties, health facilities are required to provide information/education to patients in their native language. Check for state and local requirements.

## **Miscellaneous**

- Medical record checklist
- CMS-2728
- Insurance information
- Correspondence
- Transient dialysis information

## **Progress Notes**

Progress notes should provide an accurate picture of the patient, which reflects changes in patient status, plans and results of changes in treatment regimen, diagnostic testing, consultations, unusual events, etc. Either single discipline or integrated multidisciplinary progress notes may be utilized. The following are minimum entries:

- Each discipline (physician, nurse, social worker, dietitian) should record the progress of the patient at regular intervals:
  - Monthly – unstable patients
  - Semi-annually (6 months) – stable patients\*  
(\*as defined by facility or physician)
- Patient condition and response to treatment noted on daily treatment record
- Regular review of abnormal labs/clinical findings and any action taken
- Monthly review of laboratory results (including adequacy) and hepatitis status
- Vascular Access Assessment

## **Patient Education (routine or facility-specific)**

- Disease, treatment, modality options, access care
- Services available
- Emergency preparedness: initial, quarterly or semi-annual
- Vaccine Information Statements (VIS) – required

## **Problem List (optional)**

- Initial
- Updated as needed, at least minimum annual review
- Either separate or integrated cumulative list of patient's medical, psychosocial, nutritional problems

## Care Plans

- Long term program
  - Initial
  - Current year, annual update
- Short-term care plan
  - Reflects interdisciplinary approach
  - Monthly for unstable patients
  - Every 6 months (minimum) for stable patients
  - Prior 12 months in active record
- Significant change in medical status or modality
- Advanced care planning, clinical end of life directive annual update
- Patient's signature (or responsible party) – reflects participation

## Physician Orders

- Standing Orders (i.e. emergency procedures, cramp management): initial, annual update (minimum)
- Dialysis prescription and medication update – initial, annual (minimum)
  - Include EPO/iron
- Post-hospitalization update
  - Current 6 months of orders in active record (minimum)

## Medication Record

- Initial
- Update
  - Whenever changes occur
  - After hospitalization
  - Annually (minimum)
- Reviewed at monthly intervals, including:
  - Name of drug
  - Dose
  - Route of administration
  - Date ordered
  - Any changes to be dated
  - Drug allergies
  - EPO, Calcijex, etc. flowsheets, if such flowsheets are utilized by the facility (medication lists for outpatient, home medications may be separated from in-center medications)
  - Other allergy alerts (e.g. latex, food, etc.)

## Daily Treatment Records

- May be kept separately
- Current year readily available (past 12 months)
- Filed separately for each individual patient

## **Consults**

Reports/letters from consulting physicians (past 12 months or readily available)

## **Vascular Access Record**

- Type of access (if catheter, specify type, length, etc.)
- Date of insertion/creation/revision/declothing
- Reports on any access surgeries or interventions
- Name of surgeon(s)
- Diagram of location, flow direction, configurations
- Monitoring records (e.g. pressure run charts, recirculation, etc.)

## **Laboratory**

- Past 12 months on active chart (or readily available)
- Cumulative laboratory records acceptable, original reports must be included in a permanent record if cumulative record is not generated by original laboratory (Lab normals/reference ranges).
- Flowsheets (e.g. clotting times, adequacy of dialysis testing, recirculation studies)
- Patient-specific run charts (optional), and adequacy calculations

## **Transfusion Record (past 12 months)**

## **Diagnostic Studies (past 12 months)**

- Radiology, nerve conduction, bone densitometry, EEG, current and prior EKG

## **Preventive Care Measures**

- Vaccination Status (HBV, pneumococcal, flu)
- Exams: mammography, PAP smears, retinal and foot exams (diabetics), etc.

## **Transient Records**

- Identifying information (refer to Active Records)
- Most recent physician's orders, to include dialysis prescription (dialyzer type, reuse practice, BFR/DFR, treatment time, dry weight), EPO dose and route, dosages of other intradialytic medications)
- Most recent progress notes
- Most recent problem list (include special needs)
- Current history and physical (include cause of ESRD)
- Medication record
- Most recent laboratory (past 2 months), to include: albumin, alkaline phosphatase, BUN, CA++, Cl-, CO<sub>2</sub>, creatinine, LDH, SGPT, SGOT, total protein, Hgb, glucose or HgBAIC (if diabetic), PT (if on Coumadin), hepatitis status (within 12 months)
- Last six treatment records
- Most recent long-term care plan
- Most recent psychological (or social worker) evaluation

- Insurance information
- Chest X-ray and EKG (within last 12 months)
- Facility-specific forms for reporting transient dialysis experiences back to home unit
- HBV status (antigen positive or immune)
- Type of vascular access, location, flow diagram
- Emergency contact (local)
- Phone number of primary nephrologist
- Allergies
- Advance directives

**CLOSED RECORDS** (transferred, transplanted, recovered function, withdrew from therapy, expired)

All Records, must include:

- Treatment records and thinned records
- Additional confidential files (e.g. HIV if kept separately)
- Business file may be kept separately

File Chronologically in sections, as outlined in Active Record Recommendations

Discharge Summary

- Clearly identifies the disposition of the patient (final diagnosis/cause of death, date of discharge/death, location of death, CMS-2746)

Maintained per state law, and actual chart (or copies for satellite facilities) should be available within two weeks. Check state law for minimum requirements for record retention timeframe.

### Acknowledgments

The Forum wishes to thank the Network Q.I. Directors Medical Record Subcommittee:

Vickie Peters, ESRD Network 18 (chair)  
 Alex Rosenblum, ESRD Network 14  
 Mary Turner, ESRD Network 5  
 Debra McClure, ESRD Network 7  
 Sandra Waring, ESRD Network 2

Additional acknowledgment goes to:

Dr. Alan Kliger, Past Chair, Forum Q.I. Committee  
 Dr. Allen Nissenson, Past President, Renal Physician's Association

# Chapter 12: Pediatric Patients

Source: Federal Regulations Governing Chronic Renal Dialysis  
ESRD Network 4 Pediatric Subcommittee of the Medical Review Board

**This is a supplement to the guidelines in place for all ESRD patients.**

**When guidelines are not met, it is the expectation that the medical record will reflect the appropriate interventions taken to achieve the guideline and/or provide identification of circumstances that prevent goal outcome.**

### **CARING FOR PEDIATRIC PATIENTS**

Pediatric dialysis facilities that treat pediatric patients should:

- A. Provide care for patients from 0-21 years of age. Infants and pre-school age children must be cared for in a pediatric center under the primary supervision of a pediatric nephrologist. The committee recommends that all school-aged children receive treatment in a pediatric center. If this is not possible, the patient should be supervised by a pediatric nephrologist at regular intervals.
- B. Provide medical care and supervision by a pediatric nephrologist or a nephrologist in consultation with a pediatric nephrologist. The initial management and treatment plan must be coordinated under the pediatric nephrologist with at least three-month follow-up consultations thereafter.
- C. Provide outpatient chronic maintenance peritoneal dialysis and hemodialysis.
- D. Hospital-based facilities should also provide: inpatient acute peritoneal dialysis, hemodialysis, and continuous renal replacement therapy.
- E. Provide home training for peritoneal dialysis using manual or automated equipment.
- F. Provide educational support and psychosocial services through a multidisciplinary team.
- G. Perform assessments of pediatric growth and development. Nutritional status should be monitored by a registered dietitian with expertise in pediatric renal nutrition.
- H. Directly or by arrangement, provide histocompatibility and transplantation services.
- I. Provide delivery of care through use of equipment and supplies, which are appropriate for the age, and size of the patient.
- J. Transition most patients to an adult dialysis unit between 18-21 years of age.

### **BLOOD PRESSURE CONTROL**

- A. Hemodialysis: Pre-dialysis diastolic blood pressure is <95th percentile for normal children of the same age and height for at least 80% of the most current month's recorded readings.
- B. Peritoneal Dialysis: Diastolic blood pressures are <95th percentile for normal children of the same age and height in at least 80% of the most current month's recorded readings.

The journal article provides the updated tables from the NIH Second Task Force on Blood Pressure Control in Children by age and height. (See page 51 under “Articles”.)

#### PATIENT CARE RATIO FOR CHILDREN ON HEMODIALYSIS

Patients weighing < 20 kg shall have a 1:1-1:2 nurse to patient care ratio. Appropriate equipment will be available to provide care for all pediatric patient psychological and physiological needs.

#### GROWTH AND NUTRITION

- A1. Infants less than 36 months have monthly weight, length and head circumference plotted on a growth chart. Growth should be maintained at least at the 5th percentile and no more negative than 2 standard deviation scores (SDS).
- A2. Patients 3 years to 17 years old have height and weight plotted on a growth chart quarterly.
- B. Serum albumin is measured monthly. Serum albumin is greater than the lower limit of normal range value.
- C. PNA should be determined at least quarterly.

**The journal article provides formulas for calculation of PNA. (See page 51 under “Articles”.)**

- D1. Infants less than 36 months of age demonstrate an increase in head circumference during the preceding 4 months that is the same as that expected for a normal infant of the same sex/age.
- D2. Patients who do not maintain growth velocity and adequate nutrition e.g. as indicated by serum albumin, should be considered for nutritional supplementation. This determination should be made monthly for infants 0-36 months and quarterly thereafter (height at least at the 5th percentile and no more negative than 2 SDS).

**Refer to Tables 1 through 4 under the section in this chapter called “Daily Nutrient and Fluid Recommendations.”**

- E. Documentation exists that consideration to growth hormone therapy has been given for any child whose height is <5th percentile and/or has shown a decreasing growth rate more negative than 2.0 SDS.
- F. Sexual maturity (Tanner) staging should be performed and documented every 6 months from age 6 years until Tanner Stage 5 is reached.

**Refer to the section in this chapter called “Tanner Stages of Development of Secondary Sexual Characteristics.”**

## METABOLIC CONTROL

- A. Serum Potassium (K<sup>+</sup>) should be drawn monthly

Hemodialysis – Predialysis: K<sup>+</sup> ≤ 6.0 mEq/L prior to the first hemodialysis treatment of the week.

Peritoneal Dialysis: K<sup>+</sup> ≤ 5.5 mEq/L.

- B. Serum bicarbonate levels below 22 mmol/L should be corrected with oral administration of alkali therapy and/or use of higher sodium bicarbonate dialysate solution in patients treated with maintenance hemodialysis.\*

- C. Patient has routine monitoring of small solute clearance and dialysis prescription using one or more of the following methods.\*\*

1. Hemodialysis - monthly measurement

Pre-post BUN reduction of ≥ 65% and/or prescribed KT/V 1.4 with delivered KT/V ≥ 1.2.

2. Peritoneal Dialysis – 4 month intervals after first six months\*\*\*

Dialysate plus urine values should be monitored. However, it should be noted that dialysis adequacy should still be monitored in smaller CAPD patients in whom urine collection cannot be monitored. Cr Cl should be normalized to body surface area (L/wk/1.73m<sup>2</sup>).

Total Creatinine Clearance	and/or	Kt/V
CAPD	60 L/wk/1.73m <sup>2</sup>	2.0
CCPD	63 L/wk/1.73m <sup>2</sup>	2.1
NIPD	66 L/wk/1.73m <sup>2</sup>	2.2

## RENAL OSTEODYSTROPHY

Serum Ca, P and alkaline phosphatase will be measured at least monthly. Serum PTH level will be measured at least every 3 months.

- A. Serum phosphorous level should be maintained between 3.5 mg/dl and 6.0 mg/dl for all patients over one year of age.
- B. Pediatric patients should not routinely receive aluminum containing phosphate binders.
- C. Serum calcium level should be maintained between 8.5 mg/dl and 10.5 mg/dl.

\* Evidence and opinion Based NKF-K/DOQI Guidelines.

\*\* These criteria may be subject to change as additional pediatric data for adequacy become available.

\*\*\* NKF-K/DOQI Guidelines opinion-based recommendations are for at least two measurements within the first 6 months after initiation of peritoneal dialysis and every 4 months thereafter.

- D. Serum intact PTH should be maintained at 2-5 times the upper limit of normal for the intact PTH assay.

#### **ANEMIA CONTROL**

- A. The target hematocrit should be 33-36% (Hemoglobin 11-12 g/dl) while the patient receives dialytic therapy.\*
- B. Patients requiring transfusion(s) should receive leukocyte reduced blood products.
- C. Erythropoietin should be used in conjunction with appropriate iron therapy.
- D. Sufficient iron should be administered to maintain a TSAT of >20% and a serum ferritin level of >100 ng/ml.\*

#### **SEIZURE CONTROL**

The patient should experience no loss of consciousness and/or seizures on hemodialysis. Consultation with a pediatric neurologist is indicated for de novo seizures or a change in pattern of occurrence.

#### **PATIENT/FAMILY EDUCATION**

Medical record indicates the patient and parent(s)/guardian(s) have received the following information. This may include verbal or written information within the first 3 months of treatment. Intermittent review should occur at least annually.

- A. Effects of ESRD and its treatment on the families of pediatric patients:
1. typical parental responses and special needs of parents
  2. potential marital stresses
  3. typical sibling reaction
  4. special needs of siblings
  5. available resources for family and marriage counseling and support groups
- B. All relevant issues related to care of the dialysis access.
- C. For home dialysis patients, education on proper procedure to perform treatments at home.
- D. Information on human sexuality and reproductive potential will be provided to patients entering puberty (Tanner stage  $\geq 2$  or  $\geq 11$  years) and their families. If appropriate, this

\* Evidence based NKF-KDOQI Guidelines.

group of patients may be referred to an Adolescent Medical Clinic and/or gynecological services for reproductive counseling/education.

- E. Signature of patients should be present on dialysis consent forms signed by parent/guardian as per policy of the institution.
- F. The medical record should reflect the team's assessment of the patient's school participation.

#### **TRANSPLANTATION AS A MODALITY OPTION**

- A. Patient/parent(s)/guardian(s) should be informed of transplantation as an option with documentation by a member of the transplant team (or designee) that patient/parent(s)/guardian(s) have received transplant information.
- B. Patients should be considered for a transplant by a member of the transplant team at the onset of ESRD and at least annually thereafter.

#### **INFECTION CONTROL**

- A. Pediatric patients have documented up-to-date immunizations including hepatitis B vaccine. All patients over 12 months of age with a negative Varicella titer should receive Varivax vaccine unless otherwise contraindicated.
- B. Routine testing upon initiation of treatment to include testing for Hepatitis B and C.
- C. HIV screening should be a standard component of the transplant evaluation.
- D. Annual PPD testing should be considered based on the presence of the identified risk factors.
- E. Immunization status should be reviewed annually.

#### **ARTICLES**

The Pediatric Subcommittee of ESRD Network 4, Inc. referenced the following articles:

- "Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report From the National High Blood Pressure Education Program". PEDIATRICS, VOL. 98, NO. 4, OCTOBER 1996, 649 - 658
- "Urea and Nitrogen Excretion in Pediatric Peritoneal Dialysis Patients". KIDNEY INTERNATIONAL, VOL. 58 (2000), 2564 – 2570.

## DAILY NUTRIENT AND FLUID RECOMMENDATIONS

Table 1: Daily Nutrient and Fluid Recommendations for the Child with ESRD - Predialysis

	Infant (0-1 y)	Toddler (1-3 y)	Child (4-10 y)	Adolescent (11-18 y)
Energy	0-0.5 y: ≥108 kcal/kg 0.5-1 y: ≥98 kcal/kg	102 kcal/kg	5-6 y: 90 kcal/kg 7-10 y: 70 kcal/kg	Girls 11-14 y: 47 kcal/kg Girls 15-18 y: 40 kcal/kg Boys 11-14 y: 55 kcal/kg Boys 15-18 y: 45 kcal/kg
Protein	0-0.5 y: 2.2 g/kg 0.5-1 y: 1.6 g/kg	1.2 g/kg	4-6 y: 1.2 g/kg 7-10 y: 1.0 g/kg	11-14 y: 1.0 g/kg 15-18 y: 0.9 g/kg
Sodium	Generally unrestricted; 1-3 mEq/kg if edma or HTN present	Generally unrestricted; 1-3 mEq/kg if edma or HTN present	Generally unrestricted; 1-3 mEq/kg if edma or HTN present	Generally unrestricted; 1-3 mEq/kg if edma or HTN present
Potassium	1-3 mEq/kg if needed (usually not until GFR is < 10% normal)	1-3 mEq/kg if needed (usually not until GFR is < 10% normal)	1-3 mEq/kg if needed (usually not until GFR is < 10% normal)	1-3 mEq/kg if needed (usually not until GFR is < 10% normal)
Calcium	0-0.5 y: 400 mg/day 0.5-1 y: 600 mg/day (provided hypercalcemia does not occur and calcium phosphorus product does not exceed 70)	800 mg/day (provided hypercalcemia does not occur and calcium phosphorus product does not exceed 70)	800 mg/day (provided hypercalcemia does not occur and calcium phosphorus product does not exceed 70)	1200 mg/day (provided hypercalcemia does not occur and calcium phosphorus product does not exceed 70)
Phosphorous	Use low-content formula if serum levels of phosphate are elevated; restrict high- content foods	Usually 600-800 mg/day when serum levels are elevated	Usually 600-800 mg/day when serum levels are elevated	Usually 600-800 mg/day when serum levels are elevated
Vitamins	1 ml multivitamin drops; vitamin D metabolite if needed, based on serum calcium, PTH and alkaline phosphatase levels	Multivitamin if needed; vitamin D metabolite if needed, based on serum calcium, PTH and alkaline phosphatase levels	Multivitamin if needed; vitamin D metabolite if needed, based on serum calcium, PTH and alkaline phosphatase levels	Multivitamin or just B complex + C if needed; vitamin D metabolite if needed, based on serum calcium, PTH and alkaline phosphatase levels
Trace Minerals	Supplement zinc, iron or copper if needed	Supplement zinc, iron or copper if needed	Supplement zinc, iron or copper if needed	Supplement zinc, iron or copper if needed
Fluid	Unrestricted unless needed; then replace insensible + urinary output	Unrestricted unless needed; then replace insensible + urinary output	Unrestricted unless needed; then replace insensible + urinary output	Unrestricted unless needed; then replace insensible + urinary output

y = year

HTN = hypertension

GFR = glomerular filtration rate

PTH = parathyroid hormone

Adapted from: Nelson P. Nutritional recommendations for infants, children and adolescents with ESRD. In: Stover J, ed. *A Clinical Guide to Nutrition Care in End-Stage Renal Disease*. 2nd ed. Chicago, Ill: The American Dietetic Association.

Table 2: Daily Nutrient and Fluid Recommendations for the Child with ESRD – Hemodialysis

	Infant (0-1 y)	Toddler (1-3 y)	Child (4-10 y)	Adolescent (11-18 y)
Energy	Same as for predialysis	Same as for predialysis	Same as for predialysis	Same as for predialysis
Protein	0-0.5 y:3.3 g/kg 0.5-1 y:2.4 g/kg	≥1.8 g/kg	4-6 y:≥1.8 g/kg 7-10 y:≥1.5 g/kg	≥1.3-1.5 y:0.9 g/kg
Sodium	1-3 mEq/kg if needed	Same as for predialysis	Same as for predialysis	Same as for predialysis
Potassium	1-3 mEq/kg if needed	Same as for predialysis	Same as for predialysis	Same as for predialysis
Calcium	Same as for predialysis	Same as for predialysis	Same as for predialysis	Same as for predialysis
Phosphorous	Same as for predialysis	600-800 mg/day	600-800 mg/day	600-800 mg/day
Vitamins	1 ml multivitamin drops; 1 mg folic acid and vitamin D metabolites (in most cases)	Multivitamin, 1 mg folic acid and vitamin D metabolites as needed	C and B-complex vitamin containing 1 mg folic acid, 10 mg pyridoxine 60 mg ascorbic acid, 5 mg pantothenic acid, 1.0 mg thiamin, 1.2 mg riboflavin; 3 µg B <sub>12</sub> , 300 µg biotin, 15 mg niacin; active form of vitamin D as needed	C and B-complex vitamin containing 1 mg folic acid, 10 mg pyridoxine 60 mg ascorbic acid, 10 mg pantothenic acid, 1.5 mg thiamin, 1.7 mg riboflavin; 6 µg B <sub>12</sub> , 300 µg biotin, 20 mg niacin; active form of vitamin D as needed
Trace Minerals	Supplement zinc or copper if needed. Iron is usually needed with recombinant erythropoietin	Supplement zinc or copper if needed. Iron is usually needed with recombinant erythropoietin	Supplement zinc or copper if needed. Iron is usually needed with recombinant erythropoietin	Supplement zinc or copper if needed. Iron is usually needed with recombinant erythropoietin
Fluid	Provide insensible + urinary output + ultrafiltration capacity (if possible)	Provide insensible + urinary output	Provide insensible + urinary output	Provide insensible + urinary output

y = year

Adapted from: Nelson P. Nutritional recommendations for infants, children and adolescents with ESRD. In: Stover J, ed. *A Clinical Guide to Nutrition Care in End-Stage Renal Disease*. 2nd ed. Chicago, Ill: The American Dietetic Association.

Table 3: Daily Nutrient and Fluid Recommendations for the Child with ESRD – Peritoneal Dialysis

	Infant (0-1 y)	Toddler (1-3 y)	Child (4-10 y)	Adolescent (11-18 y)
Energy	Same as for predialysis	Same as for predialysis	Same as for predialysis	Same as for predialysis
Protein	2.5-4.0 g/kg	2.0-2.5 g/kg	2.0-2.5 g/kg	1.5 g/kg
Sodium	Same as for predialysis	Same as for predialysis	Same as for predialysis	Same as for predialysis
Potassium	Same as for predialysis	Same as for predialysis	Same as for predialysis	Same as for predialysis
Calcium	Same as for predialysis	Same as for predialysis	Same as for predialysis	Same as for predialysis
Phosphorous	Save as for predialysis	Same as for hemodialysis	Same as for hemodialysis	Same as for hemodialysis
Vitamins	Same as for hemodialysis	Same as for hemodialysis	Same as for hemodialysis	Same as for hemodialysis
Trace Minerals	Same as for hemodialysis	Same as for hemodialysis	Same as for hemodialysis	Same as for hemodialysis
Fluid	Same as for hemodialysis	Unrestricted unless needed	Unrestricted unless needed	Unrestricted unless needed

y = year

Adapted from: Nelson P. Nutritional recommendations for infants, children and adolescents with ESRD. In: Stover J, ed. *A Clinical Guide to Nutrition Care in End-State Renal Disease*. 2nd ed. Chicago, Ill: The American Dietetic Association.

Table 4: Daily Nutrient and Fluid Recommendations for the Child with ESRD – Transplant

	Infant (0-1 y)	Toddler (1-3 y)	Child (4-10 y)	Adolescent (11-18 y)
Energy	Same as for predialysis after ideal weight/length is achieved	Same as for predialysis after ideal weight/length is achieved	Same as for predialysis after ideal weight/length is achieved	Same as for predialysis after ideal weight/length is achieved
Protein	Usually 3 g/kg initially; RDA after approximately 3 mo	Usually 2-3 g/kg initially; RDA after approximately 3 mo	2-3 g/kg initially; RDA after approximately 3 mo	2 g/kg initially; RDA after approximately 3 mo
Sodium	1.3 mEq/kg initially	1/2 g/day initially; unrestricted when HTN and edema no longer present	Usually 2-3 g/day initially; unrestricted when HTN and edema no longer present	Usually 2-4 g/day initially; unrestricted when HTN and edema no longer present
Potassium	Unrestricted unless needed	Unrestricted unless needed	Unrestricted unless needed	Unrestricted unless needed
Calcium	Ad lib; supplement if necessary to RDA	Ad lib; supplement if necessary to RDA	Ad lib; supplement if necessary to RDA	Ad lib; supplement if necessary to RDA
Phosphorous	May need very high intakes; supplement as necessary	May need very high intakes; supplement as necessary	May need very high intakes; supplement as necessary	May need very high intakes; supplement as necessary
Vitamins	Usually not necessary unless severely malnourished prior to transplant; vitamin D as needed	Usually not necessary; vitamin D as needed	Usually not necessary; vitamin D as needed	Usually not necessary; vitamin D as needed
Trace Minerals	Generally unnecessary; supplement iron as needed	Generally unnecessary; supplement iron as needed	Generally unnecessary; supplement iron as needed	Generally unnecessary; supplement iron as needed
Fluid	Ad lib	Ad lib	Ad lib	Ad lib

y = year  
HTN = hypertension

Adapted from: Nelson P. Nutritional recommendations for infants, children and adolescents with ESRD. In: Stover J, ed. *A Clinical Guide to Nutrition Care in End-Stage Renal Disease*. 2nd ed. Chicago, Ill: The American Dietetic Association.

## TANNER STAGES OF DEVELOPMENT OF SECONDARY SEXUAL CHARACTERISTICS

### Boys – Development of External Genitalia

- Stage 1: Prepubertal
- Stage 2: Enlargement of scrotum and testes; scrotum skin reddens and changes in texture
- Stage 3: Enlargement of penis (length at first); further growth of testes
- Stage 4: Increased size of penis with growth in breadth and development of glands; testes and scrotum larger, scrotum skin darker
- Stage 5: Adult genitalia

### Girls – Breast Development

- Stage 1: Prepubertal
- Stage 2: Breast bud stage with elevation of breast and papilla, enlargement of areola
- Stage 3: Further enlargement of breast and areola; no separation of their contour
- Stage 4: Areola and papilla form a secondary mound above level of breast
- Stage 5: Mature stage: projection of papilla only, related to recession of areola

### Boys and Girls – Pubic Hair

- Stage 1: Prepubertal (can see velus hair similar to abdominal wall)
- Stage 2: Sparse growth of long, slightly pigmented hair, straight or curled, at base of penis or along labia
- Stage 3: Darker, coarser and more curled hair, spreading sparsely over junction of pubes
- Stage 4: Hair adult in type, but covering smaller area than in adult, no spread to medial surface of thighs
- Stage 5: Adult in type and quantity, with horizontal distribution (“feminine”)

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# **Independent Submission of Quality Improvement Materials**

*Recommendations for the Ethical Conduct  
of Quality Improvement*

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*A Report by the National Ethics Committee  
of the Veterans Health Administration*

*May 2002*

*National Center for Ethics in Health Care  
Veterans Health Administration  
Department of Veterans Affairs*

Founded in 1986, the National Ethics Committee (NEC) of the Veterans Health Administration (VHA) is an interdisciplinary group authorized by the Under Secretary for Health through the National Center for Ethics in Health Care. The NEC produces reports on timely topics that are of significant concern to practicing health care professionals. Each report describes an ethical issue, summarizes its historical context, discusses its relevance to VHA, reviews current controversies, and outlines practical recommendations. Previous reports have been useful to VHA professionals as resources for educational programs, guides for patient care practices, and catalysts for health policy reform. Scholarly yet practical, these reports are intended to heighten awareness of ethical issues and to improve the quality of health care, both within and beyond VHA.

## **Executive Summary**

The Veterans Health Administration (VHA) is a national leader in quality improvement (QI). QI activity is essential and has brought tremendous benefits for patients. Yet, while widely accepted ethical standards exist for other activities in the clinical arena, including medical treatment and research, no analogous ethical standards currently exist for QI.

This report by VHA's National Ethics Committee (NEC) is a preliminary attempt to fill this gap by providing practical recommendations for the responsible conduct of QI. The following guidelines are intended to balance the ethical imperative to adequately protect patients and the ethical imperative to continuously improve patient care:

- 1) Health care organizations should recognize that QI cannot always be meaningfully differentiated from other activities that occur in the clinical arena, notably treatment and research.
- 2) Health care organizations should ensure that the rights and interests of patients involved in all health care activities – including QI – are adequately protected.
- 3) Health care organizations should take care that efforts designed to protect patients do not unnecessarily encumber the QI process.
- 4) Health care organizations should clearly define the locus of responsibility for the ethical conduct of QI.
- 5) Health care organizations should proactively promote the ethical conduct of QI.
- 6) QI activities should produce benefits that outweigh their potential burdens or risks.
- 7) QI activities should respect each patient's right to self-determination.
- 8) QI activities should preserve patients' privacy and confidentiality.
- 9) QI activities should be distributed fairly across patient groups.
- 10) Health care organizations should develop specific policies and procedures that fit their unique circumstances and needs.

These recommendations are intended as a starting point for discussion and elaboration of standards for the ethical conduct of QI. Further discussion will be needed within health care organizations, between and among organizations, and at the societal level to assure that all patients receive the ethical treatment they deserve.

## Introduction

In the last few decades, QI activities have assumed increasing importance and influence in health care. While there is no single definition of QI that is widely agreed upon, QI activities are generally understood to be cycles of action, linked to assessment, whose goal is to improve the process, outcomes, and efficiency of health care services.<sup>1-3</sup> Health care quality is now routinely assessed through customer satisfaction surveys, clinical performance measures, and analyses of patient databases. But quality assessment does not always translate to QI – for QI to occur, the information produced by quality assessment must be translated into systematic improvements in health care practices. A wide range of approaches has been used to promote improvement. These include educational interventions, performance incentives, regulatory and policy requirements, and information technologies such as automated alerts to provide feedback to providers. When linked with the ongoing assessment of quality, such approaches have been lauded as highly effective in improving the quality of care.<sup>3-6</sup>

The basic principles of health care ethics are well established and include respect for autonomy, beneficence, non-maleficence, and justice.<sup>7</sup> More specific ethical standards relating to medical treatment are described in a variety of sources including codes of ethics, professional guidelines, consensus statements, published scholarly literature, and organizational policies. Ethical standards relating to research are also described in, for example, the Belmont Report, reports from the National Bioethics Advisory Commission (NBAC), and federal regulations.<sup>8,9</sup> In contrast, ethical standards for QI have not been clearly or thoroughly articulated.<sup>10</sup> For example, how do the ethical standards for treatment or research, such as those pertaining to confidentiality and informed consent, apply to QI activities? The answer is far from clear.

This report by the VHA's NEC is a preliminary attempt to fill this gap by providing practical recommendations for the responsible conduct of QI. VHA is a leader in QI and, as the largest integrated health care system in the U.S., maintains many complex databases and information management systems and conducts innumerable QI activities.<sup>4</sup> Offices are devoted to QI at every level of the organization: facility, network, and national. Ethical challenges pertaining to QI are therefore of considerable interest to VHA and its NEC. Such challenges are by no means limited to the VA system, however. The considerations raised in this report are relevant to all health care organizations that rely on QI activities to improve patient care.

## Recommendations for the Ethical Conduct of QI

To provide guidance regarding the responsible conduct of QI activities, VHA's NEC offers the following recommendations:

### ***Recommendation #1: Health care organizations should recognize that QI cannot always be meaningfully differentiated from other activities that occur in the clinical arena, notably treatment and research.***

While the field of QI is progressing rapidly, the concept of QI is constantly evolving and the dividing line between QI and other activities is not always clear. Although most activities can be easily categorized either as QI or not QI, some activities can be more difficult to categorize. At times, for example, it may be difficult to distinguish between QI and research.<sup>11-15</sup> In 45 CFR 46 (the "Common Rule"), research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."<sup>9</sup> Although elegant in its simplicity, this definition is

problematic in several respects. First, the definition is tautological in that the word “research” is contained in the definition itself. Second, it is not clear when knowledge should be considered “generalizable.” A recent attempt by the Department of Health and Human Services (DHHS) to address this question gives no clear-cut answer:

We understand knowledge to be generalizable when it can be applied to either a population inside or outside of the population served by the covered entity. Therefore, knowledge may be “generalizable” even if a research study uses only the protected health information held within a covered entity, and the results are generalizable only to the population served by the covered entity.<sup>16</sup>

Another problem with the Common Rule definition of research is that it hinges on the purpose for which the activity was designed (i.e., the investigator’s intent). But intent may be difficult to define, even for the investigator.<sup>13</sup> Moreover, projects may be intended for more than one purpose. For example, a single project may be designed both to improve health care operations in a particular setting as well as to produce knowledge that can be applied in other settings. DHHS regulations have attempted to clarify this issue by classifying QI activities as health care operations (rather than research) “provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities.”<sup>16</sup> When the primary purpose of an activity changes over time, such as when a QI project unexpectedly yields results that are worthy of publication and therefore generalizable, Institutional Review Board (IRB) review should be performed as soon as it is recognized that an activity meets the definition of research.

A variety of other criteria to clarify the distinction between QI and research have also been proposed. These include whether the clinician-patient relationship is disrupted, whether an activity requires specific recruitment, whether the patients involved in an activity directly benefit from the knowledge to be gained, and whether additional risks are imposed in order to make the results generalizable.<sup>13,17,18</sup> In addition, as stated by NBAC, a key distinction is whether the program in question is new or already established:

If the purpose is to assess the success of an established program, and the information gained from the evaluation will be used to improve that program, the activity should not be considered research involving human participants. Evaluation is a program monitoring tool, and the information gained will immediately benefit the program and/or the individuals involved. However, when quality improvement involving human participants is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is human participant research and subject to the oversight system.<sup>19</sup>

While all of these criteria are plausible, no clear consensus has yet developed on how to distinguish QI from research. Furthermore, some activities – such as demonstration projects or program evaluations – may not be “pure” examples of either QI or research but rather a “hybrid” of the two. This problem was aptly summarized in a recent report by the Institute of Medicine:

As an applied field of study, Health Services Research (HSR) is closely related to nonresearch investigations that are directed toward assessing and improving the

quality of operations in health care organizations. Indeed, HSR and health care operations form two ends of a continuous spectrum. Some HSR projects are clear examples of research; applying scientific methods to test hypotheses and produce new, generalizable knowledge. Other projects are certainly clear examples of internal exercises to assess the quality of the operations of the specific organization with no intention of producing generalizable knowledge. Many of these quality assessment or quality improvement (QA or QI) exercises are never intended to have any application beyond the specific unit within the organization that carries out the operation. In fact, many projects may start out as operations assessment and then become more like research, and many research projects involve doing very much what would be done in an internal operations assessment. As a result, for many projects, it is difficult to decide whether they are more like research, or more like QA or QI.<sup>20</sup>

As with the distinction between QI and research, the distinction between QI and treatment is not always clear. For example, it is a common practice in medicine for physicians to try therapies or administer drugs in a manner that differs from generally accepted practice standards.<sup>19</sup> Presumably, physicians also monitor the outcomes of these activities, at least informally, in an effort to improve care. When should such activities be considered QI as opposed to treatment?

DHHS defines treatment as follows:

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to the other.<sup>16</sup>

QI, on the other hand, is one of several activities included within DHHS's definition of "health care operations," as distinguished from treatment and research:

Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.<sup>16</sup>

DHHS further explains, "Treatment refers to activities undertaken on behalf of a single patient, not a population." Therefore, when a physician administers a therapy with the intent of improving care for that patient alone, the activity should be considered treatment; but if the physician administers the same therapy as part of a larger activity that is designed to improve care for a population of patients, the activity should be considered QI. This distinction may not be particularly helpful, however, since many activities are intended to improve care for individual patients and for a population. Just as projects can be "hybrids" between QI and research, so too can projects be "hybrids" between QI and treatment.

Although some activities are clear-cut examples of either treatment, QI, or research, some activities cannot be so easily categorized. To the extent that QI differs from research and treatment, the ethical frameworks that have been developed for these other areas may not be applicable to QI. This report presents a new framework for thinking about the ethical conduct of QI.

***Recommendation #2: Health care organizations should ensure that the rights and interests of patients involved in all health care activities – including QI – are adequately protected.***

In the United States, as in other countries, a range of specific safeguards protects patients in the clinical setting. For example, physicians and other health care professionals have a widely recognized fiduciary duty to promote the interests of their patients. Professional ethics standards also require health care providers to protect patient confidentiality and assure informed consent. Clinical behaviors are routinely scrutinized by peer review and other oversight mechanisms. Licensing standards, accreditation requirements, and statutory and case law further protects patients' interests. Health care providers who violate professional, regulatory, or legal standards are subject to a variety of sanctions and disciplinary actions.

Similarly, various government regulations, organizational policies, and professional guidelines have been developed to protect patients involved in human subjects research.<sup>21-23</sup> For example, federal law requires that, except for carefully-defined exceptions, research at organizations that receive federal funding for research be reviewed by IRBs. This review must assure that informed consent is obtained from each subject, if appropriate, and that research risks are reasonable in comparison to expected benefits, and that subjects are selected equitably.<sup>9</sup>

In contrast, there are no equivalent procedures to protect the rights and welfare of patients in QI activities. Yet there are at least four reasons why patients involved in QI activities may warrant special protections. First, the lack of a clear-cut distinction between QI and research paired with the absence of clear ethical standards for the conduct of QI provide a powerful incentive for investigators to “game” the existing system of protections by designating projects as QI rather than as research.<sup>13</sup> By doing so, they can avoid many of the time-consuming processes of research review, including stringent requirements for informed consent.<sup>9</sup> Until parallel standards are developed for QI, there will be a strong motivation to circumvent the system of research protections in favor of the more permissive environment of QI. For example, in one QI project, investigators initiated a program of preoperative ultrasound screening in an attempt to prevent preoperative blood clots, but later discontinued the program when it proved ineffective.<sup>24</sup> Some would argue that this project, approved as QI, was actually research and should have been reviewed as such. Although the prevalence of this problem is not known, several other examples of research-like projects that have been labeled QI – and many more projects that are neither clearly QI nor clearly research – have come to the attention of the NEC.

Second, while QI is essential to good patient care and has brought tremendous benefits, QI activities are not entirely without potential burdens or risks to the patients involved. For example, psychosocial or financial harm can result from improper disclosure of personally identifiable information from databases. Patients may be inconvenienced by data collection efforts. Embarrassment or resentment can result from being asked to address personal or sensitive topics in questionnaires. The actual frequency and severity of the potential burdens

or risks associated with QI is completely unknown, however, because QI projects are rarely tracked and reported in a systematic fashion.

Third, QI projects can create potential conflicts of obligation. Whereas treatment activities are primarily designed to enhance the well-being of an individual patient,<sup>19</sup> QI activities are primarily designed to improve the process, outcomes, and efficiency of health care services. When health care providers are involved in QI activities, they may face conflicts between their obligations to each individual patient and their obligations to all patients cared for by the system. For instance, a QI project might call for functional assessments to be performed on all patients in a new intensive case management program after one, three, and six months. Though such assessments may seem harmless, they are not entirely without risk. For patients who do not have paid medical leave from their jobs, the extra time required to complete these assessments might have a significant financial impact. For mental health patients with paranoia or obsessive thinking, repeated assessments could conceivably exacerbate these problems. Under such circumstances, physicians participating in the QI project would need to weigh their obligations to the individual patient against their obligations to improve care for all patients through QI.

Fourth, patients involved in QI may not always be able to protect their own interests. Patients may assume, incorrectly, that everything done to them in the clinical setting is intended to benefit them and them alone. Or patients who are dependent on the health care system for their care may feel compelled to do whatever is asked of them for fear that they may jeopardize the care they receive. In this sense, patients involved in QI projects could be unwittingly used as means toward an end.

Finally, most health care professionals have easy access to patients and patient records, but not all are trained in QI principles and methods. While ongoing QI efforts are encouraged, some QI activities may be poorly designed and unlikely to yield useful results, in which case not even minor burdens to patients can be justified. These concerns may be amplified as health care organizations offer financial rewards for involvement in QI activities.<sup>24</sup>

Thus, activities that are determined to be QI (as opposed to research or treatment) are not immune from ethical concerns about protecting patients. Instead of focusing on the distinction between QI and other activities, health care organizations should focus on assuring that the rights and interests of all patients are adequately protected, including those involved in QI. This report contains specific suggestions for how patient protections can be assured.

***Recommendation #3: Health care organizations should take care that efforts designed to protect patients do not unnecessarily encumber the QI process.***

Care should be taken to minimize any detrimental effects on an organization's QI activities that may arise from pursuing other objectives, such as expanding patient protections. Indeed, health care professionals and organizations have an ethical obligation to monitor and improve the quality of care they provide.<sup>25</sup> By ensuring that health care providers adhere to standards of care, and by making efforts to minimize deviations from standards, an organization is taking important steps to safeguard the well being of its patients. Therefore, efforts to protect individual patients should take into account the potential consequences of impeding ongoing improvements in overall patient care.

***Recommendation #4: Health care organizations should clearly define the locus of responsibility for the ethical conduct of QI.***

The effectiveness of protections for patients involved in a QI activity depends upon the identification of a person or group who is responsible for the ethical conduct of a particular activity. For research activities, this person is the principal investigator; in medical practice it is most often the attending physician. For QI projects, however, the responsible person is not always clear. Indeed, QI activities may be conducted across organizations or units of service, and may be the product of collaboration between clinical and administrative personnel. Nevertheless, it is important to identify the individual who is ultimately accountable for the appropriate conduct of a given QI project, and who has the authority to assure that applicable ethical standards are followed.

In addition to the need to define a locus of responsibility for individual QI projects, there is also a need to define an administrative locus of responsibility for all QI activities that take place within a health care organization or an organizational subunit. QI is not an activity performed by an individual acting in isolation, but by a group of individuals acting on behalf of an organization. Furthermore, to be effective QI must have organizational support: specifically, it must involve individuals with the authority to impose corrective action in response to assessment results.<sup>25</sup> Organizations should have one or more designated QI program office, standing committee, or other administrative entity that has specific responsibility for QI oversight.

***Recommendation #5: Health care organizations should proactively promote the ethical conduct of QI.***

As a matter of good management, organizations should not wait for problems to arise, but rather promote the ethical conduct of QI proactively using a systematic approach. This approach should include educating individuals about relevant policy, tracking QI projects, handling questions and complaints, assessing adherence to requirements, and instituting corrective action when necessary. Responsibility for promoting the ethical conduct of QI should normally rest with the same administrative entity that oversees other aspects of QI.

For all QI activities, consideration should be given to potential ethical concerns before an activity is performed. The level of scrutiny should correspond to the potential burdens and risks of the QI activity: activities that involve greater burdens or risks require more thorough scrutiny. For those that involve minimal burdens or risks beyond those inherent to the clinical encounter itself (e.g., projects involving only retrospective or concurrent review of existing clinical data, routine patient satisfaction surveys, or educational interventions designed to promote evidence-based practices), a brief conversation between the QI activity leader and the office that oversees QI may be sufficient for that office to exercise its obligation to assure that ethical issues have been adequately addressed. But for other types of QI activities (e.g., those involving evaluation of an innovative clinical program or service, collection of new data from patients other than by routine satisfaction surveys, or systematic assignment of interventions) a formal review process may be appropriate. Whenever burdens or risks are substantial enough to warrant formal review, and whenever there is an expectation of results worthy of publication, it is prudent to consider whether the QI activity contains one or more components that meet the definition of research found in the Common Rule and therefore require IRB review.

Who should conduct a formal review, if necessary? Possibilities include an interdisciplinary group convened specifically for this purpose; a preexisting group outside the QI office but within the organizational unit, such as an ethics committee; or a group outside

the organizational unit, such as a multi-site review committee. In any case, the group should include individuals familiar with QI methods and those familiar with ethical standards, but should not include individuals involved in the QI project under review.

***Recommendation #6: QI activities should produce benefits that outweigh their potential burdens or risks.***

In QI, as in treatment and research, it is unacceptable to impose even relatively minor burdens on patients unless a project can reasonably be expected to be valuable.<sup>26</sup> Therefore, QI projects should be well designed and the measures they use should be reliable and valid. To increase the likelihood of benefit, QI projects should be conducted by well-supervised personnel with adequate training or access to consultative advice.

In addition, efforts should be made to anticipate and minimize even minor harms to patients that could result from QI activities. For any given QI project, potential inconveniences or other burdens to individual patients should be justifiable when weighed against the expected benefits to be gained, including benefits to participating patients, future patients, or the health care organization. Because the goal of QI is to improve the process, outcomes, and efficiency of health care services, the benefits of a QI project should be considered in relation to that goal.

***Recommendation #7: QI activities should respect each patient's right to self-determination.***

A patient's right to self-determination is well established in law<sup>27-29</sup> and ethics.<sup>30,31</sup> Respect for patient autonomy can be of important instrumental value, in that the effects of a medical intervention on a patient's well-being are dependent in part on that patient's specific values and preferences. In addition, autonomy has inherent value apart from its consequences. Because the ability to make moral choices is uniquely human, respect for human beings implies respect for their moral choices.

The right to have one's health care choices respected deserves the same consideration in QI as it receives in treatment or research. Although informed consent is the standard process by which respect for patient choices is ensured,<sup>30,32,33</sup> an exhaustive informed consent process is not always practical. In practice, many minor treatments or procedures (such as splinting a broken finger or drawing blood for routine tests) are made on the basis of "presumed consent" or after only a cursory informed consent discussion.<sup>34</sup> Furthermore, only a minority of treatments or procedures requires signature consent.<sup>35</sup> In research, too, there are accepted circumstances under which the requirement of informed consent is waived entirely, or for which verbal consent but not signature consent is required.<sup>9</sup>

In general, the thoroughness of the informed consent process should be proportionate to the potential burdens or risks associated with the intervention. For instance, in clinical practice, physicians typically explain potential burdens in greater detail as the risks of a test or treatment increase.<sup>34</sup> Similarly, in research, standards are codified in federal regulations in which the need for written documentation of informed consent depends upon the study's risks.<sup>9</sup>

In most cases, informed consent for a specific QI project is not required. Instead, "general" or "blanket" consent to QI activities (as might occur during a patient's admission to an inpatient facility) is generally sufficient for QI activities that pose no significant burdens or risks beyond those the patient would otherwise experience. On the other hand, when activities require the patient's cooperation (as in, for example, a customer satisfaction survey), patients should be informed that their participation in the activity is optional and

that refusal to participate will not jeopardize their care. In addition, explicit informed consent is necessary whenever a QI activity involves significant burdens or risks. In some cases, consent may not be a reasonable option (e.g., a QI project in which attempts at cardiopulmonary resuscitation are videotaped). For such cases, formal provisions should be made for proxy consent or waivers of consent, just as they are in clinical care and research.<sup>9,36</sup>

***Recommendation #8: QI activities should preserve patients' privacy and confidentiality.***

In both research and treatment, demonstrating respect for patients' privacy and confidentiality is essential. In research, investigators often use codes to identify individuals, and may de-link these identifiers to protect the privacy of individual patients. These strategies offer important protections. Indeed, federal regulations that determine the need for research review<sup>9</sup> are tied to the extent to which data can be recorded anonymously. Similarly strict requirements exist in the treatment setting. Perhaps the best known of these are in the requirements for certification by the Joint Commission on Accreditation of Healthcare Organizations.<sup>37</sup> In addition, DHHS's Final HIPAA Privacy Rule requires specific privacy protections for medical treatment, health care operations, and research.<sup>16</sup>

To assure that privacy is protected and confidentiality maintained, all QI activities should be conducted within the context of a health care setting in which accepted clinical standards for privacy and confidentiality are upheld. QI activities are an integral part of the health care organization's activities, and as a result the systems and protection that support privacy and confidentiality standards for clinical practice must be present. For example, access to confidential patient information should occur on a "need to know" basis and information should generally be stripped of patient identifiers before it is exported.

To fully assure adequate privacy and confidentiality protections, the individual responsible for the QI project should take several additional steps. Staff members with access to QI data should receive formal training regarding their organization's privacy and confidentiality policies and should agree as a matter of record to respect these policies. The organization might also maintain systems – such as an audit trail of access to information – to monitor and trace breaches of confidentiality. Finally, data analysis should make use of anonymous, or "de-linked," data whenever possible. Where this is not possible, QI activities should identify patients by codes to limit potential breaches of confidentiality. In both linked and de-linked databases, data privacy officers may be very helpful; for example, they can ensure that the codes for linked data are maintained securely and that de-linked data are rendered anonymous before they are released.<sup>13,38,39</sup>

***Recommendation #9: QI activities should be fairly distributed across patient groups.***

Fairness is a central principle of the ethical conduct of research, and of the ethical practice of clinical medicine.<sup>8</sup> In research, fairness includes equal access to the potential benefits of research, and equal exposure to its burdens.<sup>8,40</sup> In clinical care, fairness requires that patients have equitable access to medical services and are not treated in a discriminatory fashion.

In QI activities, justice suggests two requirements. First, the potential burdens or risks of any QI activity should be distributed fairly across the population under study. For instance, risks of a loss of confidentiality, or burdens of surveys or questionnaires, should not be borne disproportionately by a single group, unless that group would also be expected to disproportionately benefit from the QI activity. Second, the potential benefits of a QI

activity should be distributed fairly. For instance, an intervention designed to improve cardiac care should be implemented across a broad cross section of cardiac patients for whom the results would be relevant.

***Recommendation #10: Health care organizations should develop specific policies and procedures that fit their unique circumstances and needs.***

Beyond the general recommendations above, this report will not suggest any specific policies or procedures for assuring the ethical conduct of QI. Before a particular approach can be recommended, a variety of approaches should be tried and their results compared. Moreover, we are not convinced that there is one best solution for all health care organizations or even for all of VHA. A policy developed for a large tertiary care medical center might be wholly inappropriate for a community clinic or nursing home. Similarly, a policy developed for a setting in which QI includes large-scale, methodologically rigorous data collection efforts might not make sense for another setting in which QI includes only small-scale Plan-Do-Study-Act cycles. For these reasons, we recommend that health care organizations use the general guidance provided in this report to develop their own unique policies and procedures that are appropriate to the types of QI activities they perform.

**Conclusion**

The distinction between QI, research, and clinical care has never been clear, and is evolving over time. Nonetheless, QI activities, like research and treatment activities, may raise ethical concerns. Health care organizations need to assure that patients involved in all of these activities are adequately protected.

This report has proposed a set of recommendations that can guide health care organizations in developing such protections. It is important to note, however, that these recommendations are not proposed changes to federal regulations and do not affect current VA policy. Instead, these recommendations are intended to provide guidance for the responsible conduct of QI activities, which is currently lacking.

Therefore, these recommendations are intended as a starting point for the protection of patients involved in QI activities. However, focused discussion will be needed at several levels. First, further discussion is needed within health care organizations to translate these general recommendations into specific policy guidance. Second, discussion must take place between and among organizations, to ensure that the protections function well and to develop consistency and ensure fairness. Finally, discussion is needed at the societal level to assure that all patients – and not just veterans – receive the ethical treatment they deserve.

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## Water Treatment for Hemodialysis

Paul M. Palevsky, M.D.

The quality of the water used for preparation of dialysate and reprocessing of hemodialyzers is a critical issue for patients receiving hemodialysis. Failure of the water treatment process can result in chemical and/or bacterial contamination of the water supply that can result in severe complications, including patient death. The average individual without kidney disease has a water intake of ~2 liters per day, for a weekly exposure of ~14 L/week. In contrast, hemodialysis patients are exposed to > 360 L of water per week. In addition to the increased magnitude of water exposure, there is a greater risk from contaminants due to the non-selective barrier provided by the dialysis membrane as compared to the GI tract.

### A. Potential toxicity of contaminants

Sign or Symptom	Possible Contaminant
Anemia	Al, Cu, Zn, Chloramines
Bone Disease	Al, F
Hemolysis	Cu, Chloramines, Nitrates
Hypertension	Ca, Na
Hypotension	Bacteria, Endotoxin, Nitrates
Metabolic Acidosis	Low pH, Sulfates
Muscle Weakness	Ca, Mg
Nausea and Vomiting	Bacteria, Ca, Cu, Endotoxin, Low pH, Mg, Nitrates, Sulfates, Zn
Encephalopathy	Al

### B. AAMI Water Quality Standards

Chemical Standards			
Contaminant	AAMI Standard	EPA Drinking Water Standard	Level Associated with Toxicity in Dialysis
Aluminum	0.01 mg/L		0.06 mg/L
Antimony	0.006 mg/L	0.006 mg/L	
Arsenic	0.005 mg/L	0.01 mg/L	
Barium	0.10 mg/L	2 mg/L	
Beryllium	0.0004 mg/L	0.004 mg/L	
Cadmium	0.001 mg/L	0.005 mg/L	
Calcium	2 mg/L (0.1 mEq/L)		
Chloramines	0.10 mg/L		0.25 mg/L
Chlorine	0.50 mg/L		
Copper	0.10 mg/L		0.49 mg/L
Chromium	0.014 mg/L	0.10 mg/L	
Fluoride	0.20 mg/L		1.0 mg/L

Lead	0.005 mg/L	0.015 mg/L	
Magnesium	4 mg/L (0.3 mEq/L)		
Mercury	0.0002 mg/L	0.002 mg/L	
Nitrate	2.0 mg/L		21 mg/L
Potassium	8 mg/L (0.2 mEq/L)		
Selenium	0.09 mg/L	0.05 mg/L	
Silver	0.005 mg/L	0.10 mg/L	
Sodium	70 mg/L (3.0 mEq/L)		
Sulfate	100 mg/L		200 mg/L
Thallium	0.002 mg/L		0.002 mg/L
Zinc	0.10 mg/L		0.20 mg/L

	Bacteriologic Standards	
	AAMI Limit	Action Level
Bacteria		
Water	< 200 cfu/mL	> 50 cfu/mL
Dialysate	< 2,000 cfu/mL	
Concentrate	< 200 cfu/mL	> 50 cfu/mL
Endotoxin		
Water	< 2 EU/mL	> 1 EU/mL

### C. Methods of Water Treatment

1. Carbon adsorption
  - a. Purpose
    - removal of chlorine and chloramines
    - removal of organic contaminants
  - b. Configuration
    - two tanks in series
    - granulated activated carbon media (iodine rating of at least 900)
    - empty bed contact time (EBCT) of 5 minutes/tank (Total: 10 minutes minimum)
  - c. Monitoring
    - test for total chlorine or both free chlorine and chloramines between 1<sup>st</sup> and 2<sup>nd</sup> tank, each shift
2. Reverse osmosis
  - a. Water purification by placing hydrostatic pressure across a semipermeable membrane
  - b. Purified water is forced across membrane (product water)
  - c. Solutes concentrated in “rejected” water
  - d. Percent rejection is a measure of function of RO system
    - 100% x [1- (Product H<sub>2</sub>O conductivity/Source H<sub>2</sub>O conductivity)]

3. Ion Exchange
  - a. resin exchanges ionic species bound with lower affinity for a solute in the feed water that is bound with higher affinity
  - b. Sodium-Calcium exchange
    - water softener
    - required pre-RO to prevent fouling of RO membrane
    - monitor with hardness test
  - c. Mixed-bed ion exchanger
    - exchanges anions for OH<sup>-</sup> and cations for H<sup>+</sup>
    - deionization provides high chemical purity
    - may be source of bacterial contamination
    - configuration should consist of one or more manifolds of two tanks in series
    - continuous temperature-adjusted resistivity or conductivity monitoring
      - > 1 megaOhm-cm at 25°C
      - < 1 microsiemen/cm at 25°C
  
4. Bacteriologic Purification
  - a. Water distribution system
    - continuous loop
    - direct feed
    - indirect feed with holding tank
    - no branch points or dead-end runs
    - flow velocity of 1.5 – 5.0 ft/sec
  - b. submicron filtration
    - RO
    - ultrafilter
  - c. UV irradiation
    - kill bacteria but may raise endotoxin levels

#### D. Monitoring

Monitor	Frequency	Action Level
Chemical Analysis	Monthly to annually	AAMI Standards
Bacteriologic Analysis	Monthly	< 50 cfu/mL
Endotoxin	Monthly	<1 EU/mL
Chloramines/Free Chlorine	Each shift	< 0.5/0.1 ppm
RO Percent rejection	Each shift	variable
DI Resistivity	Continuous	> 1 megaOhm-cm

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