2020

Inpatient Dialysis Medical Director Toolkit

Developed by the Forum of ESRD Networks' Medical Advisory Council (MAC)

This Toolkit is a reference tool that provides information about the care of patients with kidney failure in the hospital setting.

Tell us what you think!
Please take a moment to complete a short questionnaire about this Toolkit. We appreciate your insight and suggestions to make our resources better.
https://www.surveymonkey.com/r/ForumResEval

THE NATIONAL FORUM OF ESRD NETWORKS

Forum Medical Advisory Council (MAC)
The Forum of ESRD Networks
06/30/2020

This publication is the product of a workgroup under the auspices of the Forum of ESRD Networks, Inc., a non-profit organization of volunteers dedicated to improving the quality of care to patients with end stage renal disease (ESRD). This toolkit was conceived of and sponsored by the Forum of ESRD Networks' Medical Advisory Council (MAC). The toolkit committee was a multidisciplinary group of volunteers who generously contributed their time and expertise to this effort. The Forum would like to acknowledge the hard work of these individuals.

COMMITTEE MEMBER AUTHORS

David Henner, DO — Committee Chair
Berkshire Medical Center
Pittsfield, Massachusetts
ESRD Network 1

Anil Agarwal, MD, FASN, FACP, FNFK, FASDIN
University Hospital East, Ohio State University
Columbus, Ohio
ESRD Network 9

Kamyar Kalantar-Zadeh, MD, MPH, PhD
Univ. of California Irvine, School of Medicine
Orange, California
ESRD Network 18

Laura I. Rankin, MD, FACP
Kidney Specialists of Central Oklahoma
Oklahoma City, Oklahoma
ESRD Network 13

Harmeet Singh, MD, FASN, FACP
Western Nephrology
Arvada, Colorado
ESRD Network 15

Lorrie Strassel, RN, BSN
OSU Wexner Medical Center
Columbus, OH

PEER REVIEWERS

Robert J. Kenney, MD
Baton Rouge, Louisiana
ESRD Network 13

Keith C. Norris, MD, PhD
UCLA David Geffen School of Medicine
Los Angeles, California
ESRD Network 3

Louis Raymond, MD
Regional Health Medical Clinic
Rapid City, South Dakota
ESRD Network 11

EDITORS

Ralph Atkinson III, MD
Nephrology Associates, P.C.
Nashville, Tennessee
ESRD Network 8

David Henner, DO
Berkshire Medical Center
Pittsfield, Massachusetts
ESRD Network 1

Donald Molony, MD
University of Texas Medical School
Houston, Texas
ESRD Network 14

Kamyar Kalantar-Zadeh, MD, MPH, PhD
Univ. of California Irvine, School of Medicine
Orange, California
ESRD Network 18

This toolkit was formatted by Forum Coordinator Dee LeDuc. (2020)

This Toolkit is a guide, created by experienced professionals using the available evidence, produced by the Medical Advisory Council (MAC) of the Forum of ESRD Networks. The MAC anticipates revisions and additions to the Toolkit over time. The Toolkit is meant as a resource and should not be referenced as a regulatory statement. As with other MAC Toolkits this document is meant to help guide medical directors in meeting their obligations.

Table of Contents

Table 1. comparison between inpatient and outpatient dialysis medical director status

	Inpatient Dialysis Medical Director	**Outpatient Dialysis Medical Director**
Reporting Status and Accountability	Usually reports to CMO of the medical center	Reports to CMS with dotted reporting to the dialysis provider/owner
Immediate Oversight	The Medical Center has the immediate oversight	ESRD Networks Regional/County Dept. Health State Depts. Health
Ultimate Oversight	The Joint Commission (TJC), usually periodic surveillance (unannounced), State authorities in some states	CMS via the Condition of Coverage
Accreditation	Not defined	Across several areas: 1. CMS 2. State licensing (as indicated) 3. Certificate of need (as needed)
Biomed and Infection Control	Infection Control Department of the hospital interacts with the biomedical staff (or may report to the engineering department)	Biomedical staff report to Medical Director
Financial Compensation	Medical directorship fee based on contractual and administrative agreement with the Medical Center	Medical directorship fee according to contract with the dialysis provider
Administrative FTE	Equivalent of 0.1 to 0.25 FTE based on the volume	Equivalent of 0.25 FTE or higher
Outsourced Dialysis Provider	If outsourced, the staff under the outsourcing entity also reports to the medical director	Hospital owned or independent outpatient dialysis centers may have certain services outsourced including management services
In-center vs. Home Modalities	Usually one single medical director	There may be separate medical directors for different modalities

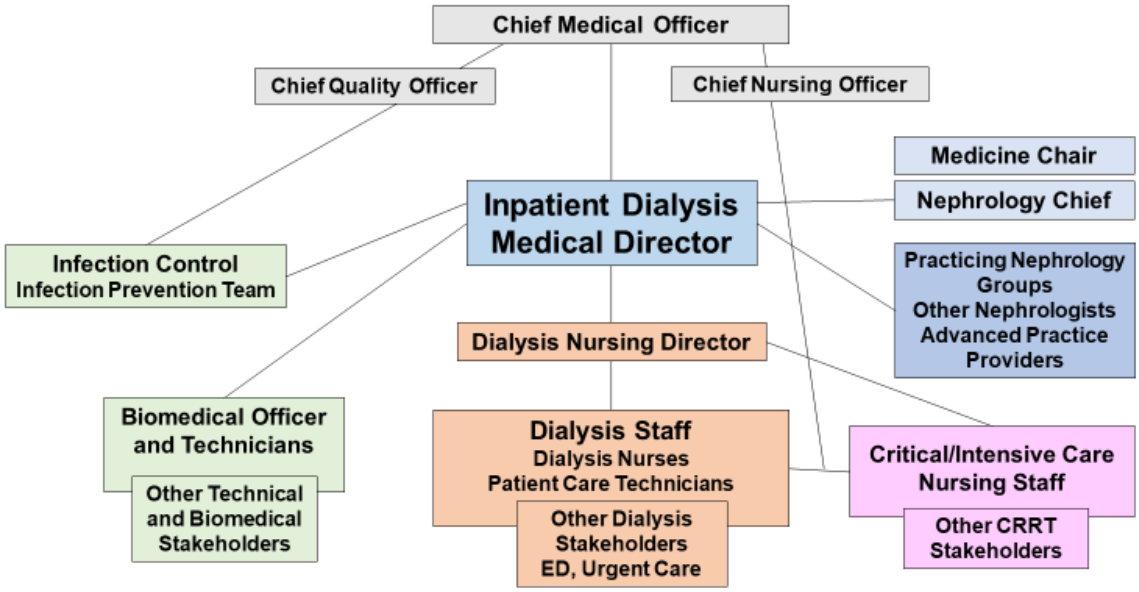

Figure 1. Organization chart and accountability hierarchy constellation related to the Inpatient Dialysis Medical Director

Introduction

Authors: Anil Agarwal, MD, FASN, FACP, FNKF, FASDIN; Harmeet Singh, MD, FASN, FACP

The CMS Conditions for Coverage (CfC) for End Stage Renal Disease (ESRD) Facilities and accompanying Interpretive Guidance (Part 494) require that any outpatient dialysis facility (independent or hospital-based) must have a Medical Director to oversee clinic quality and operations of the facility. The rationale for this seems intuitive given the complexity of dialysis therapies administered at an outpatient facility. However, there is no guideline about Medical Director oversight of Extracorporeal therapies performed in a hospital setting. Extracorporeal treatments are performed in the hospital setting in a variety of clinical scenarios including dialysis treatments for ESRD patients who are acutely ill, patients with acute kidney injury and/or congestive heart failure, and patients with poisoning. These diagnoses are associated with high acuity in both ICU and non-ICU setting. Additionally, unique to the inpatient setting therapeutic plasma exchange (TPE) is also performed for a variety of renal and nonrenal complex diagnoses. In addition to conventional hemodialysis, continuous renal replacement therapies, Sustained Low Efficiency Dialysis (SLED), and peritoneal dialysis are also performed on hospitalized patients. There are many other forms of extracorporeal treatments including but not limited to Extracorporeal Membrane Oxygenation (ECMO), pheresis etc. that are outside the scope of this toolkit.

Given the complexity and variety of extracorporeal treatments and high acuity of the patient populations undergoing these treatments in the hospitalized setting, it is important that there is a Medical Director overseeing clinical quality and operations of extracorporeal treatments in the hospital.

The Inpatient Dialysis Medical Director role should be assigned to a nephrologist as they are the most qualified clinician to perform this role, due to their training and experience. A key aspect of the Inpatient Dialysis Medical Director role, distinct from their role in a dialysis outpatient facility, is the interface with hospital quality control infrastructure which includes, but is not limited to infection control, hospital quality and process improvement programs, ICU quality programs, hospital biomedical equipment maintenance program, and pharmacy and therapeutics programs. The medical director needs to ensure compliance with applicable requirements for the accreditation of the medical center.

TPE programs at many hospitals are overseen by blood bank, hematology, or other organizational professionals and not under the purview of nephrologists; therefore, these hospital TPE programs are excluded from Medical Directorship activities as described herein.

According to the CMS Interpretive Guidance for ESRD CfC V711, the medical director of an outpatient dialysis facility should devote enough time to fulfill the responsibilities described. CMS considers that position to reflect a 0.25 FTE (full time employee). Based on the complex nature of the Inpatient Dialysis Medical Director role, the Inpatient Dialysis Medical Director should be at least a 0.1 FTE for smaller volume programs, whereas in larger medical centers 0.25 FTE position is more appropriate.

Chapter 1: Qualifications of Medical Director of Inpatient Dialysis

Authors: David Henner, DO; Harmeet Singh, MD, FASN, FACP

Similar to the qualifications described by CMS Interpretive Guidance for ESRD CfC V682, the inpatient dialysis medical director must be a physician, in internal medicine or pediatrics, who has completed a board-approved training program in nephrology (at least a 2 year nephrology fellowship), qualified as a board certified/eligible in nephrology and has at least 12 months of experience providing care to patients receiving dialysis in addition to the accredited fellowship training. Since a nephrologist does not need to maintain certification in internal medicine or general pediatrics to recertify in nephrology or pediatric nephrology, the medical director may maintain current certification in nephrology, pediatric nephrology, internal medicine, or general pediatrics. The medical director, in addition to the expected nephrology expertise, is preferred to have leadership skills and basic knowledge in data interpretation/performance as well as quality improvement, quality control and quality assurance.

Given that the role requires interfacing with hospital and interdisciplinary staff, ideally, the inpatient dialysis medical director should be a member of the active medical staff at the hospital.

Chapter 2: Design of Dialysis Unit

Authors: Kamyar Kalantar-Zadeh, MD, MPH, PhD

Whereas hospitals and medical centers have diverse and unique structural and building-technical constellations and compliance requirements, it is recommended that one-on-one ratio of dialysis providing staff (e.g. dialysis nurse, who is usually a registered nurse with established dialysis care experience, see Section 5 below) to patient be adhered during all hemodialysis therapies for less stable patients including those with hemodynamic instability or other acute conditions. For more stable patients such as dialysis patients who are electively admitted without more severe acute issues, a dialysis treatment dedicated space – often known as "Inpatient Dialysis Unit", "Dialysis Space" or "Acute Dialysis Room", amongst others – can be structured to accommodate up to 2 to 4 concurrent treatments, per team of dialysis staff, as long as there are at least 2 dialysis nurses or one nurse and one patient care technician (PCT) per each group of up to 4 concurrent dialysis treatments, and as long as patients can be safely transported to and from the Acute Room. The Inpatient Dialysis Medical Director is required to have reviewed and approved the Dialysis Space and its requirements initially and on an annual basis.

Telemetry monitoring is not a required condition for the Acute Dialysis Space. The dedicated Dialysis Space may use portable Reverse Osmosis (RO) machines, or it may be equipped with installed sets of RO and water processing infrastructures like an outpatient dialysis unit and in compliance with the internal hospital codes and other regulatory requirements (see Chapter 6 on Water Systems). However, an Acute Dialysis Room within the hospital building may not be used to provide regularly scheduled outpatient dialysis therapy unless it is certified as such to meet the CMS required Condition of Coverage. (See memo on the Forum of ESRD Networks website for more information on providing outpatient dialysis in hospital under certain circumstances.

https://esrdnetworks.org/resources/newsletters/forum-press-releases/medicare-billing-for-outpatient-dialysis-in-the-hospital-setting-4-10-19/view

For patients in the Emergency Department (ED) who may require dialysis therapy and who have been triaged as such but not yet fully admitted as an inpatient, the hospital based dialysis resources including Acute Dialysis Space can be used as long as the Inpatient Dialysis Medical Director has reviewed and approved such practices such as Urgent Care Walk-In Dialysis and as long as dialysis orders are placed by a BE/BC nephrologist, nephrology PA/NA or nephrology fellow (see Chapter 3).

Continuous Renal Replacement Therapy (CRRT) may only be performed in the critical or intensive care units with required monitors and under direct oversight of a trained critical care nurse who has the needed training and track record of CRRT (see Chapter 3 for Recommended Staff Metrics). However, it is recommended that at least once a day, a CRRT specialized dialysis nurse should review and approve or adjust CRRT, and daily CRRT orders must be entered by a BE/BC nephrologist, nephrology Advanced Practice Provider (APP) (see Chapter 3), or nephrology fellow (see Chapter 3).

Peritoneal dialysis may be performed at bedside in the patient's room. Automated (cycler) PD is generally set up by a dialysis nurse. In some cases, manual CAPD or automated PD can be performed by hospital nurse, as long as the hospital nurse has undergone formal training including skills assessment and periodic retraining. There should be a formal PD training program with lectures, hands on skills assessments and periodic in services with documentation of staff competencies as with other dialysis programs in the

hospital. Some hospitals will also permit PD patients that are stable to perform their own PD, as long as the patient has undergone appropriate home dialysis education and has had several months of track record of performing home therapies successfully and uneventfully, e.g. a home dialysis patient who is admitted to the hospital electively with no acute medical problem. At least once a day, a nurse who has completed an approved training program in providing home dialysis therapies must review and approve or adjust the PD performed in the hospital, and daily PD orders must be entered by a BE/BC nephrologist, nephrology APP (see Chapter 3), or nephrology fellow (see Chapter 3).

Chapter 3: Recommended Staff Metrics

Authors: Laura Rankin, MD, FACP; Lorrie Strassel, RN, BSN

Inpatient Dialysis Nurse Manager

It is strongly suggested that the nurse manager, with required RN with current license and suggested BSN, have at minimum two years of dialysis experience, the majority of which should be in a direct patient care role in the hospital setting. It is also strongly suggested that the nurse manager have at least one year in a management position in either a dialysis unit or a hospital ward. Leadership and interpersonal communication skills are essential. Other characteristics desired include experience with development and monitoring of fiscal state of the dialysis unit, staff management and evaluation, protocol development and oversight, personnel development, knowledge of CMS and regulatory guidelines, experience with Joint Commission standards and surveys, and knowledge of dialysis specific quality improvement guidelines.

Dialysis Nurse

Staff are licensed RNs , with a minimum of 1 year of nursing experience, who have completed a structured orientation program including: a baseline understanding of comorbid conditions and their effect on renal failure in hospitalized and critical care patients; clinical manifestations of renal failure; objectives of treatment and nursing management; mechanics of dialysis; diagnostic evaluation; emergency interventions and treatment; dietary management; family and patient psychological support, treatment modality options for chronic renal failure including hemodialysis, peritoneal dialysis and transplantation, and the option to not treat (Hospice). Proficiency with placement of needles into fistula and grafts, and with the use of catheters, is mandatory for completion of the initial training period. We recommend that all PCTs and LPNs work under the supervision of a Dialysis Nurse in hospital according to hospital requirements and state regulations.

A background in ICU nursing, hospital nursing, or chronic dialysis is preferred but not required. Ongoing monthly education modules are recommended, with required annual competency skills check offs for machine management and water room monitoring and intervention. RN's with at least two years of clinical experience are strongly encouraged to become certified in either Nephrology Nursing or hemodialysis nursing examination and maintain certification for the duration of their employment in the acute room.

The training period should be customized to the nurse's previous experience, offering basic nursing care/medical-surgical training to those without hospital or acute setting experience. Nurses being trained in hemodialysis for the first time should complete a minimum of 6-8 weeks of orientation before taking an assignment independently. In the period immediately following the end of orientation for a nurse new to dialysis, competency with management of two patients and a support nurse or technician in the same unit should be established prior to assignment of ICU patients.

For the nurse with previous dialysis experience, the training period remains supervised, but the duration can be tailored to the demonstration of competency and judgment of the precepting nurse, with the input and approval from the nurse manager.

Once competency has been demonstrated, the nurse can move on to providing unsupervised treatment of ICU patients during regular operating hours when the resource of another nurse or technician is available. On call shifts during the hours the unit is closed and for emergency cases should not be assigned until the RN has consistently demonstrated safe and competent dialysis care for a minimum of one month.

In inpatient dialysis programs, the dialysis nurse should be competent in all aspects of acute nursing and provide for the patient's medical needs (routine blood sugar measurements, incontinent care and toileting, communication with all members of the patient's health care team, telemetry monitoring, performance of additional testing such as drawing labs or performing an EKG, administration of IV/PO/IM medications-either scheduled or PRN, emptying of lines/drains/tubes, assessment and administration of emergency interventions as necessary). For programs which contract out dialysis care, the hospital and contract company should reach a mutual agreement regarding the amount and type of nursing care provided by the hemodialysis nurse or technician during treatment.

Dialysis Patient Care Technician (PCT)

The role of a dialysis technician in the hospital is more supervised than that of the PCT in the outpatient setting. Roles and responsibilities vary from state to state and may vary between facilities as well.

For technicians who are allowed to participate in the performance of the dialysis procedure according to state laws, the dialysis technician must have completed training sufficient to demonstrate proficiency with the machine, to have proficiency with placing needles in a fistula or graft, and must have demonstrated the ability to monitor patients safely while on dialysis. Training about dialysis emergencies must have also been completed. Prior experience with dialysis as a PCT is required, as the acute patient population setting is not recommended for the training of dialysis technicians. Dialysis technicians performing dialysis treatment in the hospital setting must do so under the direct supervision of a registered nurse trained in dialysis. They should not perform unsupervised treatments on patients in the ICU setting or cover on call shifts during the hours the dialysis unit is closed for emergency cases. Dialysis technicians performing direct dialysis care need to be certified and accredited according to the laws of the state they practice in.

For acute dialysis units who utilize technicians NOT performing direct dialysis care, roles and responsibilities must be clearly defined by the management, making sure that the technician is not performing duties which require certain certifications of the state in which they are located. The dialysis unit may have different support personnel, such as non-patient care technicians, whose responsibilities include removing lines and dialyzers from the machine, disinfection of machines and in the patient care area as allowed per local regulations, and movement or relocation of the machinery. They can also assist with transportation of patients in and out of the dialysis unit, and delivery of equipment and/or supplies to nurses performing treatments in the ICU. If the unit does not have non patient care support staff, these responsibilities defer to the dialysis technicians and RNs.

Other personnel required for the functioning of the inpatient hemodialysis unit are at the discretion of the facility in which the acute dialysis unit is located. These titles and/or responsibilities may include secretary, administrative assistant, transportation, supplies technician, water technician, etc.

Standards of Care and Patient Assignments

In the acute hospital setting, ratios of staff to patients should be based clinically on the overall patients' condition and acuity. In addition, any local or state staffing requirements must be adhered to (i.e. in Massachusetts there is minimum requirement of 1 direct patient care staff/3 patients on dialysis). Critically ill patients on dialysis in the Critical Care Units (CCU) should always have direct patient care staff at bedside while on dialysis. When a RN is working with a technician, the number of patients in their assignment will be defined by the nurse manager or charge nurse and based on the level of care needed during dialysis. Specific factors affecting this decision may include whether or not the nurse is hospital based (full nursing care required during dialysis), the presence or absence of telemetry monitoring, the level of care the dialysis unit is deemed, the level of experience of the staff involved, and the overall acuity or medical condition of the patient(s) involved.

Telemetry monitoring should be considered for appropriate patients receiving dialysis in the hospital setting. Hematocrit monitoring, or similar technology should also be considered, especially if unable to obtain accurate weight of patient on dialysis. For all patients, regardless of whether they are in the acute dialysis unit or the ICU, the connections and sites of the hemodialysis access should always remain uncovered and visible for the duration of the dialysis treatment.

A qualified and fully trained dialysis staff member, either a PCT or RN must be within sight of a patient receiving dialysis, at all times.

For patients on suicide precautions, or those with a sitter behavioral problems and/or dementia, the sitter must remain with the patient for the duration of the dialysis treatment and be instructed on the risk of needle dislodgment or hemorrhage due to the accidental disconnection of the dialysis circuit.

Patients on isolation precautions should be cared for in the same manner they would be in their hospital room. Personal Protective Equipment (PPE) must be changed, and hand hygiene performed between all patients receiving dialysis.

Hepatitis B Surface Antigen positive patients must be cared for in an isolated location, away from other patients and by a nurse or technician who has been vaccinated and demonstrated antibody immunity. A staff caring for the Hep B patient must only care for Hep B-immune patients afterwards the same day. For Hep B patients, dedicated machine must be used for dialysis, and the machine must be isolated after use on the Hep B patient. For further details on Hepatitis B isolation of dialysis patients in hospital setting please see Chapter 11 on Infection Control. Other care guidelines should be followed according to the recommendations of the CDC and CMS.

Peritoneal Dialysis

Nurses involved with peritoneal dialysis must be RNs, who have completed an approved training program with the technique, machinery being used, connections, complications including infections, and machine malfunctions, and with sufficient experience to be able to see patients and know when to call the physicians. An annual competency training program is highly recommended, as well as a dedicated unit or staff to care for peritoneal patients in the hospital. Nurses caring for peritoneal dialysis patients should have a physician or manufacturer resource to contact during nights or weekends to assist with any complications or questions.

Continuous and Extended Time Hemodialysis

Continuous Renal Replacement Therapy (CRRT) and/or extended time dialysis, such as Sustained Low Efficiency Dialysis (SLED) dialysis treatments may utilize portable machines, some of which contain an internal water treatment system, and others that do not require a water treatment system (i.e. preconfigured systems utilizing sterile solutions of dialysate).

Some hospitals assign the delivery of these modalities to the ICU nurses only. In these cases, the ICU nurse must have completed training in the operation of the machine, including troubleshooting. The Medical Director is ultimately responsible for approving the training program and assuring the training program is adequate. The nurse should have access to the manufacturer's 24/7 hotline, and a nephrologist should also be available to call with questions or problems. We also suggest oversight by a nurse manager to monitor the delivery of care and alert staff and the medical director to systemic problems with the procedure. Monitoring and tracking of any complications from the procedure should be recorded and reviewed as part of the inpatient dialysis QAPI program. These may include frequent instances of hemolysis, frequent access alarms, shortcuts in setting up the machine, problems with not recording data appropriately, complete clotting of the circuit without return of blood, and/or problems with interpretation of the orders by the nursing staff, resulting in calls or errors.

Additionally, there should be a hospital policy for dialysis catheter care, which the Medical Director should review and approve, that must be followed.

Some hospitals may utilize their hemodialysis staff to set up and take down continuous and extended time hemodialysis equipment and/or lines. These staff also make rounds in the ICU once or twice a day, and may be required to take call for troubleshooting, and the start or discontinuation of new patients to the modality. In these instances, the competency and educational requirements for the dialysis staff performing these tasks must be defined and managed by the dialysis manager and medical director. Staff performing these duties must be well trained on the machines in use, and familiar with complications of the therapy. The number of staff for the dialysis unit must be sufficient to support this expanded role to ensure that the patients requiring full hemodialysis treatments have sufficient nursing and/or technician time.

Chapter 4: Role of Other Providers

Authors: Kamyar Kalantar-Zadeh, MD, MPH, PhD

In addition to BE/BC nephrologists, nephrology Advanced Practice Providers (APP) including Nurse Practitioners (NP) or Physician Assistants (PA) may provide dialysis patient care including dialysis treatment orders as long as he/she remain under the supervision of a BE/BC nephrologist or a nephrology practice group with approved hospital privileges in good standing. The hospital privileges for the APPs are expected to meet the minimum requirements to perform as such in an outpatient dialysis center, including proof of adequate training in dialysis patient care and prior track record of experience in providing care to dialysis patients such as prior experience of rounding in outpatient dialysis units under the supervision of a nephrologist. The level of accountability and liability can be similar to that of outpatient dialysis care. The credentials and eligibility of APPs need to be reviewed and approved by the Inpatient Dialysis Medical Director in addition to other hospital privilege requirements. Non-nephrologists should not be certified to make changes in dialytic therapies (initiation, termination, changes in fluids or fluid removal rate), nor should their APPs be credentialed to do those modifications.

A privileged nephrology APP may supervise inpatient dialysis care and enter or revise dialysis orders including PD and HHD. The first CRRT order must be written and CRRT must be initiated only by a BE/BC nephrologist or nephrology fellow (see below); however, a nephrology PA or NP may change or adjust CRRT orders under the above conditions once CRRT has initiated and been running for at least 2 hours.

In medical centers with ACGME approved nephrology fellowship training programs, fellows in training may provide dialysis patient care including entering dialysis and CRRT treatment orders if this supervised practice is compliant with the ACGME and local GME requirements of the given medical enter or medical school. No other trainee other than a nephrology fellow may be engaged in dialysis therapy or CRRT orders. The Inpatient Dialysis Medical Director must review and approve the dialysis training and supervision portions of the training of each nephrology fellow on an annual basis in order for the fellow to be allowed to provide dialysis patient care and dialysis or CRRT orders.

The authors believe that neither dialysis, nor CRRT, should be ordered or supervised by a non-nephrology physician. A BE/BC critical care physician may order or adjust the order of a CRRT or dialysis treatment in a critical or intensive care unit, if he/she is additionally board certified or eligible in nephrology by meeting the ACGME eligibility requirements including the needed nephrology fellowship training, and is credentialed at that hospital.

Chapter 5: Equipment

Authors: Laura Rankin, MD, FACP

EQUIPMENT FOR HEMODIALYSIS

Many machines are on the market, and it is not the role of this document to dictate which one should be used. Most if not all available machines have the ability to change sodium, potassium, bicarbonate, and calcium, based upon the needs of the patient, either by changing the bath or by changing settings on the machine. The machine should similarly have the capability of changing the dialysate temperature within a narrow range, to potentially allow for hemodynamic improvement.

The machine chosen should be able to vary the blood flow (ranges in some machines may be as low as 100 ml/in to as high as 550-600 ml/min). The requirements would change for a hospital treating preterm babies to adolescents.

Standard with all machines should already be arterial and venous pressure monitoring, air detector, blood leak detector, and fluid removal rates. Although not a feature of older machines, the capability to monitor real-time dialysis effectiveness (Kt/V in some fashion) is a useful addition to some new machines. This feature should be a consideration in the purchase of new machines, though not a requirement. Similarly, some machines but not all have the capability to monitor how the blood volume is changing with fluid removal. Provided that the dialysis nurses and the nephrologists know how to interpret the information, and its accuracy, that feature may be helpful.

Most machines available now have the capability of automated monitoring of blood pressures. Depending on the patient's medical condition in the hospital, the frequency of those measurements may need to be more often than for outpatient dialysis treatments. More frequent blood pressures may also be set on all machines used in the hospital unit, as per policy approved by the Inpatient Dialysis Medical Director.

Maintenance of the machines, by standards and frequency defined by the manufacturer, and by personnel trained to be capable of that maintenance, is required. In addition, if a dialysis machine is not performing as expected, evaluation should be performed with testing more frequently.

Should there be any regenerative dialysate machines still in existence, it is important to remember that there are many intoxicants, including methanol and ethylene glycol, which are not removed with the regeneration. Therefore, these machines must not be used in the treatment of intoxications.

It is expected that available needles for cannulation will include 14-gauge, 15-gauge, and 16-gauge. The option for 17-gauge needles should be considered, especially in hospitals serving pediatric dialysis patients and/or frequent new start patients with fistula. Blunt needles should be available for patients who are using buttonholes, if that is a prevailing local/regional technique.

Tubing is standard for the machine in use. Again, for the pediatric hospital, smaller volume tubing is available.

The choice of dialyzer(s) is often dependent upon a) what dialyzers are used in the local/regional dialysis units, and b) what the cost may be with the hospital contract. The Inpatient Dialysis Medical Director should approve the dialyzers used in the hospital. In addition, availability of an alternative dialyzers should

be present, specifically for that patient with allergy to a given membrane. As with needles and tubing, smaller surface area and thus volume dialyzers are to be used with pediatric patients.

Water Treatment Equipment

If the dialysis machine being used requires external water treatment, then the options are to have a central water treatment area for a hospital dialysis unit of sufficient size, plus several portable units when the treatments must be in the ICU, ED or patient's room, or to have only portable water treatment units. Please see Chapter 6 on Water Systems for the central water treatment.

All portable water treatment machines, sometimes called portable RO's, must fulfill the same treatment standards to comply with current AAMI standards. Therefore, removal of particulate matter, water softener for removal of calcium and magnesium, carbon adsorption for removal of chloramines and chlorine, and reverse osmosis are with the units. Testing for adherence to the standards, and also periodic testing for bacteria with periodic testing, and endotoxin with LALs is required.

Dialysate Solutions (Bath) Options

The options for customizing the bath or dialysate are often more than in the outpatient unit. Given that patients may present to the emergency room with severe hyperkalemia, and some with hypercalcemia, the Inpatient Dialysis Medical Director should determine whether a lower potassium (1 K or 0 K) and/or lower Ca bath are to be stocked in the hospital.

The Inpatient Dialysis Medical Director may also consider whether all available solutions contain glucose, as frequently the blood sugar control is tighter than when the patient is at home, and also the patient is eating more at home, and not NPO.

EQUIPMENT FOR PERITONEAL DIALYSIS

The use of cyclers (or an "octopus" apparatus if still available) may be preferred over CAPD in the hospitalized patient, since the patient is ill and ward nurses are not trained in the procedure. The Inpatient Dialysis Medical Director should determine which procedure will be followed in the hospital.

There are several machines on the market. The choice of machine is partially made by the prevalence of use of a particular machine in the region, but also influenced by the company who may be providing the nursing support by contract. The Inpatient Dialysis Medical Director must approve the machine in use. The common cyclers may be similar, but familiarity with the machines must be a nursing requirement. It is not necessary for the patient or family to bring in the home cycler. However, the patient's clinic should be contacted for the details of their outpatient prescription. The inpatient nephrologist can then modify it as needed during the hospitalization.

Connection between one brand of cycler and another brand of connector set is sometimes impossible. Therefore, the nurse must be prepared to either change the connector set or must have an additional device that can allow for the connection to be made.

The hospital must recognize that the patient can only be in a private room, medical necessity.

The use of cyclers makes peritoneal dialysis much easier to accomplish. The cycler can be set up by the peritoneal dialysis nurse, with or without connection to the patient. The patient can make the connection later, if judged capable. The patient or nurse can start the programmed treatment later. Disconnection can be accomplished by the patient if capable, or by the peritoneal nurse, when the treatment ends or later.

Disinfection and maintenance are to be performed according to the manufacturer's guidelines, by personnel trained in those techniques.

The hospital should have available several dextrose concentrations of Peritoneal solutions i.e., 1.5%, 2.5% and 4.25%, in addition to icodextran for PD patients that are hospitalized. The hospital stock should be enough to be prepared for the maximum number of patients historically hospitalized, or the external availability to add more stock quickly. Local geography and weather changes should be considered as these may sometimes impede quick delivery of solution stock.

EQUIPMENT FOR CRRT AND OTHER EXTENDED FORMS OF HEMODIALYSIS

As with other modalities, several machines are on the market. Many machines are capable of performing sustained low efficiency dialysis (SLED), while some can also be used for continuous 24-hour therapy (CVVH, CVVHD, CVVHDF, etc..). Options include a regular dialysis machine with software that allows slower blood flow and much slower dialysate flow (limited to SCUF, CVVHD, and SLED and requires an RO), a machine that has its own water purification system (limited to SCUF, CVVHD, or SLED), machines with scale-based monitoring of fluid input and removal (all forms of therapy) and a machine with volumetric monitoring of fluid input and removal (SCUF, CVVH, and CVVHD). The local choice of the machine to be used is related to options thought to be needed, who will be operating the machines, pricing of machines and disposable, etc. It is beyond the scope of this document to discuss otherwise. The Inpatient Dialysis Medical Director is ultimately responsible for determining which machines are used locally, and which modalities are to be used.

The machines are usually compatible only with their brand of tubing, which may or may not come with attached dialyzer. If choices exist, there are sometimes different membranes available, so that the advantages and disadvantages of a set of membranes should be available to the ordering nephrologist.

Generally, there are few meaningful differences in the operation of the machines. An exception is that some machines have a blood leak detector that senses a difference in color, while others sense a difference in how a light beam passes through the effluent. That difference generates different ways to verify whether a blood leak has occurred.

Some machines are capable of monitoring the effectiveness of the treatment (ml/kg/hour); others are not. Some have the availability of small volume blood lines and filters, for the pediatric hospitalized patient.

Fluids for the performance of the therapies are commercially available. These are generally less expensive for the hospital to use, since otherwise the pharmacy is mixing large quantities of fluids, purchasing large volume bags, and potentially having errors in mixing (e.g., the physician or pharmacy neglecting addition of $NaHCO_3$ or calcium). Some of the commercially available fluids are distributed as only for use as

dialysate, while others are certified as infusion grade and so can be used as either dialysate or replacement fluid. Saline, half normal saline, saline with bicarbonate, calcium containing solutions, etc, may also be used in the performance of CRRT.

Anticoagulants may be prescribed for performance of CRRT. Heparin and citrate have been used. Both require careful monitoring, but the use of citrate is more complicated, due to the possibilities of citrate intoxication and both hypercalcemia and hypocalcemia. Order sets must address the intricacies of these anticoagulants and their management. In addition, for traditional hemodialysis machines, and other machines capable of performing SLED, isolated UF, etc. which utilize traditional acid concentrate, citrate containing acid concentrate can be used to minimize risk of bleeding from heparin and minimize risk of clotting. When changing acid concentrate, it is critical that the Medical Director is aware of the total base contained in the final dialysate concentration, and any adjustments to dialysis orders that may be needed to minimize the risk of metabolic alkalosis. Ultimately, the Inpatient Dialysis Medical Director is responsible for determining local policies related to anticoagulation and dialysis solutions used.

Chapter 6: Water Systems for Inpatient Dialysis Unit

Authors: Anil Agarwal, MD, FASN, FACP, FNKF, FASDIN; David Henner, DO; Laura Rankin, MD, FACP

Water treatment is the most important component of the dialysis process, since water makes up approximately 94% of the volume of standard dialysate. Dialysis patients are exposed to very large quantities of water while on dialysis (at least 360 liters or about 90 gallons of water/week given Qd 500 ml/min and 4-hour treatments 3x/week). Therefore, extreme care is required to verify that the patient is not exposed to hazardous substances in the water. Additionally, dialysis patients are immunocompromised, so exposure to bacteria, viruses, and endotoxins in the water must be eliminated and carefully monitored. In addition, chemicals used in municipal water treatment (such as chloramines) increase the risk of hemolysis and death in dialysis patients. Dialysis patients who are sick enough to be hospitalized are amongst the most vulnerable dialysis patients to all of these risks. The importance of the hospital dialysis water treatment cannot be minimized or overlooked. It is the responsibility of the Inpatient Dialysis Medical Director to approve and oversee the water treatment system and ensure that the risk of exposure of harm to dialysis patients dialyzed in hospital is minimized.

The CMS Conditions for Coverage (CfC) Interpretive Guidance (1) and the incorporated ANSI/AAMI RD52:2004 "Dialysate for Hemodialysis" (2), which specify regulations for water treatment in ESRD Dialysis facilities must also be adhered to in hospitals. In 2011, ANSI/AAMI/ISO 23500 "Guidance for the preparation and quality management of fluids for hemodialysis and related therapies" was released with updated standards that have not been incorporated into the CMS Conditions for Coverage to date.

The Joint Commission has identified dialysis as a high-risk area and will focus on dialysis during their surveys. One area of dialysis that the Joint Commission will focus is water treatment, including water and dialysate testing.

Configuration of Water Systems

Similar to ESRD outpatient dialysis facilities, a hospital dialysis water treatment system usually will contain pre-water treatment components including blend valves, back-flow preventers, and booster pumps; pretreatment including sediment filter and carbon filters; water treatment including reverse osmosis (RO) or de-ionization (DI); and a water storage and distribution loop.

If preconfigured hemodialysis systems are used, according to CMS Conditions for Coverage, the system must be FDA-approved, tested and validated to yield AAMI quality water and dialysate. The system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. According to CMS Interpretive Guidance, in preconfigured hemodialysis systems that incorporate water treatment systems, chemical analysis of product water must be done at least annually (at end of use of disposable components). Chemical analysis may need to be repeated if any repairs are done to the system which can impact the water quality. Chlorine/chloramine levels must also be tested prior to each patient treatment as per AAMI guidance and manufacturer's recommendations.

Water Safety

Often the hospital will defer to the dialysis company contracted to the hospital to provide dialysis for their patients. However regular review of those purity reports should be part of the role of the inpatient dialysis medical director and the nurse manager of the dialysis company. These reports, including routinely obtained culture results, should be readily available for review by state Health Department or The Joint Commission surveyors. These analyses should include (but not limited to):

- aluminum
- chloramine and chloride
- fluoride
- copper, zinc, and other heavy metals
- bacterial cultures and endotoxins

These are collectively defined and regulated by the Association for the Advancement of Medical Instrumentation (AAMI) standards as above.

These long accepted and standard purification standards, updated periodically, include:

- pretreatment removal of sediment and temperature adjustment
- water softener for removal of calcium and magnesium
- carbon adsorption to remove chloramines and chlorine, which can cause hemolysis in the patient and also damage the reverse osmosis membrane.
- reverse osmosis, removing metals, silt, inorganic and organic chemicals, and microbial elements including bacteria, endotoxins, and viruses.

Deionization (DI) may also be a part of the process, removing cations and ions. DI does not remove uncharged contaminants, microcystins from harmful algae bloom, bacteria or endotoxins. In fact, the deionizer beds provide a good environment for bacterial proliferation. Therefore, it is always required that an endotoxin retentive filter be present after DI is used. The resistivity of DI product water must be carefully monitored and recorded at least 2x/day, as ions can be released back into the water once the resin is exhausted. Further purification or alternate methods, especially for bacterial colonization prevention, should meet AAMI standards. Daily monitoring for effectiveness of water softener, removal of chloramine, and reverse osmosis are required, as in the outpatient CfC and CMS Interpretive Guidance for ESRD outpatient dialysis units. Chlorine and chloramine testing must be performed prior to each treatment done at the bedside, and at least every shift or 4 hours if no shifts in an inpatient dialysis unit. The same actions that are described in the ESRD CfC and accompanying Interpretive Guidance apply to inpatient dialysis. The Inpatient Dialysis Medical Director is responsible for making sure these guidelines are followed in the hospital.

Sampling of water from water treatment systems and dialysate from machines for microbial testing for cultures and endotoxins must be performed at least monthly, and more often if needed based on any actionable results. Any new water treatment system must be sampled weekly for a month initially, and then at least monthly. Each traditional dialysis machine must be sampled at least once a year, and at least 2 machines must be tested monthly. Preconfigured machines with built in water treatment systems or utilizing sterile solutions should be tested according to manufacturer recommendations. Disinfection procedures of machines and water loops should be performed monthly, or more frequently if cultures or Limulus Amebocyte Lysate (LAL) assays for bacterial endotoxins are positive. The Inpatient Dialysis

Medical Director should review the results of all microbial tests performed on dialysis machines and water treatment systems and is responsible for determining appropriate action if any actionable levels are present. The results should be reviewed at monthly QAPI meeting.

Portable Water Systems

Hospital dialysis units with more than two patient slots usually contain the same components as ESRD facilities as referenced above. However, many hospital dialysis units contain smaller treatment rooms with smaller water treatment rooms or no water treatments, and many hospital dialysis facilities treat some or all patients in their own rooms. In these common situations, portable systems are used, which often include connections to tap water and water drainage in the patient's room. These portable systems generally contain a water softener, carbon filtration, reverse osmosis, and point of use ultrafiltration. These portable systems are designed to be used in the same area as dialysis patient care and need to be supervised by dialysis staff when in use. The same standards, monitoring, and reviews of daily monitoring for safety are still applicable in these portable systems, including chloramine testing and documentation before each treatment. These portable systems also contain special microbial needs as these systems may not always be used continuously, and downtime of these systems can lead to bacterial proliferation. Therefore, at minimum monthly cultures and endotoxin testing, as well as disinfection of all portable systems must also performed.

According to the CMS Interpretive Guidance, bicarbonate and acid concentrates must be used or discarded within manufacturer's timetables. It is expected that all concentrates will be obtained from commercial sources, under their own regulatory control.

More information on water treatment systems in dialysis facilities can be found in the Forum of ESRD Networks Medical Advisory Council (MAC) Outpatient Medical Director Toolkit chapter on Water treatment. This chapter covers all of the major components of dialysis water treatment systems and the CMS regulations and AAMI guidelines.

https://esrdnetworks.org/toolkits/professional-toolkits/medical-director-toolkit

1. CMS Conditions for Coverage for ESRD Facilities, and CMS Interpretive Guidance (2008) Association for the Advancement of Medical Instruments (AAMI) RD52 standards (2004): "Dialysate for Hemodialysis".
2. UpToDate.com Water purification systems in hemodialysis. Includes dialysis units, portable systems, home hemodialysis.
3. Kasparek T and Rodriguez O: What Medical Directors Need to Know about Dialysis Facility Water Management. Clin J Am Soc Nephrology doi:10.2215, CJN.11851214
4. Coulliette AD and Arduino MJ: Hemodialysis and Water Quality. Semin Dial. 2013:26(4): 427-438. doi:10.1111/sdi.12113

Chapter 7: Dialysis Modalities

Authors: Harmeet Singh, MD, FASN, FACP

CONTINUOUS RENAL REPLACEMENT THERAPY (CRRT)

Continuous renal replacement therapy is an established modality for treatment of renal failure in the ICU setting. It allows solute and fluid removal in critically ill patients with shock who may also have high fluid intake requirements due to nutritional needs and various intravenous medications. Furthermore, due to gentle solute removal and ultrafiltration it is the preferred therapy for brain injury patients at risk of cerebral edema and ischemia.

Modalities

- CVVH: continuous venovenous hemofiltration
- CVVHD: continuous venovenous hemodialysis
- CVVHDF: continuous venovenous hemodiafiltration
- SCUF: slow continuous ultrafiltration

Who should oversee CRRT?

Nephrologists are most qualified to implement and oversee CRRT programs due to their training and experience and should be the Medical Directors of such programs. We recognize the key role of critical care physicians and nurses in management of patients on CRRT. Hence, the management of the patients on CRRT requires a collaborative approach.

Managing and/or Implementing a CRRT Program

CRRT is performed in critically ill patients in ICU who are comanaged by a multidisciplinary team which includes but is not limited to nephrologist, intensivist, surgeon, nurse, pharmacist, dieticians, etc. CRRT therapies are administered generally by dialysis nurses but increasingly by ICU nurses. Thus, for a successful CRRT program there should be collaboration between various stakeholders

Stakeholders

In addition to the Medical Director, other key stakeholders in a CRRT program include dialysis nurses, PCTs, ICU nurses, intensivists, pharmacists, nutritionists and CRRT equipment manufacturers, and biomedical technicians.

Training

Dialysis nurses and ICU nurses are key personnel in administering CRRT as they are involved in initial setup, re-setup, troubleshooting, and administering this therapy. Typically, CRRT is set up by dialysis nurses and administered by ICU nurses so there should be clear delineation of nursing responsibilities between ICU and dialysis with regards to set up, initiation, monitoring, troubleshooting, etc. In some hospitals, the ICU nurse may be trained to perform all aspects of CRRT without a dialysis nurse involved. Ultimately, the Inpatient Dialysis Medical Director should decide which model the hospital will use, and the Medical Director is also responsible for determining the appropriate training needed for any nurse performing CRRT.

There should be a formal training program for CRRT with lectures, hands on skills assessments and periodic in services with documentation of staff competencies as with other dialysis programs in the hospital. CRRT equipment manufacturers have a depth of resources including manuals, videos etc. that can assist in staff training. Pharmacists have an important role in the CRRT program given the variety of CRRT solutions some of which may be custom solutions (e.g. citrate anticoagulation) as well as altered pharmacokinetics of CRRT affecting drug dosing especially ensuring adequate antibiotic dosing. Given the catabolic state of critically ill patients and CRRT related amino acid losses, nutritionists have an important role in ensuring that such patients nutritional needs are optimized while on CRRT. Although nephrologists manage the CRRT prescription and adjustments, given that intensivists are typically in house, they are often the first to field questions on CRRT patients from ICU nurses. Thus, for a successful CRRT program, intensivists should be educated on the clinical aspects of CRRT.

Ultimately, the Medical Director should oversee training and education of all the stakeholders.

Clear Delineation of Physician Responsibilities

For best outcomes and safety, there should be clear communication and delineation of responsibilities amongst the physician care team as to the management of CRRT (solute removal, electrolyte management, fluid balance).

Vascular Access for CRRT

Either temporary dialysis catheters or tunneled dialysis catheters are utilized for CCRT. If CRRT is indicated for ESRD patients who have established AVF or AVG, dialysis catheters should be placed and used for CRRT access due to risks of needle dislodgement from the fistula or graft.

Policy and Procedures for Placement and Care of Access

There should be policies and procedures for vascular access placement, removal, disinfection and management. The ICU dialysis catheter may be a triple lumen catheter where the additional lumen is used by ICU nurses for medications. Thus, having a written policy for dialysis catheter handling and care is even more important. Given that dialysis catheters are large bore catheters it is useful also to have a protocol for safe removal of such catheters to reduce the risk of air embolism. For more information refer to Chapter 10.

Standardized Protocols and Order Sets

There should be standardized protocols and order sets for various CRRT modalities. CRRT flow sheets include monitoring of various parameters including pressures (arterial, venous, transmembrane pressures, etc.) as recommended by the machine manufacturer and fluid balance and should be standardized. Anticoagulation protocols should also be standardized. The orders should be updated at least annually or sooner if necessary.

Equipment Decisions

There are several available CRRT machines and decision to use one should take into account amongst other factors: ease of use, affordability, and clinical and technical support. (See Chapter 5 for additional information)

There are commercially available dialysis solutions to be used for CRRT. However, there is also a role of custom dialysis/replacement fluids that the hospital Pharmacy may provide. Custom dialysis fluids should be prepared in accordance with USP guidelines. For instance, during disasters and pandemics such as COVVID-19 pandemic or other extenuated circumstances, where there may be shortages, expanded use of non-conventional solutions and other innovative techniques may be necessary.

Safety

Given the complexity of CRRT procedure including machine, access, mode of CRRT, fluid balance adjustment, dialysate and replacement fluids, calcium infusions with citrate anticoagulation protocols, in some centers it is common practice that the Nephrology Nursing staff review these parameters at least once a day with ICU nursing staff. Daily pharmacist rounds on CRRT patients may also be considered and is common practice in many centers. Local practice should determine the safest and most effective oversite. The ICU Nurse and/or dialysis Nurse caring for the patient should have regular communication with the rounding Nephrologist. The Inpatient Dialysis Medical Director should ultimately determine what local safety practices are necessary to minimize risk to dialysis patients in the hospital.

ECMO (extracorporeal membrane oxygenation) in Conjunction with CRRT

In some tertiary care centers concomitant ECMO and CRRT are performed. Given the technical issues involved (inline versus separate CRRT setup) it is advisable to have a specified policy and procedure for concomitant ECMO and CRRT.

Continuous Quality Improvement Parameters in CRRT

Below are some of the suggested parameters for quality improvement tracking in CRRT programs.

- Filter life
- Treatment time daily without interruptions
- Logs: training, skills check, alarm
- Safety: Patient safety events or medical errors
- Fluid balance assessment: ordered versus removed
- Tracking other procedure related complications

PERITONEAL DIALYSIS

In the United States, peritoneal dialysis is typically used in hospitalized ESRD patients who are on PD as a chronic dialysis modality. There is increasing use of PD (Urgent/Rapid Start PD) in incident ESRD patients first starting dialysis in the hospital. There is increased focus by CMS to increase utilization of home dialysis therapies in the USA. Thus, with increased PD utilization in ESRD patients, there will be more need for PD therapies in the hospitals.

Modalities

- Continuous Cycler Peritoneal Dialysis (CCPD): Automated using cycler equipment
- Continuous Ambulatory Peritoneal Dialysis (CAPD): Manual

Managing/Implementing a PD Program in the Hospital

In addition to the Medical Director, other stakeholders in a successful hospital PD program include but are not limited to dialysis nurses, hospital staff RNs, pharmacists, nutritionists, surgeon, interventional nephrologists, equipment manufacturers, and biomedical technicians.

While it is most efficient to use automated peritoneal dialysis in the hospital setting, CAPD manual exchanges should also be available. For PD, either the hospital or dialysis contractor supplies cycler machines, PD solutions, connectors, repair kits etc.

Patients' home equipment/supplies should not be used in the hospital. Cycler equipment should be maintained and disinfected per manufacturer's recommendations. There should be surgeons and/or Interventional radiologists on staff who are trained in managing surgical issues related to PD catheters.

Automated PD should generally be set up by dialysis nurses, but manual CAPD exchanges if needed may be performed by hospital nurses who should undergo formal training, skills assessment, periodic retraining. There should be a formal PD training program with lectures, hands on skills assessments and periodic in services with documentation of staff competencies as with other dialysis programs in the hospital. PD equipment manufacturers have a depth of resources including manuals, videos etc. that can assist in staff training. The Inpatient Dialysis Medical Director is ultimately responsible for approving the training program for dialysis nurses and/or hospital nurses in PD.

Standardized Protocols and Order Sets

There should be standardized order sets for automated (cycler) and CAPD as well as standardized protocols for peritonitis management (use ISPD guidelines), accessing PD catheter, PD flow sheets for fluid balance, and for obtaining PD fluid for culture. The orders should be updated at least annually or sooner if necessary.

PD patients often present to the Emergency Department (ED) with peritonitis symptoms or may develop these symptoms while hospitalized. Standardized technique for obtaining and processing PD fluid is essential to reduce contamination and increase microbiological yield and reduce culture negative peritonitis. Hospital microbiology labs should also have the standardized protocol for processing of PD fluid to increase microbiological yield and reduce culture negative peritonitis. Preferably ED staff should have access to a written protocol for accessing the PD catheter and processing of PD fluid as well as contact information for a PD nurse.

Imaging Studies for Hospitalized PD Patients

As patients on PD therapy rely on residual renal function to maintain dialysis adequacy, preservation of residual renal function is very important to successfully maintain patients on PD therapy and reduce modality failure.

When PD patients are hospitalized it is desirable to flag their chart regarding procedures and therapies that may increase risk of loss of residual renal function so that a nephrologist approval will be needed to override such warnings.

Urgent Start PD

This therapy is now being used to avoid hemodialysis catheters for incident ESRD patients who choose PD therapy. It can be initiated within 48 hours of PD catheter placement. However appropriate PD catheter

insertion technique and subsequent standardized protocol/order sets for the therapy are mandatory to avoid complications related to early PD catheter use.

Acute PD Start Under Pandemics and Other Disasters

The need for this option may emerge during unusual circumstances and public health emergencies such as the COVID-19 with unusually high proportions of AKI cases who may benefit from acute-start PD, especially if the supply for CRRT is limited. A similar approach as urgent start PD can be adapted but with immediate urgency to start dialysis treatment.

Training resources to teach hospital nurses: https://ispd.org/PD_Video/program.html
Training resource for Nephrology nurses: https://www.pdempowers.com/hcp/hti/team-pd

Continuous Quality Improvement Parameters for PD program

Below are some of the suggested parameters for quality improvement tracking in PD programs.

- Logs: training, skills check, retraining, machine maintenance
- PD related peritonitis/exit site infections: onset in the hospital vs. outside, organisms, percent culture negative
- Missed/interrupted treatments: number, causes
- PD complications: infection, leaks, etc.

THERAPEUTIC PLASMA EXCHANGE (TPE)

Therapeutic Plasma Exchange is a procedure that separates and then removes plasma which is simultaneously replaced by replacement fluids. This procedure is done for a variety of disease states including some renal diseases. At many of the hospitals this procedure is ordered and overseen by nephrologists. However, at some hospitals TPE is managed by hematology, pathology, or blood bank services.

This document pertains to TPE (excluding selective apheresis therapies) where supervised and managed by Nephrologists so that the inpatient medical director of dialysis also oversees TPE.

Managing/Implementing a TPE Program in the Hospital

In addition to the Medical Director, other stakeholders in a successful hospital TPE program include but are not limited to dialysis nurses, hospital nurses, blood bank, equipment manufacturer, pharmacists, and biomedical technicians. Dialysis nurses typically perform TPE but in programs supervised by hematology, blood bank etc. TPE is performed by other trained RNs. There should be a formal TPE training program with lectures, hands on, skills assessments and periodic in services with documentation of staff competencies as with other dialysis programs in the hospital. TPE equipment manufacturers have a depth of resources including manuals, videos etc. that can assist in staff training.

Nephrologist Training

Nephrologist credentialing for TPE should require verification of TPE training either during or after fellowship, as there are some nephrology programs that do not provide TPE training.

TPE Equipment and Procedure

There are 2 methods of plasma separation that are utilized by the TPE machines:

1. Centrifugal
2. Membrane Separation

Each of these methods utilize a specific machine and filters.

Vascular Access

Peripheral (antecubital vein) access is typically used for centrifugal TPE as this requires low blood flow rate 70-80cc/min. For Membrane Separation technique due to higher blood flow requirement, dialysis catheters (temporary or tunneled) are used. If patient has an established AVF or AVG then it can be used for TPE also.

Anticoagulation

Citrate is exclusively used for centrifugal TPE, whereas either citrate or heparin may be used for Membrane Separation TPE.

Standardized Order Sets and Protocols

These should be used for TPE procedure. The orders should be updated at least annually or sooner if necessary. In addition to equipment manufacturer's protocols and manuals there should be protocols for access care, troubleshooting etc.

Continuous Quality Improvement Parameters for TPE program

Below are some of the suggested parameters for quality improvement tracking in PD programs.

- Logs: training, skills check, retraining, machine maintenance
- Vascular Access complications tracking

TPE procedure complications

There should be formal tracking of complications related to TPE procedure.

(Citation for CRRT Section: Graham P, Lischer E. Nursing issues in renal replacement therapy: organization, manpower assessment, competency evaluation and quality improvement processes. *Semin Dial*. 2011;24(2):183-187. doi:10.1111/j.1525-139X.2011.00835.x)

Chapter 8: Order Sets

Authors: Harmeet Singh, MD, FASN, FACP

The Institute for Safe Medication Practices (ISMP) has long been an advocate for the use of standard order sets to minimize incorrect or incomplete prescribing, to standardize patient care, and to ensure clarity when communicating medical orders. Whether in electronic or paper format, well-designed standard order sets have the potential to:

- integrate and coordinate care by communicating best practices through multiple disciplines, levels of care, and services.
- modify practice through evidence-based care.
- reduce variation and unintentional oversight through standardized formatting and clear presentation of orders.
- enhance workflow with pertinent instructions that are easily understood, intuitively organized, and suitable for direct application to current information-management systems and drug-administration devices.
- decrease the potential for medication errors through integrated safety alerts and reminders.
- reduce unnecessary calls to prescribers for clarifications and questions about orders.

The order sets should be reviewed or updates at least annually or sooner if indicated.

For Extracorporeal therapies there should be order sets (EMR or paper) which include CRRT order, Hemodialysis orders, PD orders, TPE orders. It is recommended to have a “backup” paper copy of the order sets available for EMR downtimes.

Moreover, as of 2019, The Joint Commission allows service or disease specific order sets in its accredited hospitals if they satisfy 3 criteria:

1. They must be evidence-based
2. They must have multi-disciplinary input
3. They must be reviewed for potential updating at some intervals determined by the hospital

Chapter 9: Medication Management

Authors: Laura Rankin, MD, FACP

Many of the patients being served in the inpatient arena will be established dialysis patients. As such they are probably receiving medications in their outpatient unit. These may include erythropoietic stimulating agents (ESAs), vitamin D analogs, calcimimetic agents, and of course heparin.

The inpatient dialysis unit should contact the outpatient unit to determine the most current outpatient medications, dosage and frequency. The staff should then discuss with the inpatient nephrologist how those medications should be given or held for the patient. Lack of availability on the hospital formulary may preclude using the outpatient ESA or vitamin D analog. A medication conversion tool is now available on the Forum of ESRD Networks website, which can assist the inpatient nephrologist and nursing staff convert the current outpatient dialysis medication to the correct dosage of available inpatient medication available.

https://esrdnetworks.org/resources/toolkits/mac-toolkits-1

Importantly, there are now two calcimimetic medications available for use. Parsabiv (etelcalcetide) is the intravenous one, given in the dialysis unit after dialysis has been completed. Sensipar (cinacalcet) is a tablet taken orally, either by the patient at home or administered in the unit (off-label use). These cannot be used interchangeably. Severe hypocalcemia may result if the medications are changed back and forth without holding current medication for the correct amount of time. If the patient is on cinacalcet, it must be held for 7 days before starting etelcalcetide (3). Conversely, if the patient is on etelcalcetide as outpatient, it must be held at least 30 days before safely starting cinacalcet. If the patient is on etelcalcetide as outpatient, and the hospital only has cinacalcet on formulary, then the recommendation is to either try to obtain etelcalcetide to continue in the hospital, or if this is not possible then hold it while the patient is in the hospital.

Heparin is the most common anticoagulant used in the outpatient unit. However, some patients cannot receive heparin due to active bleeding, heparin allergy, or HIT. For these patients, argatroban (direct thrombin inhibitor) can be used with dose adjusted for dialysis patients as bolus, or bolus and drip. In some inpatient units, the general policy is to not use anticoagulants unless specifically ordered. Those units may use saline flushes to address possible filter clotting and loss. For patients on intermittent hemodialysis or SLED in the hospital using traditional acid concentrate, citrate-based acid concentrate can be used instead to minimize risk of clotting and bleeding in patients undergoing heparin-free dialysis. Either policy is acceptable, but if anticoagulants are used, we would recommend a policy that the nephrologist orders the dose and frequency on an individual basis, not as a standard policy, “one size fits all” in the hospital setting.

Medications that should be available and considered when the patient is being dialyzed include:

- ESAs, vitamin D analog, other orally or intravenously medications as previously ordered
- Diphenhydramine for allergic symptoms
- Consider albumin to be available in the hospital based on local practice and policy, for patients prone to hypotension and possibly volume overloaded
- Extra saline and also oxygen should be available.

The only medication given pre-filter is usually the anticoagulant. Albumin may also be given pre-filter. All other medications are generally administered into the venous line via infusion pump or IV push, i.e., they are not to be just hung, because of the possibility of air being infused. Some machines contain a special medication port which can also be used to administer medication per manufacturer guidelines and local policy. The Medical Director should approve the local method used to administer medications. The medications should be given close to the end of dialysis, to decrease the chances of removal by dialysis.

Medications to be held until after dialysis, by ward nursing staff, include antihypertensive medications, most antibiotics, and other medications that may be dialyzable.

The Medical Director of inpatient dialysis should interface with the pharmacy and the Pharmacy and Therapeutics Committee to be sure that necessary medications are included in available stock. However, not all medications in a therapeutic group need to be stocked. Local and regional practices should influence these choices. For example, if most outpatient units in the area prefer etalcalcetide, it should be stocked, with less cinacalcet. Another example is the local and regional use of vitamin D analogs. If most units and patients are using oral medications, there is no need to stock more than one IV formulation (doxercalciferol or Zemplar).

Peritoneal Dialysis Patients

The medical director of peritoneal dialysis establishes protocols for treatment of accidental disconnect, exit site infection, suspected peritonitis, and established peritonitis. These protocols include directions for the dialysis nurse, laboratory orders, antibiotic choices that are consistent with the hospital pharmacy formulary, and other orders, e.g., heparin, laxative use. It is expected that these order sets will be consistent with the latest guidelines by Peritoneal Dialysis International and other authorities.

CRRT and Other Extended Forms of Hemodialysis

The use of all medications in the patient receiving CRRT or SLEDD is potentially the most challenging part of the therapy. The medical director should be involved with the hospital pharmacists, sufficient to define that:

- They are aware of the differences between CVVH, CVVHD, CVVHDF, SLEDD, and SCUF
- These differences account for the different clearances of a given medication
- Drug levels are important
- Recognition that literature before 2010 may be largely irrelevant
- Resources are available and include:

- Annual AKI-CRRT meeting in February or March may be proposed. The website for this meeting is crrtonline.com.
- Speakers may be invited to state hospital pharmacists' meetings
- The University of Louisville has a website that is maintained with copious information about drugs listed. https://kdpnet.kdp.louisville.edu/drugbook/adult/
- UpToDate has extensive monographs. "Drug removal in continuous renal replacement therapy" is very good.

Chapter 10: Procedures Related to Dialysis Including Vascular Access

Authors: Anil Agarwal, MD, FASN, FACP, FNKF, FASDIN; Laura Rankin, MD, FACP

The dialysis procedure, especially in the hospitalized patient, is often characterized by cardiovascular instability. A large part of this instability is predicted by the severity of concurrent illness. Efforts to minimize the instability in the dialysis unit should include limitation of extraneous stimuli, as the dialysis personnel are there to monitor the patient and perform dialysis, not to provide extensive care otherwise. The Inpatient Dialysis Medical Director should be responsible for providing guidance in specific cases.

PROCEDURES UNRELATED TO DIALYSIS OR VASCULAR ACCESS

During acute intermittent hemodialysis, it is generally expected that no elective or semi elective procedures will be performed. Exceptions may include, but are not limited to ECGs, EEGs, and echocardiograms as dictated by the patient's concurrent illness. However, bathing, physical therapy, wound dressing changes, and removal of intravenous central catheters should be delayed until after dialysis is completed.

VASCULAR ACCESS PROCEDURES

- **Placement of dialysis catheters** is generally not performed in the inpatient dialysis unit. Tunneled dialysis catheter placement is generally performed in a surgical suite, minor surgery or interventional radiology suite. Non tunneled (temporary) hemodialysis catheter placement is also generally performed in a procedure room or in the patient's room. Under emergent conditions, if the patient is in the dialysis unit, AND the nephrologist is trained in the placement of the temporary catheter, AND the nursing staff is adequate in number to provide a nurse to assist with the procedure for that patient alone while other patients are safely cared for, it is acceptable to place the catheter in the dialysis unit before the patient is started on dialysis. Exchange of one catheter for another, typically done over a guide wire, should also follow similar guidelines.
- **Access Dressing**: Dressing changes and inspection of the access site are the responsibility of the trained dialysis staff. They are to be performed with each treatment and should not be done by other hospital nurses unless trained to do so. The exception with central dialysis catheters is when dressings are specifically designed to stay in place for up to 7 days, and the manufacturer guidelines then apply. Some hospitals also use chlorhexidine-impregnated discs around catheter insertion site under dressing, or certain dressings containing chlorhexidine to help minimize risk of infection. All dressings should be changed immediately if contaminated or wet to minimize risk of infection. Care of catheter dressings in the hospital should be specified by policy, which should be approved by the Inpatient Dialysis Medical Director.
- **Use of HD catheters for Non-dialysis purposes**: The use of hemodialysis catheters for non-dialysis purposes has been generally discouraged. These circumstances include hyperalimentation, medication administration, blood product transfusions, as well as "phlebotomy". However, in some hospitals, only if approved by the Inpatient Dialysis Medical Director, if patients have no

available peripheral access for lab draws or IVs, the risk of infection (or bleeding, loss of veins, thrombosis, etc.) after placing an additional catheter may exceed the risk of using the dialysis catheter. In these cases, hospital policy may dictate that certain RNs (i.e. IV therapists, Radiology RNs, etc.) trained by dialysis Nurse Educator may access the dialysis catheter for non-dialysis use. Another exception is Therapeutic Plasmapheresis (TPE), as the personnel are trained in the use of chronic intravascular central catheters.

- **Prevention of infections in the dialysis unit**: The use of devices and procedures for the reduction of infections in dialysis catheters should follow CDC guidelines. The devices and procedures vary in effectiveness and have generally variable scientific validity. The medical director should be involved in decisions about the use of TEGO caps, ClearGuard caps and antibiotic locks.
- **Use of anticoagulants**: While outpatient dialysis units frequently use heparin for anticoagulation as a routine, it is usual for inpatients to be dialyzed with periodic saline flushes due to bleeding related to other diseases or in the perioperative phase. Novel anticoagulants are also being used for dialysis with increasing frequency. There should be a clear protocol for anticoagulant use.
- **Role in vessel preservation**: Hospital policies should include that the admitting nurse asks if the patient has a dialysis fistula or graft or is receiving chronic hemodialysis. If that is the case, a sign should be placed above the head of the bed, defining that the involved arm should not be used for blood pressures, phlebotomy, or intravenous catheters. A different colored arm band should also be placed on the arm with the fistula or graft indicating no lab draws or IVs in that arm.

The placement of PICC lines or midline catheters in any patient with stage 4 or stage 5 chronic kidney disease is to be discouraged. Placement of a midline catheter or a PICC line in a dialysis patient should be specifically approved by the inpatient nephrologist before placement is considered. These policies must be shared with the personnel responsible for the supervision of PICC line placements. If patient requires longer term IV for antibiotics or other purposes, or if peripheral IV is unable to be placed, a better alternative than a PICC line or midline catheter is placement of a small single lumen IJ tunneled catheter by IR.

PROTOCOL FOR TEMPORARY DIALYSIS CATHETER REMOVAL (standardized): to minimize risk of air embolism

Preventive strategies of venous air embolism related to cervical catheter removal[a]

1. As in the placement of a catheter, risk factors resulting in a reduced CVP should be corrected whenever possible.
2. Avoid heparin use on the day of catheter removal; administer protamine prior to removal if heparin use is unavoidable.
3. Assumption of the Trendelenburg position to increase the CVP to a level higher than the pressure of ambient air so that air will be prevented from entering the blood.
4. Two approaches to breathing instructions upon catheter removal:
    I. Valsala maneuver – preferable if patient is cooperative.
    II. Full inspiration and then hold the breath. As it is difficult for patients to observe any of the above breathing requirements for a long period of time, the catheter removal procedure should be conducted quickly.
5. Strict avoidance of coughing and talking during the procedure.
6. A positive end-expiratory pressure should be applied for those patients being treated with mechanical ventilation.
7. Immediate coverage of the catheter removal site with an impermeable dressing such as a piece of gauze generously impregnated with an antibiotic cream.
8. Local pressure for at least 20 minutes to achieve adequate haemostasis after catheter removal.
9. Observe the patient for at least 30 minutes for any bleeding.
10. Application of air-occlusive dressing for 24 hours.
11. Establishment of a catheter removal protocol/checklist.
12. Regular training for the healthcare workers responsible for catheter removal; ensure strict adherence to the protocol/checklist.

(Steve Siu-Man Wong, Hau C Kwaan, Todd S Ing. Venous air embolism related to the use of central catheters revisited: with emphasis on dialysis catheters. *Clinical Kidney Journal*, Volume 10, Issue 6, December 2017, Pages 797–803.)

Chapter 11: Infection Control

Authors: David Henner, DO

The Inpatient dialysis setting poses several unique issues which need to be considered regarding infection control. When a patient is undergoing dialysis in the hospital setting, both the hospital infection control procedures (i.e. contact precautions, MRSA or VRE precautions, C. diff precautions, etc.) and infection control procedures unique to dialysis (i.e. hepatitis B isolation, use of gloves when touching patient on dialysis, appropriate PPE when patient initiating or terminating dialysis treatment, etc.) need to be observed. There needs to be coordination with hospital Infection Control department regarding the specific procedures related to dialysis patients to ensure these are followed and monitored carefully. In addition to precautions, infection monitoring needs to be coordinated with the Hospital Infection Control department.

Infection Control Precautions unique to hospital (not followed in routine outpatient dialysis facilities) that need to be followed when the dialysis patient is hospitalized:

1. Contact Isolation Precautions: (i.e. patients colonized or with active infections with MRSA, VRE, etc.)
    a. When patient is on dialysis, dialysis staff, nephrologist, other physicians, etc. all need to adhere to contact isolation precautions including wearing gown and gloves when touching patient.
    b. RN performing dialysis must ensure there is adequate supply of hand sanitizer, gloves, and gowns present outside patient's bedroom or dialysis station if patient being dialyzed in inpatient dialysis unit.
2. Modified Contact Precautions: (i.e. Clostridium Difficile infections)
    a. If patient is on Clostridium Difficile (C diff) precautions in hospital, they should NOT be dialyzed in same room as patients without active C diff as infection could spread.
        i. These patients should be dialyzed at bedside if in their own room. (Preferably in an isolation room if in CCU or other unit, and not just bed separated by curtain.)
        ii. Alternatively, patient should be dialyzed in single patient isolation room, and room should be terminally disinfected after dialysis treatment is complete.
    b. The same isolation precautions as patients on contact isolation (see #1 above) need to be followed, but additionally these precautions need to be followed:
        i. Hand sanitizer should not be used. Dialysis staff, physicians, and anyone who enters dialysis station during dialysis needs to wash hands thoroughly with soap and water after leaving the dialysis station. Alcohol-based hand sanitizers do NOT kill C diff
    c. Gowns should NOT be reused for other patients after wearing to take care of C diff patients. Gowns need to be disposed of or placed in dirty laundry after use on patient with C diff.
    d. Dialysis RN should coordinate with Infection control department when patient can safely be taken off C Diff precautions for dialysis. Until then, the above procedures must be followed to help minimize spread of C Diff to other patients on dialysis

3. Respiratory or Droplet Precautions: Patients on these precautions (i.e. TB, Chicken Pox, etc.) must be dialyzed in appropriate isolation rooms (i.e. respiratory or droplet isolation) or at bedside in an isolation room maintaining isolation precautions. Dialysis staff and nephrologists need to wear appropriate masks per precautions and adhere to precautions when the patient is on dialysis.

4. Novel Coronavirus (COVID-19) Precautions: This may be spread by respiratory droplets but may also be spread by contact. Information is still being accumulated, and the most current information can be obtained at the Centers for Disease Control website (cdc.com).

5. Ebola Virus Precautions: Hospital infection control departments should coordinate with dialysis departments to make sure their Ebola isolation precautions cover patients who may need dialysis. Patients with Ebola Virus who require dialysis must be dialyzed in special Ebola isolation rooms, and dialysis staff and anyone else entering patient's room must adhere to Ebola isolation procedures. No staff, nephrologist, or anyone else caring for patient should enter the patient's room until they have undergone appropriate training with hospital infection control department on specific precautions related to patients with Ebola Virus.

6. Infection Control Precautions Unique to Dialysis (not followed in routine care of hospitalized patients not on dialysis): These precautions also need to be adhered to when a dialysis patient is hospitalized, in addition to above precautions:

    a. Hepatitis B Isolation: In hospitals, patients with hepatitis B infection may not be isolated, but when receiving dialysis (due to potential to transmit disease to other dialysis patients) strict isolation precautions unique to dialysis need to be followed.
        i. See CMS Interpretive Guidance- V124-V131 for specific CMS regulations adopting CDC Guidelines for details.
        ii. Hospitalized dialysis patients with Hepatitis B infection must be dialyzed in isolation, either at bedside in single patient room, or in separate isolation room. Patients with Hepatitis B must NOT be dialyzed in inpatient dialysis unit with other patients.
        iii. Any staff, nephrologist, or anyone else entering the dialysis station during dialysis must wear appropriate PPE (i.e. gown, gloves) and must perform hand hygiene afterwards and dispose of gown or place in dirty laundry. Gown should NOT be reused for other patients
        iv. Any equipment in dialysis station used during dialysis must NOT be used on other patients on dialysis unless disinfected appropriately. Examples include blood pressure cuff, dialysis machine.
        v. Dialysis Staff and nephrologist seeing patient with Hepatitis B on dialysis must be hepatitis B immune. Any staff caring for that hepatitis B positive patient must only care for patients who are hepatitis B immune afterwards that day. The hepatitis status of all patients must be tracked and known.
        vi. Machine being used for dialysis of Hepatitis B patient must be isolated after use, and not used for dialysis of any other non-hep B patient. The machine must be terminally disinfected before using on any non-hep B patient
        vii. If the hepatitis B status of patient is unknown, the machine should be isolated and not used on other dialysis patients after use until the status is known.

1. Hepatitis Serologies, including Hepatitis B Surface Antigen should be drawn on all new dialysis patients as soon as there is consideration that patient may need dialysis.
2. If not drawn before the patient starts dialysis, then Hepatitis B Surface Antigen should be drawn on the first dialysis treatment in the hospital.
3. Hepatitis serologies should also be drawn on all inpatients on dialysis if their current Hepatitis status is unknown, or if no recent Hepatitis serologies within 1 month.

The Joint Commission has identified dialysis as a high-risk area where they are focusing on their surveys. One area that the Joint Commission is focused is on infection control. Surveyors typically will focus on infection control measures to prevent transmission of blood borne pathogens, including hand hygiene and catheter care, station and equipment disinfection procedures, and isolation precautions as described above.

Chapter 12: Quality Management and QAPI

Authors: David Henner, DO

The Inpatient Dialysis Medical Director is the leader of the inpatient dialysis Quality Assurance and Performance Improvement (QAPI) program, just as the Medical Director of outpatient dialysis facilities leads their respective dialysis facilities in quality. See the Forum of ESRD Networks Medical Advisory Council (MAC) Outpatient Medical Director Toolkit for further information. The inpatient setting lends certain unique circumstances to this role, as the Inpatient Dialysis Medical Director needs to collaborate with the hospital Quality Department and leadership. The overall policies and function of the inpatient dialysis program should be consistent with the overall hospital mission and goals.

https://esrdnetworks.org/toolkits/professional-toolkits/medical-director-toolkit

Even if the hospital system has a separate outpatient QAPI program, the inpatient dialysis program should also have its own QAPI program, to oversee the quality of care being delivered in the inpatient dialysis setting. The Inpatient Medical Director should help lead an interdisciplinary QAPI team, similar to outpatient QAPI programs. The inpatient QAPI team should include the Medical Director, the Nurse Manager, the water/biomed leader for the dialysis department in the hospital, and representation from hospital Quality Department, and infection control (if not present at QAPI Meetings, there must be sufficient reporting of results and communication with Infection Control and Quality Dept of hospital).

What specific key areas should the inpatient dialysis medical director focus on as part of the Inpatient QAPI program? The Joint Commission recently prioritized dialysis as one of their key areas of high risk to be surveyed during accreditation surveys. Two key areas of focus they have cited are water treatment and infection control.

In the area of water treatment safety, areas that should be focused on are:

1. Disinfection of each machine, RO, system, etc. should occur at regular intervals per manufacturer guidelines. This should be audited and reported to QAPI meeting. Similar to outpatient CMS guidance, for traditional HD machines, at least 2 machines should be sampled each month, and each machine needs to be sampled at least once/year. This sampling should be monitored as part of QAPI program to ensure each machine is sampled as per policy and regulation.
2. Results of routine testing for endotoxins and cultures for each machine, RO, and system per manufacturer guidelines (typically monthly, although some preconfigured systems allow for quarterly testing based on manufacturer recommendations) should be reviewed at QAPI meeting each month.
    a. If machines had actionable levels for LALs or cultures, were appropriate actions per policy followed (ie notify medical director, resampling, or repeat disinfection)?
3. Daily testing logs (i.e. chlorine/chloramine testing) done prior to each shift, or every 4 hours if the patients are not treated in defined shifts, and before each bedside treatment?
4. Are pressures and conductivity being monitored and are all parameters within goal ranges?
5. AAMI Chemical Analysis for all systems and ROs, testing should be done at least annually, and if any seasonal variation is likely (ideally would recommend quarterly testing to be safe). Municipal

feed water should also be tested for comparison. Results of AAMI tests should be reviewed by Medical Director at QAPI meetings

For infection control, possible areas of focus for QAPI meeting/team:

1. Infection Control Audits: Just as in outpatient dialysis facilities, routine audits should be conducted on dialysis staff while patients are on dialysis, for policies including hand hygiene, station and/or machine and equipment cleaning between patients, catheter care and exit site care of catheters, etc.. The audits should be reported to QAPI meeting. Hospital Infection Control department can participate in these audits as applicable per hospital. Results should be reported to the hospital Infection control department.
2. Blood-Stream Infection (BSI) Rates: Rates of patients on dialysis with catheters who develop BSI in hospital (i.e. not within 2 days of admission, as those BSI would be attributed to outpatient dialysis facility) but those that occur 2 days or more after admission to hospital. Any such BSI should be reviewed by QAPI team with RCA conducted and plan implemented with timeline to address any issues found. Hospital infection control committee should be informed of plans.
3. Hepatitis Testing and Isolation: All patients with unknown hepatitis status should be tested in hospital prior to initiation of treatment; this can be a QAPI metric (i.e. % of patients with unknown status who have hepatitis studies performed). Also, proper isolation of machines prior to knowing hepatitis test results can be monitored and disinfection of machines per policy.

Other possible QAPI metrics:

1. Quality tracking reports or event reports filed in hospital involving dialysis patients. Involvement of hospital quality department is key here, ensuring proper follow-up and resolution to any events or near misses reported is important.
2. Consents: Does every patient who started on dialysis in hospital have consent for dialysis on chart? If a patient has ESRD and is continuing HD in hospital, this is not necessary medically (although some hospitals may mandate this). The Forum of ESRD Networks Medical Advisory Council (MAC) and Kidney Patient Advisory Council (KPAC) specifically disagree with having to reconsent patient with ESRD who already provided consent for chronic dialysis as outpatient. See comments from Forum of ESRD Networks to the Joint Commission:

   https://esrdnetworks.org/resources/forum-position-papers-comments/forum-letter-to-the-joint-commission-re-consent-for-dialysis-6-11-2020/view
3. Education for Patients: Track whether patients who start dialysis in hospital receive appropriate education on modality choice, including conservative care (no dialysis) if appropriate, dialysis access, etc.

Chapter 13: Collaboration with Hospital Administration, Other Staff and Specialists

Authors: Kamyar Kalantar-Zadeh, MD, MPH, PhD

The hospital or medical center shall designate a nurse manager (as described in Chapter 3), to oversee the overall operation of dialysis patient care and dialysis therapies including the performance of dialysis nurses and other dialysis staff in the hospital. The Dialysis Nurse Manager works under the co-supervision of the Inpatient Dialysis Medical Director with well-defined reporting relationships to the Medical Director, in addition to other reporting requirements to other hospital authorities such as Chief Nursing Officer as per hospital organization chart.

The Dialysis Nurse Manager is an RN in good standing with prior experience and track record of dialysis patient care including training and knowledge in CRRT and hospitalized patient care. He/she may be proposed by the hospital leadership, such as Chief Nursing Officer or Chief Operating Officer, and shall be approved by the Inpatient Dialysis Medical Director with annual review and reappointments approved by the Medical Director. The Dialysis Nurse Manager works collaboratively with the nephrology practice groups and serves as the communicative and operational conduit between the nephrologists and the dialysis staff of the hospital.

Collaboration between the Inpatient Dialysis Medical Director and hospital Infection Control Department is critical and should be performed as mentioned in Chapters 11 and 12.

Hospital Case Managers and Discharge Planners may be engaged in the process of discharge preparation of a current or prospective dialysis patient to optimize the arrangement of outpatient dialysis therapy upon hospital discharge as long as this process is closely coordinated with and approved by the nephrologist of the record and under the overall oversight of the Inpatient Dialysis Medial Director of the hospital.

No physician, APP or hospital staff may provide dialysis therapy recommendations to a current or prospective dialysis patient or his/her family members, care givers, or other decision, except for a BE/BC nephrologist, nephrology APP or nephrology fellow. This requirement also pertains to specialists or staff in Hospice and Palliative Care Medicine, who should not discuss dialysis therapy transition, dialysis continuation or dialysis withdrawal with any patient in the hospital without discussion and involvement of the inpatient nephrologist or his/her designee, or the Inpatient Dialysis Medical Director whenever such meetings or consultations are requested or planned.

The Nephrologist or Inpatient Dialysis Medical Director (if patient has no Nephrologist in hospital) needs to be involved in any discussions or decisions about palliative or end of life care. Inpatient Dialysis Medical Director may review and approve decisions about dialysis therapy including dialysis withdrawal.

The hospital staff and other physicians and specialists will pursue utmost care and sensitivity to avoid any discussion or meeting or consultation with any current or prospective dialysis patient in the hospital based on the above requirement unless the inpatient nephrologist is involved.

Chapter 14: Care Coordination and Transitions

Authors: Harmeet Singh, MD, FASN, FACP

Forum of ESRD Networks Medical Advisory Council has published a Transitions of Care Toolkit that provides additional important information regarding this topic.

https://esrdnetworks.org/resources/toolkits/mac-toolkits-1/new-toolkit-transitions-of-care-toolkit

This chapter pertains to patients who receive renal replacement treatment (RRT) in the acute care hospital setting they include established ESRD patients admitted for an acute illness or surgery, acute kidney injury (AKI) patients who are dialysis dependent at the time of hospital discharge, and patients with new ESRD diagnosis who start their RRT during hospitalization. These patients may be discharged to their homes, to receive their dialysis at a free-standing dialysis unit, or may be discharged to a Skilled Nursing Facility (SNF), Inpatient Rehabilitation facility (IRF) or a Long-Term Acute Care (LTAC) Hospital. A common denominator for all these subgroups is ongoing need for dialysis at the time of discharge. Of importance, effective January 2017 CMS has allowed reimbursement for AKI patients to receive dialysis in free-standing outpatient dialysis centers, which has facilitated timely discharge (reducing length of stay) of AKI patients who are dialysis dependent. However, this has resulted in high acuity of patients admitted to outpatient dialysis centers where the patient may not see a provider in the first days to a week or two.

Regardless of where the patient goes, coordination of care between hospital, free standing dialysis centers, SNFs, IRFs and LTACs is essential for safety and wellbeing of these patients. With every transition, coordination of care should occur, to reduce rehospitalizations, decrease morbidity and mortality, and ensure that all caregivers are aware of changes in the diagnoses and treatment of their patients.

Care coordination for these patients requires team effort among hospital, inpatient dialysis program, freestanding dialysis centers, SNFs, IRFs, and LTACs.

Key Elements of Care Coordination/Transitions of Care Include

- Clinical information sharing: This includes but is not limited to medical records, hepatitis B status, TB status, and Dialysis Prescription
- Dialysis schedule: It is important for discharge planning to coordinate with patient's dialysis schedule at their new location and to avoid unintentional long interdialytic interval during the transition. The timing should address much as possible their other needs, including but not limited to physical therapy and transportation needs.
- Dialysis Access details: site, needle size if fistula or graft, rope ladder or buttonhole cannulation, instructions not to do blood pressures or IV sticks in the access arm.
- Infection history: Proactive communication between the facilities regarding current status with regards to active infections.
- Catheter care: dressing change instructions, catheter site assessment
- AKI patients: These patients should be identified clearly so that nephrotoxic medications including imaging contrast agents are not used or if necessary, there is an approval from nephrologist.

Patient Consent for Dialysis for Established ESRD Patients

Currently, for hospitalized patients, standard practice is to require a signed consent by a nephrology physician before dialysis is initiated. While this should be mandatory for patients who are first starting dialysis in the hospital, it is recommended that for ESRD patients currently enrolled in outpatient dialysis units, a new consent for dialysis should not be required as these patients have already consented to long term dialysis. This recommendation may or may not be considered appropriate as the patient transitions to a LTAC or IRF. See the Forum comments to the Joint Commission on the subject of consent for dialysis.

https://esrdnetworks.org/resources/forum-position-papers-comments/forum-letter-to-the-joint-commission-re-consent-for-dialysis-6-11-2020/view

Chapter 15: Education in the Inpatient Dialysis Unit

Authors: Anil Agarwal, MD, FASN, FACP, FNKF, FASDIN

The Inpatient Dialysis Medical Director should manage the unit population by implementing processes, methods, and tools to deliver the highest quality care. These goals cannot be achieved without proper education directed both towards the staff and the patients. While hospitalized patients are not always in a physical or cognitive state to be able to receive such education, an effort should be made to educate those who are capable of learning. *However, the inpatient dialysis medical director should not be solely 'responsible' for educating every patient but should strive to create a culture of initiating such education*. This would be highly desirable and could impact outcomes for the patient, including appropriate discharge planning, length of stay and readmissions. Dialysis staff may not have ample time or knowledge to explain the details of AKI to the patient. Traditional literature and modern audiovisual and online resources can be made available as feasible. A dedicated kidney failure management educator is likely to be optimal. Resources can often be created in collaboration with the hospital or the dialysis company contracted to provide dialysis. There are many aspects of education that would be desirable in the inpatient dialysis unit.

Disease State Education

- Acute Kidney Injury (AKI): Many patients in the hospital require dialysis due to AKI from various causes with variable pathophysiology, clinical course and prognosis. It is important to clearly differentiate between AKI and end stage renal disease (ESRD) to the patient and teach methods of kidney protection from further injury. This has far reaching implications in performance of dialysis process itself (such as fluid removal, frequency of dialysis) as well as in ensuring patient readiness for discharge and follow up in especially an outpatient unit (in comparison to LTAC or IRF). Clear understanding by the staff, patient and physician of the nature of injury will impact adequate care of the special needs of a patient with AKI.
- ESRD patients also need to be educated about causes, consequences and management of renal failure. Additionally, they will need specific education about modalities, vascular access, bone mineral disorder, anemia and transitions of care.

Renal Replacement Modality Education

Patients with ESRD need to be informed of their choices, such as kidney transplant eligibility and process, peritoneal dialysis (ambulatory and automated), home hemodialysis, in center dialysis as well as palliative, non-dialysis options. ESRD for many patients is a catastrophic and overwhelming event and an educational experience in the hospital may be the first time they ever became aware of these options. It is very reasonable to assess patient suitability for home modalities (PD and home HD). An informed choice of treatment would impact dialysis access placement or discharge to a transitional care unit. In patients with terminal illness, palliative care option can also be offered.

Vascular Access Education

Despite evidence for the adverse effects of a catheter option, over 80% of the patients starting HD in the United States do so using a catheter. Education about vessel preservation (such as avoidance of IV access in non-dominant extremity and avoidance of PICC and midlines) can easily start in the hospital. Vein mapping and scheduling of surgery can be suggested to the attending staff in appropriate cases. In patients with dysfunctional access, a problem-solving approach can lead to a stable access at the time of discharge.

Transitions of Care

Not only is the process of dialysis daunting and confusing to most, there is a wide variability of procedures among the dialysis units in the inpatient and the outpatient setting. Further, there are multiple other life changes that range from change in diet, vascular access, dialysis modality and medications to managing finances and work, to name a few. Such transitions have the potential to result in adverse outcomes. A well-educated patient can become a partner in his/her own care by following instructions and working towards a goal, such as working towards a kidney transplant or changing from an in-center dialysis option to peritoneal dialysis or home hemodialysis. See Chapter 14 for more details on transitions of care, as well as the Forum of ESRD Network's Transition of Care Toolkit.

Educating patients in hospital during acute illness can be quite challenging and sometimes impossible. However, if resources can be established with the help from all stakeholders, initiation of education would be a desirable goal for the Inpatient Dialysis Medical Director.

Chapter 16: Business Development, Fiscal and Hospital Administrative Aspects

Authors: Kamyar Kalantar-Zadeh, MD, MPH, PhD

The Hospital or its contracting organization in charge of dialysis shall compensate the appointed Inpatient Dialysis Medical Director based on equivalent of minimum of 0.1 to 0.25 FTE according to the estimated amount of time and expertise required and based on the size of the inpatient dialysis operation of the hospital. The FTE salary compensation calculations shall be based on the average annual income of a practicing nephrologists using fair market value. For exceptionally large programs, such as those with more than 2,000 dialysis therapies per year (including number of unique HD treatments, PD days and CRRT days combined), one or more "associate dialysis medical directors" at 0.05 to 0.1 FTE may be appointed to support the medical director, whose initial and annual review and appointments are implemented by the Inpatient Dialysis Medical Director and who will be compensated by the hospital.

The hospital or medical center may not remove or change the Inpatient Dialysis Medical Director without compelling reasons such as not performing the duties as outlined in contract or in this document. The Medical Director should be afforded peer review process and other components of due process prior to consideration of termination. Prior to such steps, it is recommended that potential issues with the dialysis medical director be reviewed and discussed and corrective and mediatory efforts be exhausted before expulsion plans are issued.