AJKD
Core Curriculum in Nephrology

Management of the Hemodialysis Unit: Core Curriculum 2016

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Although an in-center hemodialysis facility is primarily perceived as a provider of health care, it is also a business that requires a leader. Analogous to the "Triple Aim" of the health care system envisioned by the Centers for Medicare & Medicaid Services (CMS), each hemodialysis facility has its own triple aim: (1) providing each patient with a safe, high-quality, pleasing experience of care; (2) complying with CMS's certification requirements; and (3) ensuring that the facility remains financially viable. The common denominator for all 3 aims is quality of care, which is a focus for Medicare survey and certification activities, affects patient outcomes and perceptions, and affects payment through the Quality Incentive Program (QIP). The facility medical director is primarily responsible for the Quality Assessment and Performance Improvement (QAPI) program within the facility, but must partner with the facility administrator to ensure that resources are directed to address opportunities for improvement. The responsibilities of the medical director have been addressed in detail in a series of articles that appeared in the *Clinical Journal of the American Society of Nephrology* in 2015 and will not be extensively discussed in this article. Both the facility administrator and medical director report to the governing body of the facility and may be members of the governing body. It is ultimately the responsibility of the governing body to adopt and enforce rules and policies to allow for safe and effective care delivery in the hemodialysis unit (Box 1). The key responsibilities and qualifications of the facility administrator are summarized in Box 2.

Box 1. Key Requirements of the Governing Body

- Adopt and enforce rules relative to:
  - Facility governance
  - Health care and safety of patients
  - Protection of patients' personal and property rights
  - General operation of the facility
- Facilities that are within a dialysis organization with multiple facilities must have a local governing body within each facility
- The governing body can be 1 person or a group of persons
- The following must be clear in governing body records:
  - Composition of governing body
  - Who has legal authority for governance and operation of facility

CERTIFICATION AND LICENSURE

The initial End-Stage Renal Disease (ESRD) Conditions for Coverage (CfC) were established in 1976 and most recently revised in 2008. To participate in the Medicare or Medicaid programs, facilities must be in compliance with the federal rules and standards for dialysis facilities found in the CfC. CMS developed the standards to ensure safe care of the highest quality to dialysis patients. The revised CfC focus on using an interdisciplinary integrated care system that emphasizes patient assessment, care planning, care delivery, and quality assessment and performance improvement. These new standards also stress patient satisfaction, as well as involvement in the development of the care plan and treatment. Outcome measures were developed and validated with input from the nephrology community so that they are clinically meaningful and reflect current scientific knowledge. It should be noted that dialysis facilities must comply with the laws and regulations of other local and federal agencies in addition to the CfC. These are summarized in Box 3.

To provide guidance in the application of these regulations, CMS developed the ESRD Interpretive Guidelines. The guidelines identify regulations with a "V tag" and include the regulation and a point-by-point interpretation of each condition. There are more than 500 V tags, so this guidance is particularly helpful with such a large volume and complexity of standards. CMS partnered with others in developing the standards, including the Association for the Advancement of Medical Instrumentation (AAMI), which developed and updates the standards for Dialysate in Hemodialysis (RD52:2004), Water for Hemodialysis (RD62:2001), and for Reuse of Hemodialyzers (RD47:2002/03). The CfC reference and use these AAMI standards due to the expertise of AAMI in this important area.

To ensure that facilities are in compliance with the standards, as well as in the provision of safe high-quality care, CMS requires an initial survey of the

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Box 2. Facility Administrator

Responsibilities
- Fiscal management
- Staff training and coverage
- Medical staff appointments and coverage
- Quality assessment and process improvement program
- Internal grievance process for patients
- Emergency coverage and backup
- Electronic data submission
- Relationship with ESRD Network

Qualifications
- Must possess sufficient educational and practical experience to fulfill expectations of role
- If also acting as nurse manager, then:
  - Registered nurse
  - At least 12 mo of clinical nursing experience
  - An additional 6 mo of experience providing nursing care to dialysis patients
  - Must be a full-time employee of the facility
  - May not cover >1 facility

Abbreviation: ESRD, End-Stage Renal Disease.

facility to achieve certification as an ESRD provider, as well as periodic resurveys thereafter. This survey is delegated to the state departments of health by CMS. States may also require separate licensure. The survey process, known as the ESRD Core Survey, uses a risk-based approach that is data driven. Data are obtained from the Dialysis Facility Report (DFR; see Quality Metrics section of this article) and other outcomes data sources to determine the priority of facility surveys. The data also focus the survey to problem areas for which outcomes are less than expected. Trained surveyors assess safety hazards related to water and dialysate, reuse, machine operation and maintenance, direct care, interdisciplinary assessment, care planning, and delivery of care. If poor outcomes are identified, it would be expected that the QAPI process in the facility had identified the issues and developed actions to address them. Depending on what conditions are found to be deficient, the survey can find the facility to be in full compliance or can issue citations at the "Standard," "Condition," or "Immediate Jeopardy" level. In circumstances of Immediate Jeopardy, considered life-threatening situations, the state agency is authorized to close a facility until it is considered safe. Helpful information can be found in the ESRD Core Survey Field Manual, the surveyor "Laminates," and the Measures Assessment Tool (MAT) on CMS website.

Box 3. Selected Laws and Regulations Affecting Dialysis Facilities

State and Local
- Local life safety codes
- Local building codes
- State dialysis facility licensure laws (if applicable)
- State board regulations regarding medical, nursing, and pharmacy practice

Federal
- Occupational Safety and Health Administration
- Office of the Inspector General
- Clinical Laboratory Improvement Act
- Centers for Disease Control and Prevention
- Americans With Disabilities Act
- Family and Medical Leave Act

National Organizations
- Association for the Advancement of Medical Instrumentation

Additional Readings

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PERSONNEL

The facility administrator is responsible for ensuring that adequate numbers of qualified staff are in place to care for patients. This includes the recruitment and appointment of medical staff physicians and nonphysician practitioners such as advanced practice nurses and physician assistants. The CfC specify that an adequate number of qualified and trained staff must be present when patients are undergoing dialysis to ensure that appropriate dialysis care is delivered and patient needs are met. Although a specific staff to patient ratio is not defined, the facility administrator must meet any applicable state regulations. Consideration must be given to the level of independence and care needs of the patients who will be served and the expertise of the staff in those areas. Adequate staffing ratios must be present to be able to see every patient during treatment and provide routine care, assessment, and monitoring, as well as respond to changes in patient conditions and attend to emergency situations. The roles and qualifications of key patient care personnel in the dialysis facility are summarized in Table 1.

The interdisciplinary team is composed of the patient's nephrologist, a registered nurse (RN) familiar

Table 1. Hemodialysis Facility Personnel

Position	Major Responsibilities and Qualifications
Medical director	• Delivery of patient care and patient outcomes • Facility quality assessment and performance improvement program • Ensuring that staff are adequately trained • Approval of training and educational materials • Development, review, and approval of patient care policies and procedures • Ensure adherence to policies and procedures by staff (including all attending physicians and midlevel providers)
Charge nurse	• RN or LPN who meets practice requirements in the state • Must have 12 mo of nursing experience, including 3 mo providing nursing care to patients undergoing dialysis • An RN must be present at all times when there are patients in the facility • A charge nurse must be designated and present for each patient shift
Nurse	• Delegates care to PCT (if applicable) when patients arrive for treatment • Assesses patients before, during, and after dialysis • Evaluates patient's response to dialysis • Develops plan and carries out action to meet patient's needs • Participates with IDT to perform initial and ongoing comprehensive assessment and POC for patients • Seeks patient's and family's input into care goals and keeps them informed of recommendations of IDT • Reviews laboratory work, medications, and other concerns and informs IDT to re-evaluate and revise POC • Assist in education of patients about disease and treatment including all RRT options (home dialysis and transplantation)
PCT	• Defined by CMS as any unlicensed staff member who has responsibility for direct patient care • Responsibilities subject to limitations of state law but may include preparing dialysis apparatus, equipment safety checks, dialysis initiation including cannulation, IV administration of heparin and normal saline solution, subcutaneous or topical administration of local anesthetics, monitoring patients during dialysis, documenting tasks and observations • Must have high school diploma and at least 3 mo of experience under direct supervision of an RN • Must complete a training program including specified topics approved by the medical director and governing body • Must be certified by a CMS-approved or national PCT certification program within 18 mo of hire
Water treatment system technician	• Must finish a training program including water testing, risks and hazards of improperly prepared dialysate, and bacterial issues • Training must be done and competency must be ensured in the use of equipment by the manufacturer • Training specific to tasks performed such as mixing dialysate, disinfection of equipment, equipment maintenance and repairs • Periodic audits of compliance with testing of technician's knowledge and skills • Training program approved by the medical director and governing body
Dietitian	• At least 1 y of professional work experience as a renal dietitian • Must be able to do complex nutritional assessments and evaluate laboratory results • Assist IDT in managing anemia, renal bone disease, performing kinetic modeling • Monitoring patients' adherence and response to diet • Recommend interventions to improve nutritional issues • Participate in POC and QAPI program • May be shared between facilities
Social worker	• Master's degree in social work with specialization in clinical practice • Must be skilled in assessing patient's psychosocial situation and how it will affect or influence treatment outcomes • Interventions designed with the IDT, patient, and family to maximize the effectiveness of treatment • Use of validated tools such as the SF-36 and KDQOL to improve care and monitor the outcomes of directed interventions • Counseling services as needed • Assist patients in adapting to chronic disease • Participate in POC and QAPI program • May be shared between facilities

Abbreviations: CMS, Centers for Medicare & Medicaid Services; IDT, interdisciplinary team; IV, intravenous; KDQOL, Kidney Disease Quality of Life; LPN, licensed practical nurse; PCT, patient care technician; POC, plan of care; QAPI, Quality Assurance and Performance Improvement; RN, registered nurse; RRT, renal replacement therapy; SF-36, 36-Item Short Form Health Survey.

with the patient, the dietitian, the social worker involved in the patient's care, and other personnel as appropriate. The RN performs an initial and ongoing comprehensive assessment of the patient and seeks the patient's and family's input into care goals. The patient is expected to be a member of his/her interdisciplinary team and a participant in the discussion regarding the plan of care. On a regular basis,

the RN reviews the patient's laboratory work, medications, and other concerns and brings them to the attention to the interdisciplinary team to re-evaluate and revise the plan of care as needed. Patients are taught about their disease and the various aspects of their treatment. Patients are informed about all renal replacement options, including transplantation, and are supported in their decisions to investigate these options.

The facility administrator must ensure that all staff have the appropriate licensure and certifications and have successfully completed a training program and orientation to prepare them for their role in the care of dialysis patients. There must be a process to provide and document ongoing education and competency testing to ensure safe effective practice, including emergency situation response. Staff not found to be competent must be retrained. Employees must have periodic health screening and must meet the federal and state guidelines, including testing for tuberculosis and hepatitis B virus (HBV).

The facility administrator must also ensure that there are adequate numbers of staff and professionals needed to support the QAPI process. The facility administrator has the responsibility, along with the medical director, to ensure the quality of services being provided in the facility. Communication between the facility administrator and the governing body regarding the QAPI program is a must. Areas of need require planning and action, with follow-up to determine the effectiveness of interventions. The need for staff requires a thorough assessment of quality data by the governing body and QAPI committee to identify areas requiring improvement. When the areas have been identified, the facility administrator must develop a plan to meet the needs in a fiscally responsible manner. If it is determined that issues are more related to a need for practice or process changes or education, the facility administrator must ensure that those plans are developed, operationalized, and evaluated to determine effectiveness. If individual performance issues are found, staff must be held accountable and a plan of re-education and competency testing or corrective disciplinary action must be taken. This is reported to the governing body as well. Differences between the interdisciplinary team and QAPI committee are summarized in Table 2.

Education needs are considerable in dialysis facilities and include orientation and initial competency testing of all staff, as well as ongoing education and retesting. The development and provision of a patient care technician training program must include the elements of patient care, understanding ESRD and its related conditions, machine technology, water treatment, infection control, patient education concepts, and understanding of quality components and the QAPI process. Effective staff recruitment and hiring, as well as ongoing staff retention, is an important area of focus for the facility administrator. Reviews of salaries and benefit options for competitiveness, as well as financial impact, must be done on a regular basis. This also requires an understanding of labor laws and practices, workers' compensation, Family Medical Leave Act regulations, Americans with Disabilities Act requirements, affirmative action, and other human resources–related topics.

Table 2. Comparison Between Interdisciplinary Team and QAPI Committee

	Interdisciplinary Team	QAPI Committee
Level of focus	Individual patient	Facility system
Goal	Develop individualized plan of care	Improve system processes and outcomes
Chair	Patient's nephrologist	Facility medical director
Members	Nurse, dietitian, social worker; patient participates during or after meeting by discussing and signing off on patient's plan of care	Facility administrator, dietitian, social worker; other stakeholders of processes as appropriate
Frequency of meetings	Within 30 d of patient's arrival in facility, 3 mo after patient's arrival, annually after patient's arrival; monthly if patient is unstable	Monthly; more frequently as appropriate for rapid-cycle improvement

Abbreviation: QAPI, Quality Assurance and Performance Improvement.

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FINANCES

Budget and Costs

Fiscal responsibility is a key role of the facility administrator. Capital and operating budgets must be developed annually and monitored for expense variances to budget. An operating budget is an in-depth projection of all estimated income and expenses that is based on forecasted revenue for the upcoming year. It often comprises several subbudgets, the key one being the expected revenue budget, which is done first. Preparing an operating budget requires a balancing act of analyzing the existing data for revenue and expenses, then forecasting the numbers for the year ahead based on knowledge of volume, revenue, or expense changes. Because capital expenses are long-term costs, they are excluded from the operating budget. Major items to be considered in an operating budget are listed in Box 4. Revenue begins with correctly capturing complete and accurate data at the time the patient is dialyzed. In addition to careful case management and process reviews, it involves complete charge capture with accurate coding. Claims must then be prepared and submitted, with follow-up with payers as needed. The handling of rejections and appeals is important, as are opportunities to accelerate collection of accounts receivable and prevention of bad debt.

It is important for the facility administrator to calculate a break-even point to determine how much to charge or how much patient care volume must be delivered to cover costs. In other words, the revenue collected from providing dialysis services must equal or exceed the costs to provide them. Because payment for health care is more fixed than in many industries, this calculation often distills down to a patient volume analysis. All costs must be considered in the budgeting process. Fixed costs must be determined and then divided by expected volume to determine fixed costs per treatment, costs such as labor and supplies can be calculated and analyzed on a cost per treatment, and then total cost merged from both fixed and variable costs. Total revenue would be the expected revenue per treatment multiplied by the expected volume. Even in a not-for-profit business, there must be a favorable margin that is reinvested in the facility to support growth and unanticipated costs.

Box 4. Major Items in an Operating Budget

Employment costs
- Salaries
- Contract labor
- Orientation and education
- Benefits

Nonemployment direct costs
- Medical supplies and pharmaceuticals
- Equipment lease and rentals
- Repair and maintenance

Nonemployment indirect costs
- Office supplies
- Utilities
- Rent
- Association fees
- Administrative expenses
- Contracted services (laundry, housekeeping, landscaping, security)

Reimbursement

Medicare

Public law 92-603, the Social Security Act of 1972, provides Medicare eligibility for patients with ESRD. If the patient already receives Medicare benefits due to being disabled or 65 years or older, Medicare payment for dialysis begins immediately. If the patient does not already receive Medicare benefits, full Medicare benefits including payment for dialysis begin the first day of the third calendar month after the Medical Evidence Report (form 2728) certifying that the patient has ESRD is signed by the nephrologist. Only patients who have paid into the Social Security system for a total of 20 quarters or are a dependent of someone who has can qualify for Medicare benefits. Medicare part B pays 80% of the cost of dialysis ("primary"); the patient needs coinsurance to pay the other 20% ("secondary"). If the patient has employer-paid group health insurance at the time he/she develops ESRD, the commercial insurance is primary for 30 months if the patient is already Medicare eligible or 33 months (the 3 month waiting period with no Medicare plus 30 months) if the patient is not Medicare eligible. Medicare is the secondary (20%) payer (MSP) during the 30 monthly "coordination of benefits" period. The 3-month Medicare waiting period is waived if a patient initiates home dialysis training or undergoes kidney transplantation during the waiting period. In the case of home dialysis training, Medicare becomes effective the first day of the month that home training began. In the case of kidney transplantation, Medicare becomes effective the first day of the month of the transplantation or up to 2 months before if transplantation evaluation was initiated during that period. The 30-month MSP period still applies for home dialysis patients.

The concept of bundling payment for dialysis patients was initiated in 1981. However, it was revised substantially with the Medicare Improvements for Patients and Providers Act (MIPPA) in 2009, which established a bundled reimbursement system for dialysis to include the previous "composite rate" items and services, injectable drugs and oral equivalents, and additional previously separately billable

laboratory tests beginning in 2011. The primary goal of the bundled payment system was to disincentivize the overuse of drugs that were previously separately reimbursable. The original MIPPA legislation provided for the inclusion of oral ESRD drugs with no intravenous equivalent (such as phosphate binders and calcimimetics) into the bundle in 2014. Subsequent legislation has postponed the inclusion of these drugs into the bundle to 2024.

Medicaid

Medicaid is the health care safety net for low-income patients in the United States. Patients who qualify for Medicare as primary payer for dialysis (80% payment) may also qualify for Medicaid if they meet low-income requirements that vary by state. Patients who have both Medicare and Medicaid coverage are termed dual eligible. Dialysis patients who do not qualify for Medicare because they have not contributed to the Social Security system for 20 quarters or are a dependent of someone who has may qualify to receive Medicaid benefits as their sole source of dialysis payment. For patients who are dual eligible (Medicare 80%, Medicaid 20% payment), reimbursement for the 20% due from Medicaid varies by state. Some states do not pay the entire amount and some states pay nothing at all. For patients who are Medicaid only, most states pay the dialysis facility significantly less than the Medicare-allowable amount, which may be far less than the cost of the treatment. Because Medicare covers only 80% of the cost of dialysis, patients who do not qualify for Medicaid must seek co-insurance or "Medi-Gap" coverage for the remaining 20%. Some states do not allow Medi-Gap coverage to be sold to Medicare patients younger than 65 years, so those patients are left with no co-insurance.

Commercial Insurance

Patients with commercial insurance as the primary payer are generally those in the 30-month (if already eligible for Medicare due to age $\geq$ 65 years) or 33-month (if not already eligible for Medicare due to age $<$ 65 years) "coordination of benefits" period with an employer-paid health plan. Commercial insurance typically pays for dialysis treatments at several times the Medicare rate, which is individually negotiated with the dialysis provider or its parent company. The dialysis treatment margin provided by commercial payers compensates for the negative margins on Medicaid patients. In some dialysis organizations, a favorable payer mix in one facility compensates for an unfavorable payer mix in another facility that is operating at a loss and, if independent, could not survive economically.

Additional Readings

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PHYSICAL ENVIRONMENT

In addition to clinical care activities and financial oversight, consideration and attention must be paid to issues related to the physical environment of the dialysis facility. Physical environment requirements of the CfC address building safety, equipment maintenance, the patient care setting, emergency preparedness, and fire safety. This includes the ensurance of proper maintenance and repair of such items as the dialysis equipment, operating systems, water treatment systems, and physical building and grounds.

In a health care space such as a dialysis facility, patients usually occupy 70% of the space, with other services using the remaining 30%. Full visibility is a part of the standards and requires all patients to be fully visible to staff at all times. The space should be both safe and efficient, but also pleasant and conducive to patient needs during treatment, as well as during other activities in the facility. The dialysis facility must ensure that all equipment (including that for emergencies, dialysis, and water treatment) is maintained and operated following the manufacturer's recommendations.

Additional items covered in the physical environment section of the CfC apply to patient comfort and privacy. Consideration must be given, for example, to the environmental temperature so that it is comfortable for both patients and staff. Patients who feel cold must be allowed to use blankets, whether provided by the patient or the facility. The patient must be provided privacy during examination or treatment of the exposed body. Despite the need for privacy, patients should be in direct view of staff during the entire treatment. This allows staff to monitor patients for untoward reactions to dialysis or accidental needle removal or disconnection. Patients must have their faces and accesses uncovered at all times to allow staff to monitor their safety. There should be a mechanism

for both patients and staff to give regular feedback and share concerns about safety or quality issues.

Emergency Preparedness

Dialysis facilities must have plans for emergency preparedness that include fire, equipment or power failures, care-related emergencies, interruption of the water supply, and likely natural disasters based on the facility's geographic area. Facilities may prepare for other types of emergencies, including bioterrorism or active shooters, that are identified after the performance of a facility risk assessment. In addition to having a plan for emergency management, it is necessary for the dialysis facility to provide appropriate training and orientation in emergency preparedness to the staff that are assessed at least annually. This includes quarterly fire drills that involve both staff and patients. Patients also must be educated and prepared for emergency situations. This training must occur often enough so that staff and patients can implement emergency plans. State or local fire codes must be met. All other Life Safety Code provisions in New and Existing Ambulatory Health Care Occupancies apply to dialysis facilities, including those about automatic notification–equipped fire detection and alarm systems. Dialysis facilities must have a plan and educate staff and patients where to go during an emergency. Dialysis facilities should provide an alternate telephone number for patients to use when the dialysis facility is unable to receive telephone calls because of an emergency. The facility administrator should establish contact with its local disaster management agency at least once a year to check that they are aware of the dialysis facility's needs in cases of emergency.

Nurses at the facility should be trained and ready to handle clinical emergencies that are likely to happen in dialysis. The facility should have equipment available for treating medical emergencies such as suction machines and defibrillators. Nurses and patient care technicians must be certified in cardiopulmonary resuscitation. The medical director should decide the specific emergency drugs to be available, and they should be described in the facility's policies and procedures.

Water Quality

Water quality is the responsibility of the medical director, and a detailed discussion is beyond the scope of this article. Without appropriate monitoring and maintenance of water quality, the lives of patients are placed at significant risk. There have been numerous incidents with catastrophic consequences as a result of poor water quality. Water quality is mentioned frequently in the CfC and is a frequent trigger for citation by state surveyors. The water technician should review the AAMI guidelines annually and incorporate the most recent recommendations into practice. State surveyors will directly observe chlorine/chloramine testing in a dialysis unit, interview staff to assess their fund of knowledge and competency regarding water quality, and review documentation of testing and maintenance of the water system. The recommended frequency of checking for chlorine/chloramines, the appropriate calibration of a conductivity meter, and the proper preparation of the bicarbonate mix are all processes that involve multiple individuals, and the procedures must be standardized to minimize error.

Water quality measurements include chemical, electrolyte, and microbial levels. Some compounds that deserve special attention include aluminum, chloramine, fluoride, and nitrate. Aluminum at high levels is detrimental to bone and hematologic and neurologic axes. Chloramines and nitrates can induce methemoglobinemia. CMS requires that the total viable microbial count must be <200 colony-forming units (CFU)/mL and endotoxin concentration <2 endotoxin units (EU)/mL. However, the action level is 50 CFU/mL and 1 EU/mL, respectively, for product water, that is, water used to prepare dialysate. At the action level, the typical plan is to repeat cultures, sometimes to disinfect the system and again repeat cultures. Documentation of the testing, results, and the action plan for water quality is critical to the successful management of a hemodialysis unit. Whether to continue dialysis or stop dialysis and the specifics of the action plan are based on the final determination of the medical director; however, the medical director relies on the QAPI team, and in particular, the lead water technician to present the abnormal data and potential action plans. Water quality is an important component in the monthly QAPI meetings, and the status of the facility's water and any deviations in protocols or quality metrics are subject for review. It can be helpful to have logs available to the group at the monthly QAPI meetings to make everyone aware of the shared responsibility of water quality. Water quality assurance is a team effort and vital for the safe care of dialysis patients.

Infection Control

Infection control is the responsibility of the medical director, and a detailed discussion is beyond the scope of this article. Infection control issues are often cited by state surveyors. All facility staff should be held accountable for infection control. Handwashing is essential for infection control in a hemodialysis unit. Gloves should be worn prior to patient contact or equipment manipulation. Hands should be washed before and after use of gloves. Gloves should be changed when soiled or when moving from one

patient chair to another, as well as any time that access manipulation or intravenous medication administration occurs. The facility must be designed with enough sinks to facilitate handwashing, with separate utility sinks for cleaning equipment.

Staff should wear personal protective equipment, which includes designated garments with sleeves appropriate to the anticipated potential exposure. The most robust protection should be used during high-risk components of the dialysis procedure, such as treatment initiation and termination. Any items that are in the patient's dialysis station could become contaminated and should be handled with caution and cleaned after the treatment (ie, a patient's blanket). Staff, along with patients, should be vigilant not to cross-contaminate clean and dirty equipment. For example, unused medications would be "clean" and used needles would be considered "dirty." The patient treatment area should have designated clean and dirty partitions. Disinfection of the dialysis treatment equipment should be done according to manufacturer's guidelines. At the end of every patient treatment, the dialysis station needs to be thoroughly cleaned.

Hepatitis and Isolation

Cleaning equipment and following proper isolation protocols is essential to infection control. Hepatitis serologic evaluation is important to prevent the transmission of HBV in patients with ESRD. All new patients should have hepatitis B surface antigen (HBsAg), total antibody to hepatitis B core antigen (anti-HBc), and antibody to HBsAg (anti-HBs) results determined before admission for treatment. When results of this testing are unknown at admission as a result of an emergency, the patient should be tested as soon as possible. Any patient whose anti-HBs level is <10 mIU/mL should have HBsAg tested monthly. Patients who have received and responded to the HBV vaccine should have an anti-HBs titer measured annually to determine whether a booster dose of the vaccine is needed. All patients and staff whose anti-HBs levels are <10 mIU/mL should be offered the vaccine. Cases of HBsAg-positive seroconversions must be reported to the health department as mandated by local regulation. Patients who have positive test results for HBsAg must be isolated, and follow-up testing should be performed to determine when the patient may be taken out of isolation. State surveyors may look for documentation for seroconversions, including actions taken in response and analysis to evaluate for potential transmission of the virus within the facility. Any HBsAg-positive patients should dialyze in separate isolation rooms, although in facilities built prior to the 2008 update in regulations, any separate isolation area would suffice. There must be separate equipment for HBsAg-positive patients, and staff members should not be caring for both HBsAg-positive and HBsAg-negative patients simultaneously.

In January 2016, the Centers for Disease Control and Prevention (CDC) issued an advisory to dialysis facilities because of an increased number of reports of newly acquired hepatitis C virus (HCV) infection among hemodialysis patients. The CDC urged dialysis providers to assess current infection control practices to ensure that infection control standards are being followed; any gaps identified by the assessments are addressed; patients are screened for HCV according to CDC guidelines to detect infections, determine treatment potential, and halt secondary transmission; and all acute HCV infections are promptly reported to health authorities. The CDC recommends that all hemodialysis patients be screened for HCV antibody (anti-HCV) upon admission to the dialysis facility and every 6 months thereafter. For patients with positive anti-HCV results, nucleic acid testing for HCV RNA is recommended to confirm infection. Any HCV seroconversion of a hemodialysis patient should trigger QAPI activities to determine the source of the transmission.

Staff must be oriented to infection control policies and procedures at the start of employment and annually at a minimum. Infection control is another integral part of the facility's QAPI meetings, and discussion of infections and action plans should be recorded and available for review.

Immunizations

It is recommended that susceptible patients undergoing maintenance dialysis receive HBV vaccination. All patients should undergo annual influenza vaccinations unless there is a specific contraindication. The newer pneumonia vaccination guidelines recommend that for patients who have never received the pneumococcal vaccine, adults should receive a dose of the pneumococcal conjugate vaccine (PCV-13) followed by a dose of the pneumococcal polysaccharide vaccine (PPSV23) a minimum of 8 weeks later. Patients who previously received PPSV23 should receive a dose of PCV-13 at least 1 year after the most recent PPSV23.

Violence in the Dialysis Facility

The dialysis facility has many diverse people in one space at a given time. Conflicts are inevitable but need to be addressed in a systematic way to help diffuse tension and promote safety for both patients and staff. CMS and ESRD Networks carefully review all involuntary patient discharges. Facilities must follow protocols carefully for any involuntary discharges or involuntary transfers or the facility may be subject to

sanctions from CMS. There must be documentation of multiple attempts to resolve the issues of conflict prior to patient discharge or transfer, including the following required steps: (1) notification of the ESRD Network, (2) comprehensive reassessment and revision to plan of care to address the problem, (3) documentation of the ongoing issues and their effect on others and the facility, (4) documentation of steps to resolve conflict, (5) documentation of patient's response to interventions, (6) written orders for involuntary discharge or involuntary transfer must be signed by the attending physician and medical director, and (7) the patient must be given a minimum of 30 days' notice of impending involuntary discharge or involuntary transfer. If a patient is an imminent threat to the safety of patients or staff, the patient can be immediately transferred or discharged and law enforcement authorities should be promptly notified. The social worker is a critical liaison in helping address conflict.

Any member of the facility staff could also be participating in disruptive behavior. Ultimately, the staff managers should give feedback and develop a plan to improve behavior, but if these interventions are not productive, disciplinary action may need to be taken. The medical director should be notified in a timely manner in order to contribute to the improvement plan.

Additional Readings

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QUALITY METRICS

The QAPI team is responsible for ongoing quality assessment and performance improvement in the dialysis facility. The QAPI team includes the medical director, facility administrator, social worker, dietitian, and any other stakeholders in the quality improvement effort, such as a water treatment system technician, infection control expert, and/or nurse with a particular area of responsibility (eg, anemia or vascular access management). Some quality metrics are publicly reported and affect payment, so these can have a significant impact on patient census and the financial health of the facility.

The MAT

The CfC for dialysis facilities were last revised in 2008, and because the CfC cannot adapt to changes in the standards of care for anemia, mineral metabolism, and vascular access, for example, CMS has purposely excluded such quality metrics from the CfC. Instead, these measures are included in the ESRD Interpretive Guidelines used by state surveyors as a guide to the survey process. Metrics included in the interpretive guidelines can be changed at will by CMS in response to changes in medical practice because they do not require written legislation or regulation. The set of quality metrics used by state surveyors is known as the MAT, and because these measures do not involve public reporting or payment, their use does not require a strong evidence basis or vetting by a consensus panel from the ESRD community. It is intended that state surveyors use these measures not as a "pass/fail" grading system, but rather to determine whether a facility has undertaken the appropriate QAPI process if the results of the measure demonstrate opportunities for improvement. Key patient-level indicators in the MAT at the time of this writing include hemoglobin level, indicators of iron status, serum calcium level, serum phosphorus level, parathyroid hormone level, dialysis adequacy, dialysis session duration, serum albumin level, weight loss, overall infection rate, patient immunizations, arteriovenous fistula (AVF) prevalence, prevalence of central venous catheters longer than 90 days, vascular access thrombosis rates, vascular access infection rates, vascular access patency, patient quality of life, patient experience of care, patient grievances, patient survival, and hospitalizations.

The DFR

The DFR is an annual report provided as a resource to each dialysis facility for describing certain aspects of clinical experience at the facility compared with those of other caregivers in the state, ESRD Network, and United States. The DFR is based on data from Medicare claims and CROWNWeb and provides demographics of patients in the facility; standardized ratios (observed to expected counts based on case-mix) for mortality, hospitalization, and transplantation; transplant waitlist and influenza vaccination rates; and clinical data including hemoglobin level, adequacy of dialysis, and vascular access. The DFR can be useful for internal quality improvement activities at a facility. The report is also distributed to the respective state department of health and may trigger a facility survey if there are significant perceived deficiencies. The DFR is distributed to the ESRD Network and may trigger

targeted quality improvement activities directed by the Network.

Dialysis Facility Compare and 5-Star Rating

Dialysis Facility Compare is a publicly available website (www.medicare.gov/dialysisfacilitycompare) that allows any individual to view quality metrics from dialysis facilities and compare selected facilities side by side. The data derived primarily from CROWNWeb and Medicare claims are usually revised in the third or fourth calendar quarter to include the previous calendar year. Dialysis Facility Compare metrics at the time of this writing include: (1) standardized transfusion ratio (based on Medicare claims and case-mix adjusted), (2-4) dialysis adequacy (adult hemodialysis, pediatric hemodialysis, and adult peritoneal dialysis, respectively), (5) fistula prevalence, (6) prevalence of dialysis catheters longer than 90 days, (7) hypercalcemia (percentage of patients with 3-month average serum calcium $>$ 10.2 g/dL), (8) standardized mortality ratio, (9) standardized hospitalization ratio, and standardized hospital readmission ratio. These 9 metrics (ie, excluding standardized hospital readmission ratio) are grouped into 3 domains: (1) standardized outcomes (STrR standardized transfusion ratio, standardized mortality ratio, and standardized hospitalization ratio), (2) vascular outcomes (fistula prevalence and catheter prevalence), and (3) other outcomes (all dialysis adequacy and hypercalcemia). Each domain is given a score from 0 to 100 by averaging the normalized scores within that domain. A final score between 0 and 100 is obtained by averaging the 3 domain scores. A dialysis facility is awarded its star rating based on its total score's relative position compared with all other facilities, rather than the total score itself. The facilities with top 10% scores receive 5 stars, facilities with the next 20% highest scores receive 4 stars, facilities in the middle 40% of scores receive 3 stars, facilities with the next 20% lower scores receive 2 stars, and facilities with the bottom 10% of scores receive 1 star.

The QIP

The 2009 MIPPA legislation established the bundled payment system for dialysis and mandated the establishment of a QIP. The rationale is that because bundling shifts what were previously separately billable items from being profit centers to being cost centers for the provider, the patient must be protected from underutilization of resources with performance measures that affect payment and public reporting. The MIPPA legislation prescribes that the QIP for dialysis is a 2% withhold from the bundled payment, some or all of which can be earned back by the provider by achieving prespecified performance benchmarks. Because the QIP allows the provider to earn some or all of its bundled payment back, but does not provide any additional payment to high achievers, it is a penalty system and not a reward system. The QIP penalty, if there is one, is in increments of 0.5% and affects all of a dialysis facility's Medicare payments for an entire calendar year, known as the payment year (PY). The QIP penalty is determined for a given PY based on the facility's performance 2 years prior. Therefore, for example, a facility's QIP penalty for PY 2019 will be based on its performance in 2017. The performance data are collected in real time during the performance year from Medicare claims and from additional information submitted electronically to the CROWNWeb reporting system, which has been used since 2013. Mandatory QIP measures in MIPPA are anemia management, dialysis adequacy, and patient satisfaction (as possible). Discretionary QIP measures in MIPPA are iron management, mineral metabolism, and vascular access. The QIP began in PY 2012, based on performance data from 2010. At that time, CMS was able to collect performance data only for anemia management and dialysis adequacy from claims, so those were the only 2 domains in the QIP for PYs 2012 and 2013. By 2012, Medicare claims forms were modified to include vascular access, so the QIP for PY 2014 included anemia management, dialysis adequacy, and vascular access. The inclusion of data from CROWNWeb in performance year 2013 has allowed Medicare to expand the QIP to embrace additional domains as directed by MIPPA, starting in PY 2015. The QIP for PY 2015 and beyond includes clinical measures and reporting measures. The clinical measures are scored according to national benchmarks established during the year prior to the performance year. Therefore, for clinical measures in PY 2019, the performance year was 2017 and the benchmarks are established based on national data from 2016. For each of the clinical measures, there is an achievement score and an improvement score. The facility is able to claim the better of these 2 scores. The achievement score is calculated on a 10-point scale between the national achievement threshold (15th percentile from the year prior to the performance year) and the national benchmark (90th percentile). Thus, for example, if a facility has an AVF prevalence rate of 54%, the achievement threshold is 46%, and the benchmark is 74%, the facility would receive 3 points for that measure because 54% is 3/10 of the distance from 46% to 74%. The improvement score is calculated on a 9-point scale between the facility's prior year performance on the measure and the national benchmark. Therefore, for example, if a facility has an AVF prevalence rate of 54%, a prior year AVF prevalence

Table 3. Quality Metrics for Dialysis Facilities

Measure	MAT	DFR	DFC and 5-Star	QIP: PY 2019	Networks: 2016 SOW
Hemoglobin	x	x		Reporting	
ESA dose				Reporting	
Iron status	x				
Transfusions			x	Clinical	
Serum calcium	x		x	Clinical	x
Serum phosphorus	x			Reporting	
PTH	x			Reporting	
Dialysis adequacy	x	x	x	Clinical	
Dialysis session duration	x				
Serum albumin	x				
Body weight loss	x				
Overall infections	x				x
Immunization of patients	x	x			x
AVF prevalence	x	x	x	Clinical	x
CVC prevalence	x	x	x	Clinical	x
VA infections	x				x
VA thrombosis	x				
VA patency	x				
Patient QoL	x				
Experience of care	x			Clinical	x
Patient grievances	x				x
Survival: SMR	x	x	x		
Hospitalizations: SHR	x	x	x		
Readmissions			x	Clinical	
Care transitions					x
Transplantation referral	x	x			x
Home dialysis referral					x
Immunization of staff				Reporting	
Rate of fluid removal				Reporting	

Abbreviations: AVF, arteriovenous fistula; CVC, central venous catheter; DFC, Dialysis Facility Compare; DFR, Dialysis Facility Report; ESA, erythropoiesis-stimulating agent; MAT, Medical Assessment Tool; PTH, parathyroid hormone; PY, payment year; QIP, Quality Incentive Program; QoL, quality of life; SHR, standardized hospitalization ratio; SMR, standardized mortality ratio; SOW, scope of work; VA, vascular access.

rate of 26%, and the benchmark is 74%, the facility would receive 5 points for that measure because 54% is 5/9 of the distance from 26% to 74%. Because the improvement score is higher than the achievement score in this example, the facility can claim the 5-point improvement score for that measure.

In addition to the clinical measures for PY 2015 and beyond, there are also reporting measures that are scored based on whether a facility provided the required data to Medicare, but not on the quality of care represented by those data. For PY 2019, the clinical measures will include adequacy of dialysis (a composite of adult hemodialysis, adult peritoneal dialysis, pediatric hemodialysis, and pediatric peritoneal dialysis), vascular access (prevalence of AVFs and catheters $>$ 90 days), hypercalcemia, National Healthcare Safety Network bloodstream infections (outcomes, not just reporting), standardized hospital readmission ratio, standardized transfusion ratio, and patient experience of care (In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems [ICH-CAHPS] survey outcomes, not just reporting that the instrument was administered). Reporting measures for PY 2019 will include anemia management (hemoglobin level and erythropoiesis-stimulating agent dose), mineral management (serum calcium, phosphorus, and parathyroid hormone levels), pain assessment and follow-up, depression screening and follow-up, personnel influenza vaccination, and rate of fluid removal during hemodialysis. Clinical measures will constitute 90% of the weighted score, and reporting measures, 10%.

ESRD Networks

The ESRD Networks work with consumers and providers of care for ESRD patients to refine care delivery systems and improve the quality of care for this vulnerable population. The Networks have access to facility-specific data from the DFR and CROWNWeb, which allows them to target quality activities to facilities with the greatest opportunity for improvement. The Networks provide educational resources, support services, and other tools to assist both patients and providers. The Network also provides assistance to evaluate and resolve patient grievances and ensure that patients' rights are maintained while reducing involuntary discharges. ESRD Network activities are defined by their scope of work, which is revised annually based on what CMS perceives as the greatest areas of need for quality improvement in the ESRD program. Quality metrics for the MAT, DFC, 5-Star Rating, QIP for PY 2019, and domains of network quality improvement activities for the 2016 scope of work are summarized in Table 3.

The ESRD Networks offer a 5-Diamond Safety Program to assist dialysis facilities in improving staff and patient awareness regarding specific patient

Box 5. Topic Areas in the 5-Diamond Safety Program

- Patient safety principles
- Communication
- Constant site cannulation
- Emergency preparedness
- Hand hygiene
- Health literacy
- Influenza vaccination
- Transplantation
- Medication reconciliation
- Missed treatments
- Patient-provider conflict
- Patient self-managed care
- Sharps safety
- Slips, trips, and falls
- Stenosis/vascular access monitoring

safety issues and promoting a culture of safety. The program consists of educational modules, and the completion of each module earns a "Diamond" for the facility. The topics of the modules are listed in Box 5.

Additional Readings

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