

What Medical Directors Need to Know about Dialysis Facility Water Management

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Abstract

The medical directors of dialysis facilities have many operational clinic responsibilities, which on first glance, may seem outside the realm of excellence in patient care. However, a smoothly running clinic is integral to positive patient outcomes. Of the conditions for coverage outlined by the Centers for Medicare and Medicaid Services, one most critical to quality dialysis treatment is the provision of safe purified dialysis water, because there are many published instances where clinic failure in this regard has resulted in patient harm. As the clinical leader of the facility, the medical director is obliged to have knowledge of his/her facility's water treatment system to reliably ensure that the purified water used in dialysis will meet the standards for quality set by the Association for the Advancement of Medical Instrumentation and used by the Centers for Medicare and Medicaid Services for conditions for coverage. The methods used to both achieve and maintain these quality standards should be a part of quality assessment and performance improvement program meetings. The steps for water treatment, which include pretreatment, purification, and distribution, are largely the same, regardless of the system used. Each water treatment system component has a specific role in the process and requires individualized maintenance and monitoring. The medical director should provide leadership by being engaged with the process, knowing the facility's source water, and understanding water treatment system operation as well as the clinical significance of system failure. Successful provision of quality water will be achieved by those medical directors who learn, know, and embrace the requirements of dialysis water purification and system maintenance.

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Introduction

Be Engaged

It can be disconcerting to medical directors when they realize that, as a Centers for Medicare and Medicaid Services (CMS) condition for coverage (CFC), “the medical director is responsible for the safety and quality of the water used for dialysis treatments” (1). Although this reaction is understandable, with education and training, all medical directors can show the appropriate leadership necessary to keep their clinic's water treatment system running smoothly and provide a foundation for optimal patient care through the provision of purified water for dialysis. To this end, informed engagement from the medical director around water quality is critical. The medical director shapes the facility attitude toward water quality, and he/she has both the authority and responsibility to make the issue a high priority (2).

Verifying efficient operation of the water treatment system should be an integral component of each clinic's quality assessment and performance improvement program (QAPI). Achieving the necessary CMS CFC for dialysis water quality involves reaching thresholds for both chemical purity (Table 1) and microbiologic and endotoxin purity (Table 2), all of which require proficient operation of the water treatment system and vigilant monitoring. QAPI meetings are convened regularly and attended by the medical director and the clinic's interdisciplinary team, so that among

facility, personnel, and patient care topics, results of product water chemical analyses, dialysate and product water laboratory testing, and microbiologic testing of the water distribution system can be reviewed. In the context of continuous improvement and CFC compliance (Section 494.40 Condition: Water and Dialysate Quality [1]), the medical director and the facility biomedical technician should review the operation and testing records of the water treatment system recorded in the maintenance and monitoring log. Over and above remaining compliant in this regard, a monthly QAPI meeting would be the appropriate forum for risk analyses and assessment of water quality improvement initiatives. As necessary, the medical director should drive root-cause analyses to establish indicators of water quality problems, evaluate the associated risks, and determine mitigation in the context of existing QAPI processes.

Know Your Source Water

With assistance from the facility's biomedical technician or another person with operational understanding of the dialysis facility, the medical director should ascertain from where the clinic's water is derived. The quality and characteristics of the facility's source water could affect the operation of the facility's water treatment system and guide planning efforts, especially in cases where the source water may become compromised, which may be the case in a

Table 1. Drinking water standards versus dialysis water standards

Chemical	Water Safety Thresholds	
	Maximum Allowable Chemical Contaminant Levels (mg/L)	EPA Drinking Water Standard (mg/L)
Calcium	2 (0.1 mEq/L)	—
Magnesium	4 (0.3 mEq/L)	—
Potassium	8 (0.2 mEq/L)	—
Sodium	70 (3.0 mEq/L)	—
Antimony	0.006	0.006
Arsenic	0.005	0.01
Barium	0.10	2
Beryllium	0.0004	0.004
Cadmium	0.001	0.005
Chromium	0.014	0.1
Lead	0.005	0.015
Mercury	0.0002	0.002
Selenium	0.09	0.05
Silver	0.005	0.1
Aluminum	0.01	0.5–0.2
Chloramines	0.10	4.0 (Cl ₂)
Free chlorine	0.50	4.0 (Cl ₂)
Copper	0.10	1.0
Fluoride	0.20	2.0
Nitrate (as N)	2.0	1.0
Sulfate	100	250
Thallium	0.002	0.002
Zinc	0.10	5.0

Information from the Association for the Advancement of Medical Instrumentation RD52 (5) and the US Environmental Protection Agency (EPA) (4).

Table 2. Testing thresholds for microbiologic contaminants

Guideline and Contaminant	Maximum Allowable Level	Typical Action Level
ANSI/AAMI RD52:2004 and current CMS standard for United States dialysis facilities		
Bacteria water and dialysate	<200 CFU/ml	50 CFU/ml
Endotoxin water and dialysate	<2 EU/ml	1 EU/ml
ANSI/AAMI/ISO 13959:2009^a and 23500:2011 and ANSI/AAMI RD 23500:2014		
Bacteria water and dialysate	<100 CFU/ml	50 CFU/ml
Endotoxin water	<0.25 EU/ml	0.125 EU/ml

ANSI, American National Standards Institute; AAMI, Association for the Advancement of Medical Instrumentation; CMS, Centers for Medicare and Medicaid Services; EU, endotoxin unit; ISO, International Standards Organization.

^aThe 2014 ANSI/AAMI United States guideline cites the thresholds of the 2011 and 2009 documents but diverges from ISO with respect to recommended bacterial culture methodologies. Currently, these documents are not CMS conditions for coverage.

natural disaster. As a best practice, medical directors should verify that the clinical team communicates directly with the providers of source water no less frequently than annually to advise providers of the water's intended use and the need for advance notice when there may be a disruption in provision of source water. In addition, advance warning is needed in the case of urgent or scheduled source water disinfection by hyperchlorination or permanganate treatment. Similarly, any medical director of an acute-care facility located on the campus of a medical center must consider that the medical center could further

treat source water for use in the hospital setting. In such instances, maintaining close communication with hospital operations is critical to know when the plant manager may be treating the hospital water, so that the dialysis facility does not draw hospital water during times of disinfection or treatment (3).

The Environmental Protection Agency (EPA) has minimum standards for municipal drinking water (4); however, the EPA standards for acceptable levels of contaminants are many times greater than those permissible for water used in dialysis treatment (Table 1) (3,5). The 2004

Association for the Advancement of Medical Instrumentation (AAMI) RD52 thresholds for acceptable levels of inorganic chemical contaminants in purified dialysis water have been adopted by the CMS (Table 1) (1,5). Accordingly, chemical testing should be performed for facility-purified product water and source water annually or as required by local regulation. Additional testing should also be considered when system monitoring shows a decline in product water quality or after repairs to the water treatment system that could affect product water quality, such as when reverse osmosis membranes are replaced. Medical directors should know that, since the original publication of RD52, the AAMI has updated its recommendations for tolerable bacterial and endotoxin concentrations in product water and dialysate without modifying its threshold for inorganic contaminants (Table 2). Despite these changes, the CMS continues to use the AAMI RD52 guideline to define CFC compliance. However, it is possible that, in the future, the CMS may update its position, although currently there is no definitive timeline for any changes.

Understanding the characteristics of the facility's source water will allow the medical director, biomedical technician, and clinical team to create a practical and effective quality assurance plan in the event that the source water is compromised because of natural or manmade disasters (Table 3) (6–8). Appropriately, any quality assurance plan should identify backup water sources for emergencies (9). Plans that include the use of tap water or dechlorinated tap water

are feasible only with “evidence the source water has been found safe for such use (*i.e.*, has levels below the AAMI accepted limits of aluminum, copper, chloramines, fluoride, nitrate, sulfate, zinc, and other contaminants known to be toxic to dialysis patients)” (2). The quality assurance preparations of every dialysis clinic should outline both a plan of action and a plan of correction for anticipated failures in source water availability as well as within the water treatment system itself.

Understand the Water Treatment System

Water treatment systems are designed to produce dialysis-quality water, but the types of components used can vary significantly according to the local water quality–defined pretreatment needs, the volume of product water needed by the facility, and the chosen water treatment technology. The water system components depicted here are typical but by no means represent the totality of those used. There is no one size fits all water treatment system, because water treatment steps are routinely tailored to the local water and the contaminants that must be removed.

The dialysis facility water treatment system is usually located in a dedicated, secured, and access-controlled water room that has been fitted appropriately to provide source water, drains, and electric power needed to support the system. The water room should be well organized, uncluttered, clean, and dry. There should be no water leaks or unpleasant odors. The system should have accurate

Table 3. Expect the unexpected: Quality assurance planning

Event	What Happened	Medical Director Takeaway
Charleston, West Virginia chemical spill	A chemical spill in the Elk River contaminated the municipal water source, poisoning water for 300,000 residents and a number of dialysis clinics in the area (6)	Plan ahead; quality assurance plans should identify the dialysis clinic water source in case the municipal water becomes nonpotable
Lake Erie algal bloom	Algae blooms involving cyanobacteria (blue-green algae) have been known to contaminate public water with the hepatotoxin microcystin at levels five times the acceptable level (8)	Be alert; changes in source water can occur, creating chemical contamination that is not easily testable; quality assurance plans should include contingencies for diverse contamination scenarios
Water treatment system bacterial contamination	Fouling of a reverse osmosis membrane caused an epidemic of illness in 44 patients on hemodialysis, of whom two patients died; a sulfur-smelling odor was detected during water sampling from the reverse osmosis device (19)	Ask questions; any water room variable (appearance or odor) out of the ordinary may indicate a problem
Carbon filter failure	Patients receiving dialysis were exposed to chloramine-contaminated water caused by inadequate carbon filter dechlorination (20,21)	Test frequently; chloramine should be tested multiple times every day to protect patients from hemolysis associated with chlorine contamination of dialysis water
Municipal pipe repair	A change in a source water pipe caused aluminum contamination, subsequent aluminum intoxication, and possibly, hard water syndrome; 10 patients died (22)	Stay current; source water quality can change at any time



B



PURPOSE:

The mixing valve blends hot and cold water to establish a preset water temperature at the valve outlet;

77° +/- 5° F for 23G RO systems

70° +/- 5° F for CWP RO systems

The performance of downstream components, in particular the carbon filters and the RO system will be affected if the water temperature varies outside of this range.

HOW DOES IT WORK:

The mixing valve is equipped with a thermometer and an adjustment knob, which allows the operator to set the desired temperature. Water must be flowing through the mixing valve when making temperature adjustments. When the operator has set the desired temperature, temperature sensitive springs will automatically adjust to make minor changes and keep the temperature at or near the desired setting.

QUALITY CHECKS:

Daily observation and recording of the blended water temperature.

NOTIFY FA AND BMT IF WATER TEMPERATURE IS NOT BETWEEN ____ AND ____ DEGREES FAHRENHEIT.

FACTORS AFFECTING OPERATION:

Improper operation of the mixing valve is usually denoted by an inability to adjust the valve to a proper temperature, leaking or dripping from the valve, or a large pressure drop across the mixing valve. The inability to adjust the mixing valve to the desired temperature may be caused by a lack of hot water entering the valve, or an incoming cold water temperature, which exceeds the operators desired temperature setting.

Leaks or excessive pressure drop (delta pressure) across the valve may cause shutdown or improper operation of the downstream water treatment components.

For detailed information on operating this component of the water system, refer to the system operator manual and/or clinic policies.

Figure 1. | A well kept water room is orderly with labeled treatment system components. (A) A well kept water room. Shown is a photograph of a dialysis facility water room. The space is immaculate, and system components are properly labeled. (B) Appropriate labeling for a water treatment system component. This blending valve label describes the device and refers operators directly to clinic reference materials for maintenance and troubleshooting. BMT, biomedical technician facility; CWP, clean water products; FA, facility administrator; RO, reverse osmosis.

up-to-date signage and flow diagrams indicating the direction of water movement and on and off valve positions, as well as a log book listing system components with fields for recording device pressure readings, water flow readings, and purity measures made by the facility team (Figure 1). Each system component should be labeled (1,2), and component manufacturers should be identified on each label, including contact information and a source for the manufacturer's recommendations for correct use (Figure 1).

Medical directors should fully acquaint themselves with the components of their water treatment system and recognize the appearance of a smoothly running water room. Additionally, he/she should inspect the water room whenever possible; if conditions are not as they should be, prompt follow-up with the facility's clinical leaders and biomedical technician is imperative. To identify potentially dangerous conditions or failure of water treatment system components (Table 3), the medical director should never hesitate to question conditions that seem unusual.

Pretreatment

Water treatment system source water will need to be pretreated before it can be purified. Pretreatment consists of several steps, including temperature adjustment, backflow prevention, pressurization, filtration of grit and sediment, water softening, and carbon filtration for dechlorination (Figure 2).

Typically, the first step in pretreatment is temperature adjustment. This step occurs in the blending valve, where heated and unheated source water is mixed to a desired temperature, typically between 60°F and 85°F. It is important to have a properly sized water heater to provide adequate hot water that will accommodate the clinic's demand. The facility team should monitor and record the output temperature at least daily, which should remain relatively constant within a 2–3°F range (Figure 2, Table 4).

After the source water temperature has been adjusted by the blending valve, the system should be fitted with a backflow or reverse flow prevention device. This water treatment system component keeps the water flowing in the direction of the purification system and never backward

toward the water source. There is a pressure gauge on either side of it as well as a filter, which may become clogged. Pressure differences >30 psi across the device suggest an obstruction of the filter that requires maintenance (Figure 2, Table 4).

After the backflow prevention device is the booster pump, which pressurizes the system. As its name implies, the purpose of the booster pump is to keep water moving through the water treatment system, optimizing system performance and purification. A pressure switch turns the booster pump on and off as needed. When system pressure falls below the required threshold (the set point), the pump will automatically turn on; it will turn off again when the system pressure is adequately restored. Set points will vary according to the facility's water need and are unique to the system. The biomedical technician should periodically check the booster pump to ensure that it is applying the appropriate pressure (Figure 2, Table 4).

The next step in pretreatment is filtration of grit and sediment from the feed water (Figure 2, Table 4). This is accomplished by the depth multimedia filter. This device removes large suspended particles from the water and prevents clogging of downstream water system components, including the reverse osmosis unit. At the start of each day, a facility team member should ensure there is a <15-psi difference across the filter. The depth multimedia device should be equipped with a backflush feature programmed to occur automatically outside the normal hours of facility operation.

After larger particulate matter has been reduced, the feed water is ready for water softening (Figure 2, Table 4). The resin media contained in the water softener have a high affinity for calcium and magnesium cations, which are known to make water hard. Feed water containing calcium and magnesium can form scale deposits downstream on the reverse osmosis membrane, fouling the membrane (Table 3) and reducing the quality of purified product water. The calcium- and magnesium-binding capacity of the water softener resin should be regenerated on a routine basis by washing with a concentrated sodium chloride solution or brine. Located adjacent to the water softener is a brine

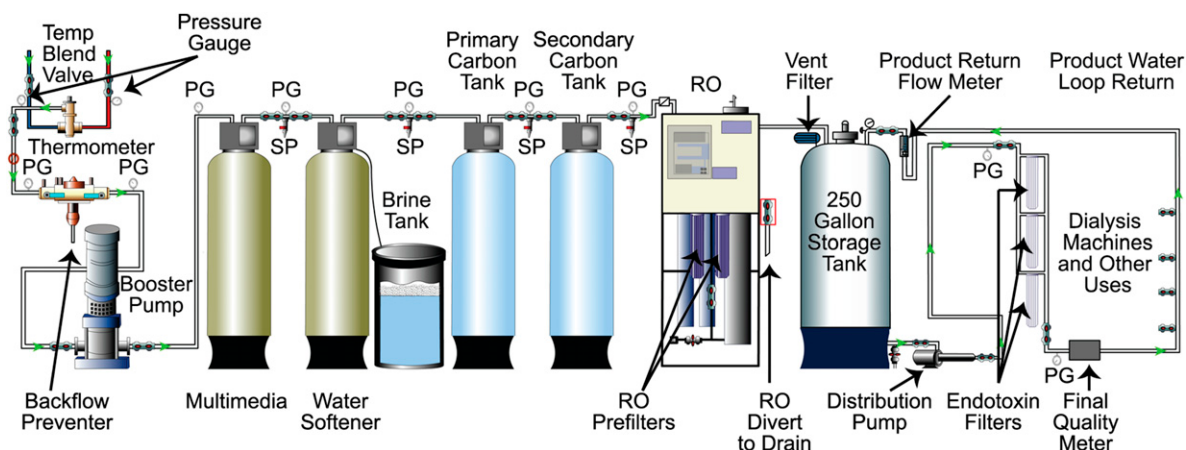


Figure 2. | The water treatment system. This schematic delineates a water treatment system with indirect product water distribution (*i.e.*, a holding tank). PG, pressure gauge; RO, reverse osmosis; SP, sampling port.

Table 4. Monitoring tasks for a clinic water treatment system

Component	Monitor	What to Look For	How Often
Pretreatment			
Blending valve	Water temperature	Appropriate temperature (65–85°F)	Start of each day of operation
Booster pump	Water pressure	Pump turns on and off at appropriate times or flow rates	Periodically
Depth/multimedia filter	Pressure drop across device; backflush timer	$\Delta \leq 15$ psi; set to backflush after facility operation hours	Start of each day of operation
Water softener	Pressure drop across device	$\Delta \leq 15$ psi; timer always visible	Start of each day of operation
Water softener	Media regeneration time	Set to regenerate media with brine wash after facility operation hours	
Brine tank	Salt level in tank	Adequate amount of salt pellets; no salt bridge in the tank	Start of each day of operation
Carbon tanks	Pressure drop across device; backflush timer	$\Delta \leq 15$ psi per tank; set to backflush after facility operation hours	Start of each day of operation
Carbon tanks	Chlorine and chloramine levels in the water between primary and secondary tanks	Total chlorine ≤ 0.1 PPM	Before the first patient treatment of the day and every 4 h after the first patient until the end of day
Reverse osmosis prefilter	Pressure drop across device	$\Delta \leq 20$ psi	Start of each day of operation
Purification			
Reverse osmosis device	Percentage rejection level	$\geq 90\%$	Start of each day of operation
Reverse osmosis device	Product water purity	Device sensors for conductivity and TDS are set according to the manufacturer's recommendations	
Distribution			
Distribution loop	Flow of water at end of the loop	>3 ft/s (indirect) >1.5 ft/s (direct)	Periodically
Bacterial cultures and LAL testing			
Reverse osmosis device, holding tank, and distribution loop	Water cultures	<50 CFU/ml	No less than one time per month
Reverse osmosis device, holding tank, and distribution loop	LAL testing for endotoxin	<1 EU/ml	
Chemical testing			
Source water entering the water treatment system; product water from the reverse osmosis product line	AAMI inorganic chemical analysis; contamination analysis	Chemical compounds below the AAMI safety thresholds for purified dialysis water ^a	Annually and when a new water system is installed, the reverse osmosis membrane is replaced, rejection is $<90\%$, or there are seasonal changes in source water

PPM, parts per million; TDS, total dissolved solids; LAL, limulus amoebocyte lysate; EU, endotoxin unit; AAMI, Association for the Advancement of Medical Instrumentation.

tank containing salt pellets and water, creating a supersaturated salt solution used for softener regeneration. After a media backwashing step, brine is drawn from the tank into the water softener. During the regeneration process, the calcium and magnesium are displaced from the softener resin media through competitive inhibition by sodium ions in the concentrated brine. Afterward, residual salt solution is rinsed out of the water softener. Automatically regenerating water softeners should be equipped with a lockout device to prevent the regeneration process from occurring during patient treatments. The clock and timer integral to the water softener should be read at the start of each treatment day, compared with real time, and adjusted as necessary (Figure 2, Table 4), because power failures might possibly reset media regeneration to occur during patient treatment hours. Pressure gauges on the inlet and outlet of the water softener should be fitted to monitor pressure drop (Δ), and softener water samples should be tested at the end of the use-day to verify that appropriate capacity is maintained. Immediate postsoftener water test results showing <1 grain per gallon or 17 mg/L hardness indicate adequate water softening. The timer-setting verification, Δ -pressure, and hardness test results should be documented daily in the maintenance log (Figure 2, Table 4).

The next step in water pretreatment is carbon filtration, which is used to remove the chlorine and/or chloramines added to municipal water systems. This process typically involves use of a pair of filter tanks placed in series that contain granular-activated carbon (GAC). The first carbon filter tank, called the primary or worker tank, must have adequate capacity to provide a sufficient volume of GAC media to dechlorinate the feed water given the water demands of the dialysis facility. Frequent testing of the feed water flowing from the primary tank outlet is necessary to verify that total chlorine levels remain ≤ 0.1 parts per million (PPM). Thus, the facility team should test total chlorine at the total chlorine sample test port between the two tanks several times a day during clinic operation: at the beginning of each use day, before the start of patient treatment, and no less than every 4 hours throughout each treatment day (Figure 2, Table 4).

The carbon filtration process is critical: chlorine and chloramine exposure can harm patients (Table 3). Moreover, chlorine compounds are reactive and can damage the reverse osmosis membrane, the water treatment system component most necessary for purification. Because this step is so essential, a secondary polisher GAC filter tank is placed immediately downstream from the primary worker tank and after the total chlorine sample test port. In the event that the worker filter has a chlorine breakthrough, this series design provides dechlorination redundancy. Like the primary worker filter, the secondary polisher filter is adequately sized to protect the patients from chlorine and chloramine exposure and also fitted with a sample test port. Should the worker filter have a chlorine breakthrough, the facility team must use the sample test port after the secondary polisher GAC filter to verify total chlorine levels. If total chlorine levels are ≤ 0.1 PPM threshold, patient dialysis treatments can continue. However, after any incidence of chlorine breakthrough from the primary tank, it is recommended that the facility team monitor the total chlorine level at the sample port after the secondary GAC filter tank every

30 minutes until patient treatment is completed, the primary GAC filter tank is replaced, or the primary filter GAC media are replaced (10).

The last component typically considered part of the pretreatment system is the water purification system prefilter (Figure 2, Table 4). This particulate filter (or filters) is positioned in the water treatment system after the secondary GAC filter tank and just before the feed water inlet to the water purification system. The prefilter will catch residual carbon fines (small carbon particles), resin beads, and other debris in the pretreated feed water that might otherwise foul or damage the downstream water purification system. Typically, the prefilter will have a pore size ranging from 1 to 5 μm . Two gauges monitor the inlet and outlet pressures across the filter, and therefore, the operator can monitor filter pressure drop. The facility team must record all filter changes in the water treatment system maintenance log. The reverse osmosis prefilter is typically changed after the cleaning and/or disinfection procedures are completed or whenever pressure drop readings indicate that filter replacement is needed.

Purification

With the pretreatment steps completed, the feed water is ready for purification. The most common method used to purify water for hemodialysis treatment is reverse osmosis. (Figure 2, Table 4). The reverse osmosis device is a self-contained unit that uses a high-pressure pump and a semi-permeable membrane to purify water (Figure 2, Table 4). In this purification process, pretreated water pressurized by the reverse osmosis high-pressure pump is forced to flow across and through the reverse osmosis membrane, which is specifically designed to reject or not allow passage of most dissolved inorganic elements, such as ions of metals, salts, and chemicals as well as organic materials, such as bacteria, viruses, and endotoxin. A properly functioning membrane will reject organics with >200 D as well as 95%–99% of ion particles, which are concentrated and redirected to drain. Device performance is determined by percentage rejection ($>90\%$) and the conductivity of final product water (measured in micro-Siemens per 1 cm or by the total dissolved solids in milligrams per liter or PPM), both of which are measured continuously by an integral monitor set according to the manufacturer's recommendations. The device should display these data and have working audible and visual alarms that, when quality thresholds are not met, can be heard at the reverse osmosis device and in the patient care area. The reverse osmosis device needs periodic maintenance administered by qualified service technicians strictly adhering to the manufacturer's instructions. All maintenance procedures should be accurately recorded.

A less common approach for water purification is deionization (DI). Using DI as a primary water purification method is strongly discouraged (2), but if used as an additional purification step (*i.e.*, for polishing) or in emergency circumstances, DI requires fail-safe systems to divert or block product water flow when product water resistivity drops to <1 M Ω cm, precluding patient exposure to product water outside accepted quality limits. DI may be used to polish product water after reverse osmosis or as a standby method when a reverse osmosis system fails. DI water resistivity readings should be measured

continuously using an appropriate temperature-compensated monitor that will stop product water flow to the distribution system and provide both audible and visual alarms in the water treatment room and patient care area when product water quality drops below the acceptable range. Operator documentation of DI status and performance should be recorded in the water system log before starting patient treatment on a given use-day; additional checks should be documented at the end of a use-day (2).

Distribution

The last step in dialysis water preparation is distribution of purified water to the points of use required to make dialysate solution for patient treatment (Figure 2, Table 4).

The two common types of distribution systems used in dialysis clinics are known as direct and indirect feed systems. With direct feed water distribution systems, pressurized by the reverse osmosis high-pressure pump, the purified water exits the reverse osmosis system and passes through an endotoxin filter before proceeding to the distribution loop designed to provide purified water to the various points of use on the dialysis floor. The unused purified water is returned through the loop to the pump inlet of the direct feed reverse osmosis system to be recycled through the reverse osmosis pump and membrane(s). With indirect water distribution systems, the purified water exiting the reverse osmosis system enters a specially designed holding tank equipped with water-level control devices. These devices interact with the reverse osmosis system, turning it off and on as needed and keeping the appropriate water level in the holding tank, so that the tank does not go dry or overflow. The purified water in the holding tank is repressurized by the distribution booster pump, which directs the purified water from the tank through an endotoxin filter before proceeding out to the distribution loop, providing purified water to the various points of use on the dialysis treatment floor. Indirect purified water distribution systems return unused purified water back to the holding tank. The distribution loop and holding tank should not be made of materials that could contribute chemicals to the purified water, including tubing and plumbing made of aluminum, copper, lead, or zinc.

Ultraviolet (UV) irradiation is sometimes used to help control bacterial proliferation in dialysis water distribution systems (both direct and indirect types). It is important that any UV device used for bacterial control be sized to allow appropriate irradiation contact time at the maximum expected water flow of the water distribution system and be followed by an endotoxin filter. UV devices must also be monitored and serviced as required by the manufacturer to prevent sublethal UV dose delivery. Failure to size and maintain a UV device can lead to proliferation of UV-resistant bacteria in the water distribution system.

Microbial Surveillance

Bacteria and Endotoxin

The water treatment and distribution systems are designed to include sample ports to allow water collection. Collected samples should be sent to an accredited laboratory (preferentially one that specializes in dialysis water testing) for bacterial cultures and endotoxin-level examination (11); sample collection should always occur before

disinfection of the water treatment system, distribution loop, or dialysis machines (2). The facility team should draw water samples from the first and last outlets within the distribution loop and other outlets used to provide purified water for dilution of concentrate and other applications, such as dialyzer reprocessing, using the sampling and testing methodologies specified in the RD52 document (5). The CMS RD52 standards for action-level contamination within dialysate and purified water are 50 CFU/ml and 1 endotoxin unit/ml for bacterial and endotoxin contamination, respectively (Table 2) (5). Necessary "actions may be to repeat cultures, particularly when one in a set of cultures was above the action limit, or to disinfect the system and repeat cultures at several sites" (2). Tests showing bacteria and endotoxin concentrations in excess of the maximum allowable levels (<200 CFU/ml and <2.0 endotoxin unit/ml) can result in discontinuation of dialysis treatment and immediate remediation as deemed most appropriate by the medical director.

The RD52 document contains a map outlining the appropriate sample collection and culturing methods (5). All new dialysis water purification and distribution systems should be tested weekly for bacterial growth and endotoxin until a pattern of compliance with RD52 is shown. After some weeks consistently reaching the required CMC CFC quality standards, testing can be performed monthly; however, more frequent testing will be necessary when cultures from multiple sites are repeatedly positive (2). Using the test results to determine where the system contamination might be is essential; isolation and disinfection of the potential point of contamination are required accordingly. An analysis of bacterial contamination data over time is also recommended to deduce whether contamination by microorganisms, both above and below the action level, may have changed compared with prior testing. Additional testing would also be necessary on clinician request should patients experience illness or pyrogenic reaction during or after dialysis.

Disinfection

The pipes and storage tanks of water distribution systems are at risk for microbiologic contamination, and, therefore, need regular disinfection. All routine and urgent disinfection actions should be recorded in the water treatment system maintenance log and regularly reviewed as a CFC and best practice. The general strategy should be for the biomedical technician to keep a strict schedule designed to avoid the proliferation of organisms in purified water rather than disinfect for bacteria after an action-level contamination test result. There are guidelines for medical directors to consider in this regard: the RD52 document contains a map outlining the necessary steps according to the chosen disinfection method (5).

The methods used to provide the scheduled routine disinfection of the water purification equipment and distribution loops will depend, in part, on the type of system and material being disinfected. The appropriate disinfection process for a particular system should be recommended and/or approved by the manufacturer of the system. Peracetic acid-type chemicals are commonly used to disinfect most systems; in some cases, sodium hypochlorite (bleach) or ozone might be recommended for use. Hot water disinfection is becoming more commonly

used to provide disinfection in a number of systems. In the absence of unacceptable bacteria and endotoxin results, distribution equipment should be disinfected no less frequently than every 4 weeks.

Microorganisms and in particular, Gram-negative bacteria remaining in pipes outside the hours of dialysis operation will proliferate and adhere to wet surfaces, likely forming communities of microorganisms called biofilms (5). In fact, biofilm may be present in water storage and distribution systems even when bacteria and endotoxin test results are low. However, inconsistent and erratic bacteria testing results could suggest the presence of bacteria-shedding biofilm in the water storage or distribution system (2). Microorganisms detected through testing represent only those organisms suspended in water; it may take weeks to detect any biofilm problem. It is also important to recognize that cultures quantifying planktonic bacteria represent a small fraction of organisms released from accumulated biofilm within

the system. When bacterial contamination persists despite frequent and aggressive disinfection, it may be necessary to determine if biofilm is a cause. In such instances, use of alternative disinfection methods or even replacement of equipment may be required to remediate biofilm.

Monitor System Functions

All water systems are susceptible to failure without monitoring, even contemporary systems using the most advanced equipment. The medical director can trust that the water treatment system is running smoothly and that dialysis water is adequately pure only through collaboration and verification with his/her facility team. Water systems and their individual components should be maintained according to the manufacturer's recommendations, and maintenance information should be accurately recorded (Table 3).

Table 5. Contaminants toxic to patients on dialysis

Contaminant	Source	Adverse Event	Notable
Aluminum	Municipal water treatment	Fatal encephalopathy syndrome, bone disease, anemia	Aluminum is usually included in the laboratory AAMI water quality panel of compliance tests
Calcium/magnesium	Municipal source water, municipal water treatment	Nausea, vomiting	Calcium and magnesium can scale and foul the reverse osmosis membrane, reducing membrane performance
Copper	Dialysis water treatment	Hemolysis, nausea, vomiting	Copper can leach from plumbing and fixtures in acidic conditions
Cyanotoxin	Municipal water treatment	Hepatic failure	Blue-green algal toxins should not be in the treated water; may create a pyrogenic reaction in exposed patients
Endotoxin	Dialysis water treatment	Pyrogenic reaction, chronic inflammation	Reverse osmosis and endotoxin filtering work to reduce endotoxin contamination in purified water; if endotoxin is present, however, it can pass through the dialyzer membrane into blood by backfiltration
Fluoride	Municipal water treatment	Nausea, abdominal pain, pruritus, arrhythmia	Fluoride may also be associated with uremic bone disease
Monochloramine	Municipal water treatment	Hemolysis	In addition to depleting carbon filters, chloramines can degrade some reverse osmosis membranes
Nitrates	Municipal water treatment	Anemia	Nitrates have no known effects on the function of the water treatment system
Zinc	Dialysis water treatment	Hemolysis, nausea, vomiting	Zinc oxide can interfere with carbon filter function and cation exchange in the water softener

AAMI, Association for the Advancement of Medical Instrumentation. Modified from ref. 11, with permission.

Typically, the water system maintenance log should be kept with the same standard that is expected of medical records. Monitoring functions are conducted by trained facility teammates, sometimes including a biomedical technician. However, all service repair, preventive maintenance, and troubleshooting should be performed by the facility's biomedical technician. The maintenance log should be used to record all monitoring and maintenance data, including the date and time of record as well as the personnel who completed the task. Such documentation will be an important part of the CMS surveyor evaluations.

Know the Clinical Significance of Water System Failure

The wellness of patients on dialysis starts with meeting the minimum standards for dialysis water quality (Table 1). Chemical and metal contaminants that are safe in drinking water for ingestion by healthy patients are not safe in patients on hemodialysis who are exposed to approximately 400 L dialysis water per treatment three times per week (12).

The associations between illness and dialysis water contaminants are well described (Table 5), ranging from sometimes benign (pruritus) to deadly (encephalopathy) (13). Chloramine is widely known to cause hemolysis, anemia, and death in patients on dialysis (14). However, high concentrations of other minerals can also be fatal: eight patients had fatal encephalopathy shown to be associated with the addition of aluminum compounds to municipal water, resulting in a 3- to 16-mg load of aluminum with each dialysis treatment (15); the outbreak of illness was stopped with the addition of a DI step in the dialysis water purification process. More recently, dialysis water contaminants have been implicated in the lack of response to erythropoietin of patients on hemodialysis. Fluck *et al.* (16) published that, over time, chloramine levels in water were inversely associated with mean hemoglobin and directly associated with mean erythropoietin dosing in patients on hemodialysis. Rahmati *et al.* (17) published that, under stable erythropoietin dosing, patients' mean hemoglobin levels increased after the addition of a new reverse osmosis filter. Masuhashi and Yoshioka (18) showed a similar result. When additional endotoxin was removed from dialysis water, mean patient hematocrit was increased, whereas mean erythropoietin dosing was reduced in the 5 months after the removal. Cumulatively, these results suggest that endotoxin contaminants in dialysis water at concentrations below those causing clinical symptoms, such as fever, may reduce patients' response to erythropoietin therapy, possibly through chronic inflammatory stimulus. These studies call into question whether the minimum purity standards currently used by the CMS for dialysis water could be raised to potentially improve clinical outcomes in patients. Data such as these should inspire medical directors to think beyond the minimal requirements used by the CMS.

Consider Continuing Improvements

When the processes to provide product water of appropriate quality and quantity for the facility are adequately routinized, the medical director might consider goals for continuing improvements in water quality, such as adoption of higher quality thresholds. In 2014, the AAMI

released a revised guideline for dialysis water quality, providing new recommendations for acceptable bacterial testing methods, although the inorganic contaminants, viable bacteria, and endotoxin thresholds remain at the AAMI 2009/2011 guideline levels (11). Despite these AAMI updates over the past decade, the CMS compliance is still defined by the 2004 AAMI RD52, and many dialysis clinics have voluntarily chosen to use the more stringent newer guidelines.

As a part of QAPI discussions at every dialysis facility, the medical director and clinic staff should decide what level of water quality they wish to attain (Tables 1 and 2) to meet the CMS CFC and promote patient wellness. For some dialysis facilities, voluntarily providing higher-quality water than outlined in RD52 might involve upgrades in water treatment system components or even replacement of older systems. Decisions to do so will keep facilities ahead of the curve in terms of compliance and continuing improvement but must not be made in a clinical vacuum. Having a sound understanding of the needs and requirements of water treatment allows the medical director to help the facility find the best system for the facility, both clinically and financially.

Conclusions

Medical directors should be equipped to tackle water quality standards in their dialysis facilities and understand the level of accountability that the CMS expects. Those medical directors who learn, know, and embrace the requirements for providing high-quality dialysis water will be most successful in this task.

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