

A Surveyor's Perspective: Water Quality for Hemodialysis

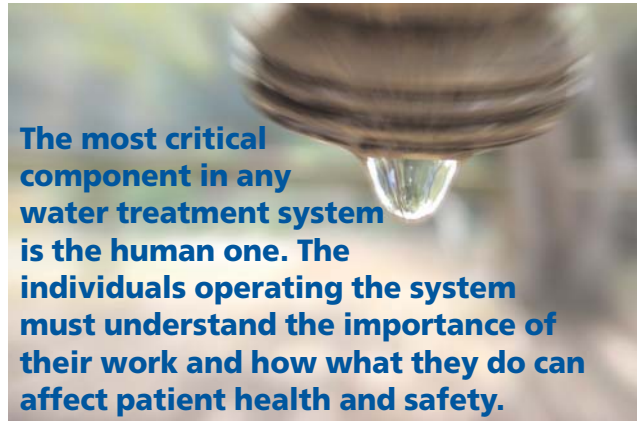
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Water is the common risk factor for all patients receiving hemodialysis. Errors in water treatment affect all patients on treatment in a facility at the same time. Failure to recognize poor quality water, failure to adequately treat water contaminated with chemicals, bacteria, or toxins, or failure to recognize that treatment components are not operating effectively puts hemodialysis patients at risk of injury and death. Other articles in this monograph will detail the various contaminants that can affect patient health and safety; this article will discuss Medicare surveys of the water treatment system to ensure the system is safe for use in hemodialysis. The Basic ESRD Surveyor Training Course emphasizes the importance of safe water for dialysis, and teaches surveyors to include a review of the water treatment system in every dialysis facility survey.

Keeping Patients Safe: The Risks from Water

Because water does present significant patient risks, failure to provide safe water may result in findings of non-compliance with the Medicare Conditions for Coverage. The current Conditions require that the chemical contaminants in the treatment water meet the standards published by the Association for the Advancement of Medical Instrumentation in ANSI/AAMI RD5:1992, *Hemodialysis systems*. The Centers for Medicare & Medicaid (CMS) is not allowed to adopt newer publications as regulation without publishing such for comment. As a total revision of the Conditions for Coverage for ESRD is in process, CMS has not chosen to go

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through that process to update the current Conditions to endorse newer AAMI recommendations. The proposed changes to the Conditions for Coverage for ESRD (published for comment 2/5/05) included reference to current AAMI recommendations for water and dialysate, and included much detail as to treatment components and monitoring. Until those changes are final, surveyors are tasked with using the “olde” regulations, with the references to the older AAMI guidelines.

What do the current regulations require? As mentioned, the primary requirement is the water used for treatment meets the AAMI 1992 recommendations for the levels of chemical and bacteriological contamination. Other regulations that apply to the survey of the water treatment system include those that require “All members of the facility’s staff are qualified to perform the duties and responsibilities assigned to them....” (405.2135(d)(2)), and that the Physician Director responsibilities include “assuring adequate training of nurses and technicians in dialysis techniques” (405.2161(b)(2)) and “assuring adequate monitoring of the...dialysis process” (405.2161(b)(3)).

Note that the Medicare regulations are considered “minimum standards.” Adopting the updated AAMI recommendations as facility policy would more than meet the minimum standard, and many facilities have adopted more current recommendations, including ANSI/AAMI RD52:2004, *Dialysate for hemodialysis* as the new bench-

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mark. Surveyors also consider whether facility policy is being followed. Staff members should know and follow current facility policy. A regulation that applies here is “The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out.” (405.2135(f)). It is important to ensure your staff members are following your policies, whether those policies meet or exceed the Medicare minimums.

Expected Monitoring of the Water Treatment System: Chemical, Bacteriological, and Daily Testing

Current regulations require either bacteriological or endotoxin testing of the water and dialysate systems. The frequency specified for an established system is at least monthly. Sites to be tested are not specified, but they are expected to be defined by facility policy to include at least the start and end of the water distribution system, mixing stations for dialysate components, and reprocessing stations. For dialysate cultures, facility policy should define how many machines are tested each month, and a system should exist to ensure that all machines are tested at least annually. The cultures can be done on-site with dip samplers, and a quality control program to ensure that the results of self-performed testing are accurate is expected to be in place. The more current AAMI guidance recommends use of duplicate samples with one being incubated on-site and the duplicate being sent to an outside laboratory for confirmation at least annually. This recommendation is not regulatory, but could serve as guidance for developing a quality control program. If methods such as membrane filtration or spread plate are used for on-site testing, AAMI does not recommend for or against duplicate testing.

While most facilities routinely perform both cultures and endotoxin testing, endotoxin testing may substitute for cultures under the current Medicare regulations. This testing may also be done on-site, using one of the testing kits commercially available.

Chemical analysis must be done annually at a minimum, with the sample taken from a point after all the water treatment components. The laboratories performing hemodialysis water testing report results on the panel of contaminants specified by current AAMI recommendations. Thus, facilities are monitoring for the additional three elements (antimony, beryllium, and thallium) added by AAMI in its updated table. Facilities mixing acid from powder on site should be aware that

the manufacturer of at least one of the mixing systems requires that quarterly water analysis be performed.

Daily testing related to patient safety includes monitoring the function of the system, the quality of the product water, and testing for chlorine and chloramine. To ensure that the staff members are monitoring the function of the system, the surveyor reviews operating logs to see that these are complete, and that parameters set for the specific water treatment system in use are met or, if not met, that corrective action is taken. The water to be used for treatment must be monitored continuously during patient treatment via resistivity or conductivity meters (as applicable), alarm set points must be relevant to the expected quality of the product water, and the alarms for readings outside of the set targets must be able to be seen and heard in the patient treatment area.

Testing for chlorine and chloramine is expected to be done prior to each patient shift. While the current Medicare regulations do not include this specifically, the U.S. Food and Drug Administration (FDA) has issued warnings related to patient injuries with exposure to chlorine/chloramine, and recommends testing prior to each patient shift. Facility policies should address the expected frequency of testing, the test to be used, and should detail the methodology of the selected test. Space does not permit detailing all the ways testing for chlorine and chloramine can be done inaccurately! A short list of examples would include using too large or too small a water sample for the test in use, comparing the test for total chlorine against the test for free chlorine rather than against a blank, putting the reagents for both tests (free and total chlorine) into the same tube, not using the color wheel to determine the absence of any change in color, and recording the test result for free chlorine as “chloramine” rather than subtracting this result from the test for total chlorine to determine the chloramine level. It is critical that clearly written directions, proper, clean, and intact equipment, and supplies appropriate to the test in use are available and in use for every test. Orientation of staff responsible for this testing, spot audits of practice, and re-education could prevent many adverse survey findings.

Basic Knowledge for Staff Responsible for the Water Treatment System

The most critical component in any water treatment system is the human one. The individuals operating the sys-

tem must understand the importance of their work and how what they do can affect patient health and safety. Often, the newest hire is put in charge of “opening up” the facility, coming in very early and alone, to start up the system and do the testing. Perhaps the trainer’s emphasis was on having everything ready to get patients on as soon as possible, rather than the critical nature of water treatment system. Surveyors interview the staff members directly responsible for the water treatment system start-up and testing. There can quickly be issues of non-compliance if those individuals do not demonstrate understanding of their assigned tasks and of the risks of unsafe water.

While the surveys are generally outcome based, CMS does not expect surveyors to “wait” for an outcome (e.g., patient injury) from unsafe water: state surveyor citations of Condition level non-compliance for unsafe practices that could result in adverse patient outcomes will be supported by CMS. Such findings are most often related to the staff doing the work not being adequately trained or supervised, and have included not testing chlorine/chloramine at least daily, not monitoring the

quality of the product water, and not taking action when the data collected are outside the acceptable parameters.

Using Quality Management to Assure Compliance

The medical director of the dialysis unit is ultimately responsible for the water treatment system. Issues concerning the operation of the system and results of monitoring should be reported routinely to the medical director. Incorporating these reports as part of a monthly quality management meeting is an effective way to achieve and document this communication, with the understanding that some issues would need to be reported immediately. Audits of practice, e.g., observation and interview of the persons doing the work on a random, unannounced basis by local or area managers, are another good way to be sure that staff are following facility policy, and can help identify when changes might need to be considered.

Safe water for hemodialysis is critical. Thank you for your efforts to ensure that this is a “given” in the renal community. ■

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