



DIALYSIS DIALOGUE

Welcome to this edition of *Dialysis Dialogue*, a newsletter published by the North Dakota Department of Health, Division of Health Facilities. *Dialysis Dialogue* is designed to help dialysis departments stay up-to-date on various issues. Please share with your dialysis staff.

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Most Commonly Cited Deficiencies

Following is a breakdown and summary of the most common deficiencies cited in the North Dakota ESRD program, listed in order of citation frequency from Oct. 1, 2009, to Sept. 30, 2010.

V403

Equipment maintenance. The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer’s recommendations.

Identified deficient practices included:

- Failure to ensure maintenance of hemodialysis machines, mechanical lifts and ice machines.
- Expired laboratory supplies.
- Expired calibration solutions.
- Expired dressing supplies.
- Expired chlorine/chloramines test strips.

V407

Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).

Identified deficient practice included:

- Observations of access sites and bloodline connections completely covered with blankets.

V113

CDC RR-5 as Adopted by Reference 42 CFR 494.30(a)(1)(i) Wear disposable gloves when caring for the patient or touching the patient’s equipment at the dialysis station. Staff must remove gloves and wash hands between each patient station.

Identified deficient practice included:

- Facility staff failed to remove gloves and wash/sanitize hands between clean and dirty tasks.



(Continued from page 1)

V175

494.40 Condition: Water and dialysate quality. Noncompliance at the condition level is cited if the identified water and dialysate quality deficient practices are pervasive throughout the standards included in the water and dialysate quality condition, serious in nature, or a potential risk to patient health and safety.

V180

ANSI/AAMI RD52: 2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 4.3.2.1. Bacteriology of conventional dialysate: maximum and action limits. Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL. The action level for the total microbial count in conventional dialysate should be 50 CFU/mL and the action level for the endotoxin concentration should be 1 EU/mL. If levels exceeding the action levels are observed in the dialysate, corrective measure, such as disinfection and retesting, should promptly be taken to reduce the levels.

Identified deficient practice included:

- Facilities failed to test dialysate for endotoxin concentration.

V187

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 8 Environment: Schematic diagrams/labels. Water systems should include schematic diagrams that identify components, valves, sample ports and flow direction. Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow. If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range.

Identified deficient practice included:

- Failure to have a schematic diagram of the water treatment system.

- Failure to label the pipes in the water room to indicate contents and direction of flow.
- Failure to label the major water system components to identify device, function, performance verification, and what actions to take if not in range.

V196

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 6.2.5 Carbon adsorption: monitoring, testing frequency. Testing for free chlorine, chloramine or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are not set patient shifts, testing should be performed approximately every four hours. Results of monitoring of free chlorine, chloramine or total chlorine should be recorded in a log sheet. Testing for free chlorine, chloramines or total chlorine can be accomplished using the N,N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramines concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L]. Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.

Identified deficient practice included:

- Facility staff failed to follow the correct procedure/method for testing water for chlorine/chloramine.

V715

The medical director must ensure all policies and procedures relative to patient admissions, patient care, infection control and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers.

Identified deficient practice included:

- Facility did not establish/develop policies and procedures and/or staff did not follow the established policies and procedures.



QUESTIONS AND ANSWERS (Q&A) COMPILED BY CMS

The Centers for Medicare and Medicaid Services (CMS) provides specialized technical training courses for state surveyors, as well as an annual ESRD update. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. The Q&A is a regular feature of the Dialysis Dialogue newsletter.

If the primary carbon tank is exhausted, and the total chlorine reading after the secondary tank is at 0.1mg/L, can patients still be dialyzed?

If the primary carbon tank is exhausted, dialysis may continue up to 72 hours, as long as the reading after the secondary carbon tank is <0.1 mg/L chloramines. If the only test the facility is doing is total chlorine, the level must be < 0.1mg/L. More frequent testing after the secondary carbon tank would be expected and the exact times the tests were done recorded.

With bicarbonate, what is over-mixing? Why would it be a problem? Where is the time limit for mixing specified?

Manufacturers of bicarbonate powder for use in making the bicarbonate concentrate for dialysis specify the mixing time. Mixing longer can result in off gassing of the bicarbonate, which will change the pH of the mixture, and can result in the formation of a precipitate, lowering the calcium level of the concentrate, and potentially causing the patient's serum calcium to drop.

Should a facility use the qualitative method when using test strips to test chlorine levels in the water to be used for treatment? At V196 under "additional guidance" regarding test strips, the guidance says "In choosing whether to use "quantitative" or "qualitative" test methodology, it is important to recognize that the determination of low levels of chlorine (i.e., <0.1 mg/L ppm) requires the use of the quantitative method."

The facility should use the quantitative method. Directions for some test strips offer two testing methods. One, a qualitative method, only provides a positive or negative result; the other, a quantitative method provides a numerical value for the result. The quantitative test must be used to determine low levels of chlorine (i.e., less than 0.1 mg/L ppm), and should be used for testing water for use in dialysis treatment.

Medical injuries/errors: What should be trended and tracked for medical injuries and errors?

Facilities are expected to track patient/staff injuries, treatment errors (e.g., wrong dialysate, wrong dialyzer, shortened time, failure to remove targeted fluid), equipment errors, medication errors, hospitalizations, deaths, cardiac arrests in the facility, acute allergic-type reactions and major blood loss, at a minimum. Additional information about medical injuries and errors in dialysis can be found at the website for Patient Safety sponsored by the Renal Physician's Association.

Must staff, such as dietitians, social workers, etc., wear gloves when in the patient treatment area if they are not delivering care to the patients?

Gloves are not necessary for casual contact with the patient, e.g., shaking hands, taking his/her arm, touching a shoulder. Any staff member who touches any potentially contaminated surface is required to wear glove when touching that surface.



SURVEY AND CERTIFICATION LETTERS

CMS transmits memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS regional offices through use of Survey and Certification (S&C) letters. Below is a list of the S&C letters that came out since Sept. 9, 2009. The S&C letters are available at www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage.

- **S&C -10-17-ESRD Dated April 23, 2010. End Stage Renal Disease (ESRD) Program Survey Guidance on Patient Care Dialysis Technicians (PCTs) Certification.**

The ESRD Conditions for Coverage, published on April 15, 2008, require that PCTs who have been employed since Oct. 14, 2008, must be certified by either a CMS-approved state or national dialysis technician certification program by April 15, 2010. PCTs hired after Oct. 14, 2008, must be certified within 18 months of their date of hire. After April 15, 2010, uncertified technicians who have been employed for more than 18 months may not provide direct patient care and may not be counted as direct care staff. The S&C letter provides guidance to surveyors on how to determine compliance with the PCT certification requirement. This letter also includes Frequently Asked Questions (FAQs) regarding Patient Care Technicians.

- **S&C-10-30-ESRD Dated Sept. 10, 2010. End Stage Renal Disease (ESRD) Program Information and Communication: Keeping Informed about Survey and Certification Areas Related to the ESRD Program.**

This S&C letter contains websites that have been developed to keep state survey agencies informed about the CMS ESRD Program. Although some of these websites are password protected, there are sections that are open to the public as well.

- **S&C-11-13-ESRD Dated March 18, 2011. ESRD Program Update.**

CMS wants to promote common understandings about the regulatory process and the specific rules that guide the CMS S&C process. In order to promote consistency of standards and expectations regarding the ESRD Conditions for Coverage, CMS actively supports their ESRD e-mail mailbox for questions and comments and periodically refreshes the compendium of FAQs on the CMS S&C website.



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