Guide to the Elimination of Infections in Hemodialysis

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Exterior Cleaning and Disinfection of Dialysis Machine

Exterior (surface) cleaning and disinfection of dialysis machine can be accomplished between each treatment using any approved EPA-registered disinfectant labeled for use in healthcare settings and in accordance with facility policy and procedure. In a typical HD setting, dialysis technicians and registered nurses generally perform the process of cleaning of the patient station between dialysis sessions. Dialysis schedules and pace must accommodate comprehensive cleaning between patient treatments.

Interior Disinfection of Dialysis Machine

Disinfection of the internal pathways of the dialysis machine between patient uses is not required. Dialysis machines are engineered so that the pathways segregate blood and dialysate. The pathways further segregate clean (affluent) dialysate from effluent dialysate (that which has passed through the dialyzer). The term used to describe the flow schematic of HD machines is “single-pass.” This means that the dialysate solution passes through the hemodialyzer once, where it picks up renal waste from the blood through a one way membrane, and then is routed to drain without contaminating any fresh dialysate being introduced into the hemodialyzer. When a single machine is used in succession by patients, cross-contamination via the internal pathways of the machine is prevented by the single-pass feature of the HD machine. The exception is if a blood leak event occurs. In the event of a blood leak outside of the blood pathway, the CDC recommends internal disinfection before the dialysis machine is used on a successive patient. A blood leak results when the hemodialyzer fiber membrane is compromised and allows blood to enter the dialysate pathway. In this event, disinfection of this pathway must be performed prior to use of the HD machine on a successive patient.

There are two methods of disinfecting the dialysate pathways (internal) of the HD machine: heat and chemical. The standard as recommended by HD machine manufacturers is to perform disinfection of the dialysate pathways at the end of each treatment day using heat disinfection. Heat disinfection is an auto-cycle that subjects the pathway to an 80°+ centigrade water temperature for approximately 30 minute exposure time. The process is convenient and excludes the use of any chemicals to achieve disinfection for the purpose of bacterial control. Alternatively, chemical disinfection can be accomplished using a variety of solutions including sodium hypochlorite (bleach) and peroxyacetic acid (compound comprised of peracetic acid and hydrogen peroxide). When using a chemical disinfectant, it is important to follow the manufacturer’s recommendation regarding concentration and dwell time. In the acute setting where dialysis may not be performed on a daily basis, HD machines may be inactive for prolonged periods of time and could potentially develop bacterial growth. In this situation, inactive machines must be chemically disinfected prior to patient use.

Monitoring Dialysis Machine Disinfection

The effectiveness of disinfection for the internal pathways of the dialysis machine can be validated by routine bacteriologic and endotoxin analysis. Testing of HD machine dialysate and reverse osmosis (RO) water (a central system) for bacteria and endotoxin assay are required at least monthly. This should involve testing of at least two HD machines each month. The sampled machines must be rotated so that each machine in the facility is tested at least annually. Testing of dialysate should be performed at the end of the treatment day. The process of sampling versus testing all machines each month is practiced for two reasons. First, the testing of every machine every month can be labor intensive and costly. Secondly, since all outpatient machines receive the same water via a single distribution loop and each machine is disinfected on the same frequency and same procedure, testing two machines randomly on a rotating basis provides a comprehensive testing model. Dialysate testing for a dialysis machine using portable RO or in a home setting should be performed on a quarterly basis at a minimum.

The maximum allowable level for dialysate bacteria is 200 colony forming units (CFU)/mL, with an action level of 50 CFU/mL. An action level of 50 CFU/mL has been established so that corrective measures are performed to
prevent bacteria proliferating to higher levels. The maximum allowable level for dialysate endotoxin is 2 endotoxin unit (EU)/mL, with an action level of 1 EU/mL. As with bacteria, the action level for endotoxin has been established so that corrective measures are performed as an early intervention, preventing endotoxin proliferating to the maximum allowable levels. A decision tree that is published in AAMI RD52 is attached and can be used to guide the analysis and action taken in response to test results.

**Auxiliary Equipment**

Additional or auxiliary equipment in an HD setting can include jugs for acid concentrate, sodium bicarbonate concentrate, a priming bucket, and the transducer protector (disposable). Bicarbonate powder can be mixed with processed water in a centralized vat, in individual jugs, or via automated process on the individual machines (e.g., BiCART, Gambro, Lakewood, CO). All disposable equipment is to be used for only one patient and then must be discarded. Acid concentrate and sodium bicarbonate concentrate can be delivered to the dialysis machine via a distribution loop similar to the RO water loop. Acid, because of its high sodium concentration and low pH, is not conducive to bacterial growth and therefore this system would not require routine bacterial control strategies. Sodium bicarbonate can support bacterial growth, and this system (which includes the mixing tank, distribution tank, pipe loop, and outlet connectors) must be disinfected at least weekly, using the same process as that used for the RO loop. For facilities that do not use central delivery for concentrate solutions, the use of disposable or reusable jugs is the alternative. For these facilities, each dialysis treatment would utilize two jugs: one for acid and one for sodium bicarbonate. Disposable jugs must be discarded after each use. “Topping off” or adding additional sodium bicarbonate solution to single use jugs is not permitted. The growth of bacteria can occur with prolonged use of the sodium bicarbonate solution in an opened container. Consequently, sodium bicarbonate jugs should not be used 24 hours or more after opening.

Reusable jugs for sodium bicarbonate must be treated as all other reusable dialysis equipment and subjected to cleaning and disinfection (exterior of jug) prior to removal from the machine after each patient session. With the acid concentrate, it is not necessary to empty, rinse, clean, and disinfect the jug. Sodium bicarbonate reusable jugs must be emptied and rinsed with AAMI quality water (RO water) after use. Tap water should not be used for the cleaning and rinsing of the container. Water that is of AAMI quality water (dialysis quality) should be used. Disinfection of the inside of the sodium bicarbonate jugs must be performed at least weekly. The new CMS regulation references the use of bleach at 1:100 dilution as an example of an acceptable disinfectant for this purpose.

Priming buckets are containers that can be attached to the side of some HD machines. This container serves to collect the solution used for preparing the extracorporeal system (blood lines and dialyzer). The procedure for use of the priming buckets may vary from facility to facility. Consequently, the initiation of the dialysis session may or may not introduce blood into the priming bucket. Regardless of the procedure, the priming bucket should be emptied, cleaned, and disinfected after the initiation of each treatment. Cleaning and disinfection of the priming bucket should follow the same procedure used for the sodium bicarbonate jug.

The arterial segment of the blood line is connected to the patient's arterial access and removes blood from the patient. The venous segment of the bloodline is connected to the patient's venous access and returns blood to the patient. The transducer is a component within the electronic modules of the dialysis machine which monitors the condition of these blood pathways by measuring the flow pressure in both venous and arterial segments of the pathway in the dialysis machine. Transducer protectors serve as an additional barrier between the dialysis machine and the patient's blood. Internal transducer filters do not need to be changed routinely between patients. External transducer protectors need to be changed after each dialysis session. In addition, during the dialysis session, if the external transducer protector filter becomes wet with blood or fluid, it must be replaced immediately and the
transducer inspected. If blood or fluid is visible on the side of the filter that connects to the machine, inspection of the internal hardware of the dialysis machine must be performed prior to use on subsequent patients. A qualified biomedical engineer or a trained and qualified dialysis HCW must inspect the external and internal hardware for blood or fluid intrusion. If the equipment has been contaminated with either blood or fluid, the internal lines and filter must be replaced and the external machine connector port disinfected with an intermediate-level disinfectant such as 1:100 bleach solution.

Reprocessing and Reuse of Hemodialyzer

The practice of reusing dialyzers (for the same patient) has been performed in the U.S. since the 1960s. The U.S. Food and Drug Administration (FDA) published “Guidance for Hemodialyzer Reuse Labeling” on October 6, 1995. The document requires that dialyzers labeled for multiple uses must include instructions for their safe and effective reuse. This means that instructions for cleaning, rinsing, disinfecting, and testing the dialyzer as well as instructions for preparation before use (priming) must be included in the labeling package (package insert). Warnings must be included regarding the use of any reprocessing agents or processes known to adversely affect the manufacturer’s dialyzer. The percentage of centers practicing reuse declined after 1997 to 63% in 2002, and in 2005, it was estimated that 61% of patients were being treated with single-use dialyzers.

The terms reprocessing and reuse have often been used interchangeably within the dialysis community. In fact, the two terms describe different aspects of the multiple use practice. Reprocessing is the act of cleaning, testing, and filling dialyzer with germicidal solution. This is performed outside of the dialysis treatment area. Reuse is performed in the treatment area and refers to verification of germicide, rinsing and testing to ensure the comprehensive removal of all germicide, and “reusing” the reprocessed dialyzer for the designated (same) patient. Reuse and reprocessing must follow all applicable AAMI standards to receive CMS reimbursement.

See Appendices for details.

References


Further Readings


CDC. Recommendations for preventing transmission of infections among chronic hemodialysis patients. MMWR 2001;50(RR05):1–43.

