Centers for Disease Control and Prevention

Dialysis Safety

Water Use in Dialysis

By reducing risk from water in the healthcare setting many infections and outbreaks can be avoided

During an average week of hemodialysis, a patient can be exposed to 300-600 liters of water, providing multiple opportunities for potential patient exposure to waterborne pathogens. Adverse patient outcomes including outbreaks associated with water exposure in dialysis settings have resulted from patient exposure to water via a variety of pathways; including improper formulation of dialysate with water containing high levels of chemical or biological contaminants, contamination of injectable medications with tap water, and reprocessing of dialyzers with contaminated water. For the health and safety of hemodialysis patients, it is vital to ensure the water used to perform dialysis is safe and clean.

AAMI Water Standards

The Association for the Advancement of Medical Instrumentation (AAMI) in conjunction with the International Standards Organization (ISO) have established chemical and microbiological standards for the water used to prepare dialysate, substitution fluid, or to reprocess hemodialyzers for renal replacement therapy. The AAMI standards address:

- Equipment and processes used to purify water for the preparation of concentrates and dialysate and the reprocessing of dialyzers for multiple use.
- The devices used to store and distribute this water.
- The allowable and action threshold levels of water contaminants, bacterial cell counts, and endotoxins. Refer to specific reference listed for full details on maximum allowable chemical contaminates and bacterial/endotoxin limits.

Table. AAMI Water Standards

Reference Document	Allowable water Total Viable Count (TVC)	Action level water Total Viable Count (TVC)	Allowable Level water Endotoxin Unit (EU)	Action Level water Endotoxin Unit (EU)
AAMI RD52:2004 (Minimum regulatory requirement)	<200	≥50	<2	≥1
ANSI/AAMI/ISO 13959:2014 (Preferred recommendation)	<100	≥50	<0.25	≥0.125

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Infection Control Guidelines in Health- Care Facilities

For the rationale for water treatment in hemodialysis: “Water Systems in Health-Care Facilities” in the Guidelines for Environmental Infection Control in Health-Care Facilities.

The Guidelines for Environmental Infection Control in Health-Care Facilities (MMWR June 6, 2003) [PDF – 48 pages] provides recommendations on dialysis water quality and dialysate on pages 19 &20.

VIII. Dialysis Water Quality and Dialysate

#	Recommendation	Category
A	Adhere to current AAMI standards for quality assurance performance of devices and equipment used to treat, store, and distribute water in hemodialysis centers (both acute and maintenance [chronic] settings) and for the preparation of concentrates and dialysate.	IA, IC

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(The AAMI guidelines listed in this document are from 1993, refer to the current AAMI standards for the most up to date information.)

Rating Categories

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Boil Water Advisory Procedures

What to do when your municipal water supplier issues a "boil water advisory".

What is a boil water advisory(BWA)?

A BWA is issued to protect the community from waterborne infectious agents. A BWA is issued only after careful consideration among representatives from public health, regulatory agencies, and municipal departments after positive tests (e.g., positive samples for fecal coliforms, changes in turbidity measurements) or line breaks.

Can we dialyze patients during a boil water advisory (BWA)?

Yes, if the water treatment components in use are sufficient to remove or destroy bacteria, Reverse Osmosis (RO) will protect the product water from having microbial contamination. Deionization (DI) unit does not remove or destroy bacteria, so if DI is being used as the main water treatment (rather than RO), you will need a submicron or endotoxin/ultrafilter downstream of the DI unit. If an ultraviolet (UV) irradiator is used, the filter should be located after the UV irradiator. Close monitoring of the resistivity of the product water will be needed to detect any decrease in quality. Also consider weekly microbial assessment of the product water during the BWA.

Keep in close contact with the municipal water supplier because they may choose to "shock" treat (hyperchlorinate) their distribution system to bring it back into compliance with the acceptable standards for drinking water. If the city "shocks" their water system, you may see chlorine/chloramine break through. Review your testing procedures with staff and alert them to be vigilant for potential break through so that patients will be protected from exposure to chlorine/chloramine.

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