Fundamental Infection Prevention Applied to Inpatient Hemodialysis

A Guide for Infection Preventionist

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NEBRASKA INFECTION CONTROL ASSESSMENT AND PROMOTION PROGRAM

Dialysis Water and Essentials and Related Infection Risk

Presented by Chris Cashatt BSN, RN, CIC
NE ICAP Infection Preventionist Dialysis Lead

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NEBRASKA INFECTION CONTROL ASSESSMENT AND PROMOTION PROGRAM

Outcomes

Assess

Assess basic infection prevention and control requirements for dialysis water treatment and reporting for quality departments.

Recognize

Recognize specific areas within dialysis that are higher risk for exposure to waterborne organisms.

Water Rooms

- Water softener and brine tanks
- Carbon filters
- Particulate filter
- Reverse Osmosis
- Deionizer
- Ultraviolet light
- Ultrafilters

ANSI/AAMI (American National Standards Institute/Association for the Advancement of Medical Instrumentation)

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Water Treatments

Reverse Osmosis (RO)	• Removes ions and organics by utilizing osmotic and hydrostatic pressures over semipermeable membranes. • Removes 90-99% of all bacteria and endotoxins. • Follow manufacturers' IFU for cleaning and restoration of semipermeable membranes.
Backflow Prevention	• Cause of backflow is usually a reduced water pressure due to water main breaks, major supply pipe breaks, or unexpected high demand. • Break tank or reduced pressure zone valves eliminate backflow from water the supply line which can cause contamination of the water supply.
Water Softener	• Exchange calcium and magnesium ions for sodium ions. • Reports of bacterial contamination have been reported on portable water softeners.
Carbon Filter	• Remove chlorine, chloramine, and organic materials. Free chlorine and chloramine can degrade some RO systems. • Prone to bacterial contamination. Filters should be replaced not regenerated.
Particulate Filters	• Removes sediment from water that can damage or clog the water treatment system. • Bacterial growth can occur on the filter. • Filters are changed and disinfected according to the manufacturers' IFU.
Deionizers	• Removes cations and ions. Rarely used as the main water treatment, but usually is used as a backup to RO • Contains resin beds which can contribute to substantial bacterial growth.
Ultraviolet Light	Reduces microbial contamination.
Ultrafilters	Removes bacteria and endotoxins. Last component of the water processing system prior to the distribution loop

Water Distribution Systems

- Plastic Pipes
- Continuous Loop
- Constant Flow with flow velocity of 1.54 feet per second
- Minimal use of elbows or T-joints
- Testing outlets should be at the highest level
- Storage tanks are discouraged, but if used should be the smallest tank possible.
- Disinfect at intervals

Bedside/Portable Dialysis Machine

Bedside or Portable Hemodialysis

- Portable reverse osmosis (RO) water treatment-must meet the same AAMI standards
- Portable water sources include showers, sinks, or water boxes
- Waste may drain into a commode, shower drain, or water box drain-Ensure an air gap between tubing and water in either location. Tubing should be secured to prevent backflow, contact and splatter.

Joint Commission (TJC)-Water Management Program-2021.06.01

Address the need for organizations to minimizes pathogenic biological agents in cooling towers, domestic hot- and cold-water systems, and other aerosolizing water systems. The expectation is that this process includes:

- risk assessment
- water management plan
- testing protocols
- acceptable ranges

The Joint Commission: r3-report-water-management-final_nov1.pdf

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*Which AAMI standards they are following?

- Action levels may be different depending on the year

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 RDS52-2004 (Minimum regulatory requirement)	< 200	≥ 50	< 2	≥1
ANSI/AAMI/ISO 135059: 2014 (Preferred recommendation)	<100	≥ 50	≤0.25	≥0.125

Association for Advancement of Medical Instrumentation (AAMI) in conjunction with **International Standards Organization (ISO)** have established chemical and microbiological standards for water used in dialysis.

Action levels are set at 50% of the maximum allowable levels.

ANSI/AAMI/ISO 23500-2:2019; Preparation and quality management of fluids for haemodialysis and related therapies—Part 2: Water treatment equipment for haemodialysis applications and related therapies

Dialysate: Aqueous fluid containing electrolytes, usually buffer and glucose, which is intended to exchange solutes with blood during hemodialysis; also known as dialysis fluid, dialyzing fluid, or dialysis solution

Dialysate Solutions (Bath)

Composed of two concentrates

Bicarbonate (sodium bicarbonate)

- Supports rapid bacterial growth and endotoxin production.
- Comes in powdered or aqueous forms
- Reusable jugs and associated tubing should be emptied, rinsed and allowed to air dry after each treatment.
- Cartridges for automated bicarbonate mixing should be discarded after use.

Acetate (Acid)

- High salt molarity inhibits bacterial growth.
- Premixed gallon containers or 55-gallon drums.

Chlorine and Chloramine Monitoring

Chlorine is added to drinking water to destroy microbes and make it safer for drinking.

Chloramine is created when ammonia is added to boost the effect of chlorine

Chlorine and **Chloramine** in dialysis water cause severe harm in patients

- Hemolysis
- Hemolytic anemia
- Methemoglobinemia

Monitoring is required every 4 hours or at the start of every shift

Immediate action is required when unsafe levels are detected.

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Microbiological Testing

Purpose: involves assessing the presence, identity, and characteristics of microorganisms (such as bacteria, viruses, fungi, and parasites) in various samples.

Endotoxins are harmful components found in the cell walls of gram-negative bacteria that can be deadly to humans.

Water Testing Frequency

Microbiological Testing

- Monthly testing
- Weekly testing for 1 month on new water systems
- Dialysis machines:
  - All machines yearly
  - Two machines tested monthly

Chemical Testing

- Installation and Annually Testing
- Seasonal changes
- Substantial changes to system or system is not performing adequately

Quality Assessment Process Improvement

What should you review?

- Routine monthly water and dialysate testing
- Endotoxin and bacterial colony counts
- How often the system is disinfected

QAPI Reporting

What are you looking for?

- Look for trends, watch for consistent zeros
- Note if disinfection increased and ask why

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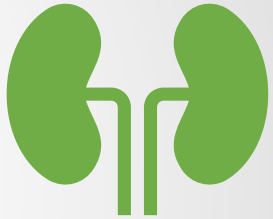
Disinfection

Water Treatment Systems

Monthly-includes RO and loops



Dialysis Machines

Follow manufacturers' instructions (IFUs)

Most common types of disinfection are heat and chemical disinfection

Guidelines for Environmental Infection Control in Health-Care Facilities, 2003

Essentials of Dialysis and Related Outbreaks

From 2011 to 2021

11 articles from 9 countries

154 patients impacted

7 patients died (4.5%)

BSIs reported in 9 articles (81.8%): GNB [N=10 (90.9%)]

Country, Year	Reservoir	Transmission	Organism	Type of Infection
USA, 2021	Prime buckets, drains in wall buckets, RO product water	Inadequate disinfection	Candida tropicalis	BSI
USA, 2019	Wall boxes	Pooling and regurgitation of waste fluid, infection control deficiencies (hand hygiene, aseptic technique)	GNB	BSI
Canada, 2017	Incoming water supply (city water)	Cultures from dialysis port and RO negative. Incoming water positive.	Mycobacterium mucogenicum	BSI
Brazil, 2020	Dialysis water (post osmosis points, reuse rooms, looping pipe, dialysis machines)	Inadequate disinfection of water systems, error in dilution of peracetic acid, use of filters beyond expiration date.	Stenotrophomonas maltophilia, Burkholderia cepacia	BSI

Waterborne Outbreaks in Hemodialysis Patients and Infection Prevention - PMC

Wall boxes

- Staff education
- Hand Hygiene
- Surface disinfection
- HAI Surveillance for Gram-negative bacteria
- Facilities Maintenance

ORIGINAL INVESTIGATION | VOLUME 74, ISSUE 5, P610-619, NOVEMBER 2019 Download Full Issue

Multicenter Outbreak of Gram-Negative Bloodstream Infections in Hemodialysis Patients

Shannon A. Novosad • Jason Lake • Duc Nguyen • ... Alison Laufer Halpin • Jennifer Layden • Priti R. Patel • Show all authors

Published: July 30, 2019 • DOI: https://doi.org/10.1053/j.ajkd.2019.05.012 • Check for updates

Multicenter Outbreak of Gram-Negative Bloodstream Infections in Hemodialysis Patients - American Journal of Kidney Diseases (ajkd.org)

This large outbreak was linked to wall boxes, a previously undescribed source of contaminated fluid and biofilm in the immediate patent care environment.

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Prime buckets

A multi-center outbreak of Candida tropicalis bloodstream infections associated with contaminated hemodialysis machine prime buckets - PubMed (nih.gov)

EMPTY **CLEANED** **DISINFECTED** **DRY**

A cluster of gram-negative bloodstream infections in Connecticut hemodialysis patients associated with contaminated wall boxes and prime buckets - PubMed (nih.gov)

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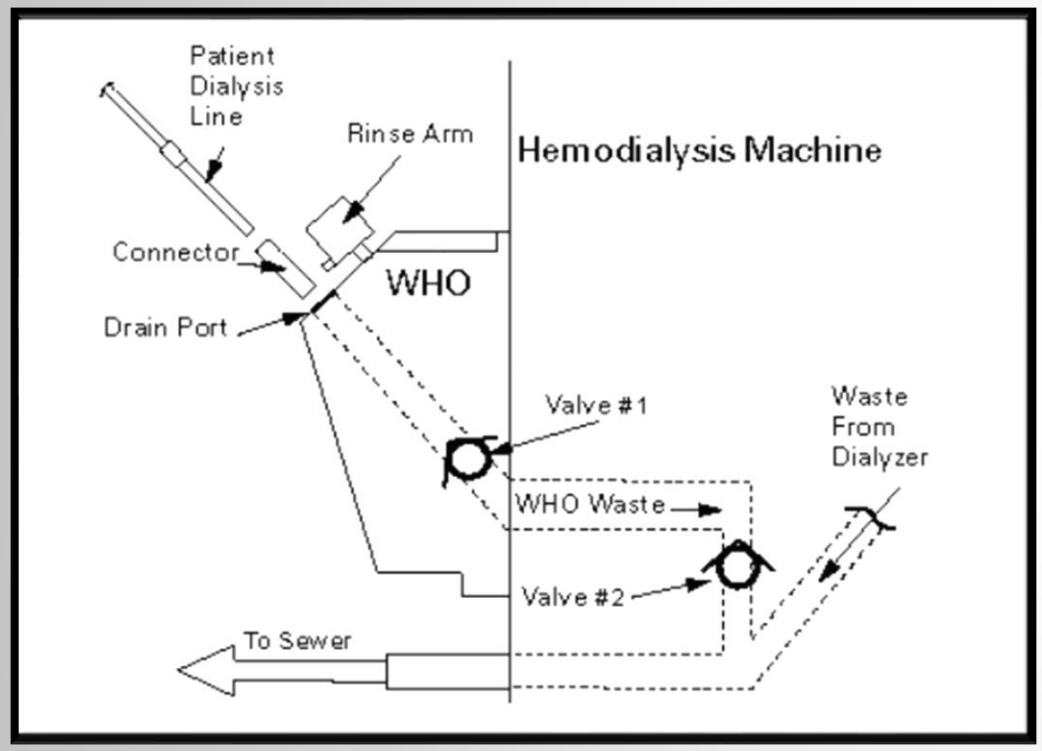
WHO (Waste Handling Options) Ports



Cross-contamination of dialysis bloodlines

- Faulty valves
- Inadequate cleaning and disinfection

Control measures when using WHO ports

- Daily testing of WHO valve for competency
- Cleaning and disinfection according to manufacturers' IFU
- Staff education
- Disconnect arterial blood line directly from the connector

Outbreaks of Gram-Negative Bacterial Bloodstream Infections Traced to Probable Contamination of Hemodialysis Machines -- Canada, 1995 United States, 1997; and Israel, 1997

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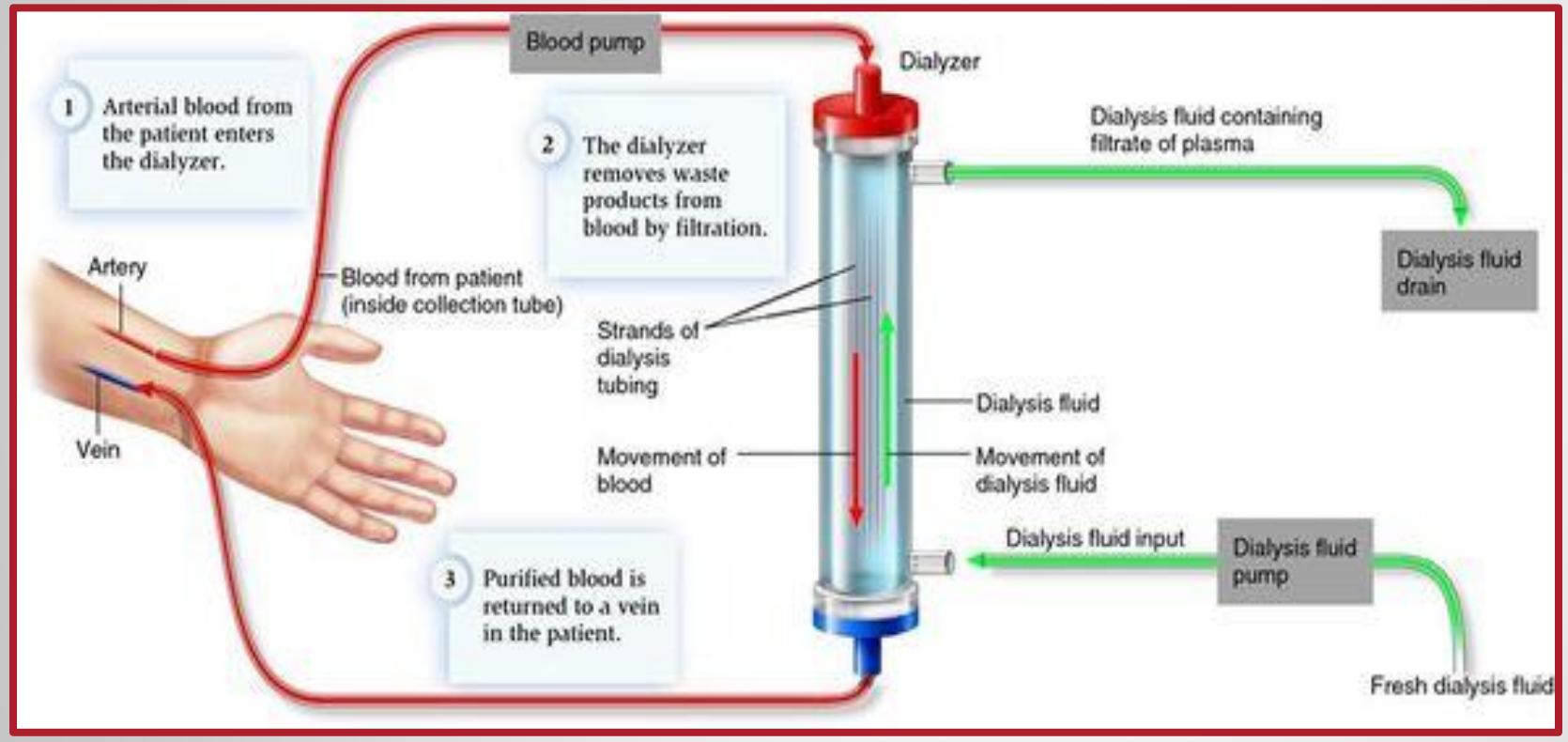
Bled Onto Machine



The process where blood is allowed to reach or almost reach the prime waste receptacle or WHO port to avoid giving the patient a bolus of saline.

Allowing patients to bleed directly onto the machine increases staff exposure to blood and poses a heightened risk to patients and is **NOT** recommended.

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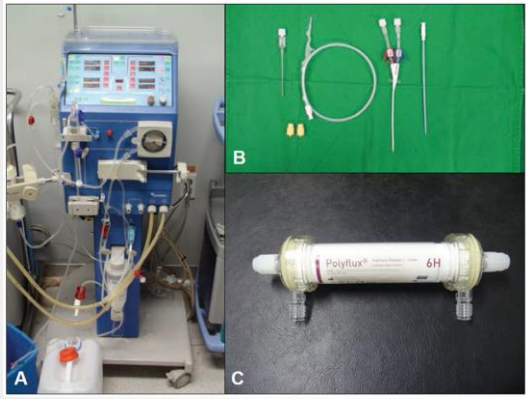
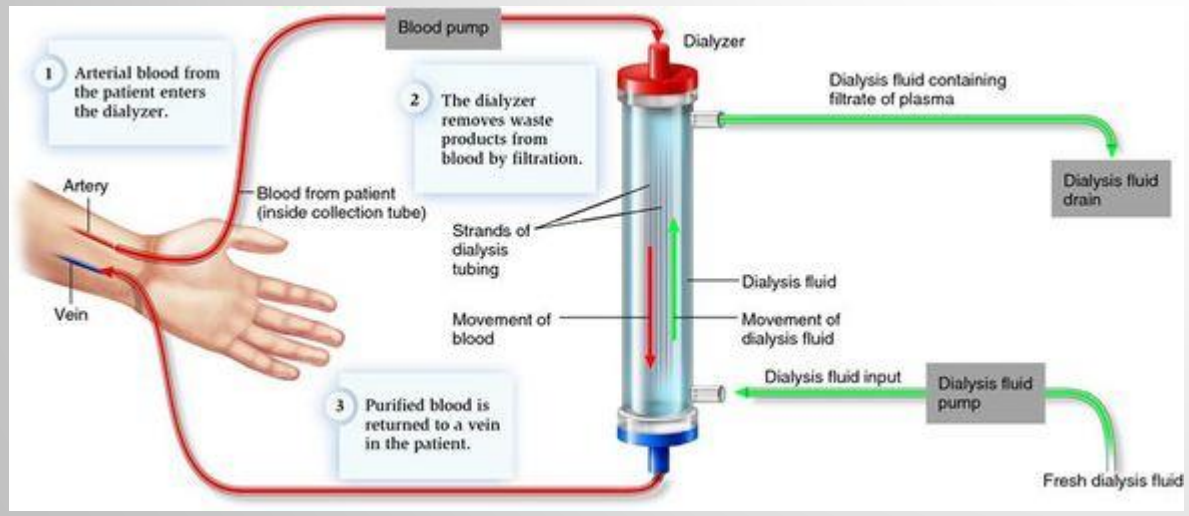
Dialyzer Reuse





[Hemodialyzer Reuse and Gram-Negative Bloodstream Infections - PubMed (nih.gov)]

17 cases (9 B cepacia and 8 S maltophilia bloodstream infections) occurred in 5 clinics owned by the same dialysis organization. Case patients were more likely to have received hemodialysis with a dialyzer that had been used more than 6 times

Reprocessing Dialyzer for Reuse

- **Single patient use only**

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Contact Us

Call our main department number: 402-552-2881

Office hours are Monday – Friday from 8:00 am – 4:00 pm (CST)

For emergencies, our on-call hours are Saturday – Sunday and Holidays from 8:00 am – 4:00 pm (CST)

E-mail our department: NebraskaICAP@NebraskaMed.com

E-mails will be answered during office hours

Resources

- The Joint Commission: r3-report-water-management-final_nov1.pdf
- ANSI/AAMI/ISO 23500-2:2019; Preparation and quality management of fluids for haemodialysis and related therapies—Part 2: Water treatment equipment for haemodialysis applications and related therapies
- ESRD Interpretive Guidance Version 1.1 (cms.gov)
- Guidelines for Environmental Infection Control in Health-care Facilities, 2003
- Multicenter Outbreak of Gram-Negative Bloodstream Infections in Hemodialysis Patients - American Journal of Kidney Diseases
- A multi-center outbreak of Candida tropicalis bloodstream infections associated with contaminated hemodialysis machine prime buckets – PubMed
- A cluster of gram-negative bloodstream infections in Connecticut hemodialysis patients associated with contaminated wall boxes and prime buckets – PubMed

Resources

https://www.cdc.gov/mmwr/preview/mmwrhtml/00051244.htm

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Hemodialyzer Reuse and Gram-Negative Bloodstream Infections - PubMed

Water Use in Dialysis | Dialysis Safety | CDC

Guidelines, Recommendations and Resources | Dialysis Safety | CDC

Dialysis – ICAP

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