Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases

Hemodialysis Water Wisdom

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Disclaimer and Disclosures

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

- No Disclosures
  - None of the faculty or planners for this activity have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients

Outline for today's session

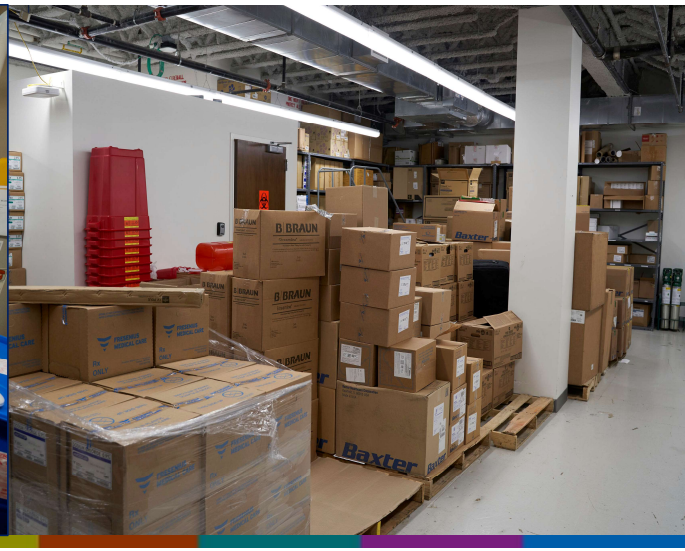
- Dialysis water treatment system/room components
- Water quality monitoring and disinfection processes
- Interpretation of water test results
- Identifying high-risk areas for water contamination and outbreak reports

Importance and Components

Water Treatment System

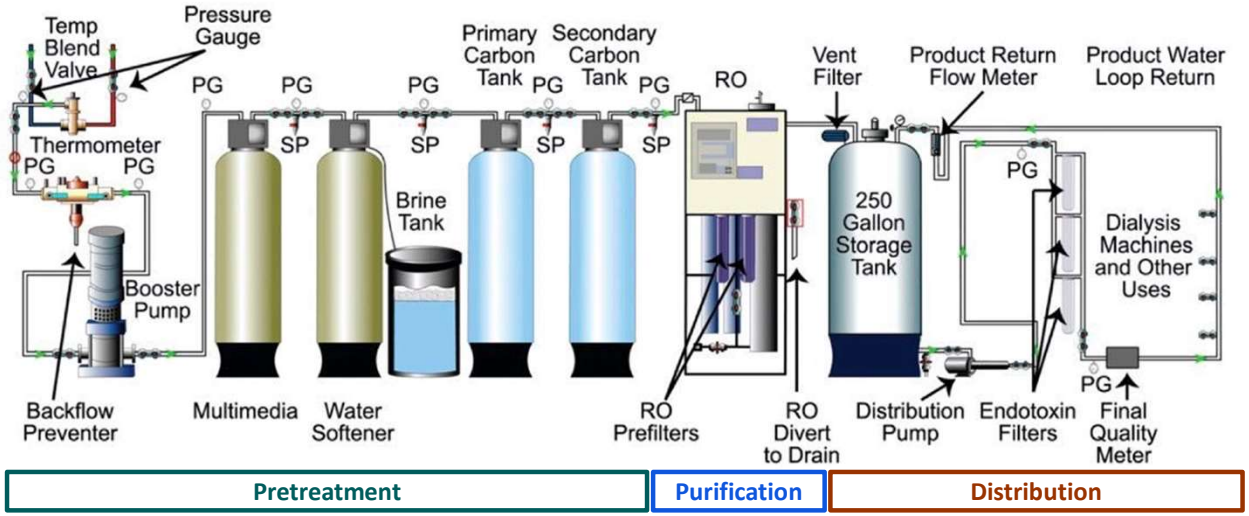
If you have seen one water room . . .
you've seen one water room

- Design and components vary according to space, source water analysis, needs of clinic
- Locked room next to clinic



Components of a water treatment system

- Temperature blending
- Backflow preventer
- Booster pump
- Multimedia filter
- Water softener / brine
- Carbon tanks
- Reverse osmosis (RO) membranes
- Storage or direct feed
- Endotoxin filters



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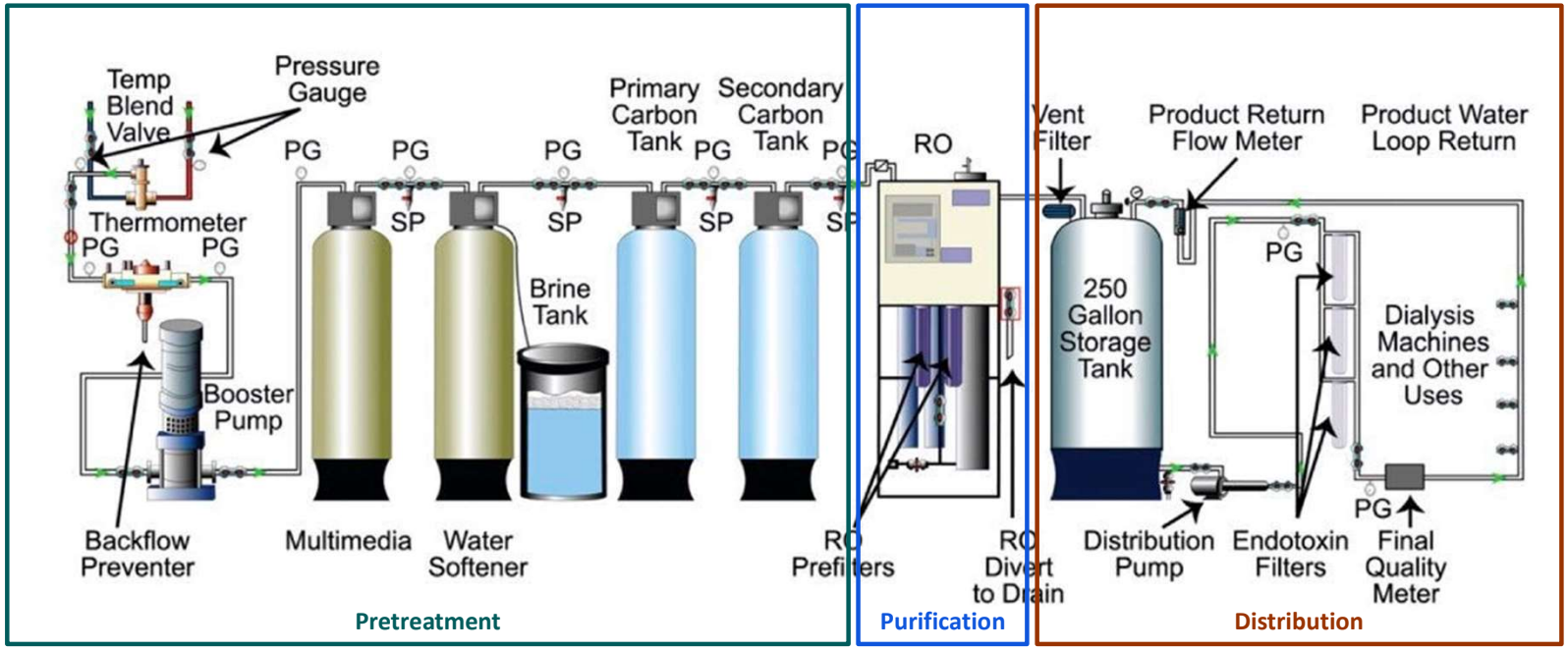


Importance of Water Treatment System

- It is vital to ensure the water used to perform dialysis is safe and clean
  - Hemodialysis patients are exposed to 300–600 liters of water per week
  - Standards for dialysis water are higher than those for drinking water
  - Poor water quality can lead to adverse patient outcomes including outbreaks associated with water exposure in dialysis settings

*Kasparek, Ted; Rodriguez, Oscar E.. What Medical Directors Need to Know about Dialysis Facility Water Management. Clinical Journal of the American Society of Nephrology 10(6):p 1061-1071, June 2015.

Pretreatment:
Temperature blend, backflow preventor, booster pump

- Temperature blend: mixes hot and cold water to create optimal temperature for filtering
  - Tanks and filters will perform best at 72–82°F
- Backflow preventor: prevents water from flow backwards into source water lines
  - Keep other patients in system (e.g., hospital, building) safe from de-chlorinated water or water with chemicals from treatment/disinfection processes
- Booster pump: ensures enough pressure in system to maintain flow

Pretreatment:
Multimedia, water softener, and brine tank

- Multimedia: Several layers of granite /sand to remove particles
- Water softener: Ion exchange of calcium and magnesium for sodium
  - Too much calcium or magnesium can cause nausea, vomiting, weakness, blood pressure issues, calcium crystal formation in soft tissues, seizures
- Brine tank regenerates the sodium medium in the softener

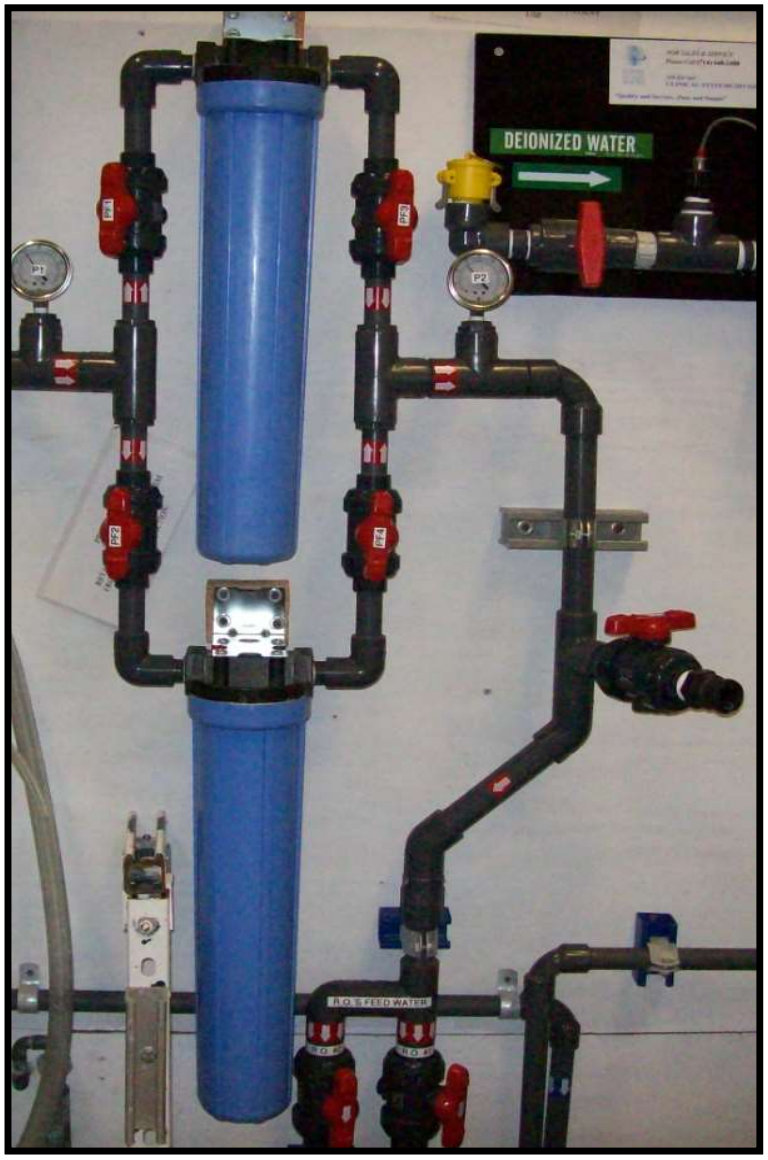
Pretreatment: Carbon tanks

- Contain granular activated charcoal (GAC) to remove **chlorine, chloramines,** pesticides, solvents, and trace organic matter
  - Exposure to chlorine/chloramine can cause hemolysis, hemolytic anemia, and methemoglobinemia
- Series of 2 tanks for redundancy
  - 1) Worker or primary
  - 2) Polisher or secondary
  - Tanks cannot be regenerated, should be tested every 4 hours

Pretreatment:
Pre-filter

- Final filter before the processed water goes to the reverse osmosis (RO) purification system

- Prevents any sediment remaining in pretreated water from harming the RO system



Purification:
Reverse osmosis (RO)

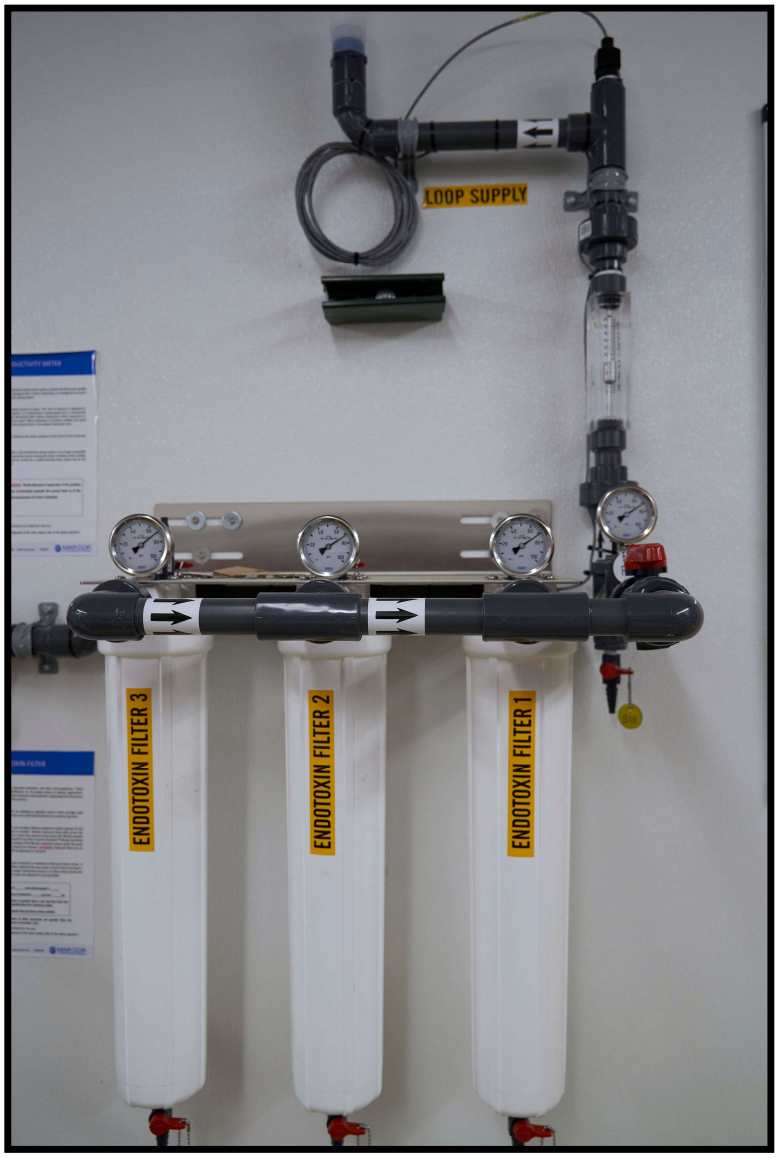
- Uses high-pressure pump to force water from one side of a semi-permeable membrane to another
- Captures 96–99% of solutes
  - Metal ions, salts, chemicals, bacteria, viruses, endotoxins
- Creates clean permeate (or product) water

Distribution:
Holding tank or direct feed

- Indirect feed systems use a holding tank that allows the RO system to work intermittently.
  - Water is processed through the RO system and stored in the tank
  - RO system will start again as soon as the water drops below a certain level
- Direct feed systems omit the holding tank, and the RO system is “on” continuously
  - Clean water is sent directly to the distribution loop

Distribution:
Endotoxin filters

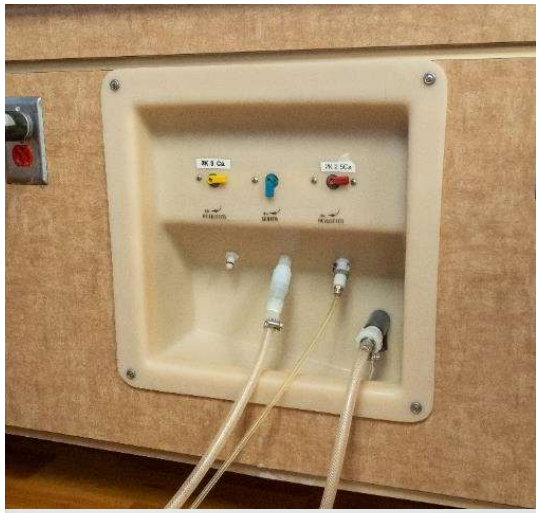
- Destruction of bacteria produce endotoxins
- Endotoxin filters are a last line of defense before water is distributed
  - Changed on a regular basis
- In some cases, ultraviolet (UV) irradiation used for bacterial control before endotoxin filters



Distribution:
Distribution loop and connections

- Continuous “loop” runs from water room to dialysis clinic floor back to water room

- Dialysis wall boxes
  - Treated water source from loop
  - Drain
  - Acid and base concentrates



Distribution: Bicarbonate/Acidification

- Final dialysate solution consists of treated water, acidified, and bicarbonate solutions that are mixed by the dialysis machines
  - Matches conductivity and pH of blood
- Solutions can be prepared in mixing tanks, or through purchase of jugs or large drums (acidified)

Standards, Testing, Maintenance, and Risks

Monitoring & Disinfection

Recommendations for dialysis water quality and dialysate

- Outlined in *Guidelines for Environmental Infection Control in Health-Care Facilities (MMWR June 6, 2003)*
  - CDC & Healthcare Infection Control Practices Advisory Committee (HICPAC)
- General recommendation topics:
  - Adherence to current AAMI water standards
  - Microbiological and bacteriologic testing of dialysis water
  - Routine disinfection of dialysis water distribution systems

https://www.cdc.gov/mmwr/PDF/rr/rr5210.pdf
https://www.cdc.gov/dialysis/guidelines/water-use.html

AAMI water standards

- Association for the Advancement of Medical Instrumentation (AAMI)
- Details standards of water for use in dialysis, including:
  - 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.
- AAMI standards have been adjusted over the years
  - Facilities may follow different sets of standards depending on what year they started performing dialysis

Routine chemical analysis

- Analyses of the source water to a clinic that must be performed at installation to assure that water systems can meet the AAMI standards
- Analyses of treated water required by AAMI standards at system installation and then annually, but can be performed more often:
  - Surrounding seasonal changes
  - Whenever substantial changes to system take place
  - If the water system is not performing adequately

Monitoring for chlorine and chloramines

- Chlorine may be added to drinking water to destroy microbes
  - Ammonia may also be added to boost effect of chlorine, creating chloramine
- Chlorine/chloramine in dialysis water can cause severe patient harm
  - E.g., hemolysis, hemolytic anemia, and methemoglobinemia
- Water sampled between 2 carbon tanks require frequent monitoring
  - Every 4 hours **OR** at the start of every shift
- Unsafe levels require immediate action to ensure patient safety

Bacterial and endotoxin testing

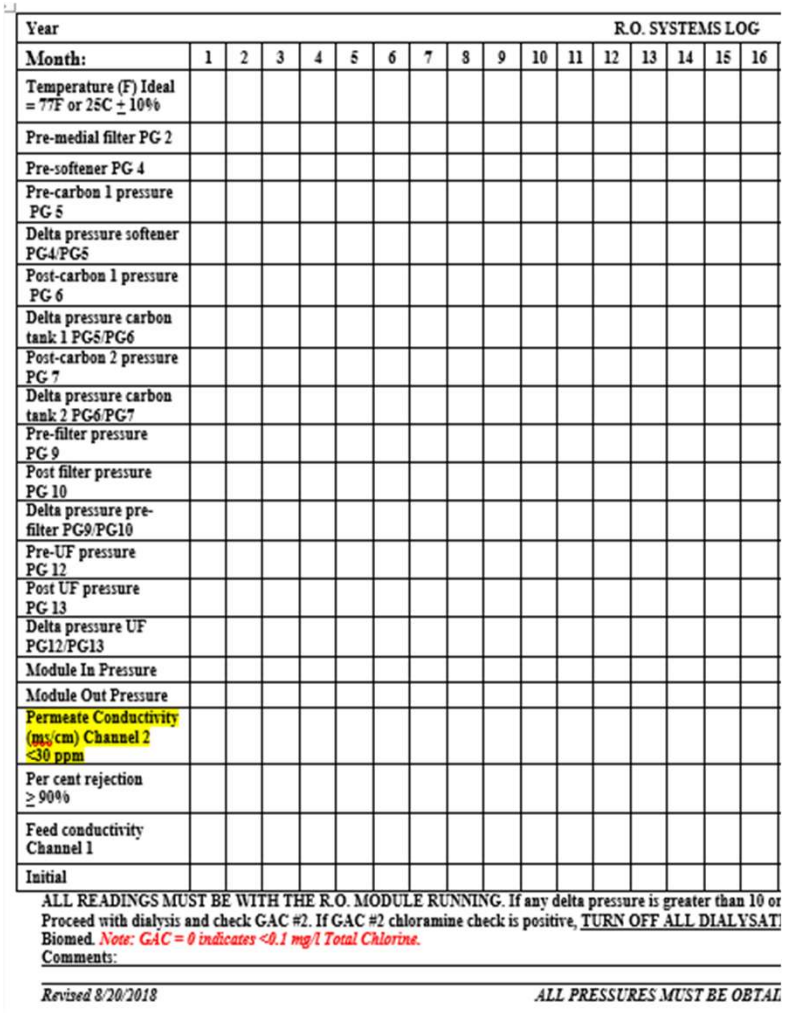
- The entire water system require bacteria and endotoxin monitoring at least once a month (or more often if problems occur), with samples from:
  - RO system
  - Distribution/delivery system (beginning and end)
  - Mixing systems (acidified and bicarbonate solutions)
  - Point of use (dialysis machines)
- Monthly testing of representative sample of dialysis machines

Disinfection

- Water treatment system disinfection should be proactive
  - RO systems and “loops” should be disinfected at least monthly
- Follow specific disinfection steps based on manufacturer recommendations
  - Most common disinfection types are heat and chemical disinfection
- Monthly cultures for bacteria and endotoxins should be drawn prior to monthly system disinfection
- Reactive disinfection should take place at the first sign of any growth

Daily water system tests

- Water treatment system parameters tested daily to document proper function
  - Typically performed by bio-medical staff
- Parameters tested include:
  - Dissolved solids
  - Conductivity
  - Resistivity
  - Pressure drops
  - Rejection



Year R.O. SYSTEMS LOG

Month:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Temperature (F) Ideal = 77F or 25C ± 10%																
Pre-medial filter PG 2																
Pre-softener PG 4																
Pre-carbon 1 pressure PG 5																
Delta pressure softener PG4/PG5																
Post-carbon 1 pressure PG 6																
Delta pressure carbon tank 1 PG5/PG6																
Post-carbon 2 pressure PG 7																
Delta pressure carbon tank 2 PG6/PG7																
Pre-filter pressure PG 9																
Post filter pressure PG 10																
Delta pressure pre-filter PG9/PG10																
Pre-UF pressure PG 12																
Post UF pressure PG 13																
Delta pressure UF PG12/PG13																
Module In Pressure																
Module Out Pressure																
Permeate Conductivity (ms/cm) Channel 2 <30 ppm																
Per cent rejection ≥ 90%																
Feed conductivity Channel 1																
Initial																

ALL READINGS MUST BE WITH THE R.O. MODULE RUNNING. If any delta pressure is greater than 10 or
Proceed with dialysis and check GAC #2. If GAC #2 chloramine check is positive, TURN OFF ALL DIALYSAT
Biomed. *Note: GAC = 0 indicates <0.1 mg/l Total Chlorine.*
Comments:

Revised 8/20/2018 *ALL PRESSURES MUST BE OBTAI*

Reports and Interpretation

Interpretation of water test results

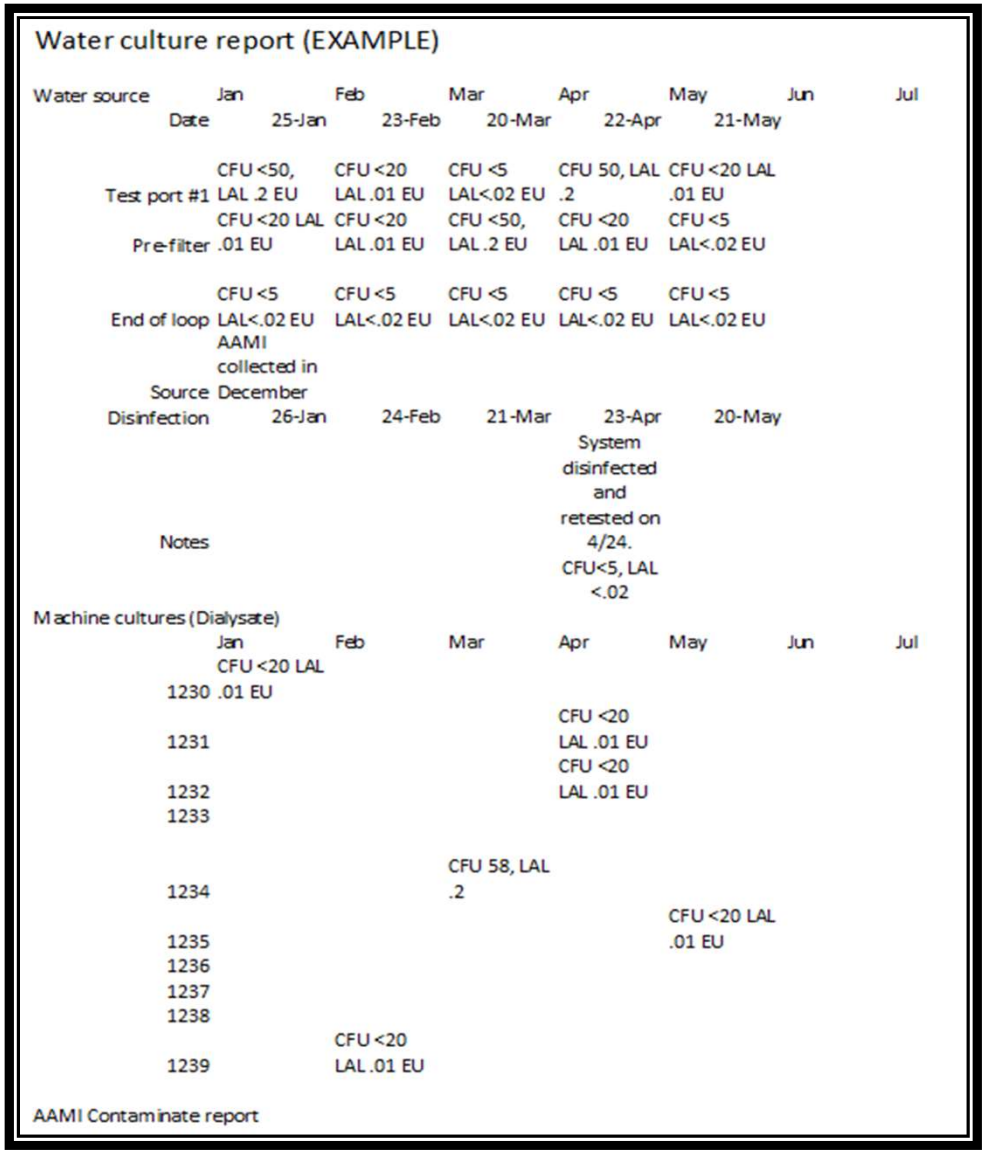
What should you review?

- Request the water report - results of routine monthly water and dialysate testing, including endotoxin and bacterial colony counts
- Ask how often the system is disinfected
- Which AAMI standards are they following?
  - Action levels are important
  - May be different, depending on year

https://www.cdc.gov/dialysis/guidelines/water-use.html

Sample report

- AAMI standards test results:
  - Annual contaminate testing
  - Disinfection schedules
  - Testing for endotoxin (EU) and bacteria (CFU) counts
- System components, typically monthly
- Specific machines



Water culture report (EXAMPLE)

Water source	Jan	Feb	Mar	Apr	May	Jun	Jul
Date	25-Jan	23-Feb	20-Mar	22-Apr	21-May		
Test port #1	CFU <50, LAL .2 EU	CFU <20 LAL .01 EU	CFU <5 LAL<.02 EU	CFU 50, LAL .2	CFU <20 LAL .01 EU		
Pre-filter	CFU <20 LAL .01 EU	CFU <20 LAL .01 EU	CFU <50, LAL .2 EU	CFU <20 LAL .01 EU	CFU <5 LAL<.02 EU		
End of loop	CFU <5 LAL<.02 EU	CFU <5 LAL<.02 EU	CFU <5 LAL<.02 EU	CFU <5 LAL<.02 EU	CFU <5 LAL<.02 EU		
Source	AAMI collected in December						
Disinfection	26-Jan	24-Feb	21-Mar	23-Apr	20-May		
Notes				System disinfected and retested on 4/24. CFU<5, LAL <.02			

Machine cultures (Dialysate)

	Jan	Feb	Mar	Apr	May	Jun	Jul
1230	CFU <20 LAL .01 EU						
1231				CFU <20 LAL .01 EU			
1232				CFU <20 LAL .01 EU			
1233							
1234			CFU 58, LAL .2				
1235					CFU <20 LAL .01 EU		
1236							
1237							
1238							
1239		CFU <20 LAL .01 EU					

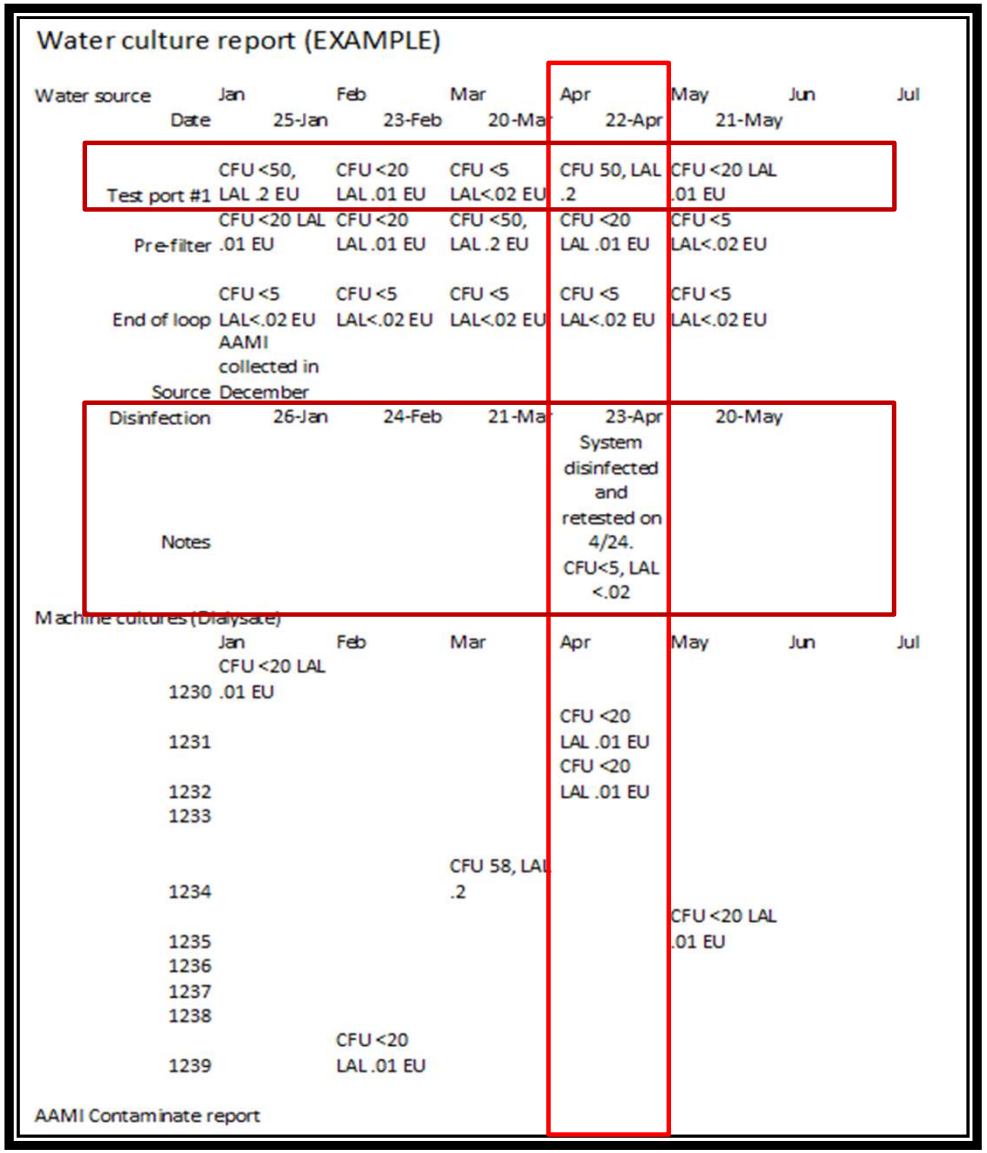
AAMI Contaminate report

Interpretation of the water report

- Focus on action levels and results outside of parameters
  - Do not accept “positive” or “no growth” as a result
  - Want a full count of every viable colony
- Look for trends
  - Watch for consistent zeros
  - Can often see issues arising
- Note if disinfection increased and ask why
- Consider machine specific results

Report review 1

- Take a closer look at April
  - Action level 50 CFU (bacteria counts)
  - Action level 1 EU (endotoxins)
- All labs drawn on 4/22, prior to regular system disinfection
- Results of Test Port #1 (RO System) met or exceeded action level
- System re-disinfected and Test Port #1 was retested on 4/24
- Results within normal limits



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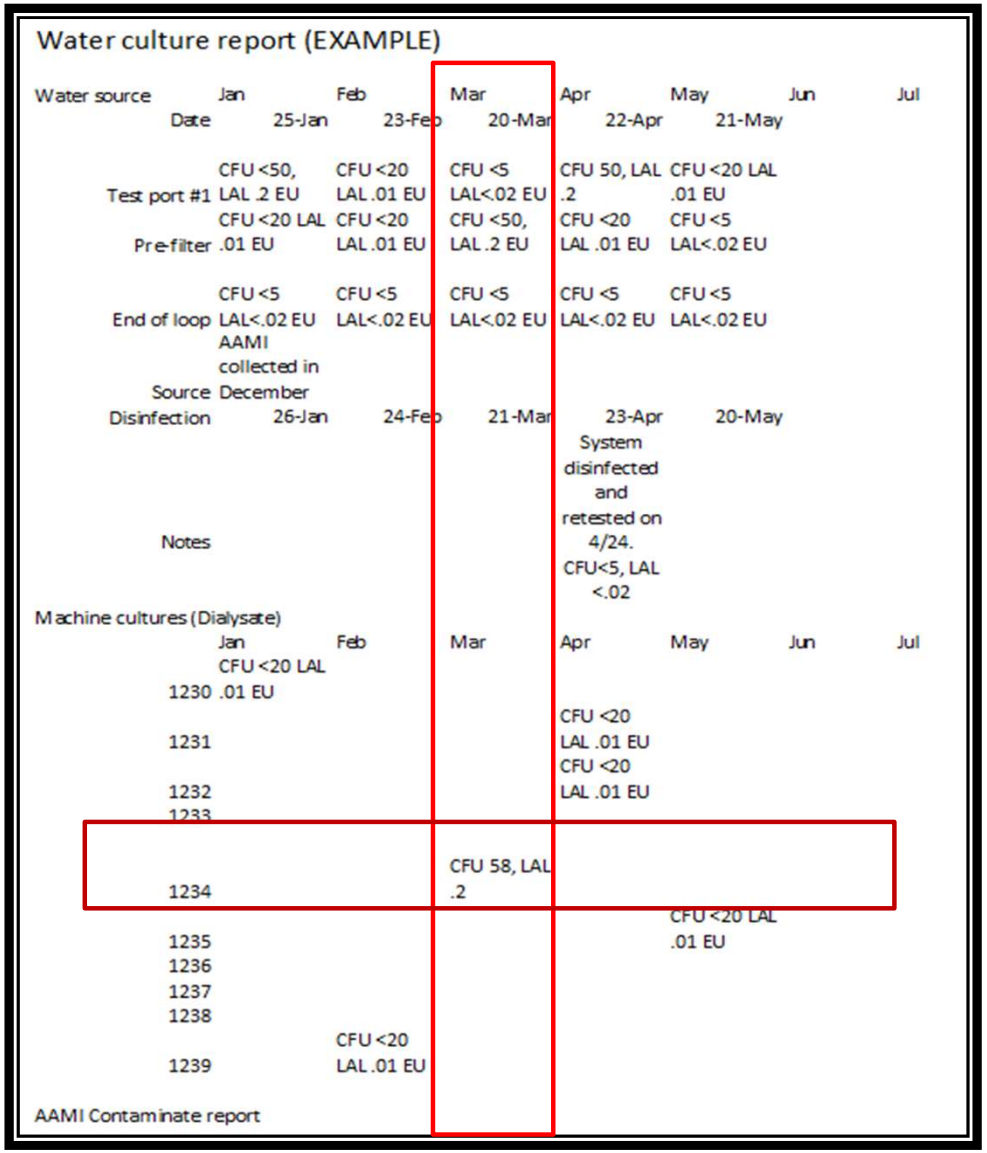
1236							
1237							
1238							
1239		CFU <20 LAL .01 EU					

AAMI Contaminate report

Report review 2

- Take a closer look at March
  - Action level 50 CFU (bacteria counts)
  - Action level 0.125 EU (endotoxins)
- Results of machine #1234 met or exceeded action levels with no indication of action steps taken
- Will need to ask more questions
  - Is there a missing report page?
  - Was it pulled from service and re-disinfected / re-tested?
  - Are there any infections that could be linked to this machine or wall box?



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AAMI Contaminate report

Quality Assessment Performance Improvement (QAPI)

- Facility interdisciplinary monthly meeting with medical director sign off
- Infection component
  - Review new infections
  - Discuss root cause analysis
- Water component
  - Review water reports and note the results
  - Discuss any issues or trends
- Minutes will be detailed

Interpretation of water testing summary

- Do not necessarily need to visit the water room itself
- Rely on water reports or QAPI minutes
- Focus on action levels and results outside of parameters
  - Want a full count of every viable colony
- Look for trends

Identify high-risk areas for water contamination

Outbreak of *Candida tropicalis* bloodstream infections associated with prime buckets

American Journal of Infection Control 49 (2021) 1008–1013

Contents lists available at ScienceDirect

American Journal of Infection Control

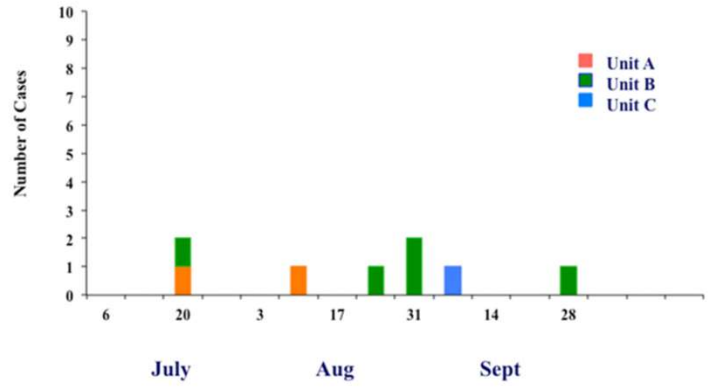
journal homepage: www.ajicjournal.org

Major Article

A multi-center outbreak of *Candida tropicalis* bloodstream infections associated with contaminated hemodialysis machine prime buckets

John M. Boyce MD [a,*], Diane G. Dumigan RN, BSN, CIC [a], Nancy L. Havill MT, MHA, CIC [a], Richard J. Hollis MS [b], Michael A. Pfaller MD [b], Brent A. Moore PhD [c]

[a] Department of Medicine, Hospital of Saint Raphael, New Haven, CT
[b] Department of Pathology, University of Iowa College of Medicine, Iowa City, IA
[c] Department of Psychiatry, Yale University School of Medicine, New Haven, CT



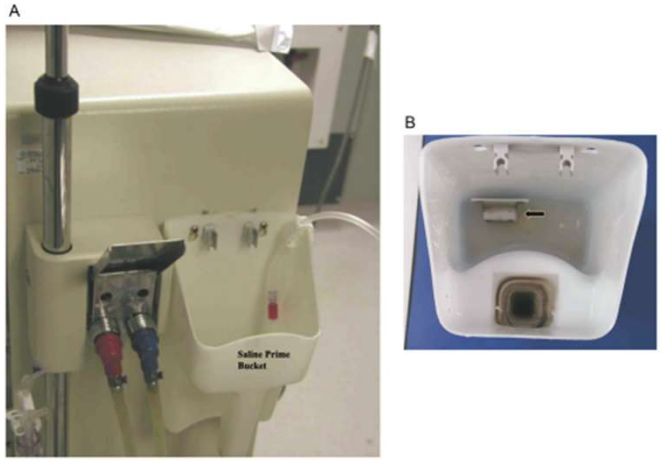


Fig 2. (A) Saline prime bucket (SPB) with tubing attached. (B) SPB with turbid fluid in bottom of bucket and in hollow handle of bucket. The "saline bucket plate" (arrow) was removed by investigators from the top of the hollow handle and placed in the bottom of bucket. Turbid fluid yielded *C tropicalis*.

https://pubmed.ncbi.nlm.nih.gov/33631306/

Outbreak of gram-negative bloodstream infections associated with wall boxes in the setting of breaches in infection control

AJKD

Original Investigation

Multicenter Outbreak of Gram-Negative Bloodstream Infections in Hemodialysis Patients

Shannon A. Novosad, Jason Lake, Duc Nguyen, Elizabeth Soda, Heather Moulton-Meissner, Mai T. Pho, Nicole Gualandi, Lurit Bepo, Richard A. Stanton, Jonathan B. Daniels, George Turabelidze, Kristen Van Allen, Matthew Arduino, Alison Laufer Halpin, Jennifer Layden, and Priti R. Patel

Rationale & Objective: Contaminated water and other fluids are increasingly recognized to be associated with health care–associated infections.

Results: 58 cases of Gram-negative bloodstream infection occurred; 48 (83%) required hospitalization. The predominant organisms were

Complete author and article information provided before references.

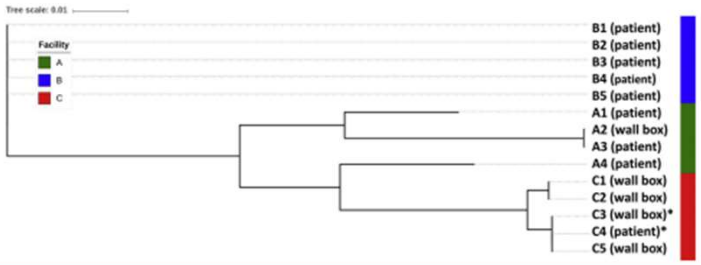


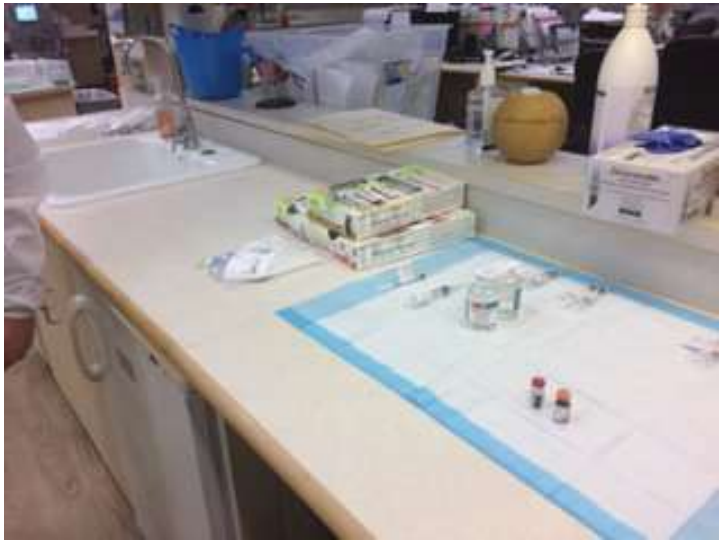
Figure 3. Phylogenetic trees of reference-based single-nucleotide polymorphism (SNP) analysis comparing *Serratia marcescens* case-patient and wall box isolates from 3 different outpatient hemodialysis facilities (A, B, and C; SNPs from core genome size of 29.87%). The phylogenetic tree represents genetic distances based on branch length; that is, isolates A2 and A3 (which have short branches between one another) are closely related to one another and more distantly related to isolates A1 and A4; *C3 and C4 were found to be indistinguishable using pulsed-field gel electrophoresis. Core genome size of isolates for individual facility whole genome sequencing comparisons are as follows: Facility A, 46.47%; Facility B, 78.46%; Facility C, 85.94%. The sequence reads generated as part of this study are available at National Center for Biotechnology Information BioProject ID PRJNA454492.

https://www.sciencedirect.com/science/article/pii/S0272638619307978?via%3Dihub

Infection prevention practices

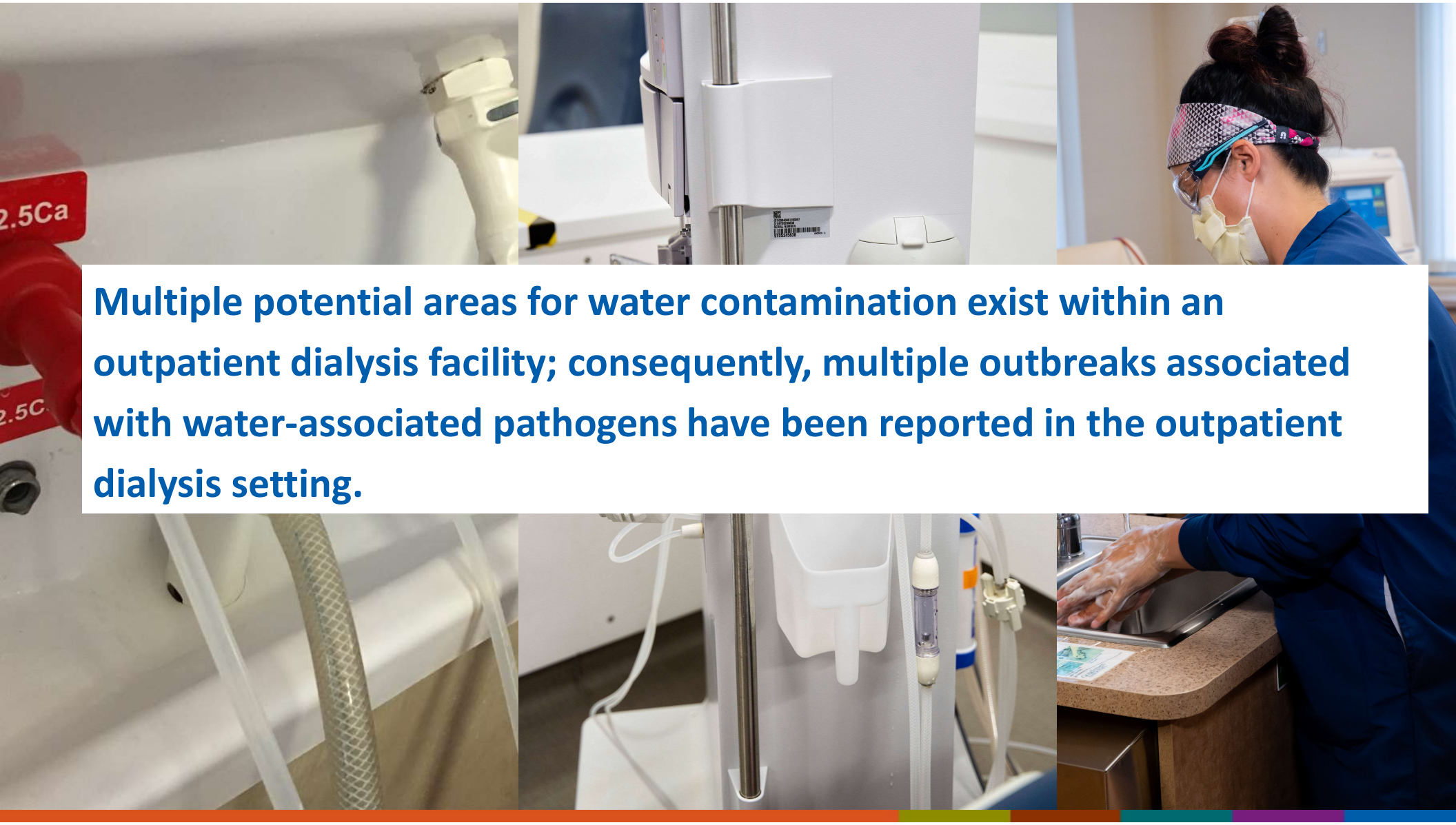
Sinks

Medication preparation



Water or wall boxes

Prime buckets



Multiple potential areas for water contamination exist within an outpatient dialysis facility; consequently, multiple outbreaks associated with water-associated pathogens have been reported in the outpatient dialysis setting.

Summary

What a "non-water expert" needs to know about water in dialysis setting

- Water treatment system critical to keep patients on dialysis safe
- Multiple opportunities for water exposure and contamination in the dialysis setting
- Know where to start and who to ask when you have questions
  - Reports, reports, reports
  - The biomed is your friend
- Adherence to recommended infection prevention practices is critical

QUESTIONS

#DialysisPatientsFirst

DialysisCoalition@cdc.gov

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

http://www.cdc.gov/dialysis/

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.