Dialysis Water Quality And It's Impact On Patient's Outcomes

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Objectives



Discuss the rationale for the treatment of water for Hemodialysis



State the microbial standards for water treatment



Identify water contaminants that must be removed for dialysis and possible patient symptoms if exposed to those contaminants



Discuss the functions of the Water Treatment System's critical components that can impact pateint outcomes and safety



Discuss Water Treatment System Checks an Monitoring Documentation

Water Treatment for Dialysis

- Why Water Treatment?
 - Patient safety
 - Prevent equipment damage





Water Treatment System Issues That Can Impact Patient Safety and Outcomes

- High Water Hardness (Water Softener)
- Low Product Water Volume (RO Membranes)
- Trace Metal Exposure (Incorrect Distribution Loop Materials)
- High Chlorine Level (Carbon Tank)
- Poor Product Water Quality (RO Membranes)
- Microbial or Bacteriological Growth Issues (Disinfection Protocols)

Water Unsafe = Unsafe Patients!

Dialysis Historical Water Incidents (Center for Disease Control-CDC)

- Annapolis 1979 Fluoride
- Philadelphia 1987 -Chlorine/Chloramine
- Chicago 1993 DI Water
- Youngstown, OH 2000 Pyrogen

Water Contaminants & Patient Symptoms

| WATER CONTAMINANT | PATIENT SYMPTOMS |
|--|---------------------|
| Aluminum, Chloramines, Copper, Zinc | Anemia |
| Aluminum, Fluoride | Bone Disease |
| Chloramines, Copper, Nitrates | Hemolysis |
| Calcium, Sodium | Hypertension |
| Bacteria, Endotoxin, Nitrates | Hypotension |

Water Contaminants & Patient Symptoms

| Water Contaminant | Patient Symptoms |
|--|------------------------|
| Low pH, Sulfates | Metabolic Acidosis |
| Calcium, Magnesium | Muscle Weakness |
| Bacteria, Calcium, Copper, Endotoxin, Low pH, Magnesium, Nitrates, Sulfates, Zinc | Muscle Weakness |
| Aluminum | Nausea and Vomiting |

Water Treatment

Regulatory Agencies

- AAMI (Association for the Advancement of Medical Instrumentation)
- ISO (International
 - Standards Organization)
- Ministry of Health or Local

Water/ Dialysate Culture Parameters

- Acceptable level: below 50 cfu/ml
- Action level: 50-99 cfu/ml
- Unacceptable level: 100 cfu/ml or greater

Water Endotoxin Parameters

- Acceptable level: below 0.12 EU/ml
- Action level: 0.12 EU/ml to less than 0.25 EU/ml
- Unacceptable level: 0.25 EU/ml or greater

Dialysate Endotoxin Parameters

- Acceptable level: below 0.25 EU/ml
- Action level: 0.25 EU/ml to less than 0.50 EU/ml
- Unacceptable level: 0.50 EU/ml or greater

Microbial Standards for Dialysis Quality Water (DQW)



Water Treatment Processes

Typical Pre-Treatment System



11

Water Softener

- Primarily for RO protection
- Removes "hardness" ions (calcium and magnesium)
- Sized for at least 1 day's operation
- Regenerate with pellet salt



Water Softener Monitoring

Off-line hardness testing at the end of each operating day post water softener

> On-line monitoring of Delta pressure with pressure gauges located pre and post water softener tank

> > Daily verification of timer setting for the correct time of day

Primary and Secondary Carbon Tanks/Filters

 Essential for the removal of total chlorine and chloramines



Primary and Secondary Carbon Filters



Empty Bed Contact Time (EBCT)

Empty Bed Contact Times

Amount

| to Onder | | | | 0.1 | | Minute | | | | 4 | | | | | | |
|----------|-------------|-------------|-------|-------|--------|---------|---------|-----------|--------|---------|----------|---------|------------------|--------|--------|--------|
| to Order | | | | Gall | on per | Minute | e RO u | sage (p | permea | te and | concen | trate) | | | | |
| cu.ft. | 7.48 factor | 1 gal | 2 gal | 3 gal | 4 gal | 5 gal | 6 gal | 7 gal | 8 gal | 9 gal | 10 gal | 11 gal | 12 gal | 13 gal | 14 gal | 15 gal |
| 1 | 7.5 | 7.5 | 3.7 | 2.5 | 1.9 | 1.5 | 1.2 | 1.1 | 0.9 | 0.8 | 0.7 | 0.7 | 0.6 | 0.6 | 0.5 | 0.5 |
| 2 | 15.0 | 15.0 | 7.5 | 5.0 | 3.7 | 3.0 | 2.5 | 2.1 | 1.9 | 1.7 | 1.5 | 1.4 | 1.2 | 1.2 | 11 | 1.0 |
| 3 | 22.4 | 22.4 | 11.2 | 7.5 | 5.6 | 4.5 | 3.7 | 3.2 | 2.8 | 2.5 | 2.2 | 2.0 | 1.9 | 1.7 | 1.6 | 1.5 |
| 4 | 29.9 | 29.9 | 15.0 | 10.0 | 7.5 | 6.0 | 5.0 | 4.3 | 3.7 | 3.3 | 3.0 | 2.7 | 2.5 | 2.3 | 2.1 | 2.0 |
| 5 | 37.4 | 37.4 | 18.7 | 12.5 | 9.4 | 7.5 | 6.2 | 5.3 | 4.7 | 4.2 | 3.7 | 3.4 | 3.1 | 2.9 | 2.7 | 2.5 |
| 6 | 44.9 | 44.9 | 22.4 | 15.0 | 11.2 | 9.0 | 7.5 | 6.4 | 5.6 | 5.0 | 4.5 | 4.1 | 3.7 | 3.5 | 3.2 | 3.0 |
| 7 | 52.4 | 52.4 | 26.2 | 17.5 | 13.1 | 10.5 | 8.7 | 7.5 | 6.5 | 5.8 | 5.2 | 4.8 | 4.4 | 4.0 | 3.7 | 3.5 |
| 8 | 59.8 | 59.8 | 29.9 | 19.9 | 15.0 | 12.0 | 10.0 | 8.5 | 7.5 | 6.6 | 6.0 | 5.4 | 5.0 | 4.6 | 4.3 | 4.0 |
| 9 | 67.3 | 67.3 | 33.7 | 22.4 | 16.8 | 13.5 | 11.2 | 9.6 | 8.4 | 7.5 | 6.7 | 6.1 | 5.6 | 5.2 | 4.8 | 4.5 |
| 10 | 74.8 | 74.8 | 37.4 | 24.9 | 18.7 | 15.0 | 12.5 | 10.7 | 9.4 | 8.3 | 7.5 | 6.8 | 6.2 | 5.8 | 5.3 | 5.0 |
| 11 | 82.3 | 82.3 | 41.1 | 27.4 | 20.6 | 16.5 | 13.7 | 11.8 | 10.3 | 9.1 | 8.2 | 7.5 | 6.9 | 6.3 | 5.9 | 5.5 |
| 12 | 89.8 | 89.8 | 44.9 | 29.9 | 22.4 | 18.0 | 15.0 | 12.8 | 11.2 | 10.0 | 9.0 | 8.2 | 7.5 | 6.9 | 6.4 | 6.0 |
| 13 | 97.2 | 97.2 | 48.6 | 32.4 | 24.3 | 19.4 | 16.2 | 13.9 | 12.2 | 10.8 | 9.7 | 8.8 | <mark>8.1</mark> | 7.5 | 6.9 | 6.5 |
| 14 | 104.7 | 104.7 | 52.4 | 34.9 | 26.2 | 20.9 | 17.5 | 15.0 | 13.1 | 11.6 | 10.5 | 9.5 | 8.7 | 8.1 | 7.5 | 7.0 |
| 15 | 112.2 | 112.2 | 56.1 | 37.4 | 28.1 | 22.4 | 18.7 | 16.0 | 14.0 | 12.5 | 11.2 | 10.2 | 9.4 | 8.6 | 8.0 | 7.5 |
| | | | | Minim | um Co | ntact T | Time 3. | 5 . If Ch | lorami | ne, mir | nimum is | 6.5 Ide | al is 5 8 | . 10 | | |

Carbon Filter Monitoring

- When do we test?
- Where do we get the sample?
- What are acceptable limits?



Carbon Filter Monitoring

What do you do if the total chlorine levels are too high after the Primary Carbon tank?

If post-second tank levels are within limits, how often do we monitor?

Repeat, check after 2nd tank

Q 30 minutes and document

If post-second tank levels become too high, what do we do?

Stop dialysis!

Notify Dialysis Center Manager and Biomed Manager for ANY high levels

Reverse Osmosis

- Semi-permeable membrane and pump to produce purified water
- What does the RO remove?
 - Organic and inorganic contaminants
 - Bacteria and endotoxin
- Primary device for water purification used in dialysis

Reverse Osmosis



REVERSE OSMOSIS





Reverse Osmosis Unit



Direct Feed Design



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Indirect Feed Design



RO Monitoring

Continuous on-line Water Quality Monitoring

- Percent rejection, >90%
- TDS/Conductivity, facility specific limits
- Audible and visual alarms on treatment floor

Off-line Monitoring

- Analysis for AAMI
 inorganic contaminants
- Bacterial and endotoxin levels

Final RO & DI Water Quality Alarms

- Located in treatment area
- Audio and visual alarms if final water conductivity or resistivity becomes unsafe for dialysis
- Response to Final Water Quality Alarm
 - Put all dialysis machines in bypass mode
 - Notify Charge Nurse, Biomed, Administrator, Medical Director
 - If water quality cannot be restored, terminate all treatments and submit a facility Adverse Occurrence Report

Distribution Systems

- Convey purified water to each point of use
- Must maintain purified water quality and water flow
- Components include pipes, valves, regulators and other piping fixtures and must be non leaching materials such PVC, PEX, 316SS
- No copper, brass, iron or materials with the potential leaching liquid or chemical exposure
- May be indirect feed (holding tank) or direct feed design

Ultraviolet Light

Action

- Slows growth of bacteria or makes them incapable of reproducing
- Used only in conjunction with Indirect feed (storage tank) water treatment systems



Ultrafilter/Endotoxin Filter

- Last component before water is distributed to patient stations (or first point of use such as bicarb mixer, reuse)
- Submicron filter for small particles (Ultrafilter Must be Place Post UV Lamp)
- Bacteria and endotoxin



MONTH

| | FACILITY: | | Date: | · · · · | | · · · · · | | - | | | <u> </u> | |
|----|--|--|------------------------------------|---------|-----|-----------|-----|------------|-----|-----|-----------|-----|
| ľ | Monitored Process or Component | Acceptable Limit(s) | Monitor Location | MON | TUE | WED | THU | FRI | SAT | SUN | | |
| 1 | Is RO On? (RO must be running for 15 | YES (Y) | RO Pump | | | | | | | | | |
| | minutes) Protectionent Food Water Pressure | Fata Facility Provide | Deres Course | | | | | | | | | |
| * | Pretreatment reed water Pressure | Enter Facility Specific | Pressure Gauge # | - | | - | | | | | | |
| 3 | Feed Water Temperature | > 60 F but < 85 F | Temp Gauge # | | | | | | | | | |
| 4 | Correct time of Dav? | YES (Y) | Timer Controls | | | | | | | | | |
| 5 | Multimedia filter pressure (Pre - Post) | Delta pressure < or = to 15 psi Y / N / NA | Pre-treatment | | | | | | | | | |
| 6 | Scavenger Tank pressure (Pre - Post) | Delta pressure < or = to 15 psi / NA | Pre-treatment | | | | | | | | | |
| 7 | Scavenger Brine Tank Salt Level | Tank at least half full , Above the waterY / N / NA, | Brine Tank | | | | | | | | | |
| 8 | Cartridge filter pressure (Pre - Post) | Delta pressure < or = to 15 psi Y / N / NA | Pre-treatment | | | | | | | | | |
| 9 | Water softener pressure (Pre - Post) | Delta pressure < or = to 15 psi | Pre-treatment | | | | | | | | | -23 |
| 10 | Salt Level in Brine Tank? | Tank at least half full , Above the waterY / N / NA, | Brine Tank | | | | | | | | signatur | |
| 11 | Primary carbon pressure (Pre - Post) | Delta pressure < or = to 15 psi | Pre-treatment | | | | | | | | | |
| 12 | Secondary carbon pressure (Pre - Post) | Delta pressure < or = to 15 psi | Pre-treatment | | | | | | | | initials | |
| 13 | Is RO Bypass Valve Closed? | YES (Y) or N/A | Bypass Valve (V#) | | | | | | | | | |
| 14 | RO Pre-filter Inlet Pressure | Enter Facility Specific | Pressure Gauge # | | | | | 2 | | | | |
| 15 | RO Pre-filter Outlet Pressure | Enter Facility Specific | Pressure Gauge # | | | | | | | | | |
| 16 | RO Pre-filter Delta Pressure | < 20 psi | Line 16 - Line 17 | | | | | | | | | |
| 17 | RO Product Water Quality | Enter Facility Specific | RO Monitor | | | | | | | | | |
| 18 | RO Percent Rejection | >/= 90% | RO Monitor or Independent Meter | | | | | | | | | |
| 19 | RO Product Water Flow Rate | Enter Facility Specific | RO Monitor or Flow Meter | | | 1 | | | | | | |
| 20 | RO Reject Water Flow Rate | Enter Facility Specific | RO Monitor or Flow Meter | | | | | | | | | |
| 21 | Final Product Water Quality | Enter Facility Specific | Final Quality Monitor | | | | | | | | | |
| 22 | Ultrafilter Inlet Pressure | Enter Manufacturer Specific | Pre UF Gauge # | | | | | | | | - 21 | |
| 23 | Ultrafilter Outlet Pressure | Enter Manufacturer Specific | Post UF Gauge # | | | | | | | | | |
| 24 | Ultrafilter Delta Pressure (Pre - Post) | Enter Manufacturer Specific | Line 24 - Line 25 | | | | | | | | | |
| 25 | If In Use, Is UV light(s) On? | YES (Y) or N/A | UV Controller | | | | | | | | | |
| 26 | Time When Checks Above Completed | Prior to Start of Patient Treatment Day | Time of Day | | | | | | | | | |
| 27 | If Required, Time When Blomed Contacted for Direction or Assistance | Contact Time or N/A | Time of Day | | | | | | | | noture | |
| 28 | Initials of Teammate Performing Above Checks | Teammates Initials | Match Signature on Side | | | | | | | | 36 | 8 |
| 29 | Initials of Licensed Nurse | Licensed Nurses Initials | Match Signature on Side | | | | | | | | | |
| 30 | End of Day Hardness Test Result | = 1 gr/gal / NA</td <td>Post Softener Sample Port</td> <td></td> <td></td> <td></td> <td></td> <td>6 (5) 1</td> <td></td> <td></td> <td>Initials.</td> <td></td> | Post Softener Sample Port | | | | | 6 (5) 1 | | | Initials. | |
| 31 | Time and initials of Teammate Performing End of Day Hardness Test | Time & initials | Match Signature on Side | | | | | | | | | |

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Disinfection Schedule (minimum)

- Weekly/Monthly for distribution system depending on system and whether or not heat or chemical is used.
- Quarterly for conventional RO membranes (Chemical)

Why do you need to know when disinfection is done at your facility?

- Equipment Availability
- Microbial sampling must be complete within 72 hours prior to disinfection (NOT AFTER)
- Chemical introduction into RO and Loop
- Testing of Chemical presence and residual is residual
- NO PATIENTS on treatment floor!

Questions

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