The Future of Water Treatment for Dialysis

By
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What is Ultra Pure Water?
We will cover today.

- Introduction to Water & Water for Dialysis
- What will new regulations do to WT
- New ideas about sodium
- Bacteria and bacterial byproducts
- Ultra-Pure Dialysis fluid and Ultra-Pure Water
- New WT equipment and technologies
Introduction to Water
And
Water for Dialysis
Osmosis
Dialysis
Osmosis and Diffusion
Patient Water Exposure

- Normal person
  - 10 to 12 Liters/week

- Dialysis Patient
  - 350 to 400 Liters/week
Water

The universal solvent!
Three Types Of Contaminants Of Concern For Dialysis
<table>
<thead>
<tr>
<th>Inorganic</th>
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</thead>
<tbody>
<tr>
<td>Calcium/Magnesium</td>
</tr>
<tr>
<td>Aluminum</td>
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<tr>
<td>Sulfate</td>
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<tr>
<td>Copper</td>
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<tr>
<td>Iron</td>
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<tr>
<td>Arsenic</td>
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<tr>
<td>Antimony</td>
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<tr>
<td>Thallium</td>
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<tr>
<td>Sodium/Potassium</td>
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<tr>
<td>Fluoride</td>
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<tr>
<td>Nitrate</td>
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<tr>
<td>Zinc</td>
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<tr>
<td>Lead</td>
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<tr>
<td>Tin</td>
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<tr>
<td>Beryllium</td>
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</tbody>
</table>
Sodium

- Are you a 138 dialysis center?
- What is your patient’s sodium electrolyte level?
- Should we adjust the dialysate to be closer to the patient's sodium level?
Organic Chemicals

- Chloramine
- Chlorine
Is Carbon the only way?

- Sodium Metabisulfite and/or 185 UV pretreatment to the RO reduces Chlorine and Chloramine to Chloride which the RO removes easily.
185nm Ultra-Violet Unit
Microbiological

- Bacteria
- Endotoxin and other bacterial byproducts
Bacteria

Fig. 14-1 — (A) Typical Capsulated, Non-Flagellated, Rod-Shaped, Bacterium, And (B) Typical Non-Capsulated, Flagellated, Rod-Shaped Bacterium.
Biofilm battle
Biofilm

- Bacteria creates biofilm.
- We need to disinfect enough to try to control biofilm.
- It will probably require weekly Disinfection
- With monthly cultures and LALs on all water systems and ROs
Bacterial byproducts are the problem going forward.
Every time we dialyze a patient we attack their immune system.
Dialysis Standards

- AAMI
- CMS
- FDA
- JCAHO
- ISO
Guidance for the preparation and quality management of fluids for hemodialysis and related therapies
New AAMI/ISO standards

ISO = International Standards Organization

AAMI/ISO 23500 replaces AAMI RD52 (CMS has not included in there new rule yet).

- Bacteria < 100 CFU w. 50 CFU Action limit
- Endotoxin
  - Water < 0.25 EU w. 0.125 EU Action limit
  - Dialysate < 0.50 EU w. 0.25 EU Action limit

Ultra-Pure Dialysate and Water

- Bacteria < 0.1 CFU/ml
- Endotoxin < 0.03 EU
Antiscalant Feed

- Chemical is injected before the RO.
- The chemical ties up the calcium and magnesium which prevents the hardness scaling of the membranes and sends it down the drain.
- It can be used instead of a water softener on portable ROs, in installations with floor weight restrictions and where water softeners are not allowed.
Portable ROs

Down Time = Bugs

- Bacteria and endotoxin proliferation (caused by carbon and lack of use)
- If biofilm develops in a portable RO you may have to disinfect it daily for a week or more.
Inside the Carbon Granule
Ultra-Filters
Now required (sub-micron non endotoxin validated are not acceptable)
Disinfectant compatibility is critical
Good design and maintenance practices are very important!
222 O Ring
Endotoxin Filter
Cartridge Endotoxin Filter

Cartridge endotoxin filters have a charged surface that hold the endotoxin fragments.
Nephros Dual Stage Ultra-Filter Capsule

Produces biologically pure water which can be utilized in various dialysis applications.

The Nephros DSU has a 0.005 micron filter pore size designed to remove a spectrum of bacteria, viral agents and biological toxins including endotoxin.

This final filter withstands multiple disinfection cycles without degrading the fibers.

- Acts as a firewall for the patient by blocking microbiological contaminants like no other filter of this nature can.
- Provides up to 12 months of performance life in frequent use.
- Proven durability combined with safety and reliability of true redundant ultra-filtration.

For use with Portable RO’s

Some portable RO’s have bacteria build up due to infrequent use. The Nephros DSU provides additional security in an acute setting to ensure the highest quality water for the patient.

For use with Individual Dialysis Stations

Endotoxin and/or bacteria can colonize in the connection to the RO loop. The Nephros at each wall box is a final safeguard to ensure that the water going to the dialysis machine is ultra-pure.

<table>
<thead>
<tr>
<th>NEPHROS DUAL STAGE ULTRA-FILTER CAPSULE</th>
</tr>
</thead>
<tbody>
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<td>Model</td>
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</table>

Two Filtering Stages for Built-In Redundancy
Ultra Filter in portable RO
Ultra Filter at Wall Box
Disinfectants

- Chlorine (bleach)
- PAA (Peracidin, MinnCare, etc.)
- Ozone
- Heat
Ozone Disinfection

\[ O_1 + O_2 = O_3 \]
Dissolved Ozone

- Best chemical disinfectant
- Dissipates
- Very little rinse needed
- Test strips, ozone meter or test kit to monitor
- Filters and deionizers are not compatible with ozone (like most chemicals)
AAMI/ISO - Ozone Disinfection

- Ozone concentration levels of 0.5 ppm.
- Exposure time should be at least 10 minutes after the above level is established in the entire system.
- Ambient air in the area of use should be tested or monitored.
- Test for ozone dissipation prior to patient treatment.
- Not for disinfecting the RO, DI, or UF.
Heat disinfect loops and ROs
Double pass RO for Ultra-Pure Water
Double Pass RO
Heat Disinfect portable ROs with final ultra-filter
AAMI/ISO
Heat Disinfection

- Determine the temperature of the water in the RO or end of the Distribution Loop.
- Document the temperature and duration.
Distribution Loop
Dissolved Ozone is ok with PVC
Heat will change the loop to PEX, PTFE or Stainless Steel
Design Considerations - Distribution Loops
Design Considerations- Distribution Loop
PEX Loop Piping

PEXa is best for Dialysis

- More fully cross-linked not just on the cover
- Tubing rated for 80 psi at 200 °F
- Uses stainless steel and glass-reinforced polysulfone fittings
- Fittings rated for 150 psi at 210 °F
Piping Recommendations

- No dead legs (3 x the pipe diameter)
- Flow velocity (recirculation)
  - Minimum direct GPM = 1 1/2 ft./sec.
  - Minimum indirect GPM = 3 ft./sec.
- Good installation practices should be followed
What does continuous loop flow mean?

- Flow meter at end of loop
- Minimum flow plus treatments

Example 1 — loop indirect feed:
- Minimum flow = 6 GPM
- 24 stations @ 0.21 GPM = 5 GPM
- Total pump flow = 11 GPM
Microbial Levels

The lower the bacteria and endotoxin level, the healthier the patient.

This is especially true of endotoxin and other bacterial by products, even at low levels.
Bacteria 7 Day Plate Count

- The new 7 day plate count procedure: Use TGEA or R2A medium at 17 to 23º C for 7 days

- New 4 hour method using RNA
Rapid Bacteria Detection using ribosomal RNA to detect bacteria.

A component of the ribosome, the enzyme that is the site of protein synthesis.
Proper Sampling

Flush for 1 to 2 minutes

Clean Catch
Aseptic Sample Ports
Electronic Monitoring

- Download records using USB stick
- Online monitoring through an Ethernet
- Notification when specifications are not met through e-mail
- Wi-Fi
Remote Monitoring
Thank You!

Any questions?