

Dialysis and Water Quality

The Orange County APIC

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Objectives

- Why is Infection Prevention and Control Different in Dialysis?
- What are the (HAI) Risks with this Vulnerable Patient Population?
- Water Treatment (Quality); Where are the Health Economics?
- Trend the “Why”

Why Is Infection Prevention And Control Different In Dialysis

What are the (HAO) Risks with this Vulnerable Population?

Background

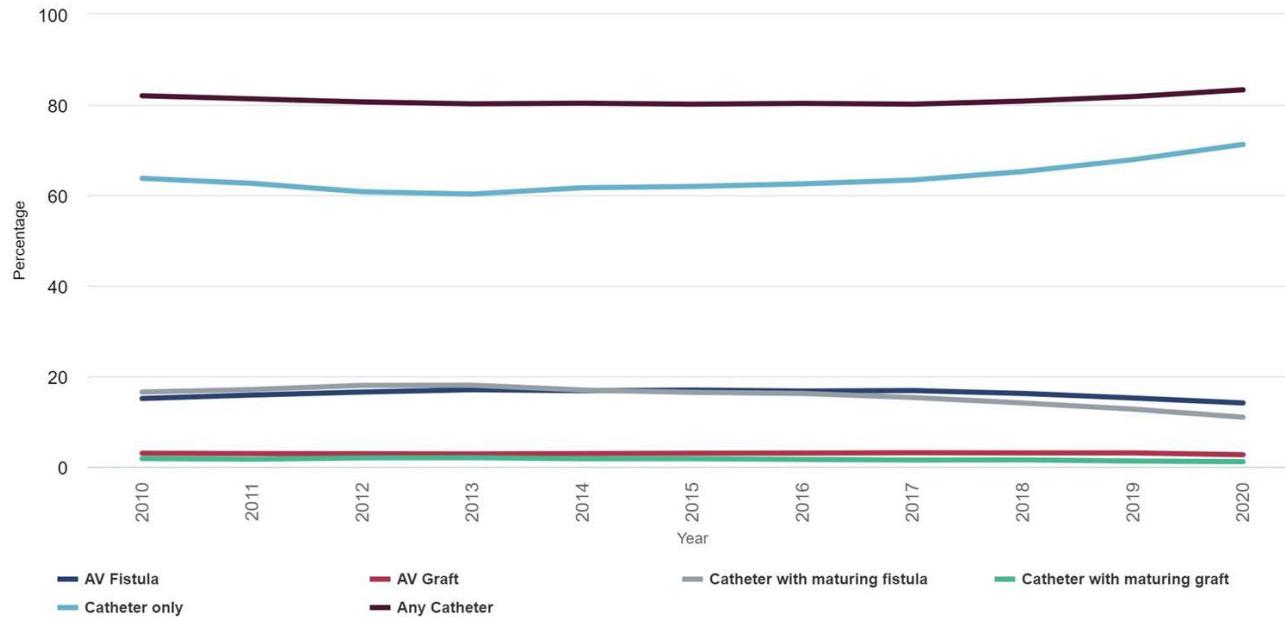
- Highly Vulnerable Population
- Repeated and Prolonged Exposure
- Invasive Procedures
- Shared Equipment and Spaces
- Challenges in Antibiotic Stewardship
- ESRD Infection Prevention and Control Evangelism

Risks Of Microbial Contaminants In Dialysate Water

- Infections and sepsis
- Inflammatory reactions
- Pyrogenic reactions
- Impaired dialysis efficacy
- Biofilm formation in Dialysis Machines
- Increased risk of cardiovascular disease
- Increases resistance to medications, i.e., Epogen and iron
- Increases B2M Accumulation
- Expedites residual renal function loss
- Contributes to anorexia and malnutrition

Background

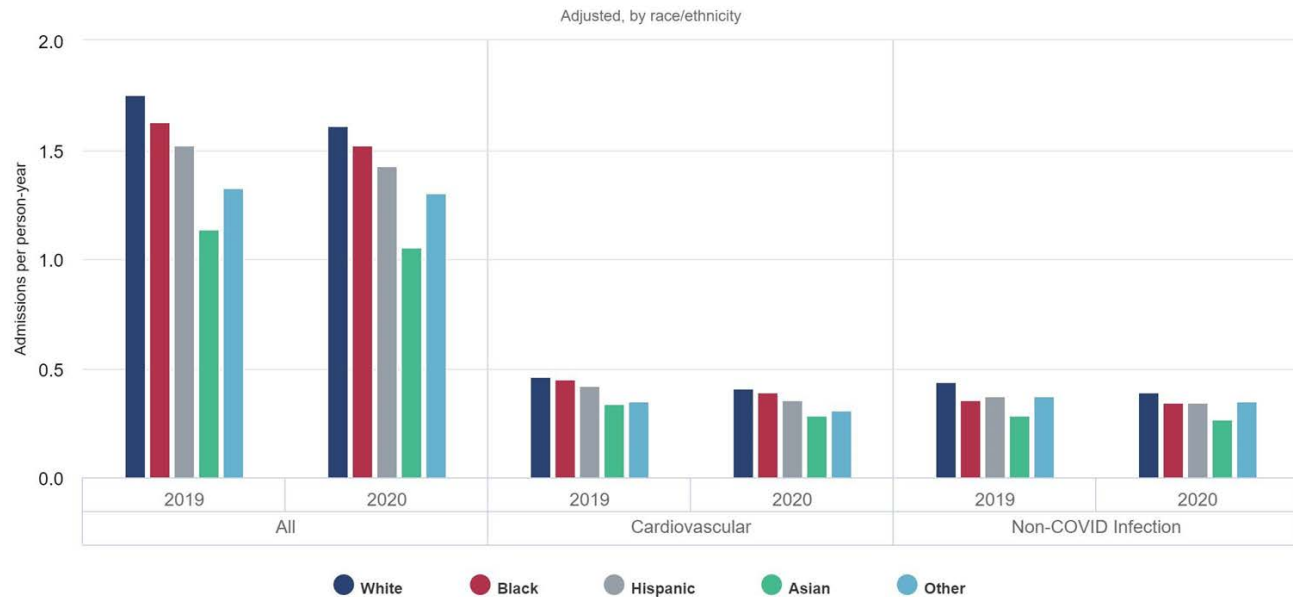
Figure 4.1 Vascular access use at HD initiation, 2010-2020



Data Source: 2022 United States Renal Data System Annual Data Report

Background

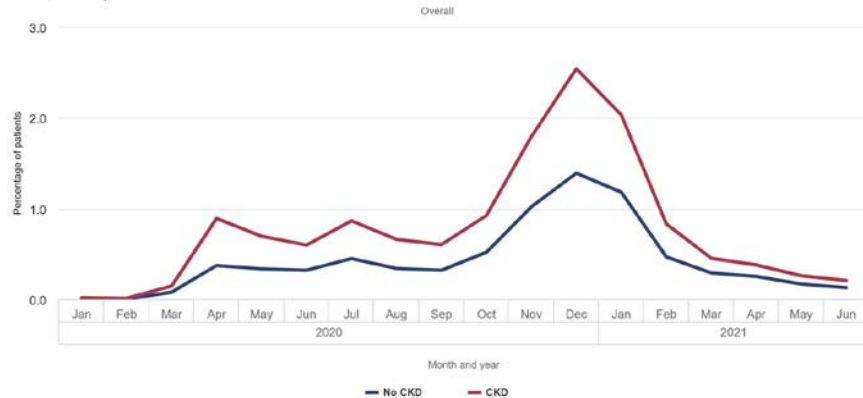
Figure 5.3 All and cause-specific hospitalization rates in adult hemodialysis patients, by demographic characteristics, 2019 and 2020



Data Source: 2022 United States Renal Data System Annual Data Report

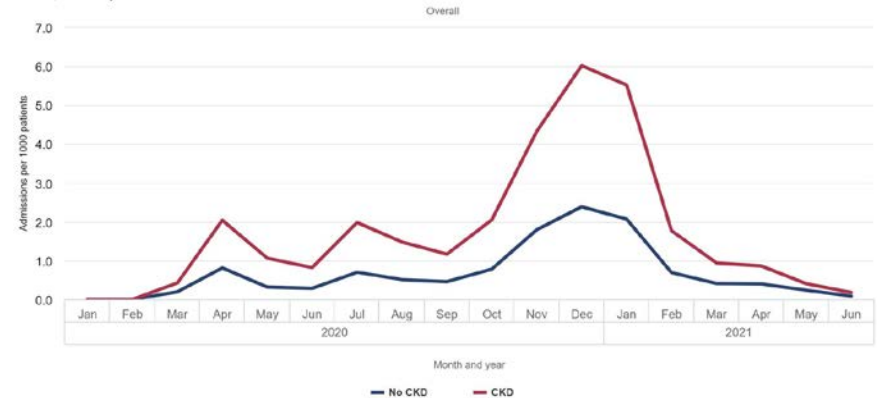
Background

Figure 13.2a Monthly incidence of diagnosed COVID-19 among Medicare beneficiaries by CKD and ESRD status, January 2020 - June 2021



Data Source: 2022 United States Renal Data System Annual Data Report

Figure 13.3 Monthly incidence of COVID-19 hospitalization among Medicare beneficiaries by CKD and ESRD status, January 2020 - June 2021



Data Source: 2022 United States Renal Data System Annual Data Report

Water Quality, Treatment, and Monitoring

Source of Water

Average Person

- Drinks ~14 L per week
- Can excrete toxins
- Some contaminants absorbed in GI tract, *indirectly* exposed to blood

Hemodialysis Patient

- Exposed to ~360-600 L per week
- Can't excrete toxins
- Contaminants *directly* exposed to blood via dialyzer membrane

Menti-Meter Question

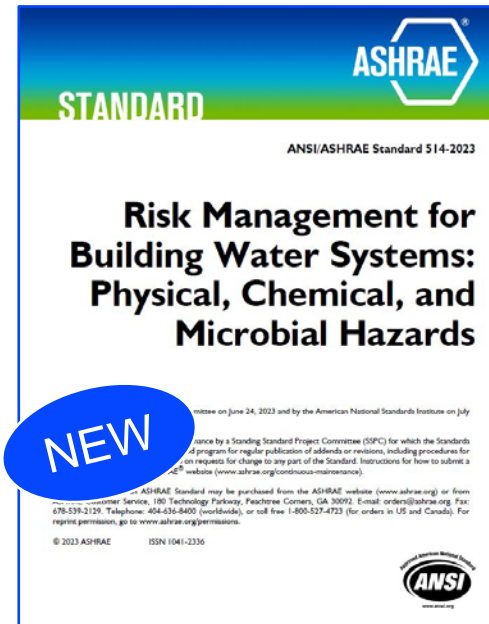
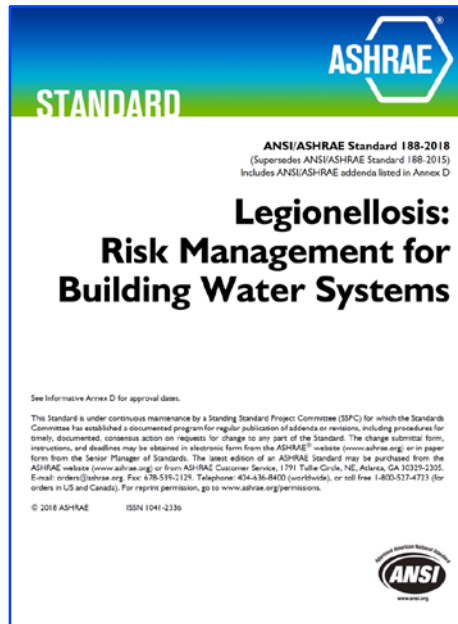
Would you consider your dialysis patients
within your “Vulnerable” Patient Population

Yes or No

Standard Of Care: ASHRAE 188 & ASHRAE 514

What is different?

- ASHRAE 188 has two informative Appendices and a focus on Legionella
 - *Most of the guidance for risk management for Legionellosis is in ASHRAE Guideline 12*
- ASHRAE 514 has 10 informative Appendices with comprehensive, detailed guidance, especially for hospitals
 - *Serves as a companion to ASHRAE 188*



ASHRAE 514 – (Appendix G) Specialty Units

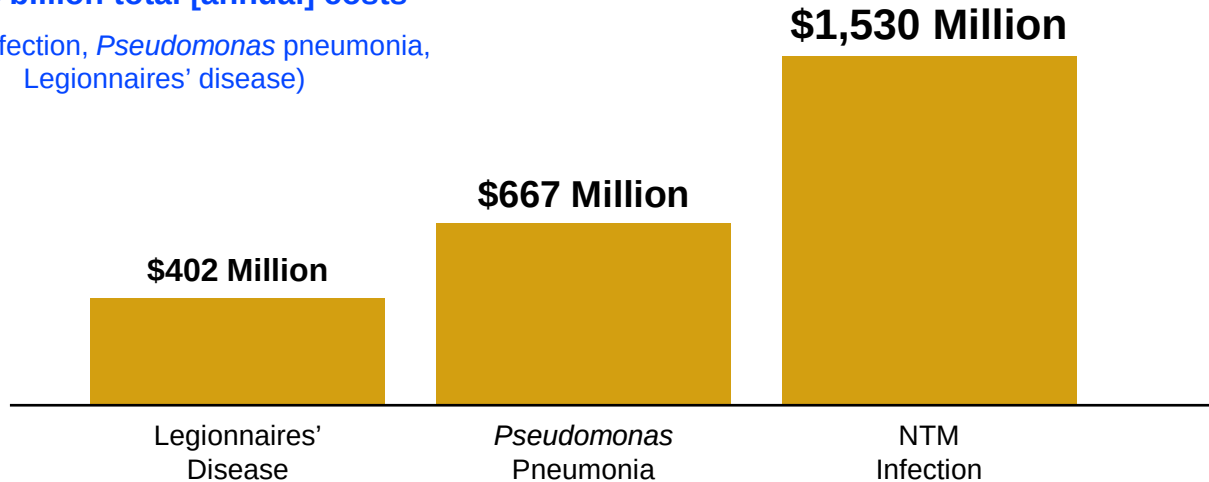
Dialysis	a. Water for use in dialysis is regulated; AAMI standards should be followed^{J62,J65, J66, J67, J68, J69, J70}. b. Consideration of effects of <i>building water system water treatment</i> on dialysis patients (<i>disinfectants/disinfection byproducts</i>) and on compatibility with reverse osmosis (RO) processing systems, including RO membranes c. Facilities with <i>supplemental disinfection</i> systems should consider potential effects on dialysis water, especially the exchange frequency of carbon prefiltration. Additional Resources Typical at this Location: • CDC Recommendations for Dialysis: www.cdc.gov/dialysis/guidelines/water-use.html • Conditions for Coverage for End-Stage Renal Disease Facilities: www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/ESRDfinalrule0415.pdf
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The Monetary Cost Of Waterborne Diseases

Direct annual healthcare costs in the US for 3 of the top 4 waterborne infection types

3 infection types accounted for 89% of
\$3.33 billion total [annual] costs

(NTM infection, *Pseudomonas pneumonia*,
Legionnaires' disease)



What's The Composition Of Dialysis Fluid Or “Dialysate”?

- 97% Water
- 2% Bicarbonate Concentrate (largely water)
- 1% Acid

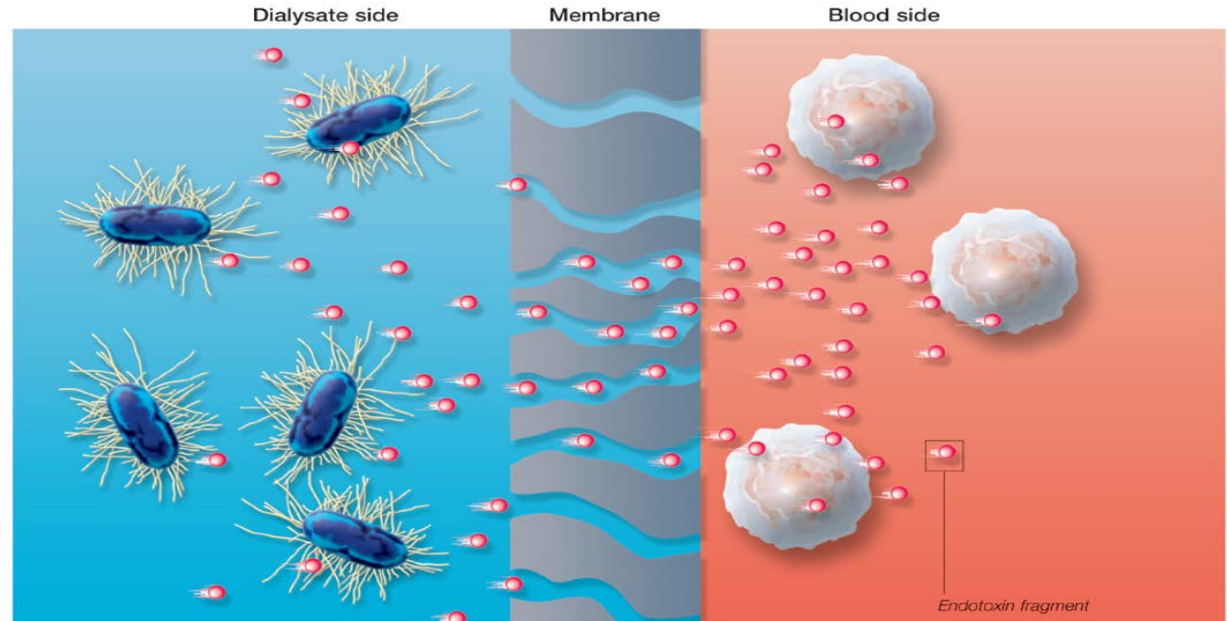


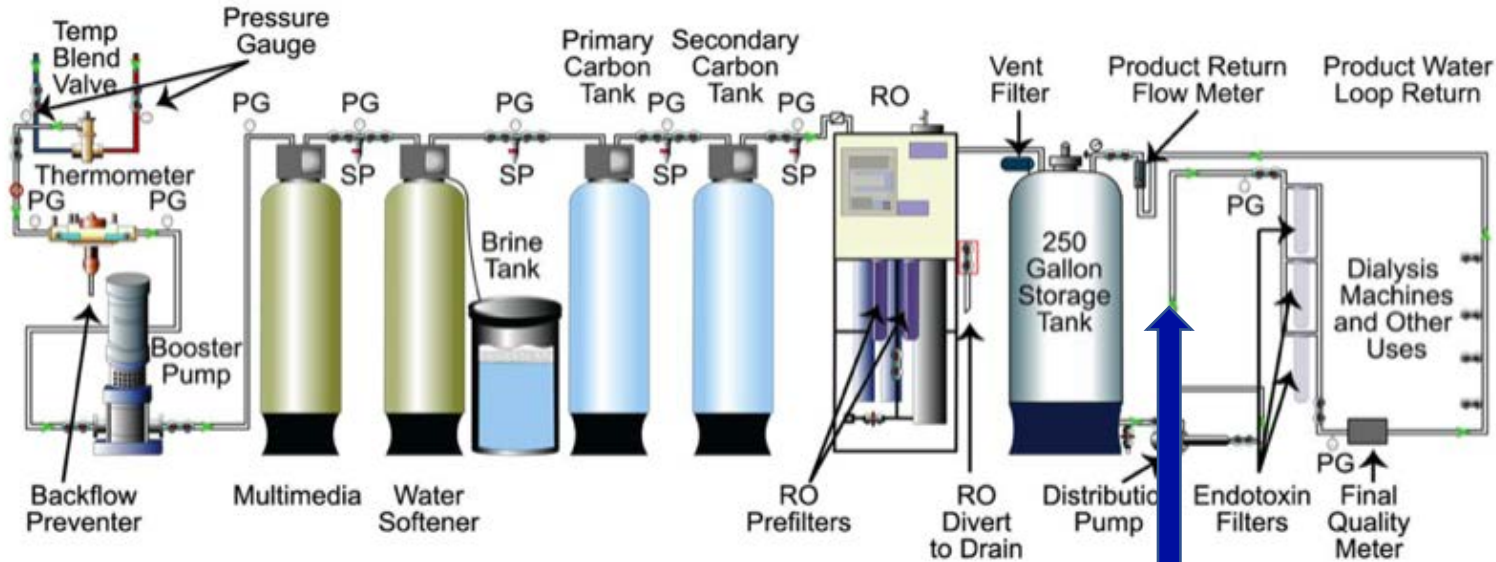
Fig.: Fragments of bacterial endotoxins enter the patient's blood-stream and activate leucocytes, thereby leading to acute and chronic complications in haemodialysis patients.

What Are The Potentially Harmful Water Contaminants?

- Aluminum** – added as a flocculating agent by many municipal water systems to remove nonfilterable suspended particles. It is toxic to dialysis patients, becoming sequestered in bone for long period of time, resulting in [adynamic bone disease and osteomalacia](#). It can also cause the well-described [dialysis encephalopathy syndrome](#).
- Chloramine** – added to water to prevent bacterial proliferation. It can cause [hemolytic anemia](#) (see Table 1 for other causes of hemolysis in patients on dialysis).
- Fluoride** – added to water to reduce tooth decay. Large amounts of fluoride can elute from an exhausted deionizer and cause [pruritis, nausea, and arrhythmias](#).
- Copper and zinc** – can leach from metal pipes and fittings. Another cause of hemolytic anemia.
- Bacteria and endotoxin** – the substances added to municipal water to suppress bacterial proliferation are removed in the water purification process for dialysis treatment. Passage of endotoxin, endotoxin fragments and other bacterial products across the dialyzer membrane and into the bloodstream can lead to pyrogenic reactions.

Health Problem	Possible Water Contaminant
Anemia	Al, chloramines, Cu, Zn
Bone Disease	Al, Fl
Hemolysis	Cu, nitrates, chloramines
Hypertension	Ca, Na
Hypotension	Bacteria, Endotoxin, Nitrates
Metabolic Acidosis	Low pH, sulfates
Neurological deterioration	Al
Nausea and vomiting	Bacteria, Ca, Cu, endotoxin, low pH, Mg, nitrates, sulfates, Zn
Death	Al, Fl, endotoxin, bacteria, chloramine

Dialysis Water Purification



Reproduced from Ted Kasperek, and Oscar E. Rodriguez CJASN 2015;10:1061-1071

UV?

Pretreatment



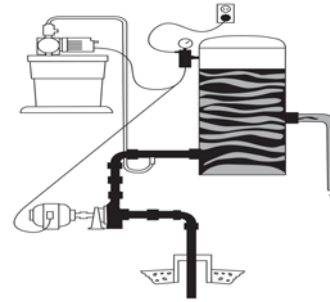
Prevent Backflow



Blend Temperature



Boost Pressure



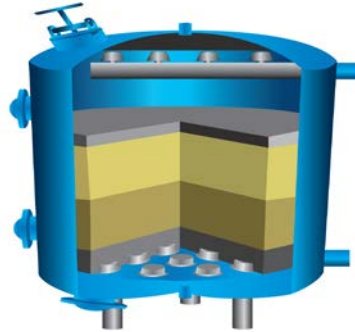
Adjust pH



Pretreatment (continued)



Remove Hard Minerals



Remove Sediment

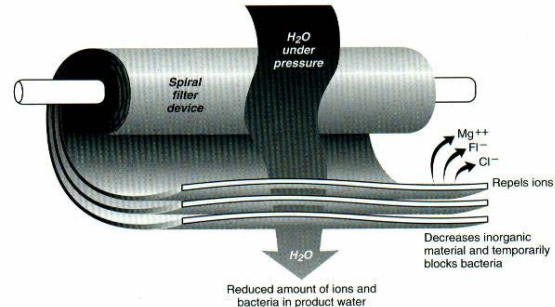


Remove Chloramines



Remove Carbon Filters

RO, DI, Or Both?

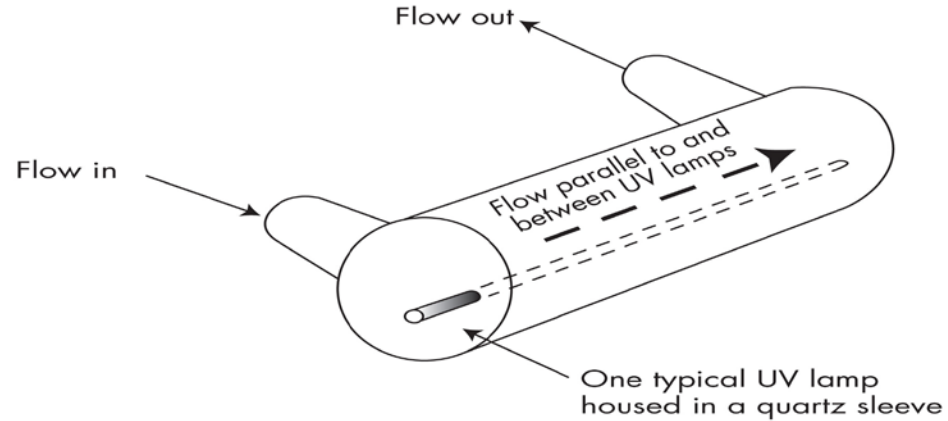


Deionization

Post Treatment



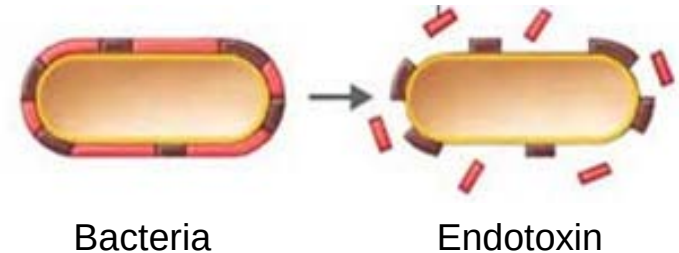
Storage Water



Ultraviolet Irradiator

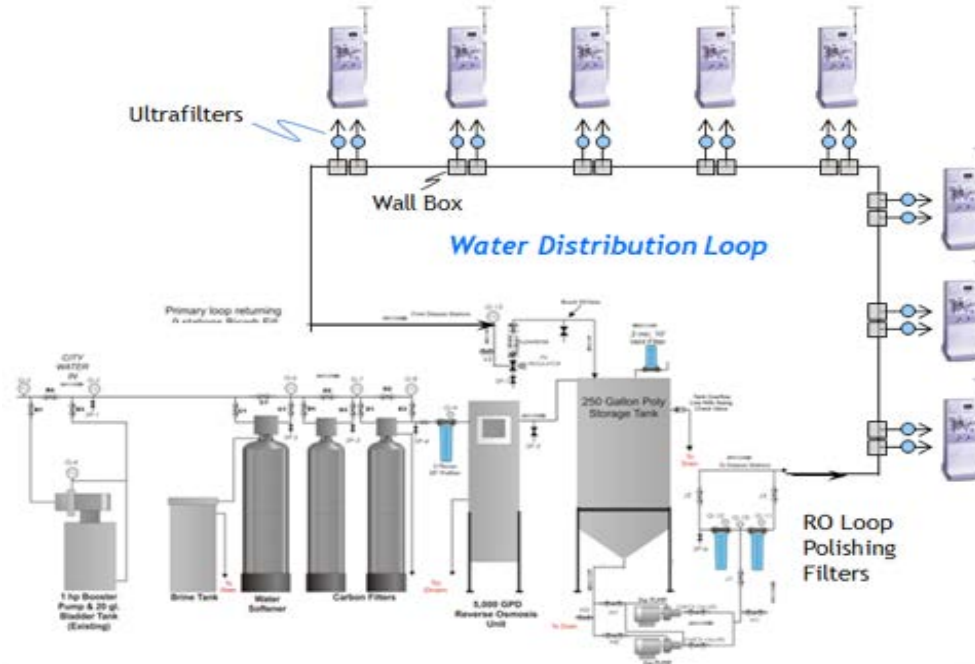
The Dangers Of Endotoxins Towards Dialysis Patients

- Endotoxin fragments or endotoxin in dialysate bath can pass through dialyzer membranes or stimulate immune cells, leading to:
 - Symptoms of septicemia or pyrogenic reaction
- Dialysate contaminants presence triggers inflammatory markers, including:
 - High-sensitivity C-reactive protein
 - Interleukin (IL)-6
 - Fibrinogen
 - Intercellular adhesion molecule (sICAM-1)
- Chronic inflammation is associated with various clinical outcomes, including:
 - Poor nutritional status
 - Reduced response to erythropoietin therapy
 - Decline in residual renal function
 - Carpal tunnel syndrome
- Chronic inflammation also contributes to cardiovascular disease (CVD).



Contemporary Ultrafiltration

- Machine
- Point of delivery
- Water bicarbonate
- RO loop polish



What is Driving Change?

NDT Advance Access published January 4, 2013

Nephrol Dial Transplant (2013) 1-9
doi: 10.1093/ndt/gfs114

Original Article

Effect of ultrapure dialysate on markers of inflammation, oxidative stress, nutrition and anemia parameters: a meta-analysis

Paweena Susantitaphong^{1,2,3}, Cristian Riella^{1,2} and Bertrand L. Jaber^{1,2}

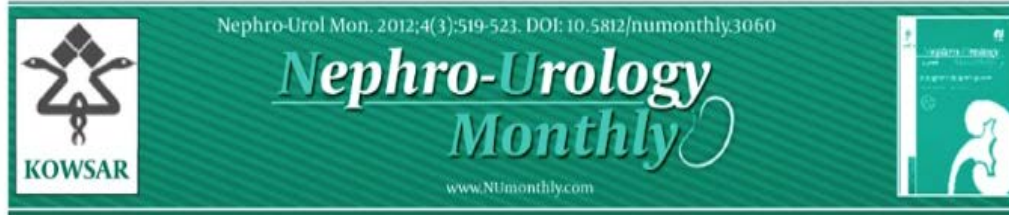
¹Department of Medicine, Division of Nephrology, Kidney and Dialysis Research Laboratory, St Elizabeth's Boston, MA, USA; ²Department of Medicine, Tufts University School of Medicine, Boston, MA, USA and ³Mekong Support Dialysis Center, Division of Nephrology, Department of Medicine, King Chulalongkorn Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand

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Blood
Purification

Blood Purif 2009;27:11-15
DOI: 10.1155/000147009

NDT
Nephrology Dialysis Transplantation



Ultrapure Dialysis Fluid: A New Standard for Contemporary Hemodialysis

Bernard Canaud^{1*}, Paungpaga Lertdumrongluk¹

¹ Nephrology, Dialysis and Intensive Care Unit, Montpellier, France

How Do Changes in Water Quality and Dialysate Composition Affect Clinical Outcomes?

Nicholas A. Hoenich^a, Robert Levin^b, Claudio Ronco^c

^aNewcastle University, Newcastle upon Tyne, UK; ^bRenal Research Institute, New York, NY, USA; ^cSan Bartolome Hospital, Vicenza, Italy

Original Article

A novel bio-assay increases the detection yield of microbiological impurity of dialysis fluid, in comparison to the LAL-test

Griet Glorieux^{1,*}, Eva Schepers^{1,*}, Ralf Schindler², Horst-Dieter Lemke³, Francis Verbeke¹, Annemieke Dhondt¹, Norbert Lameire¹ and Raymond Vanholder¹

NDT
Nephrology Dialysis Transplantation

Let's Acknowledge Influence

CMS Releases CY 2014 ESRD Final Rule

Facilities to See No Payment Cut for Two Years

On November 22, 2013, the Centers for Medicare and Medicaid Services (CMS) issued the CY 2014 final rule for the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS). The rule maintains drug utilization cuts mandated by the American Taxpayer Relief Act (ATRA) at 12 percent and phases them in over four years, however, according to the rule, there will be no changes to reimbursement levels for calendar years (CY) 2014 and 2015.



NRAA sends letter to CMS addressing price increase of Amgen's Epogen

JUNE 14, 2013 No Comments

KEYWORDS [Amgen](#) / [NRAA](#)

[PRINT](#) / [REPRINTS](#) / [f](#) [t](#) [in](#) [MORE](#)

The National Renal Administrators Association sent a letter June 13 to the Centers for Medicare & Medicaid Services outlining concerns about Amgen Inc.'s 5% price increase for their erythropoiesis stimulating agent Epogen, the NRAA said in its weekly newsletter Renal Watch.

In the letter, the NRAA describes how the price increase will shrink already small margins for small and medium sized dialysis organizations and requests that CMS take the price increase into consideration when making their congressionally mandated adjustments to the Medicare End-Stage Renal Disease payment bundle.

"Of particular note—this is the third ESA price increase for small and mid-sized dialysis providers since the implementation of the Medicare ESRD PPS system, which results in a cumulative increase in cost of Epogen of 19% to this sector of the dialysis provider community," the letter reads.

Menti-Meter Question

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

Yes,NO

Minimum Testing Requirements

Conduct microbiologic testing specific to water in dialysis settings (229,230,236–238). Category IA, IC (AAMI: ANSI/AAMI RD5:1992, ANSI/AAMI RD47:1993, RD62:2001)

1. Perform bacteriologic assays of water and dialysis fluids at least once a month and during outbreaks by using standard quantitative methods (236–238). Category IA, IC (AAMI: ANSI/ AAMI RD62:2001)

- Assay for heterotrophic, mesophilic bacteria (e.g., *Pseudomonas* spp).

- Do not use nutrient-rich media (e.g., blood agar or chocolate agar).

2. In conjunction with microbiologic testing, perform endotoxin testing

Menti-Meter Question

Does your Healthcare Organization work off of
*Do you hold your outsource provider to....

AAMI RD-52

AAMI 13959

I don't honestly know...?

Table: AAMI Water Standards

Various water standards for preparing dialysate for dialysis.				
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

CMS Guidelines & AAMI Standards

Microbial limits for hemodialysis fluids (Dialysate). Limits published by AAMI in 2004

Type of Fluid	Microbial Bioburden		Endotoxin	
	Maximum Contaminant Level	Action Level	Maximum Contaminant Level	Action Level
Water for All Purposes^a	200 CFU/mL	50 CFU/mL	2 EU/mL	1 EU/mL
Conventional Dialysate^a	200 CFU/mL	50 CFU/mL	2 EU/mL	1 EU/mL
Ultrapure Dialysate	1 CFU/10 mL	NA	0.03 EU/mL	NA

^a Adopted by CMS as regulation in the Conditions for Coverage of ESRD Facilities

The International Standards for hemodialysis fluids.
Adopted by ANSI/AAMI as the American National Standard in 2009

Type of Fluid	Microbial Bioburden		Endotoxin	
	Maximum Contaminant Level	Action Level	Maximum Contaminant Level	Action Level
Water for All Purposes	100 CFU/mL	50 CFU/mL	0.25 EU/mL	0.125 EU/mL
Conventional Dialysate	100 CFU/mL	50 CFU/mL	0.5 EU/mL	0.25 EU/mL
Ultrapure Dialysate	1 CFU/10 mL	NA	0.03 EU/mL	NA

NA=not applicable

NOTE: The current AAMI standards are more stringent than those adopted by CMS

Menti-Meter Question

What equipment does your dialysis program use?

Trend the “Why”

Portable RO / DI Units For Acute Care



Recent Advancements (2023 Focus)

1 WIRELESS CONNECTIVITY

Two-way data communication can automatically send treatment data to the cloud and provide virtual support

2 TOUCHSCREEN GUIDANCE

Animations and conversational instructions make Tablo easy to learn and use

3 SENSOR-BASED AUTOMATION

Tablo sensors help to automate much of the setup, treatment management and maintenance

4 TABLO CARTRIDGE

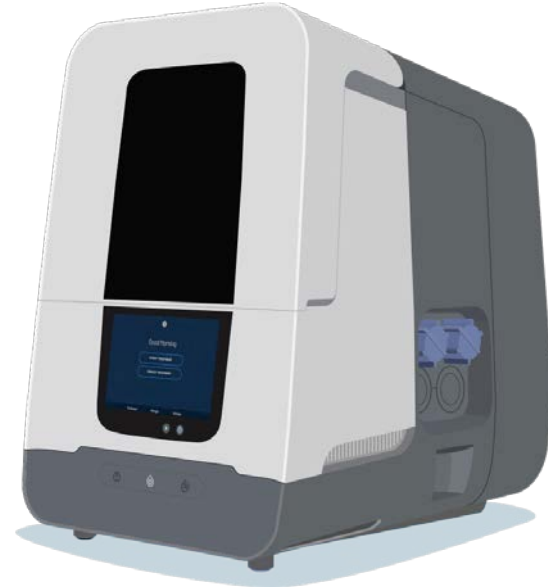
Minimizes setup and take down time by removing manual steps

5 DIALYSATE ON DEMAND

Purifies water and produces dialysate in real-time

6 MOBILITY

All you need is an electrical outlet and tap water



Why Challenge The Status Quo?

- Decreases risk of cardiovascular disease
- Improves utilization of medication, i.e., Epogen and Iron
- Reduces B2M accumulation
- Will not expedite residual renal function loss
- Will not contribute to anorexia and malnutrition

Menti-Meter Question

Did you find this presentation helpful

Very helpful, somewhat helpful, not
helpful, need time to process

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Thank You