

ULTRAPURE WATER - HEMODIALYSIS

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INTRODUCTION

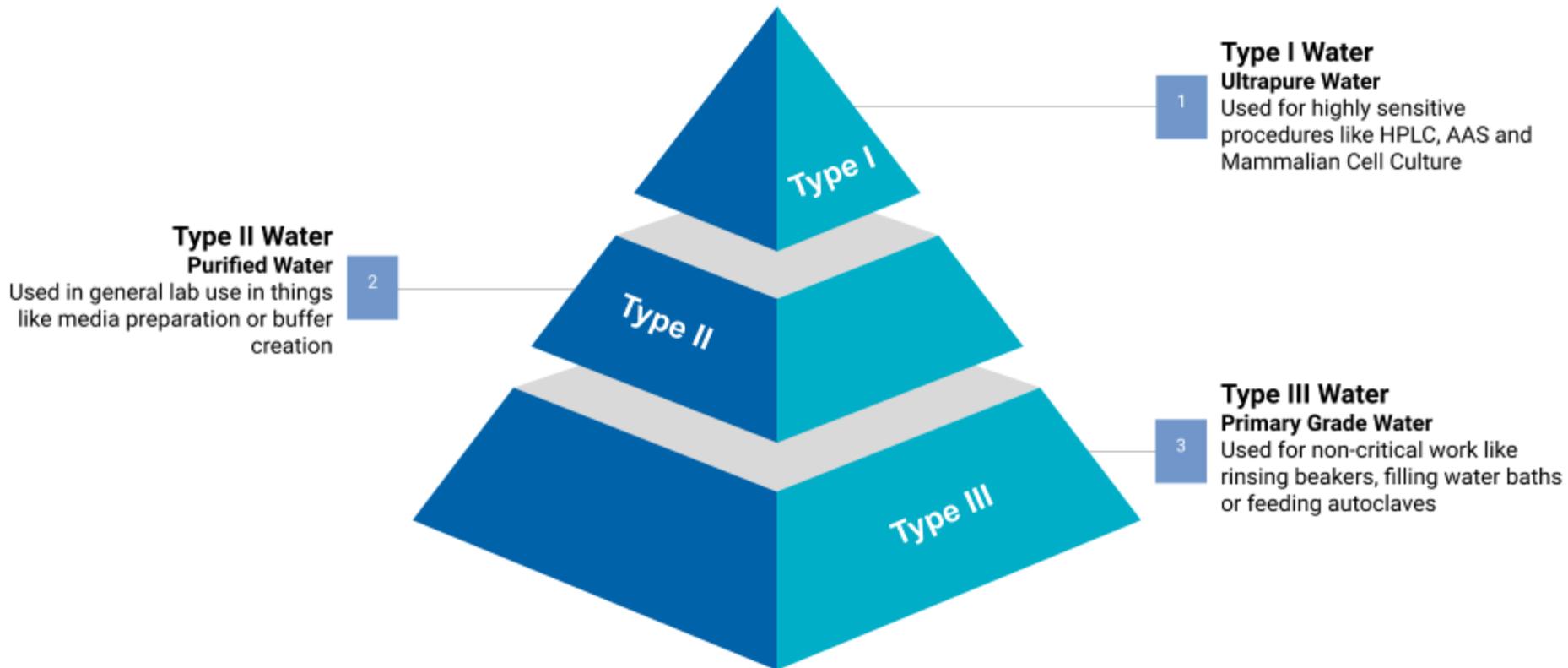
Table 5
Comparison of Maximum Allowable Levels of Bacteria
and Endotoxin in Dialysate According to AAMI/ANSI RD52:2004
and ANSI/AAM/ISO 11663:2009

		Bacteria Limit/Action Level (CFU/mL)	Endotoxin Limit/Action Level (EU/mL)
ANSI/AAMI RD52:2004	Standard	< 200/50	< 2/1
ANSI/AAM/ISO 11663:2009	Standard	< 100/50	< 0.5/0.25
	Ultrapure	< 0.1	< 0.03
	Substitution Fluid	Sterile	Non-pyrogenic

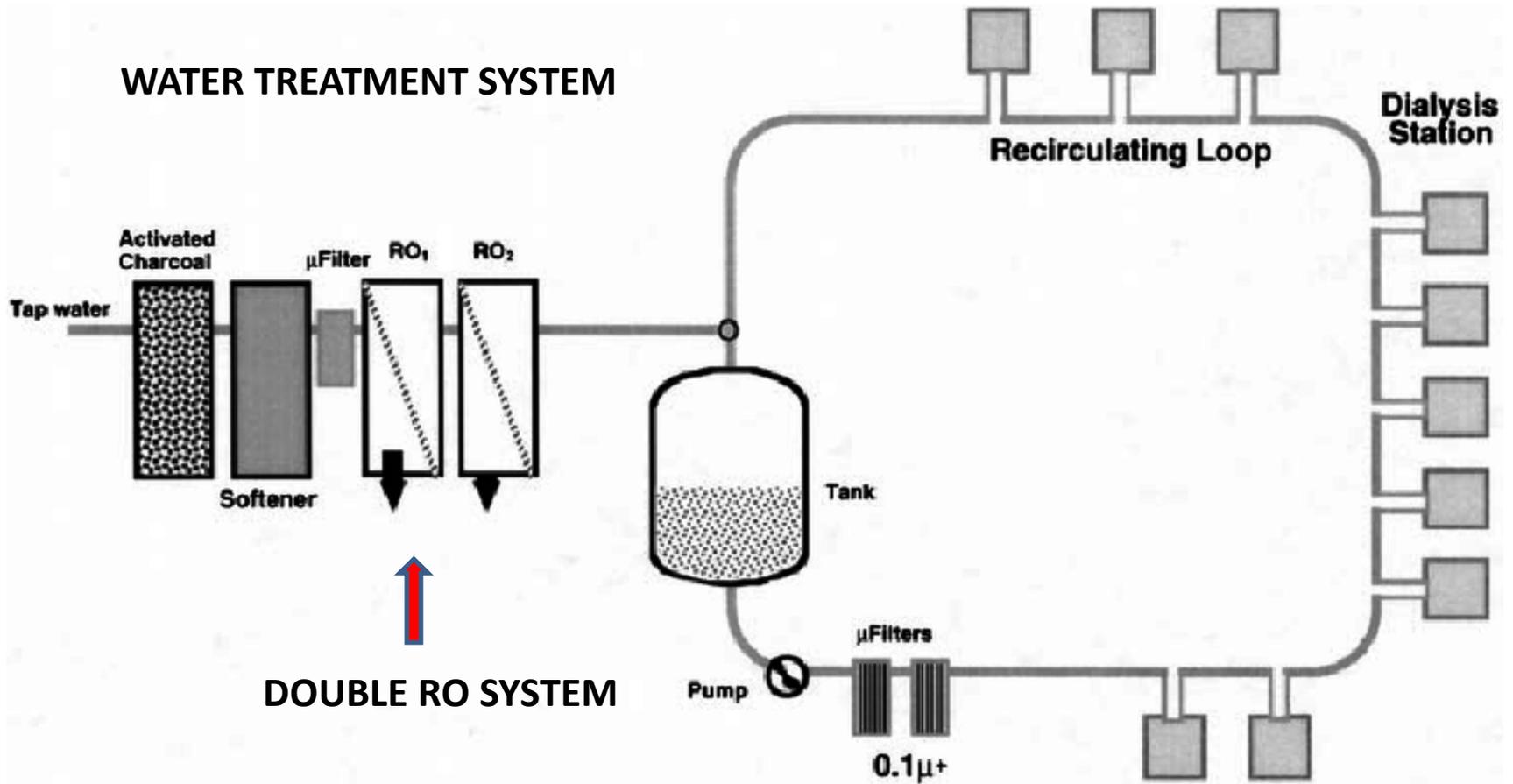
Sources: AAMI, 2009d; Ward, 2011. Reprinted with permission.

1. Bacterial count less than 0.1 CFU/ml.
2. Endotoxin levels less than 0.03 EU/ml.
3. Double RO and endotoxin filters.
4. UPW requirement for CRRT and HDF.
5. Improves overall morbidity and mortality.

TYPES OF PURE WATER IN THE LAB



WATER TREATMENT SYSTEM



Water treatment system used to **produce and deliver ultrapure water** to an HDF machine. Note that a permanent circulation and microfiltration of treated water through the positively charged membrane is maintained and HDF machines are fed directly from the recirculating loop.

ADVANTAGES

- **Mitigation of Chronic Inflammation:** UPW significantly reduces levels of inflammatory markers like **C-reactive protein (CRP)** and **Interleukin-6**.
- **Anemia Management:** Patients on UPW often show improved hemoglobin levels and a **reduced need** for Erythropoiesis-Stimulating Agents (ESA), as lower inflammation enhances iron utilization.
- **Long-term Complication Reduction:** Studies link the use of UPW to delayed onset of dialysis-related amyloidosis (e.g., carpal tunnel syndrome) and better preservation of **residual renal function**.
- **Cardiovascular events** : By reducing oxidative stress and microinflammation, UPW helps lower the risk of **atherosclerosis** and other cardiovascular events.
- **Requirement** : UPW is mandatory for high-flux hemodialysis and online hemodiafiltration (ol-HDF) to prevent the back-filtration of endotoxins into the bloodstream.

LIMITATIONS

- **Detection Gaps:** Standard testing (LAL assay) may fail to detect bacterial fragments or short DNA fragments smaller than 8,000 Da.
- **Technical Maintenance:** Systems require rigorous disinfection of the distribution loop to prevent biofilm formation.
- **Economic Barriers:** The initial setup for a double reverse osmosis (RO) system and distribution loop can cost between \$60,000 and \$100,000.
- **Environmental Impact:** High-purity systems can be water-intensive; some standard RO plants discard up to 54% of incoming water as reject water.
- **Home Dialysis Complexity:** Achieving and maintaining UPW standards in a home setting poses logistical challenges regarding plumbing modifications and less rigorous quality control.

Mortality on Hemodiafiltration Compared to High-Flux Hemodialysis

Settings & Participants



Observational cohort study



29 dialysis centers in Brazil



N = 8,391 patients



Jan 2022-Dec 2023

Results

Follow-up: 13 ± 9 months

Treatment	N	2-Year Survival Rates
High-Flux Hemodialysis (HD)	6,787	81%
Hemodiafiltration (HDF)	2,826	78%

Adjusted death risk among patients receiving HDF versus HD

Mortality Outcomes	HR (95% CI)	P
 All-Cause	0.73 (0.63-0.85)	< 0.001
 Cardiovascular	0.66 (0.50-0.88)	0.004
 Infection	0.92 (0.74-1.13)	0.4

CONCLUSION: Compared to those on conventional high-flux HD, patients treated with HDF exhibited a lower risk of all-cause and cardiovascular mortality.

Online Hemodiafiltration Compared to Conventional Hemodialysis in Critically Ill Patients



Retrospective

2017-2020



Adults in the ICU with
Acute Kidney Injury (AKI)

&



Intermittent renal
replacement therapy (IRRT)

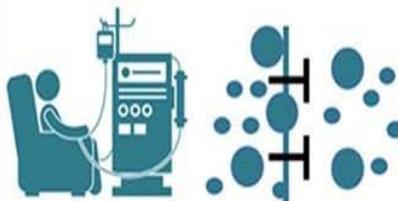


Single center



Cohort study

Hemodiafiltration (HDF)



N=125 patients
N= 532 sessions

24.8%

59.2%

28.9%

7.9 %

Results

Outcomes
Adjusted Hazard Ratio

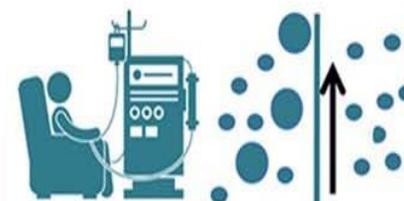
90 day mortality
0.85 (0.43-1.67) $p=0.64$

90 day kidney recovery
1.18 (0.76-1.84) $p=0.47$

Intradialytic hypotension
0.91 (0.64-1.28) $p=0.58$

Vasopressor dependence
0.60 (0.36-0.99) $p=0.047$

Hemodialysis (HD)



N=57 patients
N=316 sessions

21.1%

61.4%

30.4%

11.4%