

**“You Can’t Wash with Dirty Water”**

# **Dialysis Water Quality Management at IH**



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**Interior Health  
Biomedical Engineering**

# Overview

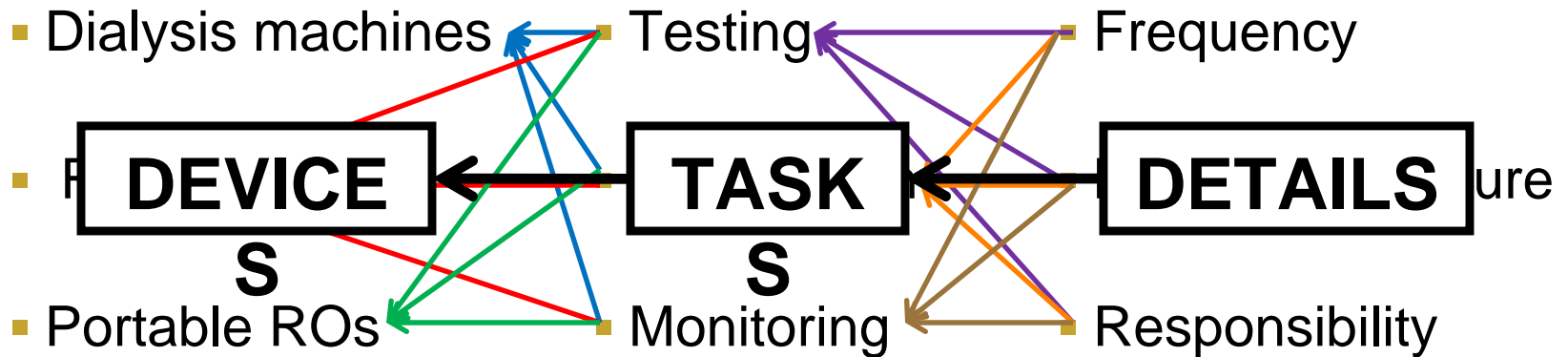
- Background
- Survey
- Survey Results
- Standards (CSA-ISO, AAMI)
- IH Clinical Practice Standards
- Implementation

# Background – What happened?

- No leadership – IH Renal Network became one program under one program director in April 2010
- No defined responsibilities – Different staff (Biomed, Renal Techs, Renal Nurses) performing tasks/duties in different ways
- No existing emphasis – other priorities; high bacteria counts at a facility prompted urgency

# Survey

- Developed and distributed to all renal sites in various regions of IH in Feb. 2011
- Content and structure:



# Survey Results

- A lot of variation between the various Renal sites
- Differences in:
  - *How often* the tasks were being performed
  - *Methods and procedures* being used to perform the tasks
  - *Who* was performing the tasks
- Obvious need for standardization of clinical practices across IH

# Standardizing Bodies

- **CSA-ISO 2011 Standards:**

- CSA adopted ISO standards in Mar. 2011
- CAN/CSA-ISO 11663-11 - Quality of dialysis fluid for haemodialysis and related therapies
- CAN/CSA-ISO 13959-11 – Water for haemodialysis and related therapies
- CAN/CSA-ISO 26722-11 – Water treatment equipment for haemodialysis applications and related therapies



- **AAMI Standards:**

- Used where CSA-ISO did not provide sufficient guidance and recommendations for routine monitoring and corrective action
- ANSI/AAMI RD52:2004/(R)2010 - Dialysate for hemodialysis
- ANSI/AAMI RD62:2006 - Water treatment equipment for hemodialysis applications
- ANSI/AAMI RD5:2003 - Hemodialysis equipment
- AAMI also adopted ISO standards in Apr. 2011



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# IH Clinical Practice Standards

- First drafts developed in March 2011; finalized in Sept. 2011
- IH clinical practice standards:
  1. Microbial Testing of Dialysate
  2. Microbial Testing of Dialysis Water
  3. Endotoxin Testing of Dialysate
  4. Endotoxin Testing of Dialysis Water
  5. Chemical Analyses of Dialysis Water
  6. Daily Chlorine Testing of Dialysis Water
  7. Cleaning and Disinfection of Dialysis Water Equipment
  8. Dialysis Water Equipment Monitoring



# IH Clinical Practice Standards

Clinical Guideline	Standards	Frequency	Responsibility	Review
<b>Microbial Testing of Dialysate</b>	Max. microbial count: <b>100 CFU/mL</b> Action level: <b>50 CFU/mL</b> (Ultrapure: < <b>0.1 CFU/mL</b> )	<b>Monthly</b> <i>(min. 2 machines, 2x/year per machine)</i>	Biomed Tech Renal Tech Renal Nurse	Monthly
<b>Microbial Testing of Dialysis Water</b>	Max. microbial count: <b>100 CFU/mL</b> Action level: <b>50 CFU/mL</b>	<b>Monthly</b>	Biomed Tech Renal Tech Renal Nurse	Monthly
<b>Endotoxin Testing of Dialysate</b>	Max. endotoxin level: <b>0.5 EU/mL</b> Action level: <b>0.25 EU/mL</b> (Ultrapure: < <b>0.03 EU/mL</b> )	<b>Monthly</b> <i>(min. 2 machines, 2x/year per machine)</i>	Biomed Tech Renal Tech Renal Nurse	Monthly
<b>Endotoxin Testing of Dialysate Water</b>	Max. endotoxin level: <b>0.25 EU/mL</b> Action level: <b>0.125 EU/mL</b>	<b>Monthly</b>	Biomed Tech Renal Tech Renal Nurse	Monthly





# IH Clinical Practice Standards

Clinical Guideline	Standards	Frequency	Responsibility	Review
<b>Chemical Analyses of Dialysis Water</b>	<i>(Various)</i>	<b>Semi-annual</b> <i>(in-centre units &amp; portable ROs)</i> <b>Annual</b> <i>(community clinics)</i>	Biomed Tech Renal Tech	Annual
<b>Daily Chlorine Testing of Dialysis Water</b>	Max. total chlorine: <b>0.1 mg/L</b>	<b>Daily</b> <i>(beginning of treatment day)</i>	Biomed Tech Renal Tech Renal Nurse	Monthly
<b>Cleaning and Disinfection of Dialysis Water Equipment</b>	Max. Residuals: Formaldehyde: 3.0 mg/L Bleach: 0.1 mg/L Ozone: 0.1 mg/L	<b>Daily*</b> <i>(machines)</i> <b>Monthly*</b> <i>(portables)</i> <b>Quarterly*</b> <i>(ROs)</i>	Biomed Tech Renal Tech	Semi-annual
<b>Dialysis Water Equipment Monitoring*</b>	Check water temp., water leaks, pressure drops	<b>Daily</b>	Renal Tech Renal Nurse	Semi-annual
	Same as daily, plus RO and DI operation, component timer settings, water hardness, and salt level, etc.	<b>Monthly</b>	Biomed Tech	

\*Manufacturer recommendations and instructions must always take precedence.

# Implementation

- 2-phased rollout

Clinical Guideline	PHASE 1 Fall 2011	PHASE 2 TBD
Microbial Testing of Dialysate	1a	
Microbial Testing of Dialysis Water	1b	
Endotoxin Testing of Dialysate		2a
Endotoxin Testing of Dialysis Water		2b
Chemical Analysis of Dialysis Water	3	
Daily Chlorine Testing of Dialysis Water	4	
Disinfection & Sterilization of Dialysis Water	5	
Dialysis Water Equipment Monitoring	6	

# Implementation

- Define roles and responsibilities
  - Biomed
  - Renal
- Education process
  - Rollout
  - Retraining
  - Sustaining
- Research training/certification methods
- BC province-wide implementation