Core Survey for Dialysis: What Technicians Need to Know Part I

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The findings and conclusions in this presentation are those of the author and do not represent the views of St. Joseph Hospital or any professional organizations

Center of Excellence BARIATRIC SURGERY

GALLUP GREAT WORKPLACE AWARD

St. Joseph Hospital ST. JOSEPH HEALTH SYSTEM

Lessons Learned Since 2008

- The Basic ESRD Survey process does not most efficiently use surveyor time to protect patients and improve care
  - Detailed reviews of areas which have no real impact on patients (e.g. all water pre-treatment components when only carbon affects patient safety)
  - "Blanket reviews of all Patient Assessment/Plan of Care areas in facilities that perform well in some of the areas (e.g. reviewing adequacy in a facility which meets adequacy goals)
- Average time for an ESRD survey has increased >38% since 2008

CMS Efficiency & Effectiveness Initiative: FY 2012 and Beyond

- Survey resources are limited, and may not improve
- A large increase in providers: ESRDs ^ 37%
- Need to focus survey activities to achieve the most **efficient** use of survey resources to conduct an **effective** survey that:
  - Focuses surveyors on areas **most important** to patient safety and qualify of patient management
  - Utilizes **facility data** to focus survey reviews in clinical areas I need of improvement at **that** facility.
  - Supports a robust facility-based QAPI program that assures **ongoing** patient safety and quality care

Survey & Certification Quality Asssurance Efficiency & Effectiveness

- In developing the core survey for QAEE, the overarching goal is to improve patient outcomes and improve the efficiency of the survey process through use of data-driven survey algorithms.
- Successful completion of this initiative requires:
  - Development of a more focused core survey process
  - Surveyor education
  - Implementation of a change management strategy

Polled ESRD S&C "Top" V-tags per CfC by Importance to Patient Safety & Quality

Infection Control:

- V113: Gloves/hand hygiene
- V122: Disinfect equip/surfaces
- V116: Items taken to station

Water/dialysate quality:

- V177: Max chemical contam
- V180: Max microbial contam
- V196: Carbon: chl/chlm testing
- V250: Dialysate pH/Cond testing
- V260: Personnel training/audits

Reuse

- V353: Test germicide residual
- V331: Dialyzer transport
- V334: Header cleaning
- V307: Personnel qualifications

Physical environment

- V403: Equip operated & maintained per DFU
- V407: Patients I view during HD
- V413: Emerg equip on site
- V409/413: Staff & patients trained in emerg procedures

Most Frequent Cited V-tags Really Impact Patients

Patient Safety

- **Infection Control**
  - V113: Gloves/hand hygiene: 31%
  - V122: Equip & surfaces disinfected: 29%
- **Technical**
  - V403: Equip operated & maintained: 21%
  - V196: Chl/chl testing: 12%

Quality of Patient Care

- Fluid & BP management: V543: 14%
- Psychosocial counseling/KDQOL: V552: 11%

Common Technical Citations

- 1380 Surveys
- 319 Vtag cited
- 81 Technical
  - 25.4%
  - Reprocessing 27 >33.9%

- **Safety of Water and Dialysis Delivery:** The highly-technical nature of dialysis treatments place the patients at significant risk if there is isolated or systemic failure to follow precise procedures.

Four Questions...

... what does it do?

... how often is it monitored?

... how would failure effect the patient?

... what do I do if it fails?

Condition for Water & Dialysate Quality

- Adopts AAMI RD52:2004
- 92 tags
- Clear requirements for the providers
- Organized by “usual” sequence of components

Out of 92 tags, the focus is on what REALLY impact patient safety???

Environmental "Flash" Tour

- **Observations of 4 patient-related areas:**
  - Hemodialysis patient treatment area
  - Water/dialysate areas
  - Reuse room
  - Home training area

*Looking for observable patient safety concerns-**Triggers***

Flash Tour Triggers

- Dummy drip chamber
- HD machines in obvious poor repair
- GAC lack of redundancy and sampling ports
- Functioning RO quality monitors (DI also)
- RO distribution in obvious disrepair or contaminated state
- A/B multiple ratio type
- A/B mixing & distribution disrepair or contaminated state

Surveyors Have Resources!

Surveyors do **not** need to be experts at water treatment to conduct Water/dialysate review

- Water Treatment/Dialysate Review Worksheet
- Water system/Critical requirements laminate
- Core Survey Process (also Outline & Triggers)
  - Refer you to the corresponding CfC V-tag

With these, surveyors can conduct an effective review!

Components Are in 3 “Sections”

- **Pre-treatment**
  - Backflow preventer
  - Blending valve
  - Booster Pump
  - Expansion tank
  - Turbidity tank
  - Cartridge filter
  - Pressure gauges
  - **Carbon system**
  - Softener
  - Chemical injection
- **Purification**
  - **Reverse Osmosis**
  - **Deionization**
  - Ultraviolet irradiation
  - Ultrafilter
  - **Water quality monitor**
- **Distribution**
  - Storage tank
  - Distribution “loop”

Critical Water and Dialysate Requirements

- Water **chemical** and **microbiological** quality
- Dialysate **microbiological** quality
- **Chlorine/chloramine** removal and testing (carbon)
- **Reverse Osmosis** unit function and monitoring
- **Deionization** system monitoring, if applicable
- Dialysate **proportioning ratios match**
- Dialysate **pH and conductivity tested** at point of use (machine) prior to treatment

Surveyors will review for compliance to assure patient safety!

Review of Water Treatment

- **Interview** persons responsible for daily operation & monitoring of water & dialysate systems
  - **Observe** the critical water treatment components
- **Observe** water testing for total chlorine
- **Review** facility documentation of monitoring & oversight of water & dialysate quality

Required Water Treatment Components **(also critical)**

- **Two** carbon tanks (for chlorine removal) with a sample port between
- Purification method-usually **Reverse Osmosis (RO)**
- **Continuous** water quality monitor

Other components will be present, but are not critical to patient safety

Water and Dialysate Review

Review the **critical components** that impact patient safety

- **Carbon system** for chlorine removal
  - Observe **total chlorine** test
- **Reverse Osmosis** function
  - Assure AAMI quality water
- **Deionization**, if present
  - Verify safe set up & monitoring

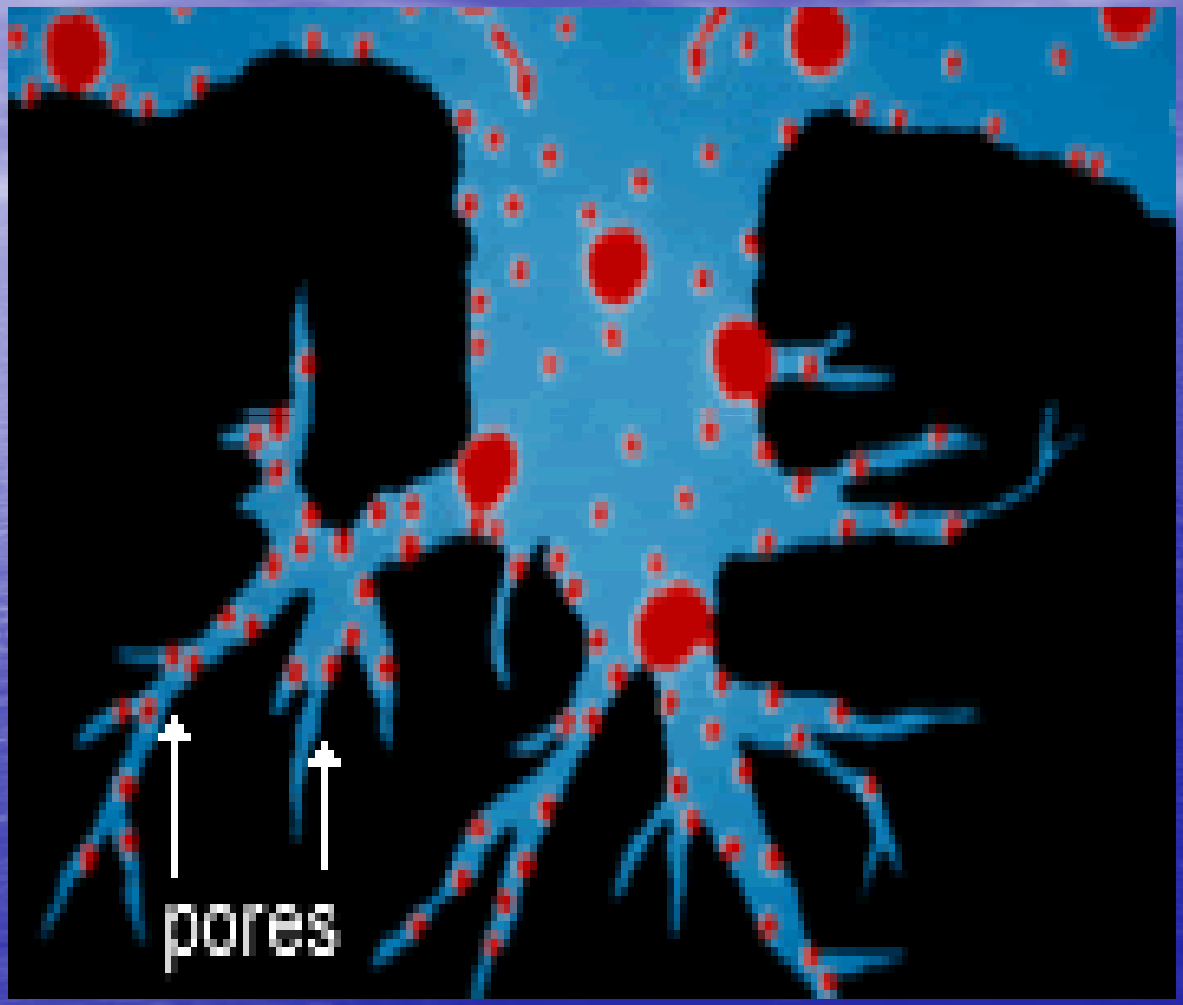
- **Dialysate proportioning ratios** match

Water & Dialysate Review (cont.)

- Assure **staff have sufficient knowledge** of procedures- **focused interview**
- Review **facility oversight** of water & dialysate systems
  - Log reviews of water & dialysate quality testing
  - **Review of technical staff practice audits**

▲ **Water & Dialysate Review Worksheet page 15 – 18**

Carbon System: A Required Component



SA = 1000 m^2/gm or >100 football fields per pound

Chloramine Review

- Formed with addition of ammonia to chlorinated water
- 3 species of chloramine
  - Monochloramine (pH>7)
  - Dichloramine (pH 4.4 – 6.0)
  - Trichloramine (pH<4.4)

Dechlorination involves a chemical reaction of the activated carbon's surface being oxidized by chlorine.

$$GAC + HOCL \rightarrow C^*O + H^+ + Cl^-$$

$$GAC + OCl^- \rightarrow C^*O + H^+ + Cl^-$$

C*O represents the oxidized site of activated carbon after reacting with chlorine – reactions occur very quickly

Chloramine involves equivalent chemical reaction of the activated carbon's surface being oxidized.

$$GAC + NH_2Cl + H_2O + \rightarrow NH_3 + H^+ + Cl^- + CO^*$$

$$CO^* + 2NH_2Cl \rightarrow N_2 + H_2O + 2H^+ + 2Cl^- + C$$

CO* represents a surface oxide on the GAC – the reaction rate for monochloramine removal is considerably slower than removing free chlorine using GAC (2 – 4x); hence the requirement for EBCT >10 minutes.

Carbon Tanks

- Iodine number of 900 or higher at 12 x 40 mesh size
- Acid washing removes manufacturing debris
- Tanks are sized for Empty Bed Contact Time (EBCT).
  - 10 minutes EBCT for chloramine removal
  - V=(Q x EBCT)/7.48
    - 1.2 gal/min EBCT 10 min./7.48 = 1.6ft^3
  - Two tanks in series for total EBCT, worker and polisher

Triggers

- 2 or more carbon tanks with sample port between not present
- Insufficient EBCT
- Observed total chlorine test result greater than maximum allowable level; test done incorrectly or with incorrect reagents/equipment
- Staff assigned total chlorine testing has inadequate knowledge.

Chloramine

- approximately 100 patients exposed to greater than 0.1 ppm chloramine and developed hemolytic anemia. 41 patients required blood transfusions
- Additional reverse osmosis unit added to increase water output. Size of carbon filter not changed
- Carbon filter became exhausted sooner than expected. Chloramine levels only tested 3 times per week

Chloramine

- 33 patients admitted to the hospital in a 14 day period for anemia with at least one patient reportedly diagnosed with hemolytic anemia and myocardial infarction
- Test strips used to detect total chlorine were found to be not reactive to chlorine.

V196: Carbon adsorption: monitoring and testing

- Test 15 minutes
- Test strip sensitivity
  - 0, 0.1, 0.5
  - Qualitative/quantitative

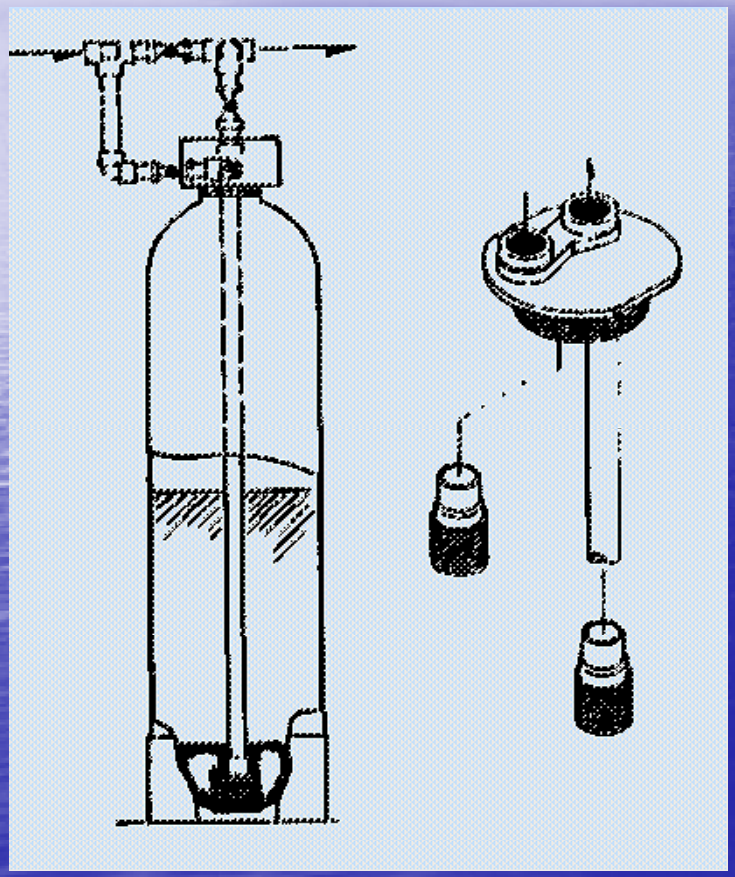
Triggers in Water/Dialysate (cont.)

DI, if present

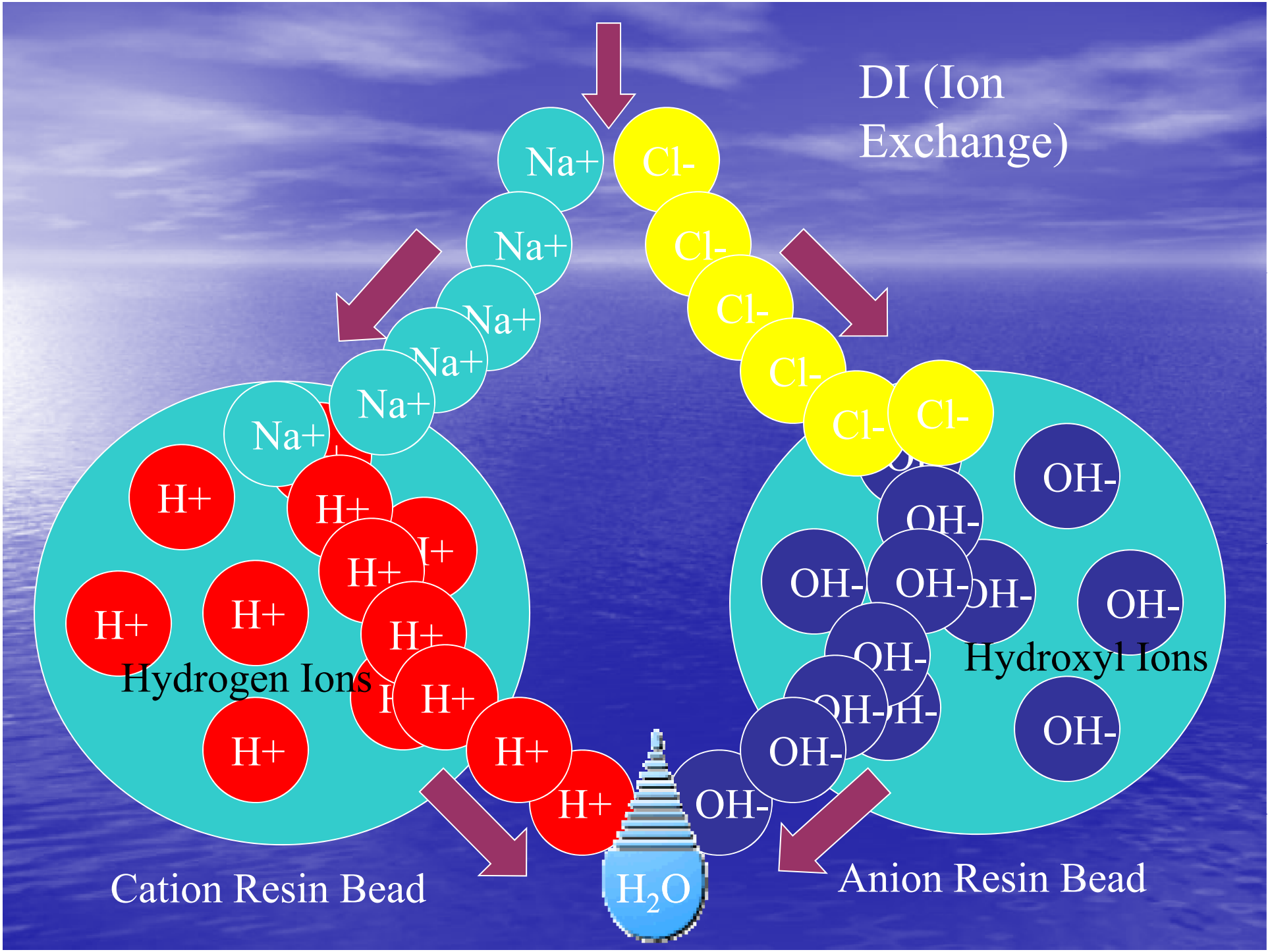
- No functional resistivity monitor/alarm, visible & audible in patient treatment area or not monitored 2x/day
- No functional automatic divert-to-drain or auto cut-off valve
- Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm or actions for DI tank exhaustion
- No ultrafilter post DI

All of these DI triggers are citable on identification

Deionization (DI) Tank



Removes positively and negatively charged ions from the water (cations and anions resp.)


DI (Ion Exchange)
Na+
Cl-
H+
OH-
Hydrogen Ions
Hydroxyl Ions
Cation Resin Bead
Anion Resin Bead
H_2O

DI Tank Configuration

- **Two tanks in a series**
  - **One as worker, one as back-up**
- **Audible and visual, temperature compensated alarms**
  - **On last tank at least**
  - **Must have a means of preventing contaminated water from reaching the patient**
- **UF post DI**

Avidity

- Cation Exchange Resin (H^+ $Resin^-$)
  - Ca^{++}
  - Mg^{++}
  - K^+
  - Na^+
  - H^+
- Anion Exchange Resin (OH^- $Resin^+$)
  - NO_3^-
  - SO_4^{--}
  - NO_2^-
  - Cl^-
  - HCO_3^-
  - F^-
  - OH^-

Triggers in Water/Dialysate (cont.)

Interviews

- Water distribution system not disinfected monthly, samples not drawn b4 disinfection, each HD machine not cultured annually
- Staff unaware of correct procedures for dialysate mixing/test

*additional staff may be interviewed, **observation** of dialysate mixing & testing, **review** water or dialysate system disinfection logs can be expanded*

Reverse osmosis system

- Absence of RO % rejection & product water TDS monitor & alarm audible in patient treatment area

This is citable. If the water treatment system appears in serious disrepair, other components can be reviewed for compliance with applicable Vtags

Water Room Environment

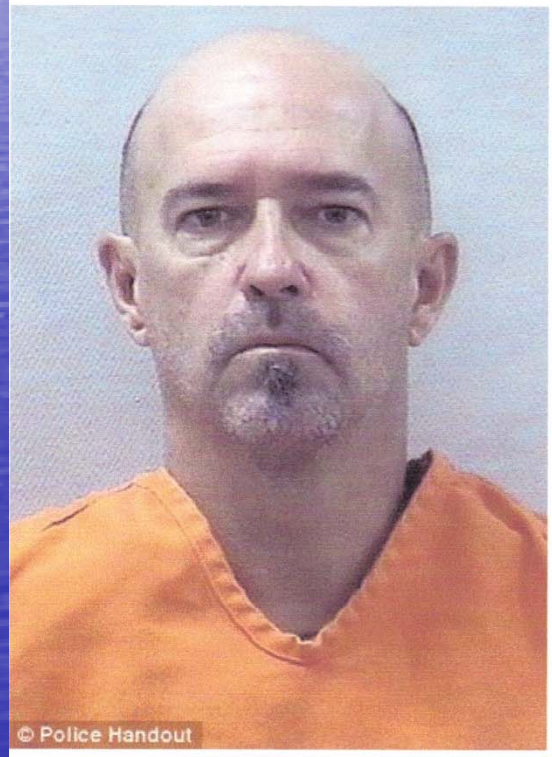
- The water purification and storage system should be located in a secure area that is readily accessible to authorized users.
- The location should be chosen with a view to minimizing the length and complexity of the distribution system.
- Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system.

Hospital technician 'wanted to kill as many patients as possible by pouring bleach into kidney dialysis machine tanks because he was being fired'

- Donald Foster III suspended from job as equipment technician in July for allegedly asking dialysis patients for their prescription pain killers
- Police allege that Foster returned to medical centre week later and filled dialysis tanks with bleach
- Accused of wanting to kill dialysis patients in order to bankrupt the company
- Held on $525,000 bond and charged with attempted murder and burglary

By Daily Mail Reporter

PUBLISHED: 17:42 EST, 2 August 2012 | **UPDATED:** 15:20 EST, 8 September 2012



Revenge: Donald Foster III, allegedly poured bleach into the water tanks used for kidney dialysis machines as revenge against his employer

Document Review

- Total Chlorine testing – 2 months
- RO monitoring by % rejection and product water quality by TDS or conductivity
- If wet DI present: 3 months of resistivity readings at least twice per day
- Product water chemical analysis – 12 months
- Microbiological monitoring of water, including ancillaries and dialysate – 6 months
- Practice audits of the operator's compliance with procedures – 12 months.

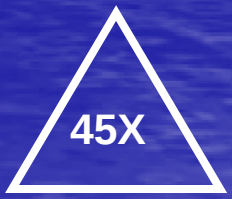
Triggers in Water/Dialysate (cont.)

Log reviews

- Total chlorine >0.1mg/L & no documentation of appropriate actions taken
- Chemical analysis of product water not done at least annually
- Irregularities, trends of omitted tests
- Microbiological results exceeding action/maximum levels & no documentation of appropriate actions taken
- Practice audits of staff conducted less than annually

Can be expanded to interview technical supervisory staff, and review of applicable logs to longer time period

Delivery Systems (Machines) Are Calibrated for Specific Mixing Ratios

Type (total parts)	Acid conc. (parts)	Bicarb conc. (parts)	Water (parts)	AAMI Designation
35X	1	1.225	32.775	
36.83X	1	1.83	34	
45X	1	1.72	42.28	

Critical Requirement:

Dialysate Proportioning Ratios Match (V248)

Determining If the Dialysate Proportioning Ratios Match

- **Environmental Tour: Observe** labels on the acid and bicarb concentrate packaging & hemodialysis machines

- **Dialysis Equipment Maintenance:** verify the machines are programmed to said ratio

If more than one proportioning ratio is used: investigate further!

Critical Requirement: Dialysate pH and Conductivity Tested at Point of Use Prior to Treatment (V250)

Review for Dialysate pH & Conductivity Testing at Point of Use

- **Observations of Hemodialysis Care**
  - **Observe** staff conducting the testing with an independent method
  - **Interview** a staff member about the accepted parameters
- **Medical Record Review**
  - **Review** documentation of pH/conductivity testing on dialysis treatment records

Additives (Spikes)

- Labeled indicating final concentration, date/time mixed, person mixing the concentrate.
  - Affixed to the container when the mixing process begins
  - Recorded in a permanent record
  - For a specific patient: name of the patient included

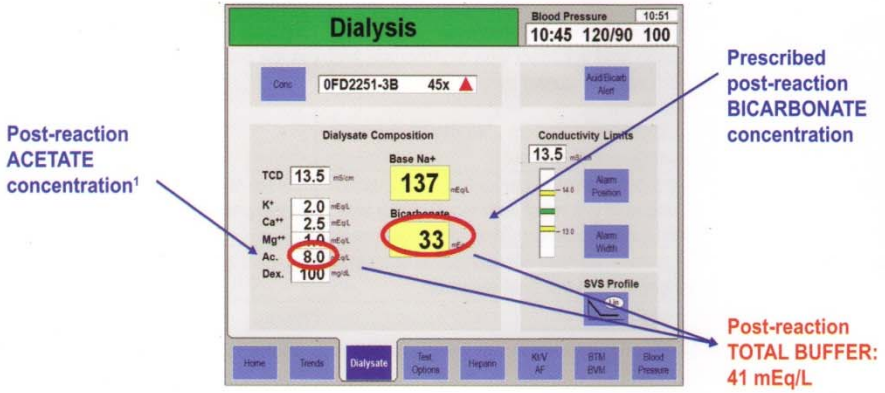
Concentrate is a prescriptive medication

Setting and Display on the Dialysis Machine[1]

The final composition of the dialysate will always match the concentrations of the post-reaction buffer components as prescribed, set and displayed on the dialysis machine. The total buffer is determined by adding the numbers displayed in the corresponding fields.

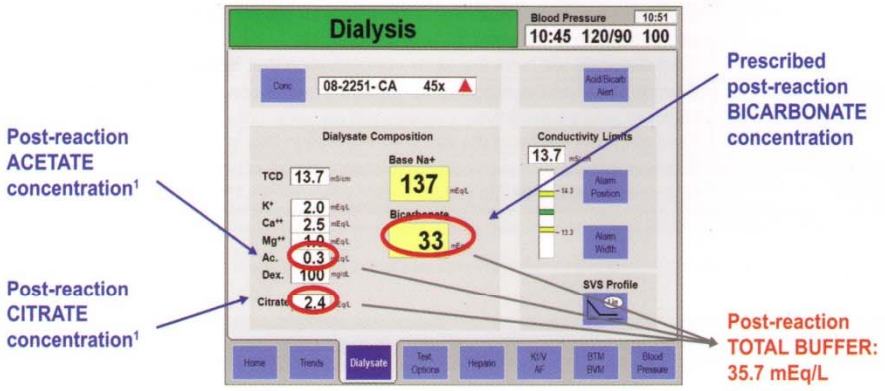
Example of buffer components and total buffer (e.g., Granuflo®).

A conceptual dialysis screen is depicted below illustrating the use of Granuflo® acid concentrate. The screen may differ depending on the dialysis machine used. The example would look similar for NaturaLyte® with the only difference being that the post-reaction value of acetate would be 4 mEq/L and total buffer 37 mEq/L.



Example of buffer components and total buffer (e.g., Citrasate®)

A conceptual dialysis screen is depicted below illustrating the use of Citrasate® acid concentrate. The screen may differ depending on the dialysis machine used.



[1] All information provided in this brochure refers to the Fresenius 2008 machine series and a 45x bicarbonate dialysis fluid.

Keeping Patients Safe and Preventing Citations

- Review logs frequently
  - Address problems promptly
  - Encourage staff honesty in reporting by not “coming down” on them-use problem resolving solutions
  - NEVER create missing records-surveyors can spot this!
- Train, train, and re-train staff
  - Audit/monitor staff frequently
- Get your water treatment and dialysate systems RIGHT and keep them that way