Preventing Adverse Outcomes in Maintenance Hemodialysis Patients
Dr. Matthew Arduino, CDC
A Webber Training Teleclass

Adverse Outcomes in ESRD
- Insufficient treatment
- Dialysis-Associated Infections
- Intoxications/Chemical Poisoning
  - Water treatment failures
  - System design
  - Human error
  - Manufacturing error
- Allergic Reactions
- Non-chemical associated hemolytic events
- Bleeding

I. Intoxications/Chemical Poisonings
- Failure to rinse germicide from dialyzers or hemodialysis system
- Water Treatment Issues
  - Trace elements in water
  - Malfunction of water treatment device
  - Biologic Toxins in water supply
- Dialysate Quality
  - Use of acid concentrate instead of acetate concentrate

Hemodialysis
- Hemodialysis patients are exposed to approximately 300-600 Liters of water/week.
- On average approximately 16-24 L of water is ingested per week.

Feed Water
- Dialysis centers use water from a public/private supply, which may be derived from either surface or ground waters
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Water Contaminants
- Biological: Water bacteria, endotoxin, cyanobacteria toxins (anatoxin-A, microcystin-LR)
- Chemical/Trace Elements: aluminum, arsenic, barium, cadmium, calcium, chloride, chloramine, chromium, copper, fluoride, lead, magnesium, mercury, nitrate, potassium, selenium, silver, sodium, sulfate, strontium, zinc
- Chemical Contaminants Associated With Dialysis Outbreaks: Aluminum, Chlorine/Chloramine, Calcium and Magnesium, Copper, Strontium

Clinical Effects of Contaminated Water

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Chemical Contaminant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>Aluminum, Chloramines, Copper, Zinc</td>
</tr>
<tr>
<td>Bone Disease</td>
<td>Aluminum, Fluoride, Strontium</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>Chlorine/Chloramines, Copper, Nitrates</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Calcium, Sodium</td>
</tr>
<tr>
<td>Hypotension</td>
<td>Bacteria, Endotoxin, Nitrates</td>
</tr>
</tbody>
</table>

Clinical Effects of Contaminated Water

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Chemical Contaminant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabolic Acidosis</td>
<td>Low pH, sulfates</td>
</tr>
<tr>
<td>Muscle Weakness</td>
<td>Calcium, Magnesium</td>
</tr>
<tr>
<td>Neurological Deterioration</td>
<td>Aluminum</td>
</tr>
<tr>
<td>Nausea and Vomiting</td>
<td>Bacteria, Calcium, Copper, Endotoxin, low pH, Magnesium, Nitrates, Sulphates, Zinc</td>
</tr>
</tbody>
</table>

Water Contaminants And The Lowest Level Concentration Associated With Toxicity In Hemodialysis Patients

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>mg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum</td>
<td>0.06</td>
</tr>
<tr>
<td>Chloramines</td>
<td>0.25</td>
</tr>
<tr>
<td>Fluoride</td>
<td>1.0</td>
</tr>
<tr>
<td>Copper</td>
<td>0.49</td>
</tr>
<tr>
<td>Zinc</td>
<td>0.2</td>
</tr>
<tr>
<td>Nitrate (as N)</td>
<td>21</td>
</tr>
<tr>
<td>Sulfate</td>
<td>200</td>
</tr>
<tr>
<td>Calcium/Magnesium</td>
<td>88 (Ca²⁺)</td>
</tr>
<tr>
<td>Sodium</td>
<td>300</td>
</tr>
</tbody>
</table>

Aluminum Intoxications
-Anemia, Bone Diseases, and Dementia

<table>
<thead>
<tr>
<th>Year</th>
<th>Outbreak Description</th>
<th>Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1982</td>
<td>Aluminum intoxication in 27 patients</td>
<td>Exhausted DI tanks</td>
<td>Install Reverse Osmosis and monitor DI tanks</td>
</tr>
<tr>
<td>1992</td>
<td>Aluminum intoxication in 27 patients; 3 deaths</td>
<td>Aluminum containing transfer pump (Acid Concentrate)</td>
<td>Discontinue pump use and substitute for a non aluminum containing pump</td>
</tr>
<tr>
<td>2007</td>
<td>Elevated serum aluminum levels in 10 patients (16–237 µg/L; median: 92)</td>
<td>Aluminum containing transfer pump (Acid Concentrate)</td>
<td>Discontinue pump use and substitute for a non aluminum containing pump</td>
</tr>
</tbody>
</table>

FDA SAFETY ALERT:
Aluminum and Other Trace Element Contamination in Dialysis Facilities
May 29, 1992

TO: DIALYSIS PERSONNEL
WATER OR DRUACUTE SERVICE CONTRACTORS

This is to alert you to a potentially life-threatening situation in which dialysis patients have been exposed to dialyzers with excessive aluminum levels. These high levels were found first in the aluminum delivery system. Other treatments (e.g., new patients) could also be used and contain the dialysis system in various locations. Please share this alert with those in your organization who are responsible for water treatment, dialysis delivery systems, and patient care.

In a recent incident at a large chain dialysis facility, investigated by the Food and Drug Administration and the Centers for Disease Control (CDC), a large number of patients were found to have elevated serum aluminum levels. Three patient deaths were associated with aluminum toxicity.

Preliminary findings indicate that the marked portion of fluoride-based dialyzer solution was stored and re-injected to the dialysis patients’ inter-dialysis bloodstream system through an aluminum-containing pump.

Aluminum from the pump was not removed into the dialysis concentrate during transfer to the patient.

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http://www.nature.com/ki/journal/v48/n2/abs/ki1995315a.html

Aluminum Exposure, 2007
- Aluminum intoxication since 1992 is rare and sporadic
- Most aluminum exposure is from ingestion
- Other sources of Aluminum include some granular activated carbons

Fluoride Intoxications, Among US Hemodialysis Patients

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
<th>Cause</th>
<th>Corrective Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980</td>
<td>Fluoride intoxication in 8 patients, 1 death</td>
<td>Excess fluoride in city water; no water treatment by the dialysis facility</td>
<td>Install pretreatment and Reverse Osmosis unit</td>
</tr>
<tr>
<td>1993</td>
<td>Fluoride intoxication in 9 patients, 3 deaths</td>
<td>Temporary DI water treatment system</td>
<td>DI tanks should be monitored by temperature compensates resistivity meters with both audible and visual alarms</td>
</tr>
</tbody>
</table>

Aluminum Monitoring in Dialysis patients
- National Kidney Foundation Disease Outcome Quality Initiative (K-DOQI) guidelines recommend serum aluminum testing at least annually in all dialysis patients, and every 3 months in those who receive aluminum-containing medications
- Cluster in 2007 was detected because of monthly serum aluminum levels
- Routine monitoring of serum aluminum levels can provide a useful tool in preventing serious illness among dialysis patients.

Fluoride Intoxications, Among US Hemodialysis patients
- Pruritis
- Burning or feverish feeling
- Headache
- Nausea or vomiting; or diarrhea
- Syncope or near syncope
- Pain in the chest, back, or abdomen

Symptoms of Acute Fluoride Intoxication

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Toxigenic Cyanobacteria, Brazil 1996
- Toxins include hepatotoxins and neurotoxins
- Microcystin-LR
- Anatoxin A
- Only known dialysis exposure was in Caruaru, Brazil
- Center received untreated water; water was treated in center with carbon adsorption and DI
- 116/130 patients had visual disturbances, nausea and vomiting, and liver failure; at least 50 patients had died
- If water was treated using reverse osmosis toxins would have been removed

Jochimsen EM, et al. Liver Failure and Death after Exposure to Microcystins at a Hemodialysis Center in Brazil. NEJM 1998;338 (13):873-8
http://content.nejm.org/cgi/content/abstract/338/13/873

Human Error and Chemical Intoxications
- Patient exposure to disinfectants:
  - Antimicrobial preservatives in filters
  - Sodium azide packed ultrafilters
  - Water treatment system disinfectants
    - Formaldehyde
    - Hydrogen peroxide
  - Resizing water distribution system for increased flow without taking into account pre-treatment needs
    - Monochloramine exposure
  - Failure to adequately rinse disinfectant from Reprocessed dialyzers
    - Peracetic acid
    - Formaldehyde

Sodium Azide Exposure
- Temporary water treatment system including DI and ultrafilters.
- New industrial ultrafilters installed (not labeled for medical use)
- Ultrafilters packed in 0.25% sodium azide and 25% glycerin to prevent bacterial contamination
- Severe life threatening hypotension in 9 patients, other symptoms included blurred vision, severe abdominal pain, headache, and loss of consciousness

http://www.nature.com/ki/journal/v37/n1/pdf/ki199015a.pdf

Volatile Sulfur Compounds August 30, 2000
- 16 patients developed chills in the absence of fever and hypotension
- Odor (H$_2$S) in the unit detected
- Other symptoms: nausea, vomiting
- All were hospitalized
- One died within hours

Toxic Effects of Sulfur Containing Compounds
- Toxic effects resulting from inhalation, ingestion or dermal exposure
  - Gastrointestinal
  - Respiratory
  - Central Nervous System
  - Skin
- NO documented parenteral exposures in humans

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Sulfur Reducing bacteria in the incoming water + Citric acid feed pre-GAC to adjust pH + Improperly maintained water system

Hypothesis

Anaerobic bacterial growth
Sulfur-containing compounds: Carbon disulfide, Methanethiol, Dimethyldisulfide, Sulfur Dioxide

Symptoms

Volatile Sulfur Compounds Summary
- Outbreak of severe and fatal reactions in hemodialysis patients
- Dialysis water contaminated with sulfur-containing compounds
- Recommendations:
  - Use pH controller and muriatic acid instead of citric acid
  - Prompt correction of reverse osmosis unit malfunction
  - Routine monthly disinfection of the water system

Manufacturing Errors
- Occluded Bloodlines: Acute Hemolysis
- Althin Dialyzers Contaminated with Perfluorocarbon performance fluid

Faulty Blood Tubing sets
- Multistate outbreak of hemolysis in hemodialysis patients traced to faulty blood tubing sets

Partially Occluded Blood Lines
- Patients in three states developed hemolysis while produced by a single manufacturer.
- 35 case patients
- 2 implicated tubing sets of lot 04D15309
- Gambro Healthcare estimated that the degree of occlusion in the defective cassette and tubing varied between 20 and 89%.
- The 300 defective cartridges went to the production of Cobe Centrisystem 3 blood tubing sets of lot numbers 04D15309, 04D15308, and 04D15310.
- Lots were recalled

Baxter/Althin Hemodialyzers
- In 2001, Baxter announced a voluntary recall of its AX, AF, and A series dialyzers following reports worldwide associated with the use of these dialyzers.
- The models of dialyzers recalled, labeled either Baxter or Althane are: Series A11, A15, A18, A22; Series AF150, AF180, AF220; and Series AX1200, AX2000
- Patients did not respond to any resuscitation efforts

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Baxter/Althin Hemodialyzers
- The total death count as a result of the use of Baxter's affected dialyzers globally is over 50 hemodialysis patients. Spain, which had the first cases reported, had a total of 12 deaths.
- Highest mortality occurred in Croatia, which had 23 deaths.
- Four deaths occurred in the U.S. with two in Austin, TX, and two in Kearney, NE.
- Deaths also occurred in Colombia, Italy, Germany, and Taiwan.

Perfluorocarbon Performance fluid
- PF5070, perfluorocarbons play a prominent role in the process known as "dialysis repair" and has been used throughout the dialysis industry for more than 30 years without a problem.
- To repair fibers in the manufacturing process that fail the initial leak test. PF5070 is then allowed to evaporate out of the dialyzer.
- PF5070 Characteristics:
  - liquid at room temperature
  - a gas at body temperature
  - insoluble in plasma

For additional information see: http://biomed.brown.edu/Courses/B1108/B1108_2007_Groups/group5/pages/baxter.html

PF5070 Exposure
- Cardiac arrest
- Respiratory Failure
- Severe hypotension, loss of consciousness
- Dyspnea
- Chest pain/Abdominal pain
- Nausea and vomiting

Allergic Reactions
- May or may not occur in clusters
- Usually patients are easily identified and respond to changes in therapy, i.e. different reuse chemicals, different dialyzer membrane, preprocessing of hemodialyzers before use, benadryl

ACE Inhibitors and Reuse
Anaphylactoid reactions associated with reuse of hollow-fiber hemodialyzers and ACE inhibitors
David A. Pellet, Constance M. Black-Jones, John W. Nasci, James O. Bickford, Gary D. Blume, Erwin E. Pinnick, Margaret S. Fiskin, and Steven D. A. Swanson.

ACE inhibitors and reuse of dialyzers have been associated with anaphylactoid reactions. The purpose of this study was to examine the association of ACE inhibitors and anaphylactoid reactions in hemodialysis patients. ACE inhibitors are associated with anaphylactoid reactions in hemodialysis patients. The association of these two conditions is significant and should be considered when evaluating patients who experience such reactions.

http://www.nature.com/kl/journal/v42/n5/abs/kl1992409a.html

Contaminated Heparin
Acute Allergic-Type Reactions Among Patients Undergoing Hemodialysis — Multiple States, 2007—2008

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5714a1.htm

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### Heparin Related Symptoms
- **confirmed case episode of anaphylactic or anaphylactoid reaction** characterized by angioedema (particularly swelling of lips/mouth, tongue, throat, or eyelids) or urticaria.
- **A probable case** had at least two of the following signs and symptoms:
  - generalized or localized sensations of warmth
  - numbness or tingling of the extremities
  - difficulty swallowing
  - shortness of breath, audible wheezing, or chest tightness
  - low blood pressure/tachycardia
  - nausea or vomiting.

### Acute Allergic Reactions from Contaminated Heparin
- **Oversulfated chondroitin sulfate (OSCS) identified as a contaminant**
- Directly activates complement and kallikrein systems
- Contaminated heparin products have now been found in at least 10 countries
- May also stimulate cytokine production
- Products from multiple suppliers received contaminated active pharmaceutical ingredient (API)
  - Baxter Healthcare
  - BBRaun
  - Covidien
  - American Health Products

### Non-chemical Associated Hemolysis
- **Dialysate temperature > 40°C**
- **Dialysis against distilled water**
- **Kinked Blood tubing**

### Hemolytic Dialysis Events
- Sometimes rare/sporadic events
- Clusters usually represent exposure to chemical agent
  - Differentiate from all potential causes
    - Kinking of tubing sets (Make sure using correct tubing set for machine)
    - Needle burs
    - Monochoramine/chlorine exposure
    - Drug reaction

### Bleeding/Exsanguination Events
- **Current CDC investigation** to determine risk factors
- **Exsanguination Deaths among Dialysis Patients:**
  - District of Columbia, Maryland, Virginia
- **Access failures**
  - Fistulas, Grafts, catheters
- **Line separation**

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Motivation for Study
- Maryland Medical Examiner review of cases
  - Bleeding or "exsanguination" deaths in dialysis pts
  - 24 deaths over 6 years via retrospective review
  - Since 7/2006 13 additional cases noted by ME
- Little known about epidemiology
  - Cluster in Maryland?
  - Incidence in the US?
  - Case finding?
  - Preventable risk factors?

Analysis of CMS Data
- CMS provided CDC with COD data for 2000-07
- Hemorrhage from Vascular access (HVA) and hemorrhage of dialysis circuit (HDC) accounted for 3.7/1000 ESRD deaths with known causes
  - 5.7/1000 ESRD deaths in MD (6th in US)
  - 6.5/1000 ESRD deaths in DC (2nd in US)
  - 5.4/1000 ESRD deaths in VA (7th in US)
  - 1700+ deaths nationwide HVA/HDC codes
  - 18% ESRD deaths listed not coded or unknown

Case Description (N=96)

<table>
<thead>
<tr>
<th>Sex</th>
<th>Female</th>
<th>47 (49.0%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
<td>64 (28-92)</td>
</tr>
<tr>
<td>Race</td>
<td>Black</td>
<td>68 (72%)</td>
</tr>
<tr>
<td></td>
<td>White</td>
<td>24 (25.3%)</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>3 (3.2%)</td>
</tr>
</tbody>
</table>

Vascular Access Type (N=96)

<table>
<thead>
<tr>
<th>Type</th>
<th>Fistula</th>
<th>Graft</th>
<th>Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>34.4%</td>
<td>56.3%</td>
<td>35.4%</td>
</tr>
</tbody>
</table>

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Bleeding and Access Complications (N=73)
- 20.5% had documented history of a serious vascular access hemorrhage
- 72.6% had documentation of ANY access-related complications within the past 6 months
  - 30.1% Clotting
  - 27.4% Prolonged bleeding after dialysis
  - 20.6% Stenosis
  - 16.4% Superficial infection at access site
  - 13.7% Extensive vascular access infection
  - 11.0% Aneurysm or pseudoaneurysm
  - 4.1% Graft erosion

Summary of Prototypes
- History of access-related problems/concerns
  - E.g. Infection, prolonged bleeding, erosions, aneurysms, clotting, repairs/revisions
- Anticoagulation-related events
  - Dialysis heparinization, systemic anticoagulation
- Psychosocial concerns
  - Depression, mental conditions, financial concerns, substance use, non-compliance
- Medical errors
  - CVC insertion events, needle dislodgements

Regional Progress on Fistula First

Regional Progress on Fistula First

Figure 6: PERCENT OF PREVALENT PATIENTS WITH AN AVF/TUNNEL
Network 3 Compared to the U.S. - December 2006

Source: CMS Dashboard

Preventing Adverse Events
- Follow standards and recommended practices
- Facility and System Designs
- Quality Assurance Performance Improvement (QAPI)
  - Surveillance Systems
  - Data Analysis
  - Inventory Control
  - Documentation
  - Know when to ask for help

AAMI Standards and Recommended Practices
- Aimed at manufacturer’s
  - Amendment 1 - Annex C: Special considerations for home hemodialysis
  - Amendment 2 - Annex D: Self-assessment of compliance with recommendations for dialysate preparation

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Water for Hemodialysis Applications

- Defined Chemical agents
  - Group I: Agents known to cause adverse effects in patients
  - Group II: Agents known to be toxic for humans when present in potable water
  - Group III: Chemicals not normally harmful and are present in physiologic fluids and potentially dangerous if present in abnormal concentrations
- Defined levels for microbial contamination

Group I Maximum Allowable Chemical Contaminants Water for Hemodialysis Applications

<table>
<thead>
<tr>
<th>Chemical Agent</th>
<th>mg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum</td>
<td>0.01</td>
</tr>
<tr>
<td>Chlorine (free)</td>
<td>0.50</td>
</tr>
<tr>
<td>Chloramine</td>
<td>0.10</td>
</tr>
<tr>
<td>Copper</td>
<td>0.10</td>
</tr>
<tr>
<td>Fluoride</td>
<td>0.20</td>
</tr>
<tr>
<td>Nitrate</td>
<td>2.00</td>
</tr>
<tr>
<td>Sulfate</td>
<td>100.00</td>
</tr>
<tr>
<td>Zinc</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Group II Chemical Contaminant Levels Water for Hemodialysis Applications

<table>
<thead>
<tr>
<th>Trace Element</th>
<th>mg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimony</td>
<td>0.006</td>
</tr>
<tr>
<td>Arsenic</td>
<td>0.005</td>
</tr>
<tr>
<td>Barium</td>
<td>0.10</td>
</tr>
<tr>
<td>Beryllium</td>
<td>0.0004</td>
</tr>
<tr>
<td>Cadmium</td>
<td>0.001</td>
</tr>
<tr>
<td>Lead</td>
<td>0.005</td>
</tr>
<tr>
<td>Mercury</td>
<td>0.0002</td>
</tr>
<tr>
<td>Silver</td>
<td>0.005</td>
</tr>
<tr>
<td>Thallium</td>
<td>0.002</td>
</tr>
<tr>
<td>Chromium*</td>
<td>0.014</td>
</tr>
<tr>
<td>Selenium</td>
<td>0.90</td>
</tr>
</tbody>
</table>

* Based on the “no-transfer” level

Group III Chemicals: Water for Hemodialysis Applications

<table>
<thead>
<tr>
<th>Chemical</th>
<th>mg/L</th>
<th>mEq/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>2</td>
<td>0.1</td>
</tr>
<tr>
<td>Magnesium</td>
<td>4</td>
<td>0.3</td>
</tr>
<tr>
<td>Sodium</td>
<td>70</td>
<td>3</td>
</tr>
<tr>
<td>Potassium</td>
<td>8</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Surveillance

- On-line monitoring of water quality
- Test for chlorine/chloramine prior to each patient shift
- Test for hardness twice a day
- On-line monitoring of TDS/Resistivity with temperature compensated meters (audio and visual alarms)
- Routine Environmental Cultures of Hemodialysis Fluids (monthly)
- At least annual chemical testing of water (preferably with change of seasons)
- Patient Monitoring
  - Pyrogenic reactions and/or bacteremia
  - Other adverse patient reactions during dialysis

Surveillance System

- Documentation
  - Do you track lot numbers (drugs administered, dialysate concentrate, blood tubing sets, dialyzers, etc)
- Separate Log
  - Blood stream infections
  - Hepatitis sero-conversions
  - Adverse events (note symptoms and circumstances)

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Understanding a Voluntary Recall

- FDA can encourage the firm to voluntarily correct the problem or to recall a faulty product from the market.

Email Listservers

- Nephrol
- Renalpro

To subscribe to Nephrol, RenalPro or other nephrology listservs see http://www.cybernephrology.org/communication/commProviders.htm
- DHQP Rapid Notification for Healthcare Professionals
- Free MMWR Subscription:
  - http://www.cdc.gov/mmwr/mmwrsubscribe.html

Additional On-line Resources

- CDC Dialysis Pages: www.cdc.gov/ncidod/dhp/dhpac.html
- FDA Medwatch and E-listserv: www.fda.gov/medwatch
- United States Renal DataSystems: www.usrsds.org
- Fistula First: www.fistulafirst.org

The Next Few Teleclasses

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 May</td>
<td>Bedside Techronology: Manual in Dialysis</td>
<td>Dr. Lynda M. Bork, DCC</td>
</tr>
<tr>
<td>10 Jun</td>
<td>Electronic Monitoring - Methods and Strategies</td>
<td>Dr. Steven McDermott, Auburn Health Board</td>
</tr>
<tr>
<td>25 Jun</td>
<td>CDC Teleclass #2: The CDC Examination Process: Computer Based Testing</td>
<td>CDC Teleclass Board Members &amp; Guests</td>
</tr>
<tr>
<td>17 Jul</td>
<td>Free Teleclass Community-Associated MSAP - What’s Up &amp; What’s Next</td>
<td>Dr. Rachel Briski, DCC</td>
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<tr>
<td>22 Jul</td>
<td>Free Teleclass Progress Report from the Chief Nursing Office</td>
<td>Christine Stueber, British Department of Health</td>
</tr>
<tr>
<td>24 Jul</td>
<td>Free Teleclass Distribution &amp; Marketing - Current Issues &amp; New Research</td>
<td>Dr. William Rusta, University of North Carolina</td>
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</table>

www.webbertraining.com.schedule1.php