New Developments in Renal Dialysis
Prof. W.H. Seto, World Health Organisation, Hong Kong
Sponsored by WHO Patient Safety, Clean Care is Safer Care

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December 5, 2012

Standards requirements
- Dialysis water: chemical contaminants
- Microbiological contaminants
- Concentrate
- Dialysis fluid: Microbiological contaminants in standard fluids
- Ultrapure dialysis fluid
- Online-prepared substitution fluid
- Record keeping

Other recommendations
- System design
- Validation of system performance: Plan
- Installation qualification
- Operational qualification
- Performance qualification
- Routine monitoring

Quality Management: Fluid quality
- Water treatment equipment
- Water storage and distribution
- Concentrate preparation, distribution and proportioning

Microbiological control: Disinfection
- Microbiological monitoring

Environment
- Personnel

SUMMARY

Water
- Fluid
- Machine

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Major important infection control issues in dialysis centre

- New microbiological standard of fluids for dialysis and related therapies
- Minimize vascular access infections in hemodialysis patients
- Concern of hepatitis C outbreaks

Water Treatment

- To remove chemical, bacterial & endotoxin contaminant that could be harmful to patients

  - Consist of:
    - Water softener
    - Particulate filter(s)
    - Carbon filter(s)
    - Deionizers, filters,
    - Reverse osmosis (RO)
    - Ultrafilters, UV light

Types of water microorganisms that have been found in dialysis systems (1)

- Gram-negative water bacteria
  - Pseudomonas
  - Flavobacterium
  - Acinetobacter
  - Alcaligenes
  - Achromobacter
  - Aeromonas
  - Serratia
  - Xanthomonas

- Endotoxin

Types of water microorganisms that have been found in dialysis systems (2)

- Non-tuberculous mycobacteria
  - Mycobacterium chelonae
    - fortuitum
    - gordonae
    - scrofulaceum
    - kansasii
    - avium intracellulalis

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The evolution of extracorporeal treatment of end-stage renal failure has enforced focus on the purity of dialysis fluid.

Bicarbonate dialysate
- Bicarbonate dialysate are commonly used for both conventional and high-flux dialysis which a good culture medium
- Potential transfer of bacteria from dialysate to patient blood

Adverse effect of high flux dialysis
- High flux dialyzers have larger pores, the bacterial particles can pass more easily into the patient’s bloodstream,
- Patients on high flux dialysis have more frequent pyrogen reactions

An other major challenge of high-flux haemodialysis (HD) and haemodiafiltration relates to the necessity for ultrapure dialysis fluid and for sterile non-pyrogenic substitution fluid.

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Monitoring of dialysis fluid

<table>
<thead>
<tr>
<th>Substance</th>
<th>cfu/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>&lt;200/ml</td>
</tr>
<tr>
<td>Dialysate</td>
<td>&lt;200/ml</td>
</tr>
<tr>
<td>Dialysate disinfectant</td>
<td>&lt;200/ml</td>
</tr>
<tr>
<td>Dialysate for infusion</td>
<td>1/1000 L</td>
</tr>
<tr>
<td>Ultra-pure dialysate</td>
<td>1/10 ml</td>
</tr>
</tbody>
</table>

Should be done at least monthly

AAMI 2004

Dialysis fluid = dialysis water and dialysate

- Microbial count <100 CFU/ml
- Endotoxin concentration <0.5 EU/ml

Explaining why an action level is needed….

Dialysis water – sampling

Samples shall be collected immediately prior to when the water re-enters the storage tank in an indirect fluid system or immediately prior to where the water returns to the reverse osmosis system in a direct fluid system. Additional samples shall be collected at, or immediately prior to, the point where water enters the equipment used to prepare concentrates or reprocess dialysers if the line supplying the equipment with water is separate from the distribution loop supplying the dialysis machine. Samples cannot be assayed within 4 h can be refrigerated up to 24 h.
Test for compliance of microbiological requirement

Dialysis fluid routine test:

Method and sample volume
- spread plate, 0.1 ml - 0.3 ml
- pour plate, 0.1 ml – 1 ml

Culture agar - tryptone glucose extract agar (TGEA)
Incubation $T^0$ - $17^\circ C$ - $23^\circ C$
Incubation time - 168 hours (7 days)

Ultrapure dialysis fluid
1. Highly purified dialysis fluid in place of conventional
2. Feed solution infusing directly to pt’s blood

Culture method by membrane filtration (10-1000ml)

For haemofiltration & haemodiafiltration, sampling of the online infusion fluid is not done.

The frequency of sampling should meet applicable local recommendations. If no such recommendations exist, the following is recommended:

a) Water system: The number of samples and points of sampling should be based on the complexity and size of the water system. The frequency will depend on the analysis of the data collected during the validation and validation study. Monthly monitoring is most frequently adopted but less frequent monitoring may be possible based on data collected during the validation and examination.

b) Dialysis machines: Dialysis machines without a validated bacteria and endotoxin-rejection filter should be sampled on a regular basis, as per the manufacturer’s instructions. The schedule of sampling will depend on the type of dialysis machines being used. Each machine should be sampled at least once per week, and different machines should be sampled on each occasion. Monthly monitoring is most frequently adopted.

c) Haemodialysis machines: It is not necessary to take samples of ultrapure dialysis fluid or substitution fluids if the production parts are filled with bacteria and endotoxin-rejection filters, validated by the manufacturer and operated and monitored according to the manufacturer’s instructions. It could be necessary to sample the dialysis fluid entering such machines and endotoxin-rejection filters, depending on the manufacturer’s instructions for use of the filters; for example, when the instructions for use specify specific quality of the fluid entering the filter. (See also Annexes D and E.)

"These types of samples also should be taken at least once monthly and after suspected pyrogenic reactions or changes in the water treatment system of disinfection protocols."

(pp 347) Bennett & Brachman’s
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Epidemiology of Infections among Hemodialysis Patients
• Infections are the 2nd leading cause of death (15% of deaths)
• Site of infection
  – 57% vascular access
  – 23% wound
  – 15% lung
  – 5% urinary tract

Burden of Dialysis Infections  
A Cause for Concern
• In the US, there are about 370,000 people relying on hemodialysis
• About 75,000 people receive hemodialysis through a central line
• Central lines have a higher risk of infection than a fistula or graft
• CDC estimates 37,000 central line-associated bloodstream infections may have occurred in U.S. hemodialysis patients in 2008

Rate of Access-Related Bloodstream Infection by Vascular Access Type

Important Trends
• Growing dialysis population; ~350,000
• Mortality, increasing morbidity from infections
• Antimicrobial resistant infections, emerging patterns of resistance

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Invasive Methicillin-Resistant S. aureus (MRSA) Infections, 2005

- Incidence of invasive MRSA infections: 45.2 cases per 1,000 dialysis population
  - 100% rate in general population (0.2 – 0.4 per 1000)
- Dialysis patients:
  - ~0.1% of the U.S. population
  - ~15% of all invasive MRSA infections
- Invasive MRSA in dialysis:
  - 88% were bloodstream infections (BSIs)
  - 90% required hospitalization, mortality = 17%

CDC, MMWR 2007; 56(06):197-8

Prevention of vascular access infections

National Kidney Foundation and CDC - USA

- No antibiotic prophylaxis – at insertion and use of catheter
- No routine change of catheter
- Use sterile techniques (cap, mask, sterile gown, large drape)
- Limiting non-cuff catheter to 3-4 weeks
- Use only for HD
- Only trained personnel care for the catheter
- Replace dressing after HD or when damp, loose & soil
- Disinfect skin with CHG for insertion and dressing change
- Ensure catheter site is compatible with catheter material

Example of an Intervention Involving A Vascular Access “Bundle”

- Healthcare worker education (May 2006)
  - Hand hygiene, aseptic technique, access site care
- Feedback of VAA-BSI surveillance data to facility staff and physicians (May 2006)
- Use of 2% chlorhexidine-70% alcohol solution for catheter site care and prior to accessing A-V fistulas and grafts (July 2006)
- Patient education (January 2007)
  - Access site care
  - Benefits of an A-V fistula
  - Vascular Access Liaison (May 2007)

Data presented at SHEA Annual Conference, Mar., 2009
Data courtesy: David Coffee, MD, Mount Sinai School of Medicine

Results:
Incidence of VAA-BSI Over Time

Careful infection control practices can prevent hemodialysis catheter-associated bloodstream infection:

- Follow established guideline for access care
- Use proper insertion and catheter care protocol

Getting to Zero: Outpatient Hemodialysis Catheter-Associated Bloodstream Infections

Virginia R. Bron, RN, MPH, Afro Health System, Grand Forks, ND
Friday, March 18, 2011 SHEA poster presentation

- Highlights from their “expanded” bundle:
  - Catheter hub disinfection with chlorhexidine gluconate 3.5%
  - Hand hygiene plus gloving prior to contacting patients or machines
  - Relocating supplies, from near the patient to a central area
  - Strengthening environmental cleaning practices
  - Chlorhexidine-impregnated sponge dressing for catheters deemed high risk
  - Strengthening of a comprehensive fistula placement program

- Results:
  - Reduction in central line BSI rate from 2.4 per 100 patient-months to 0

CDC

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Hepatitis C Virus Transmission at an Outpatient Hemodialysis Unit

In July 2008, the New York State Department of Health began investigating a cluster of hepatitis C virus (HCV) infections among patients treated at a dialysis center. Of 162 patients identifying as having hepatitis C virus infection, 133 were found to have HCV antibodies and 132 were found to have HCV RNA. Of those patients, 162 were being treated as of July 2008, Manhattan, NY. Medical director of the dialysis center was fined $300,000 in September 2008.

- No of gloves for patient care
- No change of gloves between patient and when dirty
- Not using CHG for skin disinfection
- Did not observe aseptic technique when inserting cannula

Heparin need to be diluted with saline

The dilution is done at fixed time
Dilution is done in ward area
Only one saline bag is used

Heparin saline prepared near clotting time test and patient care area

One-way flow of supplies

- No return of supplies
- No transfer of supplies
- No mobile cart

Medication area

Clean

Patient cubicle 1

Patient cubicle 2

Patient cubicle 3

Dirty

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Medication vials

Multidose vials:
Preservatives has no impact on HBV, HCV

BEST PRACTICE
one vial, one patient; no re-entry or re-use

Do not store equipment with blood sampling area

Should be prepared away from patient care area

Transducer / filters to prevent blood leak and contamination

Dedicated items for use on single patient
Disposable - disposed of
Reusable - disinfection before use on other patients

Infection control practices for HD patients
• Wear glove when caring for patient
• Change gloves between patient and hand hygiene
• Dedicated or single patient use item
• Designated area for admixture of medication
• Do not share medication vials
• Do not use common medication cart
• Do not store supplies with blood samples and patient equipment
• Use external transducer/filter to prevent blood leak
• Clean & disinfect dialysis station between patient use
• Cap and clamp tubing & kidney and use leak proof container when transport

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Infection control issues in dialysis centre

- Adopt the new AAMI microbiological standard of fluids for dialysis and related therapies
- Eliminate vascular access infections in hemodialysis patients
- Enforce infection control guideline to prevent MDRO & hepatitis C outbreaks

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