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

New Developments in Renal Dialysis

WH Seto
WHO CC, Hong Kong

Hosted by
Prof. Lance Jennings
University of Otago, New Zealand

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WHO Patient Safety Challenge
Clean Care is Safer Care

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www.webbertraining.com December 5, 2012

American National Standard

ANSI/AAMI/ISO 23500:2011

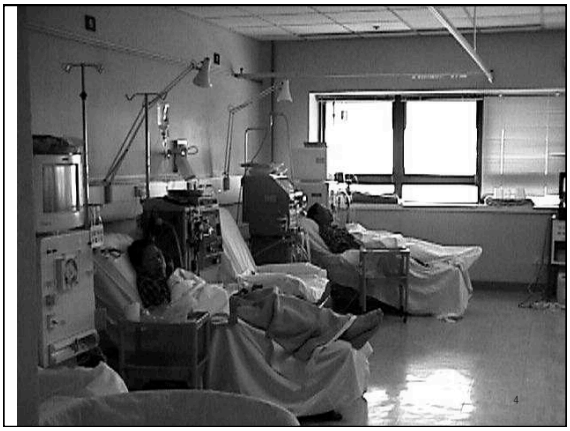
Guidance for the preparation and quality management of fluids for hemodialysis and related therapies

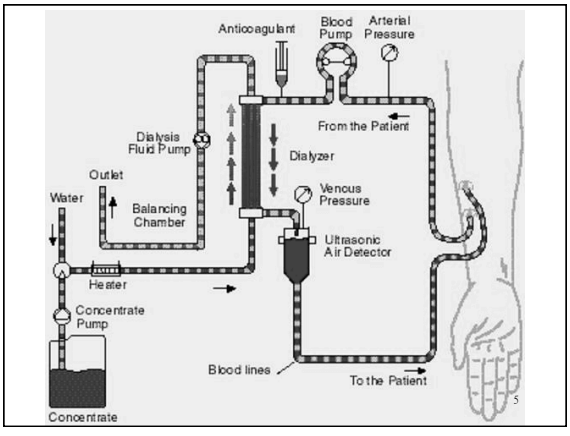
AAMI
Association for the Advancement of Medical Instrumentation

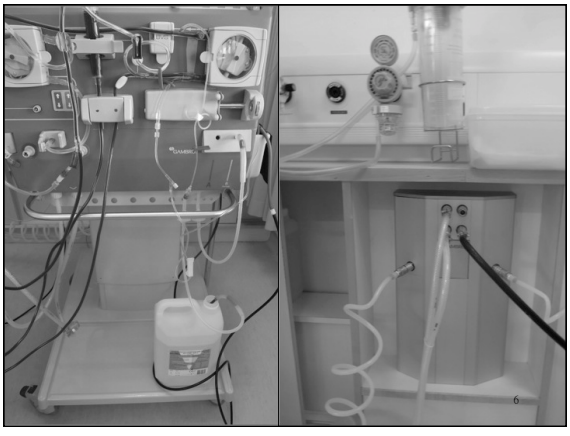
SUMMARY

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

Other recommendations
System design
Validation of system performance: Plan
Machine: Installation qualitification
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







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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

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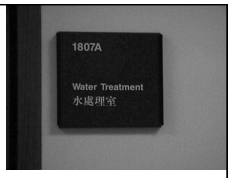
Water Treatment



- 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

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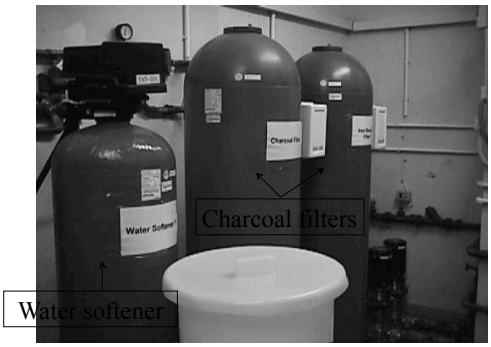

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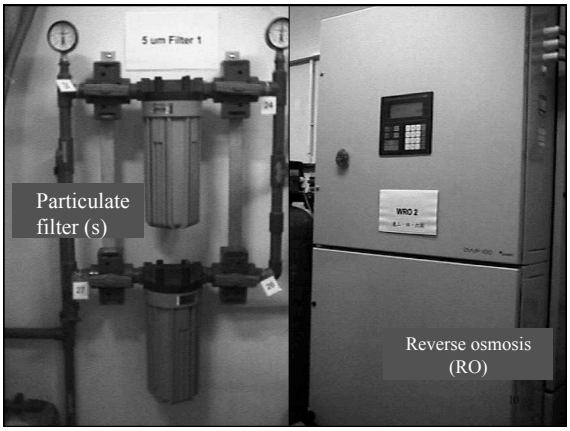

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TYPES OF WATER MICROORGANISMS THAT HAVE BEEN FOUND IN DIALYSIS SYSTEMS (1)

Gram-negative water bacteria

Pseudomonas
Flavobacterium
Acinetobacter
Alcaligenes
Achromobacter
Aeromonas
Serratia
Xanthomonas

Endotoxin

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TYPES OF WATER MICROORGANISMS THAT HAVE BEEN FOUND IN DIALYSIS SYSTEMS (2)

Non-tuberculous mycobacteria

Mycobacterium chelonae
fortuitum
gordonae
scrofulaceum
kansasii
avium intracellularis

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

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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

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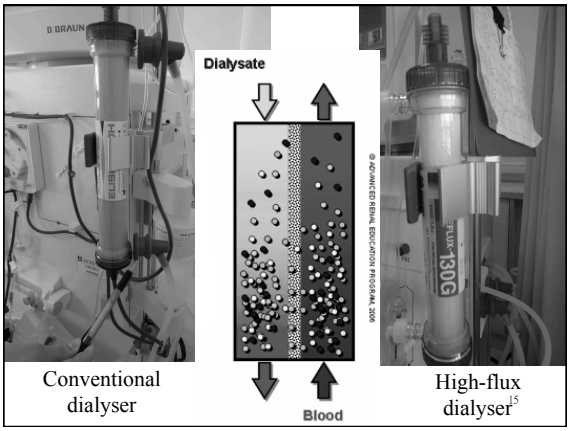

Conventional dialyser

High-flux dialyser

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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

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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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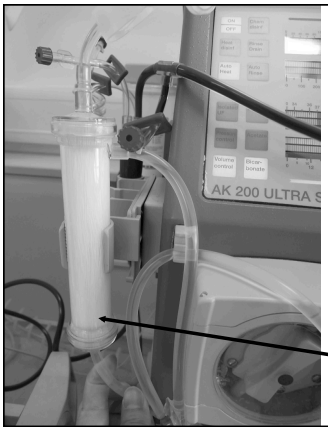

Haemodiafiltration

On-line fluid replacement

Ultra-filter

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Monitoring of dialysis fluid

	cfu
Water	<200/ml
Dialysate	<200/ml
Dialyser disinfectant	<200/ml
Dialysate for infusion	1/1000 L
Ultra-pure dialysate	1/10 ml

Should be done at least monthly

AAMI 2004

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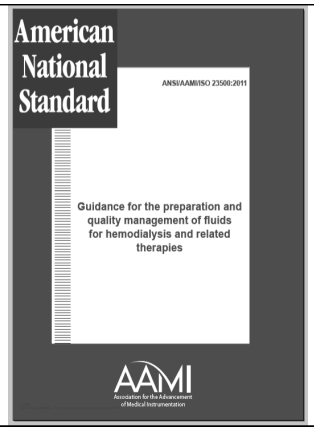

2011
New standard of fluids for hemodialysis

Association for the advancement of medical instrumentation

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4.1.1 General

The requirements contained in this clause apply to a sample of the dialysis fluid collected at the inlet to the dialyser or the reinfusion point.

4.1.2 Microbiological requirements for standard dialysis fluid

Standard dialysis fluid shall contain a total viable microbial count of less than 100 CFU/ml (when tested in accordance with Clause 5) and an endotoxin concentration of less than 0.5 EU/ml (when tested in accordance with Clause 5).

NOTE 1 The action level for the total viable microbial count in dialysis fluid should be 50 CFU/ml.

NOTE 2 If microbial counts exceeding the action levels are observed in the dialysis fluid, corrective measures, such as disinfection and retesting, should be taken promptly to reduce the levels.

Dialysis fluid = dialysis water and dialysate

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

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Table 3 is adapted from ISO 13959:2009.

Table 3 — Maximum allowable levels for total viable microbial count (TVC) and endotoxins in dialysis water[a]

Contaminant	Maximum allowable level	Action level[b]
TVC	<100 CFU/ml	50 CFU/ml
Endotoxin	<0.25 EU/ml	0.125 EU/ml

[a] The reader is cautioned to refer to the latest version of ISO 13959 to ensure that there have been no changes to the values presented in this table.

[b] Typically set at 50 % of the maximum allowable level. Lower values may be set.

Dialysis water is treated water for HD, reprocess of dialysers, preparation of concentrate, fluid for on-line convective therapy

Explaining why an an action level is needed….

Because 7 d can elapse between sampling dialysis fluid for the determination of microbiological contamination and receiving results, and because bacterial proliferation can be rapid, action levels for microbial counts were introduced into this International Standard. These action levels allow the user to initiate corrective action before levels exceed the maximum levels established by this International Standard.

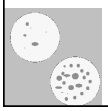
Dialysis water – sampling

Samples shall be collected immediately prior to where the water re-enters the storage tank in an indirect feed system or immediately prior to where the water returns to the reverse osmosis system in a direct feed system. Additional samples shall be collected at, or immediately prior to, the point where water enters the equipment used to prepare concentrates or reprocess dialyzers if the line supplying that equipment with water is separate from the distribution loop supplying the dialysis machines. Samples that cannot be assayed within 4 h can be refrigerated up to 24 h.

Table 4 — Maximum allowable levels for total viable microbial count (TVC) and endotoxins in standard Dialysis fluid

Contaminant	Standard dialysis fluid	
	Maximum allowable level	Action level[b]
TVC	<100 CFU/ml	50 CFU/ml
Endotoxin	<0.5 EU/ml	0.25 EU/ml

[a] The reader is cautioned to refer to the latest version of ISO 11663 to ensure that there have been no changes to this table.
[b] Typically set at 50 % of the maximum allowable level. Lower values may be set.




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 - 17^0 C -23^0 C
Incubation time - 168 hours (7 days)

4.1.3 Microbiological requirements for ultrapure dialysis fluid

Ultrapure dialysis fluid shall contain a total viable microbial count of less than 0.1 CFU/ml (when tested in accordance with Clause 5) and an endotoxin concentration less than 0.03 EU/ml (when tested in accordance with Clause 5). If those limits are exceeded in ultrapure dialysis fluid, corrective measures should be taken to reduce the levels to an acceptable range. The user is responsible for monitoring the

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Table 4 — Maximum allowable levels for total viable microbial count (TVC) and endotoxins in standard and ultrapure dialysis fluid[b]

Contaminant	Standard dialysis fluid		Ultrapure dialysis fluid
	Maximum allowable level	Action level[b]	Maximum allowable level
TVC	<100 CFU/ml	50 CFU/ml	<0.1 CFU/ml
Endotoxin	<0.5 EU/ml	0.25 EU/ml	<0.03 EU/ml

[a] The reader is cautioned to refer to the latest version of ISO 11663 to ensure that there have been no changes to this table.
[b] Typically set at 50 % of the maximum allowable level. Lower values may be set.

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)

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 positions 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 revalidation activities. Monthly monitoring is most frequently adopted but less frequent monitoring may be possible based on data collected during the validation and revalidation.

b) Dialysis fluid/hemodialysis machines without a validated bacteria- and endotoxin-retentive filter: Machines should be sampled on a regular basis to provide verification of the effectiveness of the disinfection process. The schedule of sampling will depend on the type of disinfection process being used. Each machine should be sampled at least once per year and different machines should be sampled on each occasion. Monthly monitoring is most frequently adopted.

c) It is not necessary to take samples of ultrapure dialysis fluid or substitution fluids if their production paths are fitted with bacteria- and endotoxin-retentive 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 bacteria- and endotoxin-retentive filters depending on the manufacturer's instructions for use of the filters; for example, when the instructions for use specify the 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

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

4.1.4 Microbiological requirements for online prepared substitution fluid

The requirements contained in this clause apply to online prepared fluid intended to be infused into the patient as it enters the patient's blood.

This fluid shall be sterile and non-pyrogenic.

Substitution fluid for convective therapies, such as hemodiafiltration and hemofiltration, may be produced online by a process of ultrafiltration with bacteria and endotoxin retentive filters. This online-process shall be validated to produce fluid that is sterile and non-pyrogenic.

Compliance of online produced fluid with the requirements of this International Standard cannot be demonstrated with traditional test procedures. For this reason, compliance with this International Standard shall be ensured by proper operation of a validated system, verified according to the manufacturer's instructions at the time of installation, and confirmed by the user with a regular monitoring and maintenance schedule. The user shall follow the manufacturer's instructions for use of the validated system, and the user's monitoring and maintenance schedule shall be designed to confirm that the water and concentrates used to prepare the substitution fluid continue to meet the specifications of ISO 13959 and ISO 13959.

Substitution fluid

— sterility cannot be proven by sampling

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

USRDS 2005 Annual Data Report
Tokars, Miller, Stein. AJIC 2002;30:288-295

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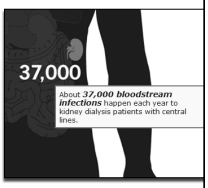
Burden of Dialysis Infections
A Cause for Concern

- 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



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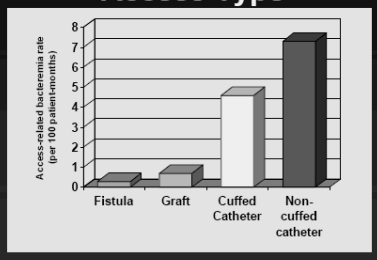
Rate of Access-Related Bloodstream Infection by Vascular Access Type



Dialysis Surveillance Network 1999-2005

CDC

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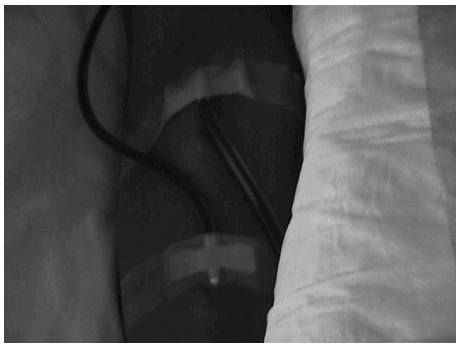

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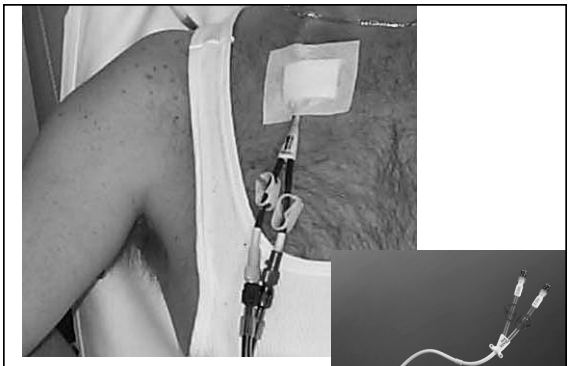

Cuffed catheter

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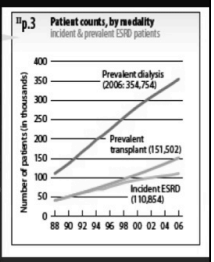
Important Trends

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



United States Renal Data System (USRDS) 2008 Annual Data Report

CDC

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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 X 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
  - 86% were bloodstream infections (BSIs)
  - 90% required hospitalization, mortality = 17%

CDC. MMWR 2007; 56(09):197-9

CDC

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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

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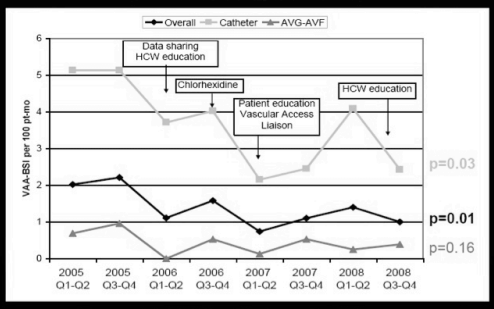
Example of an Intervention Involving A Vascular Access "Bundle"

- 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
Slide courtesy: David Calfee, MD, Mount Sinai School of Medicine

Results: Incidence of VAA-BSI Over Time



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

Getting to Zero: Outpatient Hemodialysis Catheter-Associated Bloodstream Infections

Virginia R. Bren, RN, MPH, Altru Health System, Grand Forks, ND

Friday, March 19, 2010 SHEA poster presentation

- Highlights from their "expanded" bundle:
  - Catheter hub disinfection with chlorhexidine gluconate 3.15%
  - 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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Careful infection control practices can prevent hemodialysis catheter associated bloodstream infection:

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

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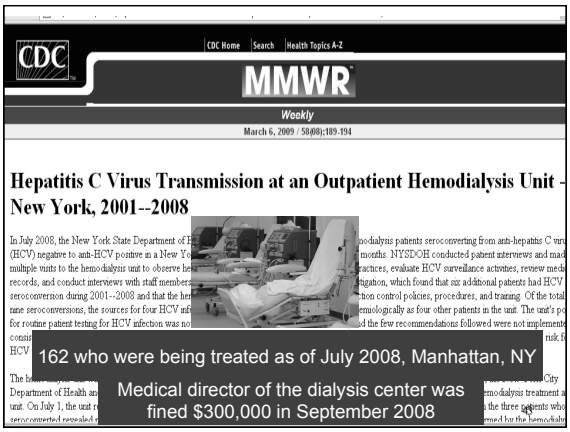

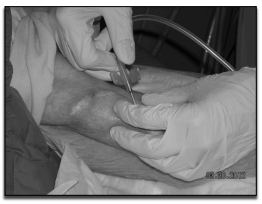

- No of gloves for patient care
- No change of gloves between patient and when dirty
- Not using CHG for skin disinfection
- Did not observe aseptic technique when inserting cannula

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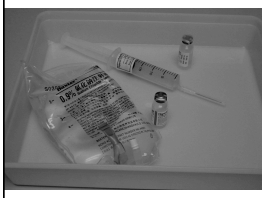
Heparin need to be diluted with saline



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

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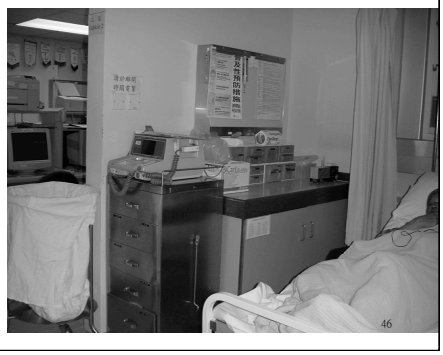
Heparin saline prepared near clotting time test and patient care area



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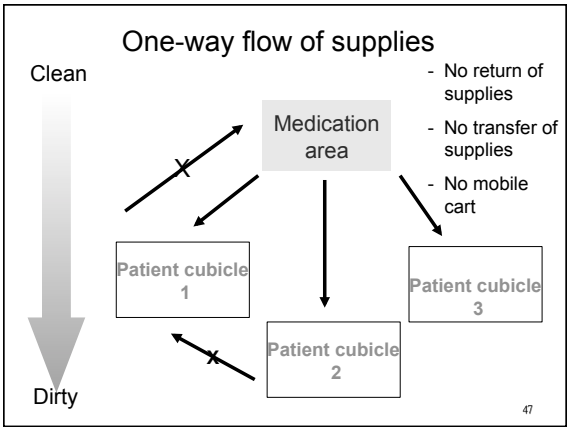

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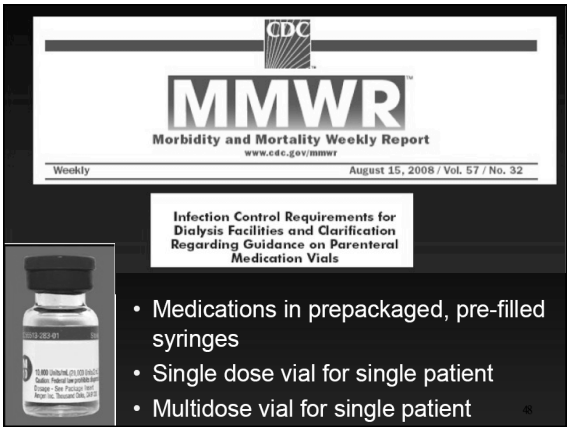

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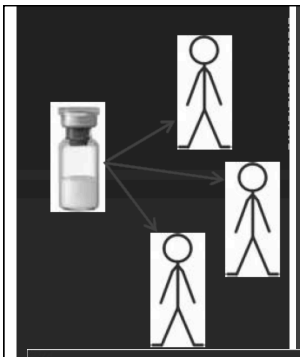

Medication vials

Multidose vials: Preservatives has no impact on HBV, HCV

BEST PRACTICE

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

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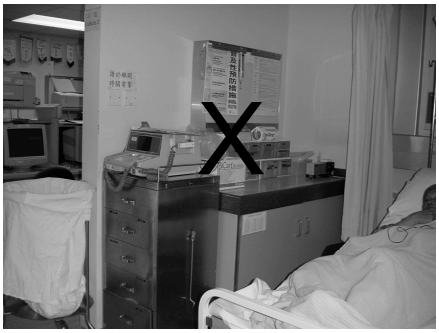
Do not store equipment with blood sampling area



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Should be prepared away from patient care area

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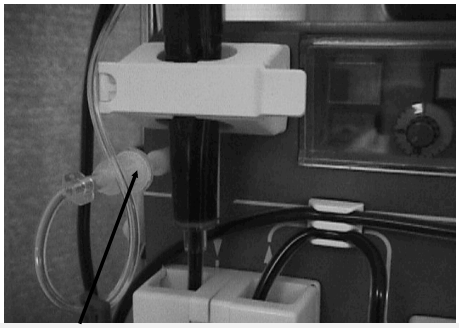

Transducer / filters to prevent blood leak and contamination

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

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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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Thank you

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2013 WHO Teleclasses

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