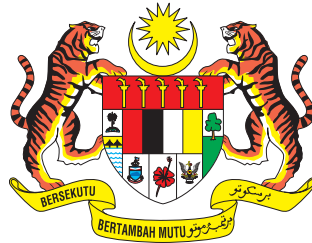




Haemodialysis Quality And Standards



**Medical Development Division
Ministry of Health Malaysia**



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Ministry of Health Malaysia**

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Foreword

**By The
Director General of Health Malaysia**

Since the first edition of 'Quality and Standards in Haemodialysis' was introduced in the Ministry of Health in 1994, much progress, development and advances have taken place. The numbers of haemodialysis units have progressively and significantly increased every year. By the end of the year 2010, the Ministry of Health was no longer the largest provider of haemodialysis services in the country. Forty-five percent of the total number of patients on dialysis in Malaysia were treated at private centres, thirty percent at the Non- Governmental Organization centres and twenty-five per cent at public centres.

While the country's ability to provide life saving long term haemodialysis treatment to so many patients with end stage renal disease may be seen as a healthsector success, the mushrooming of hospital based or free standing haemodialysis units all over the nation does pose a new set of challenges. There is a need to ensure that haemodialysis treatment is prescribed, initiated, maintained and terminated by trained and appropriate technical and clinical professionals so that the elements of safety and standard are adhered to.

As such, this revised and updated version of the national standards and quality document in haemodialysis is timely and relevant. I hope that this document will be used as a guide by all the relevant stakeholders to ensure that the provision of haemodialysis service in all health sectors will achieve a high degree of safety and efficacy commensurate with its role as a long-term life saving treatment.

A stylized, handwritten signature in black ink, consisting of a large, sweeping loop followed by several horizontal strokes.

Dato' Sri Dr Hasan Abdul Rahman



Foreword

By The

**Deputy Director General of Health Malaysia
(Medical)**

In Malaysia, the evolution of haemodialysis from the short-term therapy for acute renal failure involving a handful of patients in the sixties has quickly expanded to become the most important long-term therapy for patients with end stage renal failure.

While the haemodialysis service were mainly provided by the public sector in the eighties and early nineties, this is not the case now. While the density of public haemodialysis centres remained static at 5 per million population (pmp) between 2005 to 2010, the private haemodialysis centres doubled from 5 pmp in 2005 to 10pmp in 2010 while the Non-Governmental Organizations (NGO) centres increased from 4 to 5 pmp over the same period.

Under the Private Healthcare and Facilities Act 1998, haemodialysis services in the private and NGO sectors are subjected to licensing and monitoring so as to ensure that they are provided to meet the needs of the patients as well as delivered by taking into consideration basic requirements of safety and standards. While the contents of the Act deal with the principle and basic issues, the Ministry of Health, assisted by the members of the nephrology service has taken the additional steps to prepare this document, 'Haemodialysis Quality and Standards' to ensure that such treatments conform to the required standards. In the process of preparing this document, several public sessions were held with the participation of clinicians and technicians from both the public and private sector.

As this is a national document, the standards and requirements spelt therein will apply equally to the public, private and NGO facilities. It is my sincere hope that this document will contribute to better care for patients receiving long-term haemodialysis treatment in this country.

A handwritten signature in black ink, appearing to read 'J. Hisham', with a long horizontal line extending to the right.

Datuk Dr Noor Hisham Bin Abdullah

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CHAPTER 1: INTRODUCTION

1.1 Introduction

This document is subdivided into several sections to cover important aspects and components of chronic haemodialysis treatment

1.2 Objectives

The purpose of this guideline is to ensure that haemodialysis is performed safely and is compatible with professionally accepted current practice and local or internationally recognized standards.

CHAPTER 2: PHYSICAL FACILITIES

2.1 Introduction

There shall be adequate space and facilities for all haemodialysis activities to be performed in the haemodialysis centres and for the required volume of work, including:

- A storeroom with adequate space for supplies, consumables and equipment
- A suitable and secure area for clinical waste (Clinical Waste Area).
- Dialysis Room/Area
- Treatment/ Consultation Room
- Resuscitation Facilities
- Water Treatment Room
- Reprocessing Room
- Adequate conveniently located toilet and washbasins for the staff and patients
- Adequate ventilation by windows, ducts or mechanical means
- Janitor Room
- Waiting Area

2.2 Dialysis Room/Area

- 2.2.1 There shall be adequate space for dialysis machine and bed/couch/dialysis chair and such space shall not be less than 4.5 m² for each patient.
- 2.2.2 HBsAg seropositive patients shall be dialysed in a separate room with dedicated machines, equipment, instruments, single use items and medications.
- 2.2.3 Anti HCV seropositive patients shall be dialyzed in a separate room or a separate area with a fixed partition and dedicated machines.
- 2.2.4 HIV seropositive patients shall be dialyzed in a separate room with dedicated machines, equipment, instruments, single use items and medications.

2.3 Treatment/Consultation Room

- 2.3.1 There shall be facilities and equipment for the treatment and care of end stage renal failure patients commensurate with the clinical procedures conducted within haemodialysis facilities.
- 2.3.2 A haemodialysis centre providing or intending to provide minor procedures to haemodialysis patients under its care shall have a treatment room, which shall be located separate from the dialysis room/area.

2.4 Resuscitation facilities

The resuscitation equipment shall include, but not limited to, cardiac monitoring device with defibrillator, bag-valve-mask, suction apparatus, a functioning laryngoscope, endotracheal tube, drugs commonly used in medical emergency and oxygen supply, which shall be easily accessible.

2.5 Water Treatment Room

- 2.5.1 There shall be a separate room for water treatment. It shall be separated from the dialysis room and all other rooms.
- 2.5.2 Water treatment room shall be appropriately sized to house all the components of water treatment system, to facilitate staff and technicians movement for maintenance and daily log purposes.
- 2.5.3 Treated water shall be delivered to individual haemodialysis machines through pipes made of acrylonitrile butadiene styrene (ABS), cross-linked polyethylene (PEX) or equivalent material.

[Note: ABS is not compatible with bleach nor heat disinfection]

2.6 Reprocessing Room

- 2.6.1 Where dialysers are reused, a separate dialyser reprocessing room shall be available.
- 2.6.2 This room shall only be used for dialyser reprocessing, storing of reprocessed dialysers and sterilant.
- 2.6.3 Adequate and efficient ventilation shall be in place to reduce inhalation risk.
- 2.6.4 There shall be a separate room for reprocessing dialysers of patients with Hepatitis B.
- 2.6.5 There shall be a separate room for reprocessing dialysers of patients with Hepatitis C.
- 2.6.6 For Hepatitis B & C co-infected patients, please refer to section (3.4.3)

2.7 Drainage of effluent

The dialysate and reprocessing effluent shall drain into a covered public drainage system, or

If drained into a septic tank, formaldehyde shall not be used and the tank size shall be of adequate capacity to handle the volume of effluent.

CHAPTER 3: EQUIPMENT

3.1 Haemodialysis (HD) machines

3.1.1 HD machine shall be capable of performing conventional (diffusive) HD and preferably convective therapy.

3.1.2 The machines shall be approved by regulatory authorities in USA, Europe or Japan. The machines shall also meet the conditions and regulations set up by the Director General of Health, Malaysia.

3.1.3 Power supply

There shall be a mechanism to ensure uninterrupted power supply to return blood from the extra-corporeal circuit in the event of power failure.

3.1.4 Back-up Machine

- For centres running on full capacity [one (1) machine to six (6) patients], there shall be one back-up machine **and**
- For full capacity centres with more than ten (10) machines, a minimum of one back-up machine is required for every ten (10) HD machines.

3.1.5 High Flux HD

When performing high flux haemodialysis, endotoxin retention filter for the dialysate shall be used.

3.1.6 HD Machine Disinfection

- The external surfaces of the HD machines shall be disinfected after each dialysis session.
- Disinfection of the internal hydraulic circuit of the HD machines shall be performed after the last dialysis session of the day. However, it is preferable to disinfect after each haemodialysis session.

3.1.7 **Planned Preventive Maintenance (PPM)**

- All machines shall have a PPM and technical safety check according to manufacturer recommendations.
- All PPM shall be documented.

3.2 **Haemodiafiltration (HDF) machines**

3.2.1 HDF machine shall have a fully automated integrated unit that can perform haemodiafiltration and haemofiltration.

3.2.2 **Dialysis fluid and Substitution Solution**

- On-line HDF shall use ultrapure dialysis fluid to produce on-line substitution fluid.
- The quality of the dialysis fluid and the substitution fluid shall at least meet the ISO 23500:2011 Standards.

(Appendix 1)

3.3 **Water treatment system**

3.3.1 **Introduction**

Water treatment system is an important component in haemodialysis treatment. It has to be well maintained and monitored in order to prevent any complication that may arise from chemical and microbiological contamination. Chemical contaminants may give rise to haemolysis and encephalopathy whereas, bacterial contamination may give rise to acute pyrogenic reaction and production of pro-inflammatory cytokines, which can eventually lead to amyloidosis, suboptimal response to Erythropoiesis Stimulating Agents (ESA), malnutrition and accelerated atherosclerosis. Therefore, all centres shall adhere to the standards for maximum allowable chemical, bacterial and endotoxin contamination based on minimum requirements of ISO 23500:2011 Standards.

(Appendix 1 & 2)

3.3.2 **Basic requirements in a water treatment system**

- The room that houses the water treatment system shall be located in an area, which minimizes the noise and disruption to haemodialysis treatment.
- There shall be adequate ventilation to prevent over-heating.
- Floor traps shall be made available to drain excess water.
- Flow diagram of the water treatment system shall be displayed in the water treatment room.
- All water treatment components and equipment shall be clearly labelled.
- All columns in pre-treatment shall be opaque.
- Pressure gauge shall be installed before and after each component to monitor fouling of the components.
- Daily recording of the parameters of water treatment system shall be performed.

(See Appendix 3)

- Daily testing for chlorine/chloramine and hardness shall be done every morning prior to starting haemodialysis treatment.
- All centres shall have a water treatment system that delivers water quality that meets the ISO 23500:2011 Standards.

(Appendix 1 & 2)

3.3.3 **Components of Water Treatment System**

(a) Raw Water Tank

- Appropriate material shall be used for water storage. Examples: stainless steel-grade 316, high-density polyethylene (HDPE)
- Shall be covered
- Shall have a low-level alarm sensor shall be fixed
- Shall be inspected for defects and cleaned at 6 monthly intervals
- Shall have an appropriate capacity that is adequate to enable at least one shift of treatment to be completed if water supply is disrupted

(b) Raw water pump

- Two stainless steel raw water pumps are recommended

(c) Multimedia Sediment Filter

- Backwash is required 1-3 times per week

(d) Carbon Columns

- Empty Bed Contact Time (EBCT) shall be ten (10) minutes in total or five (5) minutes for each filter stage if two carbon filters are used to optimise the chlorine and chloramines removal.
- Backwash is required one to three (1-3) times per week and the process shall be done individually for each column by adjusting the timer one to two (1-2) hours apart.

(e) Softener Column

- Consist of polymer resin, which will be regenerated by Sodium Chloride from brine tank or equivalent
- Shall be placed after Carbon Column

(f) Guard Filter

- Removes particles between 1-5 microns in diameter
- Safe guard the Reverse Osmosis unit pump and membranes from clogging
- Casing shall be opaque
- Filter shall be replaced as necessary or when there is pressure difference of 15 psi before and after the Guard Filter. However, a reference to the manufacturer's recommendation is advisable.

(g) Reverse Osmosis (RO) Module

- The RO product water shall fulfil the ISO 23500:2011 standard. (Refer to Water Quality).
- Type of RO membrane: Spiral Wound Polyamide, TEC of Polysulfone or equivalent.
- The recovery rate of RO system shall be at least 50%.
- Standard water treatment system shall have the following parameters displayed:
 - Conductivity of permeate
 - Permeate flow rate
 - Reject flow rate
 - Raw water pressure
 - Guard-in & guard-out pressure
 - RO (membrane) system-in & system-out pressure
- Water sample ports shall be available for sampling at the following points:
 - Post first carbon column
 - Post second carbon column
 - Post softener column/Pre-RO module
 - Immediate post RO module
 - First point in the distribution loop
 - Last point in the distribution loop
 - Last point of the dialyzer-reprocessing loop.
- In the event of RO pump failure, the softened water shall be diverted into the 0.2 microns Bacterial Filter as temporary measure. However, this shall not exceed 24 hours.

(h) Treated Water Storage Tank

- The treated water storage tank is used primarily for dialyser reprocessing or indirect feed for dialysis.
- Shall be made of stainless steel (Grade 316) or High Density Polyethylene (HDPE) with a conical or bowl shaped bottom and shall drain from the lowest point of the base to ensure complete emptying of the tank.
- Tank shall be covered with tight fitting lid and fitted with Ultraviolet Irradiator for destruction of bacteria. There shall be an air vent with a bacterial filter.
- Two booster pumps are recommended for channelling the RO water through a bacteria filter (0.2 micron).

(i) Water Distribution Loop

- Treated water from the water treatment system shall be distributed to the individual dialysis stations, dialyser reprocessing stations using distribution materials and designs which will minimize or avoid microbiological contamination.
- Material of the distribution loop varies from Acrylonitrile butadiene styrene (ABS), cross-linked polyethylene (PEX), stainless steel (high grade 316L) or equivalent.
- Materials suitable for heat disinfection include cross-linked polyethylene (PEX), Polyvinylidene Fluoride and stainless steel.
- If ozone disinfection is used, all the above materials are suitable except PEX.

(j) Disinfection of Distribution Loops

- A minimum of **six (6) monthly** (or as specified by the manufacturer's recommendation) chemical disinfection of distribution loop including the connections to dialysis machine shall be done using peracetic acid 2-3% or chlorine dioxide especially when materials of distribution loop are not heat resistant.
- **Weekly** heat disinfection of the tank and distribution loop is recommended for a system which incorporates a heater and uses heat resistant piping.
- The water shall continuously flow within the loop at a minimum flow velocity of 1.5 feet per second (FPS) for direct feed system and 3.0 FPS for indirect feed system.
- Additional disinfection may be needed in the following circumstances:
 - (i) Installation of new system
 - (ii) Upgrading of existing system
 - (iii) Out-break of pyrogenic reaction
 - (iv) Breach of the closed loop system.
 - (v) When microbial testing of treated water reach action level (refer section 5.3.5).

3.4 Reprocessing

3.4.1 Dialyser Reprocessing Machine

- The reprocessing machine shall be approved by regulatory authorities in the USA or equivalent.
- The reprocessing machine shall be a fully automated integrated unit capable to clean, test and fill the dialyser with disinfectant.
- For reprocessing of dialyser, this shall include testing for total cell volume (TCV), membrane integrity and perform disinfection as per AAMI standard.
- Able to perform automatic dilution of sterilant to specified strength.
- Auto filling of sterilant into dialyser after TCV/Leak test is passed.

3.4.2 **Dialyser Reprocessing Procedure**

- The reprocessing machine shall be calibrated every morning with TCV calibration cell.
- The dialyser shall be cleansed of residual blood and blood products and rinsed with RO water.
- The dialyser shall be tested for residual membrane performance [(Total Cell Volume (TCV)] and the presence of leaks. Dialyzers with TCV<80% or failed the leak test with TCV <80% shall not be reused.
- The dialyser shall be filled with appropriate concentration of a germicide.
- The presence of adequate disinfectant in the reprocessed dialyzers shall be checked using 'Potency Test Strip'.
- At the end of the day, the machine shall be sanitized.
- Every reused dialyser shall be tested for residual disinfectant prior to use.

3.4.3 **Reprocessing of dialyzers in viral infected patients**

- A separate machine shall be used for HBs Ag positive or anti HCV positive patients.
- For Hepatitis B & C co-infected patients, single use of dialyser is mandatory.

CHAPTER 4: DIALYSIS CONSUMABLES

4.1 Dialysis Concentrate

4.1.1 Commercially prepared dialysate

Commercially prepared or ready-made dialysate shall be accompanied by a certificate of analysis from an accredited laboratory or supplied by producers with a valid GMP/ISO certificate.

4.1.2 On-site dialysate preparation

- Due to lack of technical support and expertise, on-site dialysate preparation is currently not recommended.
- However, centres that currently prepare on-site dialysate shall comply with the ISO 23500:2011 Standards and establish a Standard Operating Procedure (SOP) on dialysate preparation and dispensing.

4.1.3 The dialysate packaging shall have the following information clearly labelled:

- Address of manufacturer
- Contents
- Concentration of electrolytes
- Dialysate concentration ratio
- Date of manufacture and expiry

4.2 Dialysers

4.2.1 Dialysers used for haemodialysis treatment shall be approved by regulatory authorities in USA, Europe, Japan or local equivalent.

4.2.2 Dialysers made from biocompatible membrane shall be used.

4.3 Bloodlines

4.3.1 Bloodlines used for haemodialysis treatment shall be approved by regulatory authority.

4.3.2 Bloodlines shall not be re-used.

4.4 Arterio-venous fistula needle

Arterio-venous needle used for haemodialysis treatment shall be approved by regulatory authority.

4.5 Clinical Waste Management

The disposal of clinical waste shall follow the current Ministry of Health guidelines.

CHAPTER 5: WATER QUALITY

5.1 Dialysis water shall be produced by the process of Reverse Osmosis.

5.2 The minimum standards indicated below is based on the ISO 23500: 2011

5.3 Chemical Contaminants

5.3.1 Permissible levels of chemical contaminants shall be observed and adhered to. **(See Appendix 2)**

5.3.2 Method of Testing

- Chlorine and Chloramines and water hardness testing shall be performed onsite using commercially available test kits.
- Full analysis for chemical contaminants shall be performed by an accredited laboratory.

5.3.3 Minimum Frequency of Testing

- **Daily** using commercially available test kits for chlorine and chloramines.
- **Six (6)-monthly** testing in an accredited laboratory for chemical analysis.

5.3.4 Site of Testing

- **Daily** testing for Chlorine and Chloramines shall be done after each carbon column.
- **Daily** testing for hardness after softener column.
- **Six (6)-monthly** full laboratories testing for chemicals shall be done at raw water point, pre and post RO.

5.3.5 Action if limits exceeded

Evaluate water treatment system and rectify as necessary.

5.3.6 **Record**

- All the results shall be properly documented and made available for inspection.

5.4 Microbial Contaminant

5.4.1 **Method of Testing**

- Total Viable counts (Colony Forming Units) using spread plate or membrane filtration technique using Trypton Glucose Extract Agar (TGEA) or equivalent.
- Calibrated loop technique shall not be used.
- The presence of pyrogen/endotoxin shall be determined using Limulus Amoebocyte Lysate (LAL) method.

5.4.2 **Frequency of Testing**

- **Monthly** for bacterial count and endotoxin test

5.4.3 **Sites of Sampling**

- Minimum sites of sampling for testing
 - i. Post RO membrane
 - ii. First point of the distribution loop
 - iii. End point of distribution loop (Last machine port)
 - iv. Reprocessing bay (for indirect feed)

5.4.4 **Handling of water sample**

- Assay within 30 minutes of collection
- If immediate assay is not possible, refrigerate immediately at 5°C and assay within 24 hours of collection

5.4.5 Limits and Action Level

Maximum Allowed

- CFU level < 100 CFU/ml
- Endotoxin level < 0.25 EU/ml

Action Level

- CFU level > 50 CFU/ml
- Endotoxin Level > 0.125 EU/ml

(Ref: AAMI/ISO 23500: 2011)

If Action Levels are observed, disinfection and retesting shall be done immediately to restore the quality into acceptable level.

5.4.6 Laboratory

All samples shall be sent to an accredited laboratory recognized by the Director General of Health.

5.4.7 Record

All the results shall be properly documented and made available for inspection.

CHAPTER 6: HUMAN RESOURCE

6.1 Provision of haemodialysis facilities and services

Haemodialysis services shall be provided in compliance with existing laws and regulations.

6.2 Human Resource

6.2.1 Person-In-Charge (PIC)

The person in charge (PIC) of a haemodialysis centre shall be:

- A Nephrologist or
- A Paediatric Nephrologist or
- A Physician who had completed not less than 200 hours of recognized training in haemodialysis treatment **and** maintains an affiliation with a nephrologist or
- A Registered Medical Practitioner other than those listed above who had completed not less than 200 hours of recognized training in haemodialysis treatment before 31 Dec 2011 **and** maintains an affiliation with a nephrologist.

(Appendix 4)

6.2.2 Registered Nurse/Medical Assistant

- A registered nurse/medical assistant shall have **at least six (6) months** training and experience in haemodialysis and care of such patients under the supervision of registered nephrologists prior to performing haemodialysis treatment independently. An adequate number of staff is required in the facilities to ensure care and treatments are performed safely and effectively.
- For **every six (6) dialysis patients**, there shall be **at least one (1)** registered nurse/medical assistant with at least six months training in haemodialysis treatment and care in each shift.
- The six (6) months training and the certification program shall be as recognized by the Director General of Health.
- There shall be **at least one (1)** registered nurse/medical assistant with training in cardiopulmonary resuscitation techniques in each shift.

6.3 Prescribing haemodialysis treatments

All haemodialysis treatment including self-care haemodialysis shall be provided under the order of:

- (a) A nephrologist or a paediatric nephrologist.
- (b) A physician with requisite training under the supervision of a nephrologist.

6.4 Persons performing haemodialysis treatment

6.4.1 Haemodialysis treatment and care shall be performed by:

- (a) A registered nurse or
- (b) A registered medical assistant

With training and experience in haemodialysis treatment and care.

6.4.2 A registered nurse/medical assistant shall have at least six months training and experience in haemodialysis and care of such patients, under the supervision of registered nephrologists prior to performing haemodialysis treatment independently.

6.4.3 Nursing staff other than a registered nurse may assist in the haemodialysis treatment and care of patients but may only perform such treatment and care under direct supervision of a trained registered nurse/medical assistant.

CHAPTER 7: MONITORING OF DIALYSIS PATIENT

7.1 Monitoring of patients during dialysis

The dialysis treatment shall be monitored closely, with particular attention to:

- Any intra-dialytic complications *(Appendix 7)*
- Vital signs during dialysis: Blood Pressure, pulse & temperature
- Vascular Access *(Appendix 8)*

7.2 Records of dialysis treatments

Each dialysis treatment shall be recorded *(Appendix 9)*

7.3 Long-term monitoring of dialysis patients

7.3.1 Blood Investigations

Blood investigations shall be done regularly at three (3) monthly intervals or more often as necessary. *(Appendix 10)*

7.3.2 Dialysis Adequacy

- Dialysis adequacy shall be monitored at least every three(3) monthly.
- This can be calculated using Kt/V or Urea Reduction Ratio (URR). *(Appendix 11)*
- The delivered Kt/V shall be more than 1.2 or
- The URR shall be more than 65%.

CHAPTER 8: INFECTION CONTROL MEASURES

8.1 All haemodialysis centres shall have stringent measures to prevent the risk of cross-infection amongst haemodialysis patients.

8.2 Management of Staff working in haemodialysis unit

8.2.1 Annual screening for blood born viruses shall be performed.

Staff who are HBsAg negative and:

- 8.2.2
- If anti HBs antibody is 0, a full course vaccination shall be given.
 - If anti HBs antibody <10 mIU/ml, a booster dose shall be given.

8.3 Hepatitis B: Prevention & Isolation Practice

8.3.1 Patients shall be tested for HBsAg:

- Before initiating the first haemodialysis treatment
- After returning from another haemodialysis facility

8.3.2 All HBsAg positive persons are considered infectious and shall be isolated in a separate room. They shall be dialyzed using separate machines, equipment and instruments.

8.3.3 Serology Testing

HBsAg

- If **negative**: HBsAg shall be re-tested every three (3) months
- If **positive**: Repeat test at least annually as a small proportion may seroconvert.

Anti HBs Ab

- If HBsAg negative and HBs Ab negative; shall be vaccinated.
- If anti HBs Ab <100 mIU/ml; A booster dose shall be given.

8.3.4 **Vaccination Schedule**

- A four (4) doses double-strength vaccination schedule is recommended at zero (0), one (1), two (2) and six (6) months.
- Serum anti-HBs Ab shall be checked one to two (1-2) months after completing the vaccination course.
- Those that do not develop anti-HBs Ab response (>10mIU/ml) after primary vaccination shall be re-immunized.
- Re-immunization consists of one to three (1-3) doses, after which if they remain negative are unlikely to respond to additional doses.

8.3.5 Haemodialysis staff caring for HBsAg positive patients shall not care for Hepatitis B susceptible patients at the same shift.

8.3.6 The licensee/person-in charge shall notify Ministry of Health of any Hepatitis B seroconversion.

8.4 Hepatitis C: Prevention & Isolation Practice

8.4.1 Patients shall be tested for anti HCV antibody:

- Before initiating the first haemodialysis treatment
- After returning from another haemodialysis facility.

8.4.2 In anti HCV negative patients, serological test (ELISA) shall be repeated every three (3) months.

8.4.3 Anti HCV positive shall be confirmed with RIBA testing

8.4.4 Confirmed Hepatitis C (ELISA and RIBA positive) infected patients do not require repeated serological test.

8.4.5 In some situations such as recent transfusion of blood/blood products or temporary dialysis in another unit, it is recommended to do monthly ALT testing for three months, as it will facilitate earlier detection of new HCV infections.

If ALT is elevated:

- In patients who are anti-HCV negative, repeat anti HCV testing is warranted, however
- If anti HCV remains negative, HCV NAT (Nucleic Acid Testing) shall be done.

8.4.6 All anti HCV positive patients shall be isolated in a separate room or physically isolated with a fixed partition. They shall be dialysed using separate machines, equipment and instruments.

8.4.7 The licensee/person-in charge shall notify the Ministry of Health of any Hepatitis C seroconversion

8.5 Hepatitis B and C co-infection

8.5.1 Wherever possible, combined Hepatitis B & Hepatitis C infected patients shall be isolated.

8.5.2 If the isolation facility for combined Hepatitis B & C is not available, the patient shall be dialyzed in a Hepatitis B isolation facility during the last shift.

8.5.3 Single use of dialyser is mandatory.

8.6 Human Immuno-deficiency Virus (HIV)

8.6.1 Patients shall be tested for anti HIV antibody:

- Before initiating first haemodialysis treatment
- After returning from another haemodialysis facility

- 8.6.2 In HIV negative patients, serologic test shall be performed every three (3) months.
- 8.6.3 HIV positive patients shall be isolated in a separate room. They shall be dialyzed using separate machines, equipment, instruments and single use items.
- 8.6.4 Single use of dialyser is mandatory.
- 8.6.5 The licensee/person-in charge shall notify the Ministry of Health of any cases of HIV seroconversion.

8.7 Recommendations on preventing transmission of infection among chronic haemodialysis patients

8.7.1 Management of potentially infected patients

Patients at risk of acquiring viral infection include:

- All new patients with an unknown viral status
- All patients with negative viral status returning from another haemodialysis facility
- All patients with history of recent transfusion of blood/ blood products

These patients are **strongly recommended** to be dialysed with single use dialyser **and** either dialysed on:

- A machine that is dedicated for an unknown viral status **or**
- A machine for serology negative patient at the last shift.

until the patient is out of the window period for the respective infection.

8.7.2 Infection Control Precautions for all patients

Staff working in haemodialysis unit shall ensure implementation of, and adherence to strict infection control procedures designed to prevent cross-infection. **(Appendix 12)**

8.7.3 Infection Control Training and Education

Training and education is recommended for both staff members and patients (or their family and care givers). **(Appendix 13)**

CHAPTER 9: OUTCOME MEASURES AND QUALITY INITIATIVES IN DIALYSIS

9.1 Reporting to National Renal Registry

All centres shall submit data to NRR in a specified format.

9.2 Recommended Standards

- **Dialysis Adequacy (Kt/V)**
 - ≥ 95% of patients have prescribed Kt/V >1.3
 - ≥ 90% of patients have delivered Kt/V >1.2

OR

- **Urea Reduction Ratio (URR)**
 - ≥ 90% have URR > 65%

9.3 Anaemia

- **Haemoglobin (Hb)**
 - ≥ 70% achieved Hb > 10 g/dl
- **Ferritin**
 - ≥ 90% achieved serum ferritin > 100 ng/ml
- **Transferrin Saturation (Tsats)**
 - ≥ 80% achieved t sat > 20%

9.4 Mandatory Incident Reporting to Ministry of Health

- All hepatitis and HIV seroconversion
- Intra-dialytic death in chronic stable dialysis patient

Microbial requirements for haemodialysis and related therapies

	Colony Forming Unit [CFU/ml]	Endotoxin [EU/ml]
Dialysis Water (Permeate)	<100	<0.25
Dialysis Fluid (Dialysate)	<100	<0.5
Ultrapure Dialysis Fluid (Ultrapure Dialysate)	<0.1	<0.03
Substitution Fluid	<10 ⁻⁶	<0.03

From ISO 23500: 2011

Maximum allowable levels of toxic chemicals and dialysis fluid electrolytes in dialysis water

Contaminants with documented toxicity in haemodialysis	
Contaminant	Maximum Concentration (mg/l)
Aluminium	0.01
Total Chlorine	0.1
Copper	0.1
Fluoride	0.2
Lead	0.005
Nitrate (as N)	2
Sulphate	100
Zinc	0.1

Electrolytes normally included in dialysis fluid		
Electrolytes	Maximum Concentration	
	(mg/dl)	(mmol/l)
Calcium	2	0.05
Magnesium	4	0.15
Potassium	8	0.2
Sodium	70	3.0

Maximum allowable levels of trace elements in dialysis water	
Contaminants	Maximum Concentration (mg/l)
Antimony	0.006
Arsenic	0.005
Barium	0.1
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Mercury	0.0002
Selenium	0.09
Silver	0.005
Thallium	0.002

From ISO 23500: 2011

DAILY R.O WATER TREATMENT SYSTEM LOG BOOK

	Work Instruction	Mon	Tue	Wed	Thu	Fri	Sat	Sun
1.	Water level in Raw Water Tank (Adequate? Please Tick)							
2.	Timers of Pre Treatment Columns (Ensure corresponds to actual time)							
	2.1: Multimedia column (tick)							
	2.2: Carbon Column (tick)							
	2.3: Softener Column (tick)							
3.	Level of brine solution in Brine Tank (Adequate? Please Tick)							
4.	Pressure Reading of Pre Treatment							
	4.1: Pressure Pre Multi media Column							
	4.2: Pressure Pre Carbon Column 1							
	4.3: Pressure Pre Carbon Column 2							
	4.4: Pressure Pre Softener Column							
	4.5: Pressure of Guard Filter Inlet							
	4.6: Pressure of Guard Filter Outlet							
	4.7: Pressure of Pre RO Membrane							
	4.8: Pressure of Post RO Membrane							
	4.9: Permeate (Product) Pressure							
5.	Permeate Flow Rate (LPM)							
6.	Reject Flow Rate (LPM)							
7.	Permeate Conductivity (micros/cm)							
8.	Feed Total Chlorine (PPM)							
9.	Feed Hardness (mg/L)							
Signature of Staff								

Please record maintenance work done:

- i) Change of guard filter
- ii) Topping of vacuum salt
- iii) Sanitizing/ Cleaning of RO membrane
- iv) Sanitizing RO Water Distribution Loop

Remarks:

Definition

Nephrologist

A nephrologist is a physician who has completed a recognized post-graduate training in nephrology in an accredited centre and registered with the National Specialist Register, Academy of Medicine Malaysia.

Paediatric Nephrologist

A paediatric nephrologist is a paediatrician who has completed a recognized post-graduate training in paediatric nephrology in an accredited centre and registered with the National Specialist Register, Academy of Medicine Malaysia.

Physician

A physician is a licensed medical practitioner, who has completed a recognized post-graduate training in Internal Medicine and registered with the National Specialist Register Academy of Medicine Malaysia.

Registered Medical Practitioner

A Registered Medical Practitioner is a licensed medical practitioner with or without recognized post-graduate training.

200 hours training for Physicians

Objectives:

- To enable Physicians to acquire sufficient knowledge and skills to manage patients on maintenance haemodialysis treatment in a safe and competent manner.
- To improve the quality of care of haemodialysis patients.

Training Module

- Lectures (15 hours)
- Practical experience (185 hours) in an accredited haemodialysis centres

Eligibility

- Physicians who are registered with the National Specialist Register Malaysia

How to apply

- Eligible candidates can apply through www.msn.org.my

Certification

- At the end of the training, participants will be provided with a certificate of completion.

Role of Person-In-Charge (who is a non-nephrologist)

Responsibilities of the person in charge shall include but not limited to:

- Day-to-day medical care of haemodialysis patients.
- Ensure that each patient has a nephrologist to assume all or part of the medical care of the patient.

Role of Nephrologist

Responsibilities of the nephrologist / affiliated nephrologist shall include but not limited to:

- a) Advise on the facilities, equipment and staffing requirements of the centre.
- b) Plan for patient's dialysis requirement, dietary and fluid intake and vascular access management.
- c) Advise on policies and standards for haemodialysis treatment in conformity with the requirements of the regulations and/or any nationally accepted guidelines.
- d) Conduct **review of patients at not less than three monthly intervals**. Such review shall include but not limited to clinical examination, review of blood test results, and other test results.
- e) Recommend changes or modifications to treatment as deemed necessary from time to time in order to maintain the quality of care.

Monitoring of intra-dialytic complications

During dialysis, patient shall be closely monitored for:

- Nausea, vomiting, and headache
- Hypotension or hypertension
- Pyrogenic reaction: chills, rigors, fever during dialysis
- Haemolysis
- Acute blood loss
- Air embolism
- Altered mental status
- Signs and symptoms of First Use Syndrome including chest pain, anxiety, shortness of breath, and back pain.

Vascular Access Monitoring

Continuous assessment for signs and symptoms of vascular access complications shall be performed during each haemodialysis:

Native fistula/ Graft

- Blood flow
- Venous Pressure
- Thrombosis
- Mechanical failure
- Infection
- Skin erosion
- Aneurysm or pseudo aneurysm
- Arterial insufficiency or steal syndrome

Catheters:

- Exit site inspection
- Signs of catheter thrombosis
- Symptoms & signs of catheter related blood stream infection.

DIALYSIS TREATMENT RECORD

MONTH _____ YEAR _____

Date																			
Type of dialysers																			
No of Use																			
Blood Flow Rate																			
Dialysate Flow Rate																			
Venous Pressure																			
Heparin	Loading Dose																		
	Infusion																		
Blood Pressure	Pre HD																		
	Intra																		
	Post HD																		
Weight (kg)	Dry																		
	Pre HD																		
	Post HD																		
	IDWG *																		
Target UF																			
Intra-dialytic complications																			
Medication(s) served	ESA**																		
	Iron																		
	Calcitriol																		

*IDWG: Inter-Dialytic Weight Gain. ** ESA: Erythropoiesis Stimulating Agents

Minimum laboratory investigations for chronic haemodialysis patients

TESTS	FREQUENCY
Full blood count	Every 3 monthly
Iron Study: Serum Iron Serum ferritin Total Iron Binding Capacity (TIBC) Iron saturation (Tsats)	Every 3 monthly
Blood Urea (pre & post dialysis)	Every 3 monthly
Renal Function Test	Every 3 monthly
Liver Function Test Alanine Transaminases Alkaline phosphatase Serum albumin	Every 3 monthly <i>Consider monthly transaminases for 3 months in patients who has been dialyzing elsewhere or patients who received blood transfusion.</i>
Calcium & phosphate	Every 3 monthly
Fasting iPTH	Every 3-6 monthly
Fasting Serum Lipid	Every 6 monthly
Blood sugar	Every 3 monthly (diabetics) Every 6 monthly (non-diabetics)
HbA1C (if diabetics)	Every 3-6 monthly
Virology HBs Ag Anti HB s Ab titre Anti HCV Anti HIV	Every 3 monthly Every 6 monthly Every 3 monthly (if anti HCV neg) Every 3 monthly

Method of measurement of delivered dose of haemodialysis

The delivered dose of haemodialysis in adult and paediatric patients should be measured using formal urea kinetic modelling, employing the single-pool, variable volume model. Other methods include URR (urea reduction ratio), natural log Kt/V and the Daugirdas second-generation formula

Formal urea kinetic modelling provides a quantitative method for developing a treatment for developing a treatment prescription for a specific patient. Computational software is necessary to compute Kt/V using formal UKM.

Various websites offer free formula for calculation of Kt/V:

- www.hdcn.com/calc.html
- www.kt-v.net/
- www.ureakinetic.org

Kt/V natural logarithm formula

$$Kt/V = -\ln(R - 0.008 \times t) + (4 - 3.5 \times R) \times UF/W$$

Ln	Natural logarithm
R	Ratio of Post- Dialysis to Pre-Dialysis BUN
T	Dialysis session length (hours)
UF	Ultrafiltration Volume (litres)
W	Patient's Post dialysis weight (kg)

Urea Reduction Ratio (URR)

Formula for calculation of URR:

$$URR = \frac{\text{Predialysis Urea} - \text{Postdialysis Urea}}{\text{Predialysis Urea}} \times 100\%$$

Infection Control precautions for all patients

(Adapted from CDC guidelines)

- Proper hand washing technique.
- Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Ensure a supply of clean non-sterile gloves and a glove discard container near each dialysis station.
- Wash hands after gloves are removed and between patient contacts, as well as after touching blood, body fluids, secretions, excretions, and contaminated items.
- A sufficient number of sinks with warm water and soap shall be available to facilitate hand washing.
- If hands are not visibly soiled, use of a waterless antiseptic hand rub can be substituted for hand washing.
- Items taken to a patient's dialysis station, including those placed on top of dialysis machines, shall be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being returned to a common clean area or used for other patients.
- Unused medications or supplies (e.g., syringes, alcohol swabs) taken to the patient's station shall not be returned to a common clean area or used on other patients.
- Prepare medications in a room or area separated from the patient treatment area and designated only for medications.
- Do not handle or store contaminated (used supplies, used equipment, blood samples, or biohazard containers) in areas where medications and clean (unused) equipment and supplies are handled.
- Deliver medications separately to each patient. Common carts shall not be used within the patient treatment area to prepare or distribute medications.
- If trays are used to distribute medications, clean them before using for a different patient.
- Intravenous medication vials labelled for single use, including erythropoietin, shall not be punctured more than once. Once a needle has entered a vial labelled for single use, the sterility of the product can no longer be guaranteed.
- Residual medication from two or more vials shall not be pooled into a single vial.

- If a common supply cart is used to store clean supplies in the patient treatment area, this cart shall remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts shall not be moved between stations to distribute supplies.
- Staff members shall wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood).
- Such protective clothing or gear shall be changed if it becomes soiled with blood, body fluids, secretions, or excretions.
- Staff members shall not eat, drink, or smoke in the dialysis treatment area or in the laboratory.
- Patients can be served meals or eat food brought from home at their dialysis station. The glasses, dishes, and other utensils shall be cleaned in the usual manner; no special care of these items is needed.
- Establish written protocols for cleaning and disinfecting surfaces and equipment in the dialysis unit, including careful mechanical cleaning before any disinfection process. If the manufacturer has provided instructions on sterilization or disinfection of the item, these instructions shall be followed. For each chemical sterilant and disinfectant, follow the manufacturer's instructions regarding use, including appropriate dilution and contact time.
- After each patient treatment, clean environmental surfaces at the dialysis station, including the dialysis bed or chair, countertops, and external surfaces of the dialysis machine, including containers associated with the prime waste. Use any soap, detergent, or detergent germicide.
- Between uses of medical equipment (e.g., scissors, haemostats, clamps, stethoscopes, blood pressure cuffs), clean and apply a hospital disinfectant (i.e., low-level disinfection); if the item is visibly contaminated with blood, use a tuberculocidal disinfectant (i.e., intermediate-level disinfection).
- For a blood spill, immediately clean the area with a cloth soaked with a tuberculocidal disinfectant or a 1:100 dilution of household bleach (300-600 mg/L free chlorine) (i.e., intermediate-level disinfection). The staff member doing the cleaning shall wear gloves, and the cloth shall be placed in a bucket or other leak proof container.

- Published methods shall be used to clean and disinfect the water treatment and distribution system and the internal circuits of the dialysis machine, as well as to reprocess dialysers for reuse.
- These methods are designed to control bacterial contamination, but will also eliminate blood-borne viruses. For single-pass machines, perform rinsing and disinfection procedures at the beginning or end of the day.
- For batch re-circulation machines, drain, rinse, and disinfect after each use. Follow the same methods for cleaning and disinfection if a blood leak has occurred, regardless of the type of dialysis machine used.
- Routine bacteriologic assays of water and dialysis fluids shall be performed according to the recommendations.
- Venous pressure transducer protectors shall be used to cover pressure monitors and shall be changed between patients, not reused. If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300--600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse.
- Housekeeping staff members in the dialysis facility shall promptly remove soil and potentially infectious waste and maintain an environment that enhances patient care.
- All disposable items shall be placed in bags thick enough to prevent leakage. Wastes generated by the haemodialysis facility might be contaminated with blood and shall be considered infectious and handled accordingly.

Recommended training on Infection Control in dialysis

(Adapted from CDC guidelines)

Staff Training

Training and education for all employees at risk for occupational exposure to blood shall be provided at least annually, given to new employees before they begin working in the unit, and documented. At a minimum, they shall include information on the following topics:

- Proper hand hygiene technique;
- Proper use of protective equipment;
- Modes of transmission for blood borne viruses, pathogenic bacteria, and other microorganisms as appropriate;
- Infection control practices recommended for haemodialysis units and how they differ from Standard Precautions recommended for other health-care settings;
- Proper handling and delivery of patient medications;
- Rationale for segregating HBs Ag positive patients with a separate room, machine, instruments, supplies, medications, and staff members;
- Proper infection control techniques for initiation, care, and maintenance of access sites;
- Housekeeping to minimize transmission of microorganisms, including proper methods to clean and disinfect equipment and environmental surfaces; and
- Centralized record keeping to monitor and prevent complications, including routine serologic testing results for HBV and HCV, hepatitis B vaccine status, episodes of bacteraemia and loss of access caused by infection, and other adverse events.
- Records of surveillance for water and dialysate quality shall also be maintained.

Patient and Family Member Training

Training and education of patients (or family members for patients unable to be responsible for their own care) regarding infection control practices shall be given on admission to dialysis and at least annually thereafter and shall address the following topics:

- Personal hygiene and hand washing technique;
- Patient responsibility for proper care of the access and recognition of signs of infection, which shall be reviewed each time the patient has a change in access type; and
- Recommended vaccinations

References

- 1 *ISO 23500: 2011: Guidance for the preparation and quality management of fluids for haemodialysis and related therapies. International Organization for Standardization*
- 2 *Centers for Disease Control and Prevention. Recommendations for preventing transmission of infections among chronic haemodialysis patients. MMWR 2001; 50 (No RR-5): 1-43*
- 3 *Centers for Disease Control and Prevention: Infection Control Requirements for Dialysis Facilities and Clarification Regarding Guidance on Parenteral Medication Vials - MMWR August 15, 2008 / 57(32); 875-876*

GLOSSARY

AAMI	Association for the Advancement of Medical Instrumentation
ABS	Acrylonitrile butadiene styrene
ALT	Alanine Transferase
ANSI	American National Standards Institute
CFU	Colony Forming Units
EBCT	Empty Bed Contact Time
ELISA	Enzyme-linked immunosorbent assay
ESA	Erythropoiesis Stimulating Agents
EU	Endotoxin unit
FPS	Feet per second
GMP	Good Manufacturing Practice
Hb	Haemoglobin
HbA1C	Haemoglobin A1C
HBs Ab	Hepatitis B surface Antibody
HBs Ag	Hepatitis B surface Antigen
HCV	Hepatitis C Virus
HD	Haemodialysis
HDF	Haemodiafiltration
HDPE	High Density Polyethylene
HIV	Human Immunodeficiency Virus
IDWG	Interdialytic Weight Gain
iPTH	Intact Parathyroid hormone
ISO	International Organization for Standardization
LAL	Limulus Amoebocyte Lysate
NAT	Nucleic Acid Test
PEX	Cross linked Polyethylene
PIC	Person In Charge
PPM	Planned Preventive Maintenance
RIBA	Recombinant immunoblot assay
RO	Reverse Osmosis
SOP	Standard Operating Procedure
TCV	Total cell volume
TGEA	Trypton Glucose Extract Agar
TIBC	Total Iron Binding Capacity
UF	Ultrafiltration

UKM	Urea Kinetic Modelling
URR	Urea Reduction Ratio

For the purpose of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.



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