
The National Haemodialysis Quality Standards 2018



**MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA**



**MALAYSIAN SOCIETY
OF NEPHROLOGY**

The National Haemodialysis Quality Standards 2018



**MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA**



**MALAYSIAN SOCIETY
OF NEPHROLOGY**

This document was developed by the Malaysian Society of Nephrology in collaboration with the Medical Services Unit, Medical Development Division, Ministry of Health Malaysia and the Drafting Committee for Haemodialysis Quality and Standards

Published in July 2018

A catalogue record of this document is available from the library and Resource Unit of the Institute of Medical Research, Ministry of Health;

MOH/P/PAK/395.18(QAP)

And also available from the National Library of Malaysia;

ISBN 978-967-217322-9



All rights reserved. No part of this publication may be reproduced or distributed in any form or by any means or stored in a database or retrieval system without prior written permission from Malaysian Society of Nephrology and the Director of the Medical Development Division, Ministry of Health Malaysia.

CONTENTS

	Page
Foreword	6
List of Contributors	9
Acknowledgements	11
1 Objectives & Scope	13
1.1. Objectives	
1.2. Scope	
2 Physical Facilities	14
2.1 Introduction	
2.2 Dialysis Room/Area	
2.3 Treatment/Consultation Room	
2.4 Water Treatment Room	
2.5 Reprocessing Room	
2.6 Drainage System	
3 Equipment	16
3.1 Haemodialysis (HD) Machines	
3.2 Haemodiafiltration (HDF) Machines	
3.3 Water Treatment System	
3.4 Dialyser Reprocessing Machine	
4 Dialysis Consumables	23
4.1 Dialysis Concentrate	
4.2 Dialysers	
4.3 Bloodlines	
4.4 Arterio-venous fistula needle	
4.5 Clinical Waste Management	
5 Water Quality	25
5.1. Process of water production	
5.2. Quality Standards	
5.3 Chemical Contaminants	
5.4 Microbial Contaminants	
6 Human Resource	27
6.1 Introduction	
6.2 Person-in-charge (PIC)	
6.3 Nephrologist	
6.4 Registered Nurse/Medical Assistant	

	Page	
7	Monitoring of Dialysis Patient	30
7.1	Monitoring of patients during dialysis	
7.2	Record of dialysis treatments	
7.3	Long-term monitoring of dialysis patients	
8	Infection Control Measures	31
8.1	Introduction	
8.2	Measures to prevent transmission of infection	
8.3	Prevention and Control of Hepatitis B infection	
8.4	Prevention and Control of Hepatitis C infection	
8.5	Prevention and Control of Hepatitis B and C co-infection	
8.6	Prevention and Control of HIV infection	
8.7	Screening and Vaccination of Staff	
9	Outcome Measures and Quality Initiatives in Dialysis	35
9.1	Reporting to National Renal Registry	
9.2	Dialysis Adequacy	
9.3	Anaemia	
9.4	Incident Reporting to Ministry of Health	
10	Dialysis Disaster Quality Management	36
10.1	Mitigation phase	
10.2	Preparedness phase	
10.3	Response	
10.4	Recovery phase	
11	Appendices	38
	Appendix 1: Microbial requirements for haemodialysis and related therapies	38
	Appendix 2: Maximum allowable levels of toxic chemicals and dialysis fluid electrolytes in dialysis water	39
	Appendix 3: Certification Course For “200 Hours Training On Haemodialysis For Registered Medical Practitioners”	40
	Appendix 4: Laboratory investigations schedule for chronic haemodialysis patients	42
	Appendix 5: Infection Control Precautions for all patients	43
	Appendix 6: Recommended training on infection control in dialysis	45
12	References	46
13	Glossary of Terms and Definitions	47

Foreword

By The
Director General of Health Malaysia

Since the first edition of the Haemodialysis Quality and Standards was introduced in the Ministry of Health (MOH) in 1994, the numbers of haemodialysis units have progressively increased every year. This will not pose a major hurdle given the trend seen in the last two decades provided the country's economy continues on the upward trend. While the haemodialysis (HD) services were mainly provided by the public sector in the eighties and nineties, by 2008 MOH was no longer the largest provider of HD services in the country.

Under the Private Healthcare and Facilities Act 1998, haemodialysis services in the private and NGO (non-governmental organisation) sectors are subjected to licensing and monitoring to ensure that basic requirements for safety and standards set by the MOH and professional organisations are met. The 2nd Edition of Haemodialysis Quality and Standards was published in 2012 and this was meant to provide a comprehensive overview to ensure good quality haemodialysis for patients with end stage renal disease (ESRD). While the contents of the PHFA 1998 mainly deal with general principles and basic issues in healthcare facilities, the dialysis community in Malaysia (as represented by MOH and Malaysian Society of Nephrology) has taken the responsibility to produce this important and updated document "Haemodialysis Quality Standards 2018". This document will serve as guidance to enforcement units such as CKAPS/UKAPS (Cawangan/Unit Kawalan Amalan Perubatan Swasta) to ensure acceptable treatment is provided to patients on haemodialysis. It is important that the recommendations are appropriate for the local setting from both standards and economic perspective. This is to ensure that haemodialysis services in this country which started from humble beginnings in the seventies and which have now moved to a respectable position at both regional and international level is maintained.

The number of haemodialysis patients and as a result, the number of haemodialysis centres will continue to grow as the country's population and Gross Domestic Product (GDP) continue to increase for the next decade. A major challenge now confronts all haemodialysis providers in the country is to remain focused on maintaining and improving outcomes through improvement in the quality of treatment that we provide. It is my sincere hope that this document will play an important role and contribute to better care for patients receiving chronic haemodialysis treatment in this country.



Datuk Dr Noor Hisham bin Abdullah

Foreword

By The President Malaysian Society of Nephrology

The renal replacement therapy (RRT) programme in Malaysia started from humble beginnings and has evolved to a very respectable position over the years. The number of patients on RRT has increased manifold over the last few decades. Everyone involved in the provision and management of RRT in Malaysia can be justifiably proud of the progress made over these years. While the achievements to date have been considerable, a lot more needs to be done.

In recent years, a number of features were observed in the annual Malaysian Dialysis and Transplant Registry report which is of great concern. The survival of dialysis patients in recent years is observed to be lower than the earlier years particularly in haemodialysis (HD) patients. This may be attributed to the rapid proliferation of dialysis centres in recent years coupled with inadequate number of trained and experienced staff. As the country's gross domestic product increases so does the number of new patients on dialysis. A major challenge confronting all stakeholders is to focus on improving outcomes through improvements in quality of treatment that we provide.

The 2nd edition of Haemodialysis Quality and Standards was published in 2012. It was meant to provide a comprehensive overview to ensure good quality dialysis for patients with ESRD. This updated version was also intended to provide guidance to enforcement units as reference with regards to implementation of the Private Healthcare and Facilities Act 1998.

However, there were some statements which unintendedly became contentious which resulted in much dispute among practising nephrologists, dialysis providers and the enforcing units. It is our sincere wish that the 3rd edition will provide clarification on some of these issues. Under the facilities chapter the role of direct versus indirect feed is spelt out more clearly. This edition also adds the role of nucleic acid testing for hepatitis B, C and HIV besides conventional serology tests. The previous recommendation regarding single use dialyser practice for dialysis in patients returning from other dialysis centres was revised in accordance with current available evidence and in line with existing practice in other countries. In line with most developed countries where on-site dialysate preparation has become common for convenience and economic reasons, a statement on this has been added. Lastly considerable effort was put into re-defining the more appropriate role and terms of reference for person in-charge (PIC). With the new role of PIC, the objectives of the certification course for 200 hours training on haemodialysis for registered medical practitioners is revised and more in tune with the requirements of PHFA 1998. It is important to emphasise that this course is not intended to provide in-depth knowledge on the clinical management of haemodialysis patients. The clinical management of haemodialysis patients and related complications shall be guided by the in-centre or affiliated nephrologist.

MSN as a professional society and umbrella body representing all nephrologists from MOH, universities and private centres has the moral responsibility to ensure that haemodialysis quality in this country is maintained at a good standard which is not too costly. Hence, MSN has spearheaded this revised and updated version of Haemodialysis Quality and Standards to ensure that all practitioners in Malaysia conform to the required standards. In the process of preparing this edition, 3 public sessions involving stakeholders and dialysis providers (physicians, technicians, dialysis paramedics as well as providers from both the public and private sectors) in this country were held. This edition was finally endorsed by members of MSN in an extraordinary general meeting which was held at Q Sentral, Kuala Lumpur on 6th April 2018.

As this is a national document on the agreed Haemodialysis Quality Standards by MSN which represents all nephrologists in public, private and NGO facilities in this country, the standards and requirement spelt herein will be expected to be applicable to all dialysis facilities in the country. It is our sincere hope that this document will contribute to affordable and quality care for patients undergoing chronic haemodialysis in Malaysia.



Professor Dr Goh Bak Leong

LIST OF CONTRIBUTORS

Editors:

Dato' Dr. Ong Loke Meng
Senior Consultant Nephrologist
Hospital Pulau Pinang

Dr. Hooi Lai Seong
Senior Consultant Nephrologist Hospital
Sultanah Aminah, Johor Bahru

Past Editors:

Datuk Dr. Ghazali Ahmad
Senior Consultant Nephrologist
Hospital Kuala Lumpur

Dr. Rosnawati Yahya
Consultant Nephrologist
Hospital Kuala Lumpur

Dr. Ravindran Visvanathan
Senior Consultant Nephrologist
Hospital Kuala Lumpur

Chapter Contributors:

Malaysian Society of Nephrology

Professor Dr. Goh Bak Leong
President MSN &
Senior Consultant Nephrologist
Serdang Hospital, Selangor

Dr. Sunita Bavanandan
Vice President MSN & Consultant
Nephrologist
Kuala Lumpur Hospital

Dato' Dr. Ong Loke Meng
Immediate Past President MSN &
Senior Consultant Nephrologist
Penang Hospital

Professor Dr. Abdul Halim Gafor
Honorary Secretary & Professor
Department of Medicine
Hospital Universiti Kebangsaan Malaysia
Kuala Lumpur

Ministry of Health

Dr. Hooi Lai Seong
National Head of Service MOH &
Senior Consultant Nephrologist
Hospital Sultanah Aminah, Johor Bahru

Datuk Dr. Ghazali Ahmad
Head of Department &
Senior Consultant Nephrologist
Kuala Lumpur Hospital

Dato' Dr. Tan Chwee Choon
Senior Consultant Nephrologist
Hospital Tengku Ampuan Rahimah
Kelang, Selangor

Dr. Wong Hin Seng
Senior Consultant Nephrologist Hospital
Selayang, Selangor

*Dr. Rosnawati Yahya
Honorary Treasurer &
Consultant Nephrologist
Kuala Lumpur Hospital
Universities*

*Dr. Anita Bhajan Manocha
Consultant Nephrologist
Hospital Seberang Jaya, Penang*

*Associate Professor Dr. Lim Soo Kun
Consultant Nephrologist University Malaya
Medical Centre Kuala Lumpur*

*Associate Professor Dr. Azreen Syazril Adnan
Consultant Nephrologist
Hospital Universiti Sains Malaysia
Kota Bharu, Kelantan*

National Kidney Foundation

*Dato' Dr. Zaki Morad Mohamed Zaher
Chair NKF & Consultant Nephrologist
Ampang Puteri Specialist
Hospital Kuala Lumpur*

*Dr. Lee Wan Tin
Board of Manager NKF & Consultant
Nephrologist Subang Jaya Medical Centre,
Subang Jaya, Selangor*

*Mr. Hj Husin Harun
Senior Dialysis Manager National Kidney
Foundation Petaling Jaya, Selangor*

*Mr. Tan Chor Seong
Senior Dialysis Manager National Kidney
Foundation Petaling Jaya, Selangor*

Private Representatives

*Dr. Prasad Menon
Consultant Nephrologist
Subang Jaya Medical Centre,
Subang Jaya, Selangor*

*Dr. Fan Kin Sing,
Consultant Nephrologist
Gleneagles Intan Medical Centre,
Kuala Lumpur*

*Dr. Philip Jeremiah,
Consultant Nephrologist
Ampang Puteri Specialist Hospital,
Kuala Lumpur*

*Prof Datuk Dr. Tan Si Yen
Consultant Nephrologist
Prince Court Medical Centre Kuala Lumpur*

*Dr. Tan Hee Wu,
Consultant Nephrologist
Tan Medical Renal Clinic
Petaling Jaya, Selangor*

*Dr. Rashidi Saidin
Consultant Nephrologist
Darul Ehsan Medical Centre Shah Alam,
Selangor*

*Dr. Morris Wu
Consultant Nephrologist Gleneagles Intan
Medical Centre Kuala Lumpur*

*Dr. Chow Yok Wai
Consultant Nephrologist Pantai
Ayer Keroh Hospital Melaka*

Association of Dialysis Assistants and Nurses (ADMAN)

*Mr. Tam Chong Chiang
President ADMAN &
Senior Assistant Medical Officer
Health Department of Kuala Lumpur*

*Mr. Charles Lazar
Senior Council Member ADMAN &
Senior Assistant Medical Officer Hospital
Kuala Lumpur*

Other Contributors:

*Associate Professor Dr. Christopher Lim
Consultant Nephrologist
Universiti Putra Malaysia
Serdang, Selangor*

*Dr. Ravindran a/l Visvanathan
Consultant Nephrologist
Department of Nephrology
Kuala Lumpur Hospital*

*Associate Professor Dr. Ng Kok Peng
University Malaya Medical Centre
KUALA LUMPUR*

*Dr. Chong Yip Boon
Consultant Nephrologist
Damansara Specialist Centre Petaling Jaya,
Selangor*

*Dr. Lim Li Han
Consultant Nephrologist
ParkCity Medical Centre
52200, Kuala Lumpur*

*Dr. Ng Eng Khim
Consultant Nephrologist
Ara Damansara Medical Centre
Lot 2, Jalan Lapangan Terbang Subang
Seksyen U2, 40150 Shah Alam*

ACKNOWLEDGEMENTS

Acknowledgement for the contribution and participation in the preparation of this document:

*Datin Dr. Inderjeet Kaur Gill
Senior Principal Assistant Director
Medical Development Division
Ministry of Health Malaysia*

*Dr. Afidah Ali
Deputy Director
Medical Practice Division
Ministry of Health Malaysia*

Representatives from other dialysis providers:

Association of Private Kidney Care Providers of Malaysia

B. Braun Renal Services

Baxter Healthcare (Malaysia)

DaVita Malaysia

Fresenius Medical Care Malaysia

JKS Biomedical

Persatuan Pengusaha Hemodialisis Bumiputera Malaysia

CHAPTER 1: OBJECTIVES & SCOPE

1.1. Objectives

The purpose of this standard document is to define the requirements for haemodialysis centres to achieve the acceptable minimum level of quality, performance, safety and reliability of services provided.

1.2. Scope

The standard covers essential aspects of chronic haemodialysis treatment including physical facilities, equipment, consumables, water quality, human resource, monitoring of dialysis patient, infection control measures and quality measures.

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:

- Dialysis Room/Area
- Treatment/ Consultation Room
- Water Treatment Room
- Reprocessing Room
- Waiting Area
- Storage area/room
- Clinical waster area/room
- Janitor Room
- Toilet
- Drainage system

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 and instruments
- 2.2.3 HCV seropositive patients shall be dialysed in a separate room or a separate area with a fixed partition and dedicated machines
- 2.2.4 HIV seropositive patients shall be dialysed in a separate room or a separate area with a fixed partition with dedicated machines, equipment and instruments
- 2.2.5 Adequate wash basins should be provided for maintenance of good hand hygiene

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
- 2.3.3 A treatment/consultation room shall have a minimum area of 11.1 m²

2.4 Water Treatment Room

- 2.4.1 There shall be a separate room for water treatment. It shall be separated from the dialysis room and all other rooms
- 2.4.2 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
- 2.4.3 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 heat disinfection]
- 2.4.4 There should be floor trap(s) to drain excess water and preferably a curb to prevent flooding

2.5 Reprocessing Room

- 2.5.1 Where dialysers are reused, a separate dialyser reprocessing room shall be available
- 2.5.2 This room shall only be used for dialyser reprocessing, storing of reprocessed dialysers and sterilant
- 2.5.3 Adequate and efficient ventilation shall be in place to reduce inhalation risk
- 2.5.4 There shall be a separate room for reprocessing dialysers of patients with Hepatitis B
- 2.5.5 There shall be a separate room for reprocessing dialysers of patients with Hepatitis C
- 2.5.6 For Hepatitis B & C co-infected patients, please refer to section (3.4.3)

2.6 Drainage system

The dialysate and reprocessing effluent should preferably drain into the sewerage system or alternatively into a covered public drainage system

If drained into a septic tank, 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 applicable regulatory authorities

3.1.3 The machines shall also meet the conditions and regulations set up by the Director General of Health, Malaysia

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

3.1.5 **Power supply**

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

3.1.6 **Back-up (Standby) HD Machine**

- For centres running on full capacity [one (1) machine to six (6) patients], there shall be a minimum of one back-up machine. For every additional block of 10 machines, there shall be an additional back-up machine.
- HD machines dedicated for infected patients are excluded from the full capacity determination

3.1.7 **Disinfection of HD machine**

- 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 and preferably after each haemodialysis session

3.1.8 **Maintenance of HD machine**

- All machines shall have a planned preventive maintenance (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 On-line HDF shall use ultrapure dialysis fluid to produce on-line substitution fluid
- 3.2.3 The quality of the dialysis fluid and substitution fluid shall at least meet AAMI/ISO 23500:2014 and ISO 11663:2014 Standards

Refer to Appendix 1 & 2

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 AAMI 2015/ISO 23500:2014 Standards.

Refer to Appendix 1 & 2

3.3.2 Water distribution system

- Direct feed water distribution system is preferred over indirect feed
- However in some circumstances, indirect feed may be necessary e.g. long distribution loop, areas with frequent water interruptions. If indirect feed is utilised, the treated water storage tank shall comply with the standard described in section 3.3.3 (h)

3.3.3 Basic requirements in a water treatment system

- All centres shall have a water treatment system that delivers water quality that meets the AAMI 2015/ISO 23500:2014 Standards (refer to Appendix 1 and Appendix 2)
- The room that houses the water treatment system shall be located in an area, which minimises the noise and disruption to haemodialysis treatment
- There shall be adequate ventilation to prevent over-heating
- Floor trap(s) 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 labeled
- All columns for pre-treatment shall be opaque

- Pressure gauge shall be installed before and after each component to monitor fouling of the components
- Daily testing for chlorine/chloramine and hardness shall be done every morning prior to starting haemodialysis treatment
- Daily recording of the parameters of water treatment system shall be performed

3.3.4 Components of Water Treatment System

(a) Raw Water Tank

The raw water tank shall:

- be made from appropriate material e.g. stainless steel-grade 316, high-density polyethylene (HDPE)
- be covered
- have a low-level alarm sensor
- be inspected for defects and cleaned at 6 monthly intervals
- have an appropriate capacity that is adequate to enable 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

- A minimum of two carbon columns is recommended
- Empty Bed Contact Time (EBCT) shall be ten (10) minutes in total to optimise total chlorine 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 AAMI 2015/ISO 23500:2014 standard. (Refer to Water Quality)
- Type of RO membrane: Spiral Wound Polyamide, TFC (thin film composite) or Polysulfone or equivalent
- The recovery rate of RO system shall be at least 50%
- The RO membrane rejection rate shall be at least 90%
- Standard water treatment system shall have the following parameters displayed:
 - Conductivity of permeate
 - Permeate flow rate
 - Reject low 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 dialyser-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.
- Maximum size of tank shall be 500 litres
- The UV lamp should be replaced every 12 months
- Ultrafiltration and endotoxin-retentive filters can be included immediately after the storage tank and/or before delivery to the dialyser to remove bacteria and endotoxin (optional)
- Two booster pumps are recommended for channeling 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 minimise or avoid microbiological contamination
- Material of the distribution loop
 - 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
 - except PEX

(j) Disinfection of Distribution Loops

- A minimum of once every six (6) months (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 Dialyser Reprocessing Machine

3.4.1 Introduction

- The reprocessing machine shall be approved by the applicable regulatory authorities
- 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
- Reuse of dialysers beyond 15 times has not been shown to be cost effective

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. Dialysers with TCV<80% or failed the leak test shall not be reused
- The dialyser shall be filled with appropriate concentration of a germicide
- The presence of adequate disinfectant in the reprocessed dialysers shall be checked using 'Potency Test Strip'

- At the end of the day, the machine shall be sanitised
- Every reused dialyser shall be tested for residual disinfectant prior to use

3.4.3 Reprocessing of dialysers 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, dialyser shall not be reused

3.5 Resuscitation equipment

- 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

CHAPTER 4: DIALYSIS CONSUMABLES

4.1 Dialysis Concentrate

4.1.1 Commercially prepared dialysate

- Commercially prepared dialysate concentrate (solution or powder) shall be accompanied by a certificate of analysis from an accredited laboratory or supplied by producers with a valid GMP/ISO certificate and approved by applicable regulatory authority (ISO 13958:2014)
- Unused liquid bicarbonate concentrate should be discarded at the end of the day

4.1.2 On-site dialysate preparation

4.1.2.1 Use of commercially prepared dialysate concentrate solution is preferred.

4.1.2.2. If on-site dialysate preparation and/or central dialysate distribution is utilised:

- the system shall be fully automated and shall comply with the ISO 23500:2014, ISO 13958:2014, ISO 11663:2014 and other applicable standards or regulatory requirements
- the centre shall establish a standard operating procedure (SOP) to ensure that safety and quality standards are maintained

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

- Name of manufacturer
- Contents
- Concentration of electrolytes
- Dialysate concentration ratio
- Expiry date

4.2 Dialysers

4.2.1 Dialysers used for haemodialysis treatment shall be approved by applicable regulatory authorities

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 applicable 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 applicable regulatory authority

4.5 Clinical Waste Management

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

CHAPTER 5: WATER QUALITY

5.1 Process of water production

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

5.2 Quality standards

Water quality shall comply with the minimum standards of AAMI 2015/ISO 23500:2014.

Refer to Appendix 1 & 2

5.3 Chemical Contaminants

5.3.1 Permissible levels of chemical contaminants shall be observed and adhered to
Refer to Appendix 2

5.3.2 Method of Testing

- Total chlorine 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 Frequency of Testing

- Total chlorine and water hardness should be tested at least daily
- Chemical analysis of water should be tested at least 6 monthly in an accredited laboratory

5.3.4 Site of Testing

- Testing for total chlorine shall be performed after the first carbon column
- Testing for hardness after softener column
- Water for chemical analysis shall be collected 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 to Appendix 2)

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

5.4.6 Laboratory

All samples shall be sent to an accredited laboratory recognised 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 Introduction

This section defines the pre-requisite qualifications and responsibilities of the key personnel of a haemodialysis unit

6.2 Person-in-charge (PIC)

6.2.1 Definition

The person-in-charge (PIC) as defined in the Private Healthcare Facilities And Services Act 1998 means a person possessing such qualification, training and experience as may be prescribed and who shall be responsible for the management and control of the private healthcare facility or service to which a licence or registration relates. The PIC is the person held legally responsible in the Act to manage, control, maintain and operate the haemodialysis unit and punitive measures may be taken against the PIC who violates the Act.

6.2.2 Qualification

- The PIC of a haemodialysis centre shall be a nephrologist except:
- in areas where there is a critical need for haemodialysis services, the PIC may include physician/paediatrician and if this is not possible any Registered Medical Practitioner (RMP) who is licensed with or without recognised post-graduate training and he/she has completed not less than 200 hours of recognised training in haemodialysis treatment and maintains an affiliation with a nephrologist

(Refer to Appendix 4)

6.2.3 Responsibilities

Responsibilities of the PIC shall include (but not limited to):

- ensuring proper functioning and maintenance of the facility and equipment
- ensuring that the centre complies to the norms and standards required
- ensuring that each patient has a nephrologist to assume all or part of the medical care of the patient
- visits the centre at least once a month
- ensuring that there are standing arrangement with other medical practitioners to provide immediate medical care, essential life-saving measures and

implementing emergency procedures on any person requiring such treatment or services in the event that the PIC is not available

- ensuring the safety of patients and staff of the haemodialysis unit
- periodically review of policy and procedures
- If the PIC is not a nephrologist, the PIC should consult with the affiliated nephrologist on management of haemodialysis patients as the PIC do not have in-depth knowledge necessary to provide adequate care independently

6.3 Nephrologist

6.3.1 Definition

A nephrologist is a physician who has completed a recognised post-graduate training in nephrology in an accredited centre and registered with the National Specialist Register

6.3.2 Qualifications

A nephrologist shall be registered and comply with the conditions stipulated in the National Specialist Register

6.3.3 Responsibilities

Responsibilities of the nephrologist shall include (but not limited to):

- advise on the facilities, equipment and staffing requirements of the centre
- advise on policies and standards for haemodialysis treatment in conformity with the requirements of the regulations and/or any nationally accepted guidelines
- plan clinical management of the dialysis patients
- prescribing haemodialysis treatments. All haemodialysis treatment shall be prescribed by a nephrologist.
- review each individual patient at least once in every three months. Such review shall be comprehensive and shall include but not limited to clinical examination, review of blood and other test results and medications
- recommend changes or modifications to treatment as deemed necessary from time to time in order to maintain the quality of care
- visits the centre at least once every 3 months.

6.4 Registered Nurse/Medical Assistant

6.4.1 Qualifications

- 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.
- The six (6) months training and the certification program shall be as recognised by the Director General of Health

6.4.2 Responsibilities

Responsibilities of the trained registered nurse/medical assistant shall include (but not limited to)

- performing haemodialysis treatment. Haemodialysis treatment and care shall be performed by a registered nurse or a registered medical assistant with training and experience in haemodialysis treatment and care.
- monitoring of haemodialysis patients
- administration of medications
- supervising other nursing staff. 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
- care of dialysis equipment and systems
- education of haemodialysis patients and their families

6.4.3 Dialysis Manager

It is desirable for the dialysis manager to have at least 2 years working experience in a dialysis center and is certified in renal nursing

6.4.4 Staff-to-patient ratio

- 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 registered nurse/medical assistant with at least six months training in haemodialysis treatment and care in each shift
- There shall be at least one (1) registered nurse/medical assistant with training in cardiopulmonary resuscitation techniques in each shift

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
- Vital signs during dialysis : blood pressure, pulse and temperature
- Vascular access

7.2 Records of dialysis treatments

Each dialysis treatment shall be recorded

7.3 Long-term monitoring of dialysis patients

7.3.1 Blood Investigations

Blood investigations shall be performed at regular intervals or more frequently if necessary. The minimum frequency is listed in Appendix 4

7.3.2 Dialysis Adequacy

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

CHAPTER 8: INFECTION CONTROL MEASURES

8.1 Introduction

- 8.1.1 All haemodialysis centres shall have stringent measures to minimise the risk of cross-infection amongst haemodialysis patients

8.2 Measures to prevent transmission of infection

8.2.1 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. Refer to Appendix 5 for suggested infection control measures

8.2.2 Infection Control Training and Education

Training and education is recommended for both staff members and patients (or their family and care givers). (Refer to Appendix 5)

8.2.3 Patients with increased risk of infection

The following may increase the risk of blood borne viral infection in the haemodialysis unit:

- New patients with an unknown viral status
- Patients with history of recent transfusion of blood/ blood products
- Patients with negative viral status returning from another haemodialysis facility with higher risk of blood borne viral infections

8.2.4 Measures for preventing cross infection

Measures to prevent cross infection from the patients with increased risk of infection until the viral status is known may include:

- A machine that is dedicated for an unknown viral status or a machine for serology negative patient at the last shift
- Single use of dialyser
- Serology testing:
 - Monthly ALT testing for at least 3 months would facilitate earlier detection of new HCV infections
 - If ALT is elevated repeat anti-HCV. If anti-HCV remains negative, HCV NAT (nucleic acid testing) can facilitate earlier diagnosis of HCV

8.3 Prevention and Control of Hepatitis B infection

8.3.1 Testing for hepatitis B

The following patients shall be tested for HBsAg:

- New patients with an unknown viral status
- Patients who were negative for anti-HBs with history of recent transfusion of blood/ blood products
- Patients with negative HBsAg and negative anti-Hbs returning from another haemodialysis facility with higher risk of hepatitis transmission

8.3.2 Serology Testing HBsAg

- If negative: HBsAg shall be re-tested at least every six (6) months

Anti HBs

- Patients who are HBsAg negative and HBs Ab negative shall be vaccinated. (Refer to section 8.3.4 for vaccine schedule)
- Anti HBs shall be repeated at least yearly in patients who have responded to hepatitis vaccination
- If anti HBs Ab < 10 mIU/ml a booster dose should be given

8.3.3 Vaccination Schedule

- A four (4) doses double-strength vaccination schedule is recommended at zero (0), one (1), two (2) and six (6) months according to manufacturer recommendation
- 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-immunised. Re-immunisation consists of one to three (1-3) doses, after which if they remain negative are unlikely to respond to additional doses

8.3.4 Isolation

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

- 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 Prevention and Control of Hepatitis C infection

8.4.1 Testing for hepatitis C

The following patients shall be tested for anti-HCV antibody:

- New patients with an unknown viral status
- Patients with history of recent transfusion of blood/ blood products
- Patients with negative viral status returning from another haemodialysis facility with higher risk of hepatitis

8.4.2 Serology testing:

- Anti-HCV screening should be made with immunoassay test (e.g. ELISA) and/or nucleic acid testing (NAT)
- In anti-HCV negative patients, immunoassay shall be repeated at least every 6 months
- If anti HCV is indeterminate, confirmation can be made with nucleic acid testing (NAT)
- Confirmed Hepatitis C infected patients do not require repeated serological test

- 8.4.3 All confirmed 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

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

8.5 Prevention and Control of 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 dialysed in a Hepatitis B isolation facility during the last shift

8.6 Prevention and Control of HIV infection

- 8.6.1 Patients shall be tested for anti-HIV antibody and/or NAT:
- Before initiating first haemodialysis treatment
 - After returning from another haemodialysis facility if necessary
- 8.6.2 In HIV negative patients, serologic test shall be performed at least every 6 months
- 8.6.3 HIV positive patients shall be isolated in a separate room. They shall be dialysed using separate machines, equipment, instruments and single use items
- 8.6.4 Dialyser shall not be reused
- 8.6.2 The licensee/person-in charge shall notify the Ministry of Health of any cases of HIV seroconversion

8.7 Screening and Vaccination of Staff

- 8.7.1 Haemodialysis staff should be screened for blood borne viruses before working in the HDU
- 8.7.2 Staff who are HBsAg negative shall be vaccinated:
- if HBs antibody is non-reactive, a full course of vaccination shall be given
 - HBs antibody should be retested 1-2 months after the last dose of the hepatitis vaccine
 - if post-vaccination anti-Hbs antibody is < 10 Miu/ml, the vaccine series should be repeated and antibody retested 1-2 months after second series
 - if post-vaccination anti-Hbs antibody is ≥ 10 Miu/ml, periodic testing or booster doses of vaccination is not required
- 8.7.3 Staff who are positive for Hepatitis B, Hepatitis C or HIV shall not be involved in the exposure prone procedures on patients in the HD centre

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 Dialysis Adequacy

- Dialysis adequacy shall be assessed with Kt/V or URR
- 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 (TSAT)
 - > 80% achieved TSAT > 20%

9.4 Incident Reporting to Ministry of Health

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

CHAPTER 10: DIALYSIS DISASTER QUALITY MANAGEMENT

10.1 Mitigation phase

- The centre should prepare a standard operating procedure (SOP) on Dialysis Disaster
- PIC should risks stratify the unit in relation to the potential disaster whether at high, moderate or low risks
- High risks and moderate risks dialysis centers should identify and inform the relevant authorities to facilitate patient transfer in the event of disaster
- Patients data should be regularly updated inclusive of latest blood parameter, medication lists and contact numbers
- Dialysis equipment and facilities should be readily available to be transferred to safe place if needed

10.2 Preparedness phase

- Medical records and dialysis equipment should be placed in safe areas
- Patients and relatives should receive information on the nearest Dialysis Disaster Relief Centers and mode of safe transfer
- Exercise or drills should be conducted to ensure hemodialysis staffs, patients and relevant agencies understand the procedure
- Regular communications with the relevant authorities should be observed in preparation of evacuation

10.3 Response

- PIC and haemodialysis staff should ensure patients receive uninterrupted haemodialysis treatment throughout the disaster period
- Patient whereabouts should be tracked and be documented
- Ensure dialysis equipment and patients clinical records stored at safe place and review the need to relocate.
- Continuously communicate with the relevant authorities on latest disaster situation.
- PIC/Dialysis manager should provide latest information on the HD unit status with regards to the damages, patients, staffs and utilities disruptions to the relevant health authorities

10.4 Recovery phase

- Assessment of facility and equipment damages should be made and documented
- Prior to recommencing operation:
 - water treatment and delivery system and haemodialysis equipment should be disinfected
 - water analysis, biochemical test should be reviewed and verified
- Viral serology testing for patients should be sent and reviewed

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 ⁶	<0.03
Substitution Fluid	<10	<0.03

Source : ANSI/AAMI 2015/ISO 23500:2014

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 0.01	
	(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

Source : ANSI/AAMI 2015/ISO 23500:2014

Certification Course for “200 hours training on haemodialysis for registered medical practitioners”

Introduction

With the implementation of the Private Healthcare Facilities and Services Act 1998 (PHFSA Act), there was a need for Person-in-charge (PIC) of haemodialysis centres to be trained. Due to the lack of qualified nephrologists, registered medical practitioners (RMP) with 200-hour training and experience in haemodialysis treatment were permitted to fulfill the role of the PIC.

This certification course is designed to enable RMPs who are not qualified nephrologists to fulfill their roles and responsibilities as person-in-charge (PIC) of a haemodialysis centre.

Eligibility requirements

1. Physician registered with the Specialist Register of Malaysia
2. Other registered medical practitioners from areas with a critical need for haemodialysis services may be eligible

Learning Objectives

At the end of the course, the medical practitioner should be able to understand the:

1. responsibilities of the person in charge as described in rules and regulations of the private healthcare facilities act (PHFSA) and the National Haemodialysis Standards
2. requirements specified in the National Haemodialysis Standards
3. set up, operations and licensing requirements of a haemodialysis centre
4. basics of chronic kidney disease and end stage kidney disease
5. basic principles in the management of haemodialysis patients
6. basic principles in the management common acute and chronic complications of haemodialysis

Note: The course is not intended to provide in-depth knowledge on management of the haemodialysis patients. As such the management of haemodialysis patients and complications of haemodialysis shall be guided by the affiliated nephrologist.

Program Modules

The program comprises a theory section and a clinical attachment at an accredited haemodialysis centres.

1. **Theory**

1.1. Course

The course may be conducted face-to-face or as distance learning

1.2. Exit assessment

2. Clinical attachment at accredited haemodialysis centres

The program may be updated from time-to-time. Updates will be available on the Malaysian Society of Nephrology website

Laboratory investigations schedule for chronic haemodialysis patients

TESTS	MINIMUM FREQUENCY
Full blood count	3 monthly
Iron Study: (Ferritin, TSAT)	6 monthly
Urea (pre & post dialysis)	3 monthly
Renal Function Test	3 monthly
Liver Function Test (Albumin, ALT, ALP)	3 monthly
Calcium, phosphate	3 monthly
Fasting iPTH	6 monthly
Fasting Serum Lipid	Yearly
Blood sugar	3 monthly (diabetics) 6 monthly (non-diabetics)
HbA1C (if diabetics)	6 monthly (diabetics)
Virology (refer to section 8.3 and 8.4 for details)	
HBs Ag	6 monthly
Anti HBs titre	Yearly
Anti HCV	6 monthly (in patients Hep C negative)
Anti HIV	6 monthly (in patients HIV negative)

ALP=alkaline phosphatase, ALT=alanine transaminase, anti-HBs=anti-hepatitis B surface, anit-HBsAg=hepatitis B surface antigen, anti-HCV=anti-hepatitis C, anti-HIV=anti-human immunodeficiency virus, HbA1C=glycosylated haemoglobin, PTH=intact parathyroid hormone, TSAT=transferrin saturation

Infection Control precautions for all patients

(Adapted from CDC guidelines)

- Proper hand hygiene 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 labeled for single use, including erythropoietin, shall not be punctured more than once. Once a needle has entered a vial labeled 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 dialysers, 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 sterilisation 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, 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 HDUs and how they differ from Standard Precautions recommended for other health-care settings
- Proper handling and delivery of patient medication
- 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 minimise transmission of microorganisms, including proper methods to clean and disinfect equipment and environmental surfaces
- Centralised record keeping to monitor and prevent complications, including routine serologic testing results for HBV and HCV, Hepatitis B vaccination 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 hygiene 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
- Recommended vaccinations

References

1. ISO 23500:2014 Guidance for the preparation and quality management of fluids for haemodialysis and related therapies
2. ISO 11663:2014 Quality of dialysis fluid for haemodialysis and related therapies
3. ISO 13958:2014 - Concentrates for haemodialysis and related therapies
4. Centers for Disease Control and Prevention. Recommendations for preventing transmission of infections among chronic haemodialysis patients. *MMWR* 2001; 50 (No RR-5): 1-43
5. 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 OF TERMS AND DEFINITIONS

AMI	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
HDU	Haemodialysis unit
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
PHFSA	Private Healthcare Facilities and Services Act
PHYSICIAN	Qualified physician or paediatrician recognised by National Specialist Register
PIC	Person In Charge
PPM	Planned Preventive Maintenance
PSI	Per square inch

RO	Reverse Osmosis
SOP	Standard Operating Procedure
TCV	Total cell volume
TGEA	Trypton Glucose Extract Agar
TIBC	Total Iron Binding Capacity
TSAT	Transferrin Saturation
UF	Ultrafiltration
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.

MINISTRY OF HEALTH MALAYSIA

MEDICAL DEVELOPMENT DIVISION

Block E1, Parcel E, Federal Government Administrative Centre,
62590 Putrajaya, Malaysia.

Tel : 603-8883 1047 Fax : 603-8883 1427

ISBN 978-967-2173-22-9

