MOH/P/PAK/625.26(GU) - e

# THE NATIONAL HAEMODIALYSIS QUALITY STANDARDS



2026

MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

MALAYSIAN SOCIETY OF NEPHROLOGY

Third Edition

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 2026

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/625.26(GU) - e

And also available from the National Library of Malaysia;

eISBN 978-629-94836-1-8

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.

Published by:

**MEDICAL DEVELOPMENT DIVISION**
**MINISTRY OF HEALTH MALAYSIA**
**7th FLOOR, BLOCK E1, COMPLEX E, 62590**
**WILAYAH PERSEKUTUAN PUTRAJAYA**

**TABLE OF CONTENT**


| | | Page |
|---|---|---|
| **Foreword** | | **1** |
| **List of Contributors** | | **4** |
| **1** | **Objectives & Scope** | **7** |
| | 1.1 Objectives | |
| | 1.2 Scope | |
| **2** | **Physical Facilities** | **8** |
| | 2.1 Introduction | |
| | 2.2 Facilities | |
| | 2.3 Dialysis room/area | |
| | 2.4 Water treatment room | |
| | 2.5 Reprocessing room/area | |
| | 2.6 Waiting area | |
| | 2.7 Dry storage area/room | |
| | 2.8 Clinical waste area/room | |
| | 2.9 Clinical examination and treatment room | |
| | 2.10 Medicine preparation room/area | |
| | 2.11 Nurse station | |
| | 2.12 Hand washing facilities | |
| | 2.13 Resuscitation facilities | |
| | 2.14 Drainage facilities | |
| | 2.15 Lavatories | |
| | 2.16 Janitor's room | |
| **3** | **Equipment** | **13** |
| | 3.1 Haemodialysis (HD) machines | |
| | 3.2 Haemodiafiltration (HDF) machines | |
| | 3.3 Water treatment system | |
| | 3.4 Dialyser reprocessing machine | |
| | 3.5 Resuscitation equipment | |
| | 3.6 Pharmaceutical refrigerator | |
| **4** | **Dialysis Consumables** | **19** |
| | 4.1 Dialysate | |
| | 4.2 Dialysers | |
| | 4.3 Endotoxin retention/dialysate filter | |
| | 4.4 Bloodlines | |
| | 4.5 Arterio-venous fistula needle | |
| | 4.6 Clinical waste management | |
| **5** | **Water Quality** | **21** |
| | 5.1. Process of water production | |
| | 5.2. Quality standards | |
| | 5.3 Chemical contaminants | |
| | 5.4 Microbial contaminants | |
| | 5.5 Documentation | |

**6 Human Resource** **23**
6.1 Introduction
6.2 Person-in-charge (PIC)
6.3 Nephrologist
6.4 Registered nurse/Assistant Medical Officer (AMO)
6.5 Dialysis manager
6.6 Nurse/AMO with post basic qualification in renal nursing
6.7 Nurse/AMO without post basic qualification in renal nursing
6.8 Staff-patient ratio
6.9 Training

**7 Monitoring of Dialysis Patient** **27**
7.1 Introduction
7.2 Monitoring of patients during dialysis
7.3 Dialysis treatment
7.4 Long-term monitoring of dialysis patients

**8 Infection Control Measures** **30**
8.1 Introduction
8.2 Prevention of infection in HD units
8.3 Prevention and control of droplet and airborne disease
8.4 Prevention and control of hepatitis B infection
8.5 Prevention and control of hepatitis C infection
8.6 Prevention and control of hepatitis B and C co-infection
8.7 Prevention and control of HIV infection
8.8 Screening and vaccination of staff
8.9 Vaccination for haemodialysis patients
8.10 Catheter related blood stream infection (CRBSI)
8.11 Infection control audit

**9 Quality Initiatives in Dialysis** **36**
9.1 Introduction
9.2 Outcome measures
9.3 Process measures
9.4 Safety indicators
9.5 Clinical audit
9.6 Incident reporting
9.7 Continuous quality improvement (CQI)
9.8 Disaster preparedness

**Appendices** **41**
- Appendix 1: Maximum allowable levels of toxic chemicals and dialysis water
- Appendix 2: Prevention of infection in HD units
- Appendix 3: Clinical pathway of HBV seroconversion (HBsAg-negative to HBsAg-positive)
- Appendix 4: Clinical pathway of HCV seroconversion

**References** **48**

# Foreword
# By The Director General of Health

Kidney disease remains a significant public health challenge in Malaysia. With one of the highest rates of end-stage kidney disease in the region, and a growing dialysis population that continues to place demands on both public and private healthcare systems, ensuring that haemodialysis services are delivered to the highest possible standard has never been more important.

The ***National Haemodialysis Quality Standards 2026*** represents a timely and necessary effort to strengthen the framework within which dialysis care is provided across Malaysia. Developed through the collaborative expertise of the Malaysian Society of Nephrology, the Medical Development Division of the Ministry of Health, and a broad coalition of nephrologists, nurses, allied health professionals, and technical experts, this document reflects a shared commitment to safe, equitable, and effective kidney care for all Malaysians.

This updated standards document is comprehensive in its scope. It addresses the full breadth of haemodialysis service delivery — from the physical design of dialysis units and the quality of water used in treatment, to staffing requirements, infection control, patient monitoring, and continuous quality improvement. Crucially, it also serves a regulatory function as a reference for enforcement under the Private Healthcare Facilities and Services Act 1998, reinforcing the Ministry of Health's commitment to accountability and consistent standards across all facility types, whether public, private, university-based, or community-run.

The Ministry of Health Malaysia is committed to a healthcare system that leaves no patient behind. Safe and effective dialysis is not a privilege — it is the right of every patient with end-stage kidney disease, regardless of where they receive their care. These standards are a foundation upon which that right can be upheld. I encourage all haemodialysis service providers, clinical teams, and regulators to embrace this document not merely as a compliance tool, but as a living guide to excellence in patient care.

I wish to express my sincere appreciation to the working group, external reviewers, and all stakeholders who contributed their time, expertise, and dedication to the preparation of this document. The Ministry of Health is proud to endorse the *National Haemodialysis Quality and Standards 2026* and looks forward to its full and effective implementation across Malaysia.



**Datuk Dr Mahathar Abd Wahab**
Director General of Health Malaysia

# Foreword
# By The President
# Malaysian Society of Nephrology

Haemodialysis remains a life-sustaining therapy for many patients with end stage kidney disease (ESKD), and the quality of dialysis care has a direct impact on patient survival, safety, dignity, and overall well-being. As the number of patients requiring dialysis continues to grow, it is increasingly important that haemodialysis services in Malaysia are delivered according to clear, practical, and consistently applied standards.

The ***National Haemodialysis Quality Standards 2026*** represents an important effort to strengthen the delivery of haemodialysis care across the country. This document provides a comprehensive overview of the essential requirements for good-quality dialysis, covering areas that are fundamental to safe and effective treatment. These include patient assessment, dialysis prescription, adequacy of dialysis, vascular access care, infection prevention, water quality, equipment maintenance, medication safety, emergency preparedness, staffing, training, documentation, audit, and continuous quality improvement.

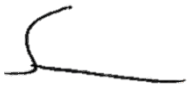
Beyond its clinical relevance, this updated document also serves an important regulatory and operational purpose. It is intended to provide guidance to enforcement units as a reference in the implementation of the Private Healthcare Facilities and Services Act 1998. In this regard, the standards outlined here are not merely aspirational, but should support consistent interpretation, practical implementation, and fair assessment of haemodialysis facilities. A shared understanding between care providers, regulators, facility operators, and professional bodies is essential to ensure that standards are applied in a manner that is both robust and realistic.

The Malaysian Society of Nephrology recognises that dialysis care is delivered across diverse settings, including public, university, private, and non-governmental community-based centres. While facilities may differ in resources and operational models, the fundamental principles of patient safety, treatment adequacy, infection control, ethical practice, and accountable governance must remain universal. This updated document therefore aims to provide a balanced framework that supports high standards while remaining relevant to real-world practice.

Quality dialysis is not achieved through infrastructure alone. It depends on competent and committed multidisciplinary teams, including nephrologists, person-in-charge (PIC), nurses, dietitians, pharmacists, administrators, and support staff. It also requires active patient engagement, clear communication, reliable monitoring systems, and a culture that encourages learning from gaps and improving care continuously. Standards should therefore be viewed not as a checklist exercise, but as a foundation for better outcomes and safer patient-centred care.

I would like to acknowledge the dedication of the working group and reviewers who have reviewed, updated, and refined this document. Their collective expertise, practical experience, and commitment to improving kidney care have made this important update possible. Special thanks to all the stakeholders, including representative from CKAPS who attended the townhall meeting on 11 April 2026. I also wish to recognise the ongoing efforts of dialysis teams throughout Malaysia, whose daily work sustains the lives of thousands of patients.

It is my hope that the ***National Haemodialysis Quality Standards 2026*** will serve as a practical, authoritative, and unifying reference for all stakeholders involved in haemodialysis care. Through consistent implementation of these standards, we can continue to improve the quality, safety, equity, and sustainability of dialysis services for patients with ESKD in Malaysia.



**Professor Dr Lim Soo Kun**
President
Malaysian Society of Nephrology

# List of Contributors

**Chair**
Dr Loh Chek Loong
Consultant Nephrologist
Hospital Raja Permaisuri Bainun

**Co-Chair**
Dr Rosnawati Yahya
Consultant Nephrologist
Sunway Medical Care
Kuala Lumpur

Assoc. Prof. Dr Ruslinda Mustafar
Consultant Nephrologist
Hospital Canselor Tuanku Muhriz,
Faculty of Medicine,
Universiti Kebangsaan Malaysia.

**Working Group**
Dato' Dr Anita Bhajan Manoca
Consultant Nephrologist
Hospital Seberang Jaya

Dr Thong Kah Mean
Consultant Nephrologist
Hospital Raja Permaisuri Bainun

Dr Suryati bt Yakob
Consultant Nephrologist
Hospital Kuala Lumpur

Assoc Prof Dr Wan Ahmad Hafiz bin Wan Md Adnan
Consultant Nephrologist
Universiti Malaya

**Working Subgroup**

A Suhaili Bin Shahri
Assistant Medical Officer
Hospital Kuala Lumpur

Dr Azhani Akmar binti Azhar
Consultant Nephrologist
KPJ Damansara Specialist Hospital

Dr Chan Chee Eng
Consultant Nephrologist
Hospital Tengku Ampuan Afzan

Dr Fong Voon Ken
Consultant Nephrologist
Gleneagles KL

Dr Hashvina a/p Sukesh
Consultant Nephrologist
Hospital Selayang

Dr Kong Boon Huei
Consultant Nephrologist
Hospital Seberang Jaya

Dr Leong Chong Men, Bryan
Consultant Nephrologist
Sunway Medical Centre Penang

Dr Low Jer Ming
Consultant Nephrologist
Mawar Specialist Hospital

Muhammad Hafiz Azizie Bin Mustapha
Nurse Ward Manager
Pusat Perubatan Universiti Malaya

Sarudin Bin Zainul
Assistant Medical Officer
Hospital Selayang

Dr Teoh Guik Lee
Consultant Nephrologist
Hospital Pulau Pinang

Dr Wong Chun Mun
Consultant Nephrologist
Pantai Hospital Penang

Dr Wong Koh Wei
Consultant Nephrologist
Hospital Queen Elizabeth

Dr Zuad Firdaus bin Rafiah
Consultant Nephrologist
Hospital Raja Perempuan Zainab II

**External Reviewers**

Prof Dr Abdul Halim Ghafoor
Consultant Nephrologist
Universiti Kebangsaan Malaysia

Prof Dr Christopher Lim Thiam Seong
Consultant Nephrologist
Universiti Putra Malaysia

Datuk Dr Ghazali Ahmad
Consultant Nephrologist
Institut Jantung Negara

Dr Hooi Lai Seong
Consultant Nephrologist
National Renal Registry

Dr Lee Yee Yan
Consultant Nephrologist
Hospital Raja Permaisuri Bainun

Dr Liew Boon Seng
Consultant Nephrologist
Klinik Dr Choo & Liew, Sabah

Prof Dr Lim Soo Kun
Consultant Nephrologist
Universiti Malaya

Dato' Dr Ong Loke Meng
Consultant Nephrologist
Island Hospital Penang

Dr Philip Jeremiah
Consultant Nephrologist
Ampang Putri Hospital

Dr Sunita Bavanandan
Consultant Nephrologist
National Renal Registry/NKF

Dr Syed Faisal Taha
Consultant Nephrologist
Aurelius Hospital

Dr Tan Li Peng
CMO/Consultant Nephrologist
DaVita Malaysia

Dr Thiruventhiran a/l Thilaganathan
Consultant Nephrologist
Sunway Medical Care KL/NKF

Dr Wan Hasnul Halimi Wan Hassan
Consultant Nephrologist
Hospital Raja Perempuan Zainab II

Dr Yudisthra M Ganeshadeva
Consultant Nephrologist
KPJ Johor Specialist Hospital

**External Technical Reviewers**

Charles a/l Lazar
Assistant Medical Officer
ADMAN

Foo Chin Jin
Managing Director
JKS Biomedical

Jesonpragash a/l Gnaniah
Managing Director
Dream Gateway Travel & Tours Sdn Bhd

Ong Chai Thiam, Jason
Managing Director
Nipro Malaysia

Tam Chong Chiang
Senior Dialysis Manager
Pahang Buddhist Association Haemodialysis Centre

# CHAPTER 1: OBJECTIVES AND SCOPE

## 1.1 Objectives

The purpose of this standard document is to define the requirements for haemodialysis units to achieve an acceptable minimum level of quality, performance, safety and reliability in the 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 patient
- Infection control measures
- Quality measures

# CHAPTER 2: PHYSICAL FACILITIES

## 2.1 Introduction

The establishment of a haemodialysis unit shall comply with the Private Healthcare Facilities and Services Act 1998 (Act 586) and its relevant 2006 Regulations and the latest requirements stipulated in the *National Haemodialysis Quality Standards 2026*. Regulatory oversight and enforcement shall fall under the authority of Cawangan Kawalan Amalan Perubatan Swasta (CKAPS).

## 2.2 Facilities

2.2.1 The unit should be free from undue noise and should not be exposed to excessive smoke, foul odours and dust

2.2.2 In the hospital setting, the facility should avoid outpatient traffic through inpatient areas. It should also avoid traffic through to any other service, diagnostic or administrative facility

2.2.3 Appropriate facilities and equipment shall be provided, commensurate with the clinical procedures and services provided in the facility

2.2.4 There shall be proper signage and labelling system to inform the public on the type or nature of facilities or services provided in the unit

2.2.5 The infrastructure shall be adequate to facilitate all haemodialysis activities

2.2.6 The unit shall have adequate ventilation by windows, ducts or mechanical means when deemed necessary

2.2.7 It shall be free from the harbourage of rodents and insects

2.2.8 The electric supply shall be appropriate and have adequate electrical sockets for all the equipment. Adaptors, extension cords or junction boxes shall not be used. Adequate lighting features for the illumination of all areas are essential. Back-up power for HD machines shall be available.

2.2.9 The water supply shall be safe and fulfil the standards required for haemodialysis

2.2.10 The physical facilities shall include:

- Dialysis room/area
- Water treatment room
- Reprocessing room/area
- Waiting area
- Storage area/room
- Storage area for clinical waste
- Clinical examination and treatment room
- Medication preparation room/area
- Nurse station
- Hand-washing facilities

- Resuscitation facilities
- Drainage facilities
- Lavatories
- Janitor room

## 2.3 Dialysis room/area

2.3.1 The dialysis treatment area shall have adequate space to accommodate the number of treatment stations

2.3.2 There shall be adequate space for a dialysis machine, bed or dialysis chair and this space shall not be less than 4.5$m^2$ for each station to allow unhindered movement of personnel and resuscitation equipment whenever needed

2.3.3 The layout should have facilities for protecting patients' privacy

2.3.4 The door size (clear opening) shall be more than 1.2m to facilitate the easy transport of patients on trolleys/wheelchair

2.3.5 The dialysis room shall have an adequate ceiling height of more than 2.4m if air-conditioned and at least 3.0m

2.3.6 Facilities which manage patients with known blood-borne viruses (e.g. HBsAg, HCV, HIV seropositive patients) shall provide separate dialysis rooms, with dedicated machines, equipment, instruments, single-use items and medications, as well as separate hand-washing facilities (Refer Chapter 8)

2.3.7 The dialysis room shall have medical equipment including weighing scale and blood pressure monitors

2.3.8 A nurse call system shall be made available in the dialysis room/area

2.3.9 Facilities for handwashing and alcohol-based hand rub/sterilant dispensers shall be made available and easily accessible in all patient areas

## 2.4 Water treatment room

2.4.1 There shall be a separate room to house a water treatment system which delivers water quality that meets the ISO 23500:2024 Standards

2.4.2 The water treatment room shall be appropriately sized to house all the components of the water treatment system to facilitate daily parameters logging by staff and movement of technicians for maintenance

2.4.3 A schematic diagram of the water treatment system shall be available and displayed in the water treatment room

2.4.4 Refer to section 3.3 for detail requirements of the water treatment system

2.4.5 There shall be floor trap(s) to drain excess water and preferably a curb to prevent overflow to other areas

2.4.6 The room shall be adequately ventilated to avoid extreme temperature excursions

## 2.5 Reprocessing room/area

2.5.1 In units practising reprocessing, a separate area for reprocessing of dialysers is recommended, preferably a room

2.5.2 This room shall only be used for dialyser reprocessing, storage of reprocessed dialysers and sterilant

2.5.3 The room shall have adequate ventilation with installation of an exhaust fan to allow air discharge to avoid cross circulation and contamination of air-supply

2.5.4 It should have a workbench to accommodate the dialyser reprocessor machine and a sink with a sideboard and drainage

2.5.5 Treated and untreated water supply should be labelled accordingly at the workbench

2.5.6 All reuse dialysers once reprocessed, shall be individually placed in containers (labelled with patients' name, number of reuse and date) and stored in designated storage racks

## 2.6 Waiting area

2.6.1 This common area shall be used for all patients who are waiting for or had completed dialysis treatment and the caregivers

2.6.2 Sufficient space shall be provided, appropriate with the workload of the facility

2.6.3 Audio-visual entertainment, educational booklets and reading materials may be provided

## 2.7 Dry storage area/room

2.7.1 Appropriately sized area/room shall be provided for storage of supplies, consumables and equipment

2.7.2 It shall have adequate ventilation with installation of an exhaust fan if required

## 2.8 Clinical waste area/room

2.8.1 Shall house the clinical waste awaiting disposal

2.8.2 Shall have designated containers for infectious and non-infectious waste

2.8.3 Shall have enough water-tight containers which are impervious, non-absorbent, and easily washable for disposal of the consumables used for dialysis treatment

2.8.4 Shall be used to keep all contaminated sharp instruments before disposal. All such instruments shall be placed in puncture-resistant sealed sharp bins at the site of use and the container with its contents shall be disposed of by incineration

2.8.5 Refer to Section 4.6 for details of management of clinical waste

## 2.9 Clinical examination and treatment room

2.9.1 The haemodialysis unit shall have a separate treatment room for minor clinical procedures

2.9.2 There shall be facilities and equipment for the treatment and care of patients commensurate with the clinical procedures conducted within the facility

2.9.3 The recommended area is at least 11.1$m^2$ with a clear door opening size of more than 1.2m

2.9.4 This room shall have a hand-washing facility with hands-free tap

2.9.5 It shall have an examination and treatment couch with a screen or curtain for patient's privacy

## 2.10 Medicine preparation room/area

2.10.1 There shall be a sufficient workspace for preparation of dialysis start-up kit/injections and medication

2.10.2 A locked cabinet for dangerous drugs shall be made available if necessary

2.10.3 A pharmaceutical refrigerator with attached thermometer and log, should be available for storage of erythropoiesis stimulating agent (ESA) and cold-chain medication

2.10.4 There shall be hand-washing facilities within the room or nearby

2.10.5 There shall be no test reagents, general disinfectants, cleaning agents and similar products in this room or area

## 2.11 Nurse station

2.11.1 There shall be sufficient space for a workstation for on-duty nurses and technicians

2.11.2 The station should be designed to allow unobstructed view of all patient treatment areas for constant monitoring of patients. It shall be easily accessible for timely action in emergencies

2.11.3 The station shall have the facilities for writing and recording patients' clinical notes and charts

2.11.4 Internet facilities shall be available for notification and for data entry for the existing dialysis registry

## 2.12 Hand-washing facilities

2.12.1 Shall be available in the dialysis room/area and separate facilities shall be available for hepatitis/HIV room/area

2.12.2 Clinical sinks with hands-free elbow taps shall be made available

## 2.13 Resuscitation facilities

2.13.1 The resuscitation equipment shall include but not limited to cardiac monitoring device with defibrillator, bag-valve-mask, suction apparatus, a laryngoscope, endotracheal

tube, drugs commonly used in medical emergency and oxygen supply, which shall be easily accessible

2.13.2 An Automated External Defibrillator (AED) is an alternative to having a defibrillator

2.13.3 A list of items in the resuscitation cart shall be made available

2.13.4 The required intravenous medication shall include IV adrenaline, IV atropine sulphate, IV sodium bicarbonate, IV hydrocortisone, IV chlorpheniramine, IV 50% Dextrose, IV 0.9% saline and IV calcium gluconate

2.13.5 There shall be documented evidence that the items in the resuscitation cart are rechecked at regular intervals

## 2.14 Drainage facilities

2.14.1 Drainage systems shall be constructed using chemically resistant, non-corrosive materials capable of withstanding exposure to dialysis effluent, disinfectants and cleaning agents, such as high-density polyethylene (HDPE)

2.14.2 The dialysate and reprocessing effluent should drain into a separate drainage system/tank with adequate capacity to handle the volume

2.14.3 The number of bends in the pipelines should be kept to a minimum and blind loops be avoided

2.14.4 All drainage systems should be connected directly to the main drainage line in a straight line without bends or blind loops

## 2.15 Lavatories

2.15.1 There should be adequate number of toilets for patients including for the disabled, accompanying persons and staff preferably separately for males and females

2.15.2 The toilet should have a nurse call button/system bell, hand washing facilities and grab bar

2.15.3 The opening of the toilet door should be at least 0.9m and should not swing inward

2.15.4 The toilets should have an incombustible waste-paper receptable with removable impervious liner

## 2.16 Janitor’s room

2.16.1 Serves as a designated area for the cleaning, disinfection, and storage of housekeeping equipment (e.g. mops, buckets, cleaning carts), detergents, disinfectants, and chemical agents

2.16.2 Allows proper handling of spills involving blood, dialysate, or body fluids in a controlled environment

# 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 Endotoxin retention filter for the dialysate shall be used for all haemodialysis machines

3.1.4 For patients with Hepatitis B, Hepatitis C, HIV and any co-infected patients, a separate dedicated machine shall be used for each category of patient

3.1.5 **Power supply**

- There shall be a mechanism to ensure backup power supply for returning blood from the extra-corporeal circuit in the event of power failure
- The power supply for the haemodialysis machine shall use 3-pin plug suitable for local usage

3.1.6 **Back-up (standby) HD machine**

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

3.1.7 **Disinfection and decalcification of HD machine**

- The external surfaces of the HD machines, as well as dialysis chairs/beds, cardiac tables, BP cuffs shall be disinfected after each dialysis session
- Rinse machine after each haemodialysis 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 and shall follow the manufacturers' guidelines for individual machine
- Decalcification/descaling should be performed at the end of the day or according to the manufacturers' guidelines

3.1.8 **Maintenance of HD machine**

- All machines shall have a planned preventive maintenance (PPM) and technical safety check according to manufacturers' recommendations
- There shall be a logbook on the maintenance and repairs of all major equipment

## 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 The quality of the dialysate and on-line substitution fluid shall meet the ISO 23500:2024 standards (Refer to 5.4.5)

## 3.3 Water treatment system

### 3.3.1 Introduction

- Water treatment system must be well designed, maintained and monitored to prevent any complication that may arise from chemical and microbiological contamination
- All units shall adhere to the standards for maximum allowable chemical, bacterial and endotoxin contamination based on minimum requirements of ISO 23500:2024 Standards (Refer to section 5.4.5 and Appendix 1)

### 3.3.2 Water distribution system

- Direct feed water distribution system is preferred over indirect feed
- However, indirect feed may be considered in units with long distribution loop or 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 and 3.3.4 (h)

### 3.3.3 Basic requirements in a water treatment system

- All units shall have a water treatment system that delivers water quality which meets the ISO 23500:2024 Standards (Refer to Appendix 1)
- The room that houses the water treatment system shall be 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 labelled
- 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. high-density polyethylene (HDPE), stainless steel-grade 316, or equivalent
- Opaque and covered

- Placed in a clean and safe environment with direct feed from the nearest water supply
- Equipped with a low-level alarm sensor
- Of appropriate capacity that is adequate to enable one shift of treatment to be completed if water supply is disrupted
- Inspected for defects and dirt particles, and cleaned at 6 monthly intervals

**(b) Raw water pump**

- Two stainless steel raw water pumps are recommended

**(c) Multimedia sediment filter (Pre-filter/sand filter)**

- Removes large particles 5-500 microns to prevent fouling of devices further downstream
- The filter shall be opaque to prevent growth of algae
- The filter elements must have pressure gauges at the inlet and outlet to detect pressure drop as an indicator of fouling
- Backwash is required 1-3 times per week or depends on raw water quality

**(d) Carbon columns**

- A minimum of two carbon columns in a series configuration is recommended
- Empty Bed Contact Time (EBCT) shall be ten (10) minutes in total to optimise total chlorine removal.
- Change in water flow rate or carbon tank volume necessitate recalculation of the EBCT
- Backwash is required 1-3 times per week and the process shall be done individually for each column by adjusting the timer 1-2 hours apart

**(e) Softener column**

- Removes calcium and magnesium by ion exchange to prevent hard water syndrome and scaling of the RO membranes
- The softener column shall be placed before or after the carbon column bearing in mind the advantages and disadvantages
- Consist of polymer resin, which will be regenerated by sodium chloride from a brine tank
- A brine tank is located adjacent to the water softener, and it contains salt pellets and water, creating a supersaturated salt solution which is used for softener regeneration
- Use only pharmaceutical-grade or high purity food-grade (>99% NaCl purity) salt for water softeners
- On daily basis, check the hardness of water softener effluent, confirm adequate quantity of sodium chloride in brine tank and check the clock on the regeneration timer

**(f) Guard filter**

- Removes particles between 1-5 microns in diameter

- Safeguards the reverse osmosis unit pump and membranes from clogging
- Casing shall be opaque
- Filter shall be replaced:
  - When there is a differential pressure drop before and after the guard filter exceeding manufacturer's recommendation
  - As a prophylactic measure against excess bacterial growth based on manufacturers' recommendation

**(g) Reverse Osmosis (RO) module**

- The RO product water shall fulfil the ISO 23500:2024 standard
- Type of RO membrane: spiral wound polyamide, TFC (thin film composite) or polysulfone or equivalent
- The recovery rate of RO system refers to the percentage of feedwater that is successfully purified and 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 and raw water
  - Permeate flow rate
  - Reject and recovery percentage
  - 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 raw water tank- sampling is only required in certain situation (e.g. when there is suspected contamination of municipal water)
  - 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 (if available)
  - On the machine at the dialysate sampling port (for HDF, where available)
- *For larger units (e.g., more than 10 dialysis stations), the use of a heat-disinfection system for the reverse osmosis (RO) module may be considered as an alternative to routine chemical disinfection. Heat disinfection offers advantages including enhanced biofilm control, reduced chemical usage, and environmental benefits, provided that the RO system components are*

*designed to withstand thermal disinfection and that operational costs are taken into account.*

**(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
- Maximum size of tank shall be 500 litres
- Tank shall be covered with tight fitting lid and fitted with Ultraviolet Irradiator for destruction of bacteria that shall be replaced every 12 months
- Two booster pumps are recommended for channelling the RO water
- There shall be a hydrophobic air vent with a bacterial filter (0.45um or less vent filter)
- Another ultrafiltration/endotoxin-retentive filters must be included immediately after the storage tank
- All filters (0.2 micron) shall be changed quarterly or as per manufacturers' specification

**(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
- The design shall meet the following criteria:
  - Continuous loop (linear configuration) with as short a journey as possible
  - Minimum number of connections and branches
  - Minimise the distance between the loop and the connection points to the machines
  - Avoid dead zones
  - Minimum pressure drops
  - Marked sampling points:
    a) First point in the distribution loop
    b) Last point in the distribution loop
    c) Last point of the dialyser-reprocessing loop
- Material of the distribution loop
  - Varies from cross-linked polyethylene (PEX), stainless steel (high grade 316L) or equivalent, and these materials are suitable for heat disinfection
  - Does not leech chemical substances (copper, aluminium, lead, zinc etc) into the product water
  - Low surface roughness

- Opaque

**(j) Disinfection of distribution loops**

- Chemical disinfection of distribution loop including the connections to dialysis machines shall be done using peracetic acid 2-3% or chlorine dioxide especially when materials of distribution loop are not heat resistant as per manufacturer's recommendations (Usually every 3-6 monthly)
- 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:
  a) Installation of new system
  b) Upgrading of existing system
  c) Out-break of pyrogenic reaction
  d) Breach of the closed loop system
  e) When microbial testing of treated water reaches action level (refer section 5.4.5)

## 3.4 Dialyser reprocessing machine

Reprocessing machine shall be:

- Fully automated integrated unit capable to clean, test and fill the dialyser with disinfectant, and approved by the applicable regulatory authorities
- Able to test for total cell volume (TCV), membrane integrity and perform disinfection as per AAMI standard
- Able to perform automatic dilution of sterilant to a specified strength
- Able to autofill sterilant into dialyser after TCV/Leak test

## 3.5 Resuscitation equipment (Refer 2.13)

## 3.6 Pharmaceutical refrigerator

3.6.1 A pharmaceutical grade refrigerator is preferred to manage cold-chain medication, such as ESA and vaccines. However, a chiller with temperature monitoring can be considered as an alternative

3.6.2 The thermometer should be capable of showing the current, minimum and maximum temperature reached over a time period and must be documented daily

# CHAPTER 4: DIALYSIS CONSUMABLES

## 4.1 Dialysate

### 4.1.1 Commercially prepared dialysate

- Commercially prepared or ready-made dialysate concentrate 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 the applicable regulatory authority
- Each package shall have the following information labelled:
    - Name and address of manufacturer
    - Contents and concentration of electrolytes
    - Date of manufacture and expiry

### 4.1.2 Central Dialysate Delivery Systems (CDS/CDDS)

- CDS/CDDS is a system designed for centralized dialysate preparation and distribution to multiple dialysis stations. The system shall be designed as a closed-loop, continuously circulating configuration to minimise stagnation
- Such systems shall only be implemented in facilities with adequate infrastructure, technical expertise, and quality assurance mechanisms to ensure patient safety
- The system shall comply with latest international standards (e.g., ISO 23500 series) and applicable national regulations
- Routine monitoring shall include microbiological testing, endotoxin testing and chemical analysis according to standards
- Personnel operating CDS/CDDS shall be appropriately trained in system operation, monitoring, and troubleshooting and be competent in dialysis water quality and infection control principles

## 4.2 Dialysers

4.2.1 Dialysers used for haemodialysis treatment shall comply with the design requirement and standard as approved by regulatory authorities in USA, Europe, Japan or Medical Device Authority (MDA) registration

4.2.2 Dialysers made from biocompatible membrane shall be used

## 4.3 Endotoxin retention/dialysate filter

4.3.1 An endotoxin retention filter shall be in place when a high flux dialyser is used

4.3.2 In HDF, a second filter is required. This filter shall be changed regularly, according to the manufacturer's recommendations

## 4.4 Bloodlines

4.4.1 Bloodlines used for haemodialysis treatment shall be approved by MDA

4.4.2 Bloodlines shall not be re-used

4.4.3 All lines (infusion, heparin, and main lines) should be equipped with clamps and line connections should be of luer-lock type

4.4.4 The priming volume of the blood lines in adults is between 100-150ml. However, the combined priming volume of blood line and dialyser should not exceed 10% of the patient's total blood volume

4.4.5 The priming volume of the blood lines in children should be appropriate for the size of the child

## 4.5 Arterio-venous fistula needle

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

## 4.6 Clinical waste management

4.6.1 The disposal of clinical waste shall be in accordance with Guidelines on the Handling & Management of Clinical Waste in Malaysia by Department of Environment, Ministry of Natural Resources and Environment 3rd Edition 2009

4.6.2 Refuse and hazardous waste shall be kept in impervious, non-absorbent and easily washable containers with tight fitting lids

4.6.3 The unit shall maintain an adequate number of such containers for clinical waste required for disposal

4.6.4 Separate designated containers are required for disposal of infectious waste

4.6.5 It shall comply with good safety practices when handling of non-infectious waste

4.6.6 Handling of all hazardous waste shall be in accordance with the above-mentioned guidelines to protect persons and environment

4.6.7 Handling of non-infectious waste shall be in accordance with safety practice and related law

4.6.8 Infectious disease prevention control measures shall be practised to prevent cross infection

# 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 ISO 23500:2024 (Refer to Appendix 1)

## 5.3 Chemical contaminants

Permissible levels of chemical contaminants shall be observed and adhered to (Refer to Appendix 1)

### 5.3.1 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

### 5.3.2 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

### 5.3.3 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

### 5.3.4 Action if limits exceeded

- Evaluate water treatment system and rectify as necessary

### 5.3.5 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 count (colony forming units) shall use heterotrophic plate count using various available and standard culture media
- The presence of pyrogen/endotoxin shall be determined using Limulus Amoebocyte Lysate (LAL) method

### 5.4.2 Frequency of testing

- Weekly for newly installed water treatment system as part of validation until a pattern of stability is demonstrated
- Monthly for bacterial count and endotoxin test
- For HD unit using HDF treatment, dialysate endotoxin and microbial colony forming unit shall be performed monthly

### 5.4.3 Sites of sampling

Minimum sites of sampling for testing

a) Post RO membrane

b) First point of the distribution loop

c) End point of distribution loop (last machine port)

d) Reprocessing bay (for indirect feed)

e) Dialysis fluid sampling port where available (for HDF treatment)

### 5.4.4 Handling of water sample

- Assay within 30 minutes of collection
- If immediate assay is not possible, refrigerate immediately at 5$^{o}$C and assay within 24 hours of collection

### 5.4.5 Limits and action level

- Current recommended microbial purity in water quality

| Solution | ISO 23500:2024 | | | |
|---|---|---|---|---|
| | Viable count (CFU/ml) | | Endotoxin (EU/ml) | |
| | Limit | Action | Limit | Action |
| Dialysis water | < 100 | 50 | < 0.25 | 0.125 |
| Dialysate/dialysis fluid | < 100 | 50 | < 0.5 | 0.25 |
| Ultra-pure dialysis fluid | < 0.1 | - | < 0.03 | - |
| Substitution fluid | $< 10^{-6}$ | - | < 0.03 | - |

- 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

## 5.5 Documentation

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 (PHSFA) 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.
- In HD units not governed by PHSFA, the above definition is not applicable. Refer to Nephrology SOP MOH/P/PAK/574.25(BK) 2025 for hospitals under Ministry of Health (MOH)

### 6.2.2 Qualification

- The PIC of a haemodialysis unit shall be:

  a) A nephrologist or

  b) A paediatric nephrologist or

- In areas where there is a need for haemodialysis services,

  a) A physician (Internal Medicine/Emergency/Family Medicine/Paediatrician) who has completed not less than 200 hours of recognised training in haemodialysis treatment and maintains an affiliation with a nephrologist, or

  b) A registered Medical Practitioner (RMP) other than those listed above who has completed not less than 200 hours of recognised training in haemodialysis treatment and maintains an affiliation with a nephrologist

- Refer to the MSN website on 200hrs training programme for further details

### 6.2.3 Responsibilities

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

- Ensures proper functioning and maintenance of the facility and equipment
- Ensures that the unit complies with the norms and standards required
- Ensures that each patient has a nephrologist to assume all or part of the medical care of the patient
- Visits the unit at least once a month
- Ensures that there are standing arrangements with other medical practitioners (if the PIC is not available) to consult during medical emergencies
- Ensures the safety of patients and staff

- Periodically reviews policies and procedures
- If the PIC is not a nephrologist, the PIC shall consult the affiliated nephrologist on management of patients
- Ensures staff and patient education programme is readily available
- Reviews and assesses performance of unit and implements improvements for quality care

## 6.3 Nephrologist

### 6.3.1 Definition

A nephrologist is a physician/paediatrician 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):

- Advises on the facilities, equipment and staffing requirements of the unit
- Ensures policies and standards for haemodialysis treatment conforms with the regulatory requirements and/or any nationally accepted guidelines
- Plans clinical management and dialysis prescription of the dialysis patients
- Reviews 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 medication
- Recommends changes or modifications to treatment as deemed necessary from time to time to maintain the quality of care
- Ensures the data submitted to the National Renal Registry (NRR) is complete and accurate
- Reviews and updates the kidney transplant status of the dialysis patients regularly into Malaysia Kidney Allocation System (MyKAS)

## 6.4 Registered nurse/Assistant Medical Officer (AMO)

The staff in haemodialysis unit shall include:

a) Dialysis manager
b) Nurse/AMO with post basic qualification in renal nursing
c) Nurse/AMO without post basic qualification in renal nursing

## 6.5 Dialysis manager

### 6.5.1 Definition

a) A registered nurse/ AMO with post basic qualification in renal nursing

b) It is desirable for the dialysis manager to have at least 2 years working experience in a dialysis unit

#### 6.5.2 Responsibilities

Responsibilities of the dialysis manager shall also include (but not limited to):

a) Clinical oversight:
   - Ensures compliance to regulatory bodies
   - Operational and facility management
   - Stock and inventory management
   - Ensures Planned Preventive Maintenance (PPM) in a timely manner

b) Quality assurance and compliance
   - Ensures incidents are reported in a timely manner
   - To conduct quality improvement and patient safety
   - Timely submission of registry data

c) Staff supervision and human resources

d) Financial and administrative management

e) Patient and family engagement
   - Coordinates communication between patients/ family, nurses, PIC and NIC

g) Coordination and stakeholder engagement

h) Emergency preparedness

### 6.6 Nurse/AMO with post basic qualification in renal nursing

#### 6.6.1 Responsibilities

Responsibilities of the nurse/AMO shall include (but not limited to):

a) Performs haemodialysis treatment

b) Monitors haemodialysis patients during treatment at regular intervals

c) Performs regular blood test and to alert the NIC/PIC for abnormal results

d) Administers medication prescribed by NIC/PIC

e) Cares and maintains the dialysis equipment and systems

f) Provides health education to patients and their families

### 6.7 Nurse/AMO without post basic qualification in renal nursing

#### 6.7.1 Requirement

- Evidence of privileging to be able to perform haemodialysis treatment
- Under supervision of post basic renal trained nurse/AMO

## 6.8 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 in each shift, there should be at least one registered Nurse/AMO with post basic qualification in renal nursing

## 6.9 Training

All clinical staff shall be trained in basic life support

# CHAPTER 7: MONITORING OF DIALYSIS PATIENT

## 7.1 Introduction

- Monitoring of dialysis patients shall be holistic which includes (but is not limited to)
  a) Management of acute and chronic complications of dialysis
  b) Evaluating treatment adequacy
  c) Monitoring and care of dialysis access
  d) Tracking clinical outcomes
  e) Preventive measure e.g., vaccinations
  f) Other complication/co-morbidities
- All dialysis patients shall be reviewed by a nephrologist at least once in every three (3) months

## 7.2 Monitoring of patients during dialysis

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

- Adequate history and physical examination related to the patient's general health and any specific complaints
- Review of any intra-dialytic complications
- Dialysis clinical charts, including vital signs before, during, and after dialysis: blood pressure, pulse, temperature, and oxygen saturation (if required)
- Status of vascular access
- Results of recent investigations
- Complications associated with long-term haemodialysis treatment, including nutritional status
- Review of current kidney transplant status
- Fluid adherence and volume assessment
- Weight monitoring
- Medications prescribed to the patient

## 7.3 Dialysis treatment

### 7.3.1 Dialysis prescriptions

Dialysis prescriptions for each patient shall be made available. This prescription shall include dialysis treatment parameters such as:

- Dry weight
- Blood flow rate (Qb)
- Dialysate flow rate (Qd)

- Target ultrafiltration (UF)
- Filtration rate (Qf) for HDF
- Type and dose of anticoagulation
- Vascular access
- Dialysis duration and frequency
- Type and size of dialyser
- Dialysate composition, especially dialysate Ca
- Dialysate temperature
- Medications given during dialysis (e.g., erythropoietin, intravenous iron)

#### 7.3.2 Dialysis records

Dialysis records shall include the above prescription and:

- Pre and post weight
- UF volume
- Ultrafiltration volume rate (ml/kg/hour)
- Online Kt/V (if done) and convective volume (in HDF)
- Blood pressure and pulse
- Presence of any intra-dialytic complications and immediate action taken
- Machine parameters - venous pressure, transmembrane pressure and total filtration rate

## 7.4 Long-term monitoring of dialysis patients

### 7.4.1 Blood investigations

Blood investigations as listed below shall be performed at regular intervals

| Tests | Minimum frequency |
|---|---|
| Full blood count | 3 monthly |
| Iron study | 3-6 monthly |
| Blood urea (pre and post dialysis) | 3 monthly |
| Renal function test | 3 monthly |
| Liver function test | 3 monthly |
| Calcium and phosphate | 3 monthly |
| Fasting iPTH (intact parathyroid hormone) | 3-6 monthly |
| Fasting serum lipid | 6-12 monthly |
| Blood sugar | 3 monthly |
| HbA1c (if diabetics) | 3-6 monthly |
| Hep BsAg, Anti HCV, HIV | Refer chapter 8 |

### 7.4.2 Dialysis adequacy

Dialysis adequacy shall be monitored/measured and ensured at least once in every

three (3) months

(a) Small molecule clearance

Measuring small molecule clearance can be calculated using sKt/V or Urea Reduction Ratio (URR). The target delivered spKt/V shall be more than 1.2 or the target URR shall be more than 65%

(b) Other parameters reflecting dialysis adequacy are as below

- Optimisation of renal anaemia
- Optimisation of CKD-related mineral bone disease
- Optimisation of nutritional status
- Volume and blood pressure management
- Residual kidney function

# CHAPTER 8: INFECTION CONTROL MEASURES

## 8.1 Introduction

8.1.1 In HD unit, infections can spread through several modes:

a) Blood-borne transmission

b) Contact transmission

c) Airborne/droplet transmission

8.1.2 The following factors increase the risk of blood-borne viral (BBV) infections in the unit:

a) Inadequate infection control practices

b) Patients' factors:

- New patients with unknown viral status
- Patients with a recent blood/blood product transfusion
- Patients who are at risk:
  - Patients with negative viral status returning from another HD unit with uncertain infection control practices
  - Recent exposure to infected individuals

c) Inadequate vaccination uptake

## 8.2 Prevention of infection in HD units

### 8.2.1 Introduction

- All HD units shall implement stringent measures to minimise the risk of cross-infection amongst patients
- Training and education are recommended for staff members, patients, as well as their families and caregivers

### 8.2.2 Pre-admission screening

- Screening of BBV infections shall be carried out before the patient and staff are accepted into the HD unit.
- Tests include Hepatitis B surface Antigen (HBsAg), Hepatitis B surface antibody (anti-HBs), Hepatitis C antibody (anti-HCV) and Human Immunodeficiency virus (HIV) antibody
- Testing for Hepatitis B core antibody (anti-HBc) is recommended

### 8.2.3 Standard infection control practices (refer Appendix 2)

### 8.2.4 Prevention of infection transmission through direct contacts (refer Appendix 2)

## 8.3 Prevention and control of droplet and airborne disease

Additional transmission-based precautions should be undertaken to prevent droplet and airborne diseases

| | Droplets | Airborne |
|---|---|---|
| Size | >5 µm | ≤5 µm |
| Organism | N. meningitidis, H. influenzae, S. pneumoniae, B. pertussis, C. diphteriae, Coronavirus, Influenza, Parainfluenza, Enterovirus, Adenovirus, Rhinovirus, Mumps, Rubella virus, Respiratory syncytial virus | Mycobacterium tuberculosis*, Measles, Varicella-zoster, Aspergillus, Histoplasma, Toxoplasma, L. pneumophila, Covid 19 |
| Mode of transmission | • Close contact via respiratory droplets generated during coughing, sneezing and talking.<br>• The particles do not remain suspended in the air and do not travel long distance | Inhalation of aerosolized particles that remain suspended in the air for prolonged periods, especially in enclosed or poorly ventilated spaces. |
| Patient placement (in order of preference) | • Single-patient room<br>• Cohort (> 3 ft spatial separation) | • Airborne infection isolation room (AIIR) with special ventilation capabilities (if available)<br>• Single room with good ventilation and door closed<br>• Cohort |
| Prevention of spread* | • Patients should wear a surgical mask<br>• Limit transport and movement of patients<br>• Patients should be educated on respiratory hygiene/cough etiquette<br>• Immunise susceptible persons from vaccine-preventable infection | |
| Staff | • Staff should wear appropriate PPE, include mask, face shield, cap, shoe cover and appropriate gown<br>• Use surgical mask for droplets precautions; but use N95 respirator (fit tested) for airborne precautions | |

*Refer Appendix 2

## 8.4 Prevention and control of hepatitis B infection

### 8.4.1 Testing for hepatitis B

| Tests | Notes |
|---|---|
| HBsAg | • Shall be checked upon admission<br>• HBsAg negative → to check at least 6-monthly<br>• Patients with chronic HBV infection (HBsAg positive) shall undergo annual testing, with concurrent anti-HBs testing, to monitor for HBsAg loss and serological status |
| Anti-HBs | • Shall be checked at least annually<br>• More frequent if indicated, to monitor response to vaccination |
| Anti-HBc | • Testing:<br>(a) Is recommended to be checked upon admission to dialysis unit<br>(b) In patients who have failed to mount an appropriate response (anti-HBs level of ≥ 10 mIU/ml) after two courses of hepatitis B vaccination |

| | |
|---|---|
| | (c) To differentiate between natural (past infection) or vaccine induced immunity<br>(d) Before undergoing kidney transplantation<br>(e) Before administration of immunosuppression therapy<br><br>• If anti-HBc is positive, further HBV DNA testing is recommended<br>(a) For patients with HBV DNA positive, they:<br>▪ Shall be dialysed with a dedicated machine for patients with Hep BsAg positive<br>▪ Follow the recommendations for HBV positive patients<br>(b) For patients with HBV DNA negative, they:<br>▪ Shall be vaccinated if anti-HBs negative<br>▪ May be dialysed at negative slot, last shift with single use dialyser<br>▪ Repeat HBV DNA testing may be warranted to monitor for infection reactivation |

### 8.4.2 Vaccination schedule

- For those who are anti-HBs negative, three to four intramuscular (IM) doses (double strength) shall be administered based on the manufacturer's recommendations
- Serum anti-HBs titre shall be rechecked 1-2 months after completion of the vaccination course
- HBsAg testing should not be performed within 4 weeks of Hep B vaccination to avoid a false positive result
- Anti-HBs > 10 mIU/mL is considered protective. However, a higher antibody level ( > 100 mIU/mL) may be desired
- Patients who do not acquire an anti-HBs response after the primary vaccination shall undergo re-immunisation. If they still fail to develop a response, they are unlikely to benefit from additional doses (non-responder)
- In a previously vaccinated patient, if anti-HBs levels fall < 10mIU/ml, a booster dose of the vaccine should be administered

### 8.4.3 Isolation

- All HBsAg positive patients are considered infectious and shall be isolated in a separate room
- They shall be dialysed using dedicated machines, equipment and instruments to prevent cross-contamination
- Haemodialysis staff caring for HBsAg positive patients shall not care for other patients at the same shift
- Single-use dialyser is mandatory

### 8.4.4 Management of HBV seroconversion (HBsAg-negative to HBsAg-positive)

- In this event, the PIC shall notify the Ministry of Health
- Refer Appendix 3 for suggested clinical pathway

## 8.5 Prevention and control of hepatitis C infection

### 8.5.1 Testing for hepatitis C

| Test | Notes |
|---|---|
| Anti-HCV | • Shall be checked upon admission and then at least 6-monthly<br>• Consider intensify testing in patients at risk (refer 8.1.2); with monthly ALT monitoring for 3-6 months. If ALT levels are elevated (unexplained), repeat early anti-HCV testing<br>• If the anti-HCV result is indeterminate or positive, confirmation shall be done using HCV RNA PCR or HCV Core Antigen (HCVcAg) |
| HCV RNA | • Testing anti-HCV together with HCV RNA provide early confirmatory diagnosis<br>• Patients with low level of anti-HCV and negative HCV RNA could be due to false positive Anti-HCV result. |

### 8.5.2 Isolation

- All HCV positive patients shall be isolated in a separate room or physically separated with a fixed partition
- They shall be dialysed using HCV dedicated machines, equipment, instruments
- Single -use dialyser is mandatory

### 8.5.3 Management of HCV seroconversion

- In the event of confirmed Hep C seroconversion, the PIC shall notify the Ministry of Health.
- Refer Appendix 4 for suggested clinical pathway of HCV seroconversion

### 8.5.4 Management of patients with hepatitis C

- All patients with HCV positive shall be evaluated for direct acting antiviral (DAA) therapy; co-manage with hepatologist/gastroenterologist
- HD patients who achieved sustained virological response (SVR) shall undergo repeat testing every 6 months using HCV RNA PCR to detect possible re-infection
- These patients shall be dialysed:
  - Via a dedicated SVR machine (preferred) or
  - At first shift of a dedicated HCV machine or
  - At last shift on a negative machine

## 8.6 Prevention and control of hepatitis B and C co-infection

- Combined hepatitis B & C infected patients shall be isolated
- Shall be dialysed using dedicated machine
- If the isolation room for combined hepatitis B & C is not available, the patient shall be dialysed in a hepatitis B isolation room during the last shift
- Single-use dialyser is mandatory

## 8.7 Prevention and control of HIV infection

### 8.7.1 Testing for HIV Ag-Ab combo test

In HIV-negative patients, a serological test shall be performed at least 6-monthly

### 8.7.2 Isolation

- HIV positive patients shall be isolated in a separate room
- They shall be dialysed using dedicated machines, equipment, instruments, and single-use items, following the recommendations of the MOH
- Single use dialyser is mandatory

### 8.7.3 Management of HIV seroconversion

- In the event of confirmed HIV seroconversion, the PIC shall notify the Ministry of Health.

### 8.7.4 Management of patients with HIV infection

- The decision to initiate/continue antiretroviral treatment for HIV positive HD patients should be based on similar grounds as HIV positive patients in the general population
- Refer to an Infectious Disease physician for appropriate antiviral therapy

## 8.8 Screening and vaccination of Staff

8.8.1 HD staff shall be screened for BBV before working in the HD unit.

8.8.2 If they are found to have BBV infectious disease, their general duties and obligation medical practices shall comply with MMC Guidelines

8.8.3 Staff who are HBsAg negative with anti-HBs < 10 mIu/ml shall be vaccinated

8.8.4 Repeat testing may be required after exposure to BBV

## 8.9 Vaccination for haemodialysis patients

- HD patients are immunocompromised, making them more susceptible to infections.
- Recommended vaccination in dialysis population is summarized below

| Vaccine | Indication | Dose Recommendation | Priority Category |
|---|---|---|---|
| Influenza (Inactivated) | Prevent seasonal flu and complications | Annually | Highly recommended |
| Pneumococcal | Prevent invasive pneumococcal disease | • PCV13/15 (single dose), followed by PPSV23 8 weeks later; and repeat PPSV23 every 5 yrs OR | Highly recommended |

| | | | |
|---|---|---|---|
| | | • PCV20 (single dose) | |
| COVID-19 | Reduce severe disease and mortality | Primary series + boosters per guideline | Highly recommended for non-vaccinated patients |
| Respiratory Syncytial Virus (RSV) | Prevent RSV pneumonia | Adjuvanted vaccines | Highly recommended age $\geq$ 60 years old |
| Herpes Zoster | Prevent shingles/ postherpetic neuralgia | Recombinant vaccine 2 doses (2-6 months apart) | Highly recommended age ≥ 50 years old |
| MMR (Measles, Mumps, Rubella) | For non-immune patients (pre-transplant) | 1-2 doses | Suggested |
| Varicella | Prevent severe chickenpox in seronegative patients | 2 doses (4-8 weeks apart) | Suggested |
| Meningococcal | Protect against meningitis and sepsis in high-risk groups | 1-2 doses depending on risk; booster every 3-5 years | Suggested |

## 8.10 Catheter-related bloodstream infections (CRBSI)

8.10.1 Strict infection control measures and routine surveillance are crucial in reducing CRBSI rates.

8.10.2 There should be a CRBSI surveillance, quality assurance and improvement program (Refer chapter 9)

## 8.11 Infection control audit

- Regular audits of infection control practices in HD units shall be performed. This may include:
  (a) Hand hygiene audit
  (b) Dialyser re-use audit
  (c) Environmental cleaning audit

# CHAPTER 9: QUALITY INITIATIVES IN DIALYSIS

## 9.1 Introduction

A quality program in dialysis ensures

- Patient safety
- Enhanced quality of care
- Improved clinical outcomes
- Regulatory compliance

## 9.2 Outcome measures

- All HD units shall submit outcome measures data to NRR in a specified format
- Outcome measures are specific indicators used to evaluate the effectiveness, safety, and patient-centeredness of care. In dialysis setting, these might include:

  (a) **Clinical outcomes**
    - Survival: patient survival, mortality rates, hospitalization rates
    - Disease-specific: dialysis adequacy (Kt/V, URR), cardiovascular events
    - Complications: infection rates (CRBSI)
    - Infection rates, cardiovascular events, dialysis adequacy, hospitalization rates

  (b) **Patient-reported outcomes (PROs)**:
    - Quality of life (KDQOL, SF-36)
    - Symptom burden (e.g., pain, fatigue, itch, depression)
    - Treatment satisfaction and shared decision-making
- Some proposed patient outcome measures are summarised in Table 9.1. HD units are encouraged to consider adopting some initiatives on their own to improve quality of care.

## 9.3 Process measures

- Referral for transplantation
- Referral for arteriovenous fistula creation
- Vaccination rates
- Adherence to guidelines (e.g., BP control, anaemia targets, CKD-MBD management)

## 9.4 Safety indicators

- Infection prevention
- Medication errors
- Adverse events
- Water quality standards

## Proposed patient-centred outcome measures*

| Outcomes | Measures | Notes |
|---|---|---|
| Mortality | Mortality rate | **Monthly mortality rate** (%)<br>= No. of deaths in the current month / No. of patients at end of previous month x 100%<br><br>**Annual mortality rate (%)**<br>= Total no. of death in the year / Average number of patients per month x 100%<br><br>• Exclude those who stopped dialysis or received transplant |
| Hospitalisation | Unplanned hospitalisation rate | **Unplanned hospitalization rate** (per 100 patient-days)<br>= (Number of Unplanned Hospital Admissions / Total Patient-Days) x 100<br>= Hospitalization rate (per 100 patient-days)<br><br>Example:<br>If an HD unit had 50 admissions and a total of 10000 patient-days, the hospitalization rate would be:<br>(50/10000) x 100 = 0.5 admissions per 100 patient-days<br><br>• Exclude planned admissions (e.g., transplant admission, AVF creation)<br>• Consider categorizing by cause to target quality improvement |
| Infection | CRBSI (Catheter Related Blood Stream Infection) | **CRBSI rate** (per 1000 catheter days)<br>= Number of confirmed CRBSI episodes / Total catheter-days × 1000<br><br>• Target: CRBSI rate < 1 in 1000-catheter day (CDC NHSN, MDTR)<br>• **CRBSI Episode**: Clinically confirmed CRBSI<br>• **Catheter-Days**: Total number of days all patients had catheters in place during the observation period. |
| | Prevention of hepatitis B infection (6-12 monthly surveillance) | • % of prevalent patients doing HD at the unit for 6 months with Anti-HBs above 10 iu/ml more than 90%<br>• Exclusion criteria:<br>  • Non-responders<br>  • Vaccination refusal |
| Dialysis outcome | Access management | • % of prevalent patient (on dialysis more than 1 year) using native AVF<br>• Suggested standard ≥ 65% (KDOQI 2019) |
| | Small molecule clearance | • 90% of patients have delivered Kt/V ≥ 1.2 or URR ≥65% (KDOQI 2015) |
| | Anaemia | • 50% patients achieved Hb 10 - 12 g/dL in patient on ESA<br>• 80% of patients achieved serum ferritin > 200 ng/ml<br>• 80% of patients achieved TSAT > 20% |
| | Nutrition | • 75% of patients' serum albumin ≥ 35g/l |
| | CKD-MBD | • 50% of patients achieved serum $PO_4$ of 0.8-1.8mmol/l |

*Data maybe skewed in units with small number of patients, elderly patients and influx of new patients. Targets should be based on MDTR report.

CDC NHSN – Centers for Disease Control and Prevention National Healthcare Safety Network

## 9.5 Clinical audit

### 9.5.1 Introduction

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria. Where indicated, changes are implemented, and further monitoring is used to confirm improvement in healthcare delivery

### 9.5.2 Infection prevention

(a) Hand hygiene compliance audit (mandatory)

(b) Equipment disinfection

(c) Environment cleaning and disinfection

(d) Antimicrobial dressings usage

### 9.5.3 Medication and dialysis treatment

(a) Medication administration audit

(b) Medication preparation audit

(c) Dialyser re-use audit

### 9.5.4 Vascular access care

(a) Fistula care

(b) Fistula cannulation and decannulation (with or without ultrasound)

(c) Catheter care connection and disconnection (based on CDC guideline)

### 9.5.5 Regulatory compliance audit

## 9.6 Incident reporting

9.6.1 Incident reporting is a system where staff document, report, and investigate incidents that have caused or could cause harm to patients, including near misses. It is a crucial component of quality and safety processes, allowing organizations to learn from incidents, identify trends, and improve patient care

9.6.2 All relevant incidents shall be investigated, root cause analysis performed and planned corrective and preventive actions implemented according to the Incident Reporting & Learning System (MOH)

9.6.3 Incident reporting to Ministry of Health for HD unit in the event of:

(a) Hepatitis B or C seroconversion

(b) HIV seroconversion

(c) Intra-dialytic death

9.6.4 Other important incidents to be thoroughly investigated include but are not limited to:

(a) Venous needle dislodgement

(b) Medication errors

(c) Fall

(d) Needlestick injury

(e) Pyrogenic reactions

## 9.7 Continuous quality improvement (CQI)

### 9.7.1 Introduction

- To ensure that patient care is consistently safe, effective, equitable, timely, and patient-centred
- CQI provides a structured, data-driven framework to improve clinical outcomes, operational efficiency, and patient satisfaction

### 9.7.2 Key components of CQI in dialysis

**(a) Benchmarking and performance monitoring**

- Regular comparison of key dialysis indicators across HD units as in Malaysian Dialysis and Transplant Registry (MDTR) reports (e.g., dialysis adequacy, anaemia control, vascular access, and mortality)

**(b) Standardisation and guideline implementation**

- Development, adoption, and periodic review of evidence-based clinical practice guidelines
- Utilization of clinical toolkits, care bundles, and checklists to enhance adherence and reduce variability

**(c) Accreditation and facility standards**

- Compliance with accreditation criteria related to infrastructure, staffing, water quality, and infection control
- Regular internal and external audits to ensure compliance with quality and safety standards

**(d) Quality Improvement (QI) projects and collaboratives**

- Implementation of targeted QI projects based on identified gaps (e.g., reducing catheter dependence, improving anaemia management, enhancing vaccination coverage)
- Participation in inter-centre collaboratives and learning networks to share successful interventions

**(e) Patient engagement and empowerment**

- Use of shared decision-making tools to enhance patient understanding and involvement in treatment plans
- Support for patient education and advocacy programs to strengthen health literacy and adherence

## 9.8 Disaster preparedness

### 9.8.1 Introduction

A disaster is a serious event that causes widespread damage or loss, beyond the ability of the affected community to manage with its own resources.

**9.8.2** Several factors affect the outcome of dialysis patients during disasters:

**(a) Timing of disasters**

This can be either anticipated, such as storms or floods or unforeseen such as earthquakes. With anticipated disasters, it gives time for better preparation.

**(b) Duration of disasters**

There is a significant difference between one time disaster, such as an earthquake and an ongoing disaster, such as storms and floods.

**(c) Variations in how disasters impact haemodialysis services:**

It is important for tailoring response, recovery and mitigation strategies. Following floods and storms, healthcare providers' response should prioritise waterborne disease prevention, vaccinations and water treatment at the dialysis units.

### 9.8.3 Management

- To improve the outcome of dialysis patients during disasters, a comprehensive framework for disaster quality management in dialysis is essential
- This comprehensive framework can be categorised by four phases of emergency management
  - (a) Prevention
  - (b) Preparedness
    - In preparation for disasters, a guide for patients, dialysis facilities and state preparedness plan is important.
    - Dialysis facilities should distribute and educate their patients and staff on disaster planning
    - These documents were developed in a collaborative effort between Ministry of Health and Malaysian Society of Nephrology. Below is the link for disaster in managing HD units and patients. https://msn.org.my/disaster-preparedness-and-contingency-plan-for-dialysis-facilities/
  - (c) Response
  - (d) Recovery

## Appendix 1

Maximum allowable levels of toxic chemical and dialysis fluid electrolytes in dialysis water (based on ISO 23500:2024)

| **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** | **mg/dl** | **mmol/L** |
| Calcium | 2 | 0.05 |
| Magnesium | 4 | 0.15 |
| Potassium | 8 | 0.2 |
| Sodium | 70 | 0.3 |

| **Maximum allowable levels of trace elements in dialysis water** | |
|---|---|
| **Contaminant** | **Maximum concentration (mg/l)** |
| Antimony | 0.006 |
| Arsenic | 0.005 |
| Barium | 0.1 |
| Beryllium | 0.0004 |
| Cadmium | 0.001 |
| Chormium | 0.014 |
| Mercury | 0.0002 |
| Selenium | 0.09 |
| Silver | 0.005 |

# Appendix 2

## Prevention of infection in HD units

## Standard infection control practices

### (a) Education and training

- Continuous education programme on prevention of infection shall be established for staff, patients and caregivers
- Universal/standard precautions shall always be practised

### (b) Hand hygiene and gloves

- Proper hand hygiene at point of care
- Staff shall wash hands with soap and clean running water when hands are soiled. If hands are not visibly soiled, use of a waterless antiseptic hand rub can be substituted for hand washing
- Hand basin should be large enough to correctly wash hands and scrub without touching the basin. Hands-free taps should preferably be provided
- Patients shall also clean their hands with soap and water or use an alcohol-based hand rub or sanitiser when arriving at and leaving the dialysis station
- 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 contact, as well as after touching blood, body fluids, secretions, excretions, and contaminated items

### (c) Staff Attire

- Staff members shall wear gowns, face shields/eye protection and 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 and reprocessing of dialyser)
- Such protective clothing or gown shall be changed if it becomes soiled with blood, body fluids, secretions or excretions
- Do not wear protective clothing outside of the work area
- Remove bracelets and rings whilst attending to patients

### (d) Separation of clean and contaminated areas

- Do not handle or store contaminated supplies (used supplies, used equipment, blood samples or biohazard containers) in areas where medications and clean (unused) equipment and supplies are handled

### (e) Injection and medication safety

- Prepare medication in a designated room or area separated from patient treatment
- When multiple-dose medication vials are used (including diluents), prepare individual patient doses in a centralised clean area
- Deliver medications separately to each patient. Do not use common trolleys within treatment area or carry multi-dose vials between stations

- If trays are used to medication delivery, clean them before using for another patient. Do not carry vials, syringes, alcohol swabs or supplies in pockets
- Single-use vials (including ESA) shall be used only once. Do not puncture or reuse them
- Unused medications (including multiple-dose vials containing diluents) taken to the patient's station should be used only for that patient and should not be returned to the designated clean area or shared
- Residual medication from two or more vials shall not be pooled into a single vial
- If a common supply trolley is used to store clean supplies in the patient treatment area, this trolley shall remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such trolleys shall not be moved between stations to distribute supplies
- Hand hygiene shall be performed before and after injections. All medications should be administered aseptically, using disposable gloves and disinfecting the injection port with an antiseptic

**(f) Transducer protector**

- External venous and arterial pressure transducer filters/protectors shall be used for each patient treatment to prevent blood contamination of the dialysis machine's pressure monitors and shall be changed between patients; do not reuse them
- Before commencing dialysis, staff shall ensure that the connection between the transducer protectors and the pressure-monitoring ports is tight, as leaks can lead to wetting of the filter
- If the external transducer protector becomes wet, replace it 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 blood 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 a 1:100 dilution of bleach (300--600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse
- Do not use a syringe to clear the flooded line as it may damage the filter and increase the possibility of blood passing into the dialysis machine

**(g) External cleaning**

- 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
- Disinfection of external machine surfaces shall not commence until the patient has left the dialysis treatment station. A complete (unit-wide) patient-free interval between shifts might facilitate more thorough cleaning and disinfection of the unit
- For a blood spill, immediately clean the area with a cloth soaked in a tuberculocidal disinfectant or a 1:100 dilution of household bleach (300-600 mg/L free chlorine) (e.g.,

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

- If a blood spillage has occurred, the exterior shall be disinfected with a commercially available tuberculocidal germicide or a solution containing at least 500 p.p.m. hypochlorite (a 1:100 dilution of 5% household bleach) if this is not detrimental to the surface of dialysis machines. Advice on suitable disinfectants, and the concentration and contact time required, should be provided by the manufacturer

**(h) Disinfection of the internal fluid pathway**

- 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
- 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
- If blood or fluid is thought to have seeped into inaccessible parts of the dialysis machine (e.g., between modules or behind a blood pump), the machine should be taken out of service until it can be dismantled and disinfected

**(i) Equipment management**

- 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 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
- Single-use items required in the dialysis process should be disposed of after use on 1 patient. Non-disposable items should be disinfected after use on 1 patient. Items that cannot be disinfected easily (e.g., adhesive tape and tourniquets) should be dedicated to a single patient and discarded after use
- The risks associated with use of physiological monitoring equipment (e.g., blood pressure monitors, weight scales, and access flow monitors) for groups of patients should be assessed and minimised. Blood pressure cuffs should be dedicated to a single patient or made from a light-coloured, wipe-clean fabric
- Between uses of medical equipment (e.g., scissors, haemostats, clamps, stethoscopes, blood pressure cuffs), clean and apply a hospital disinfectant (e.g., low-level disinfection); if the item is visibly contaminated with blood, use a tuberculocidal disinfectant (e.g., intermediate-level disinfection)

**(j) Waste and specimen management**

- Routine bacteriological assays of water and dialysis fluids shall be performed according to the recommendations
- Housekeeping staff members in the dialysis facility shall promptly remove soiled 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 or leak-proof containers for transport from station to disposable area

- For dialyser that will be reprocessed, please cap dialyser ports and clamp tubing. Place all used dialysers in leak-proof containers prior to transport from station to reprocessing area
- Wastes generated by the haemodialysis facility might be contaminated with blood and shall be considered infectious and handled accordingly, away from the treatment and preparation areas
- Needles shall be disposed of in closed, unbreakable containers, which should not be overfilled. A "no-touch" technique should be used to drop the needle into the container

**(k) Isolation practice**

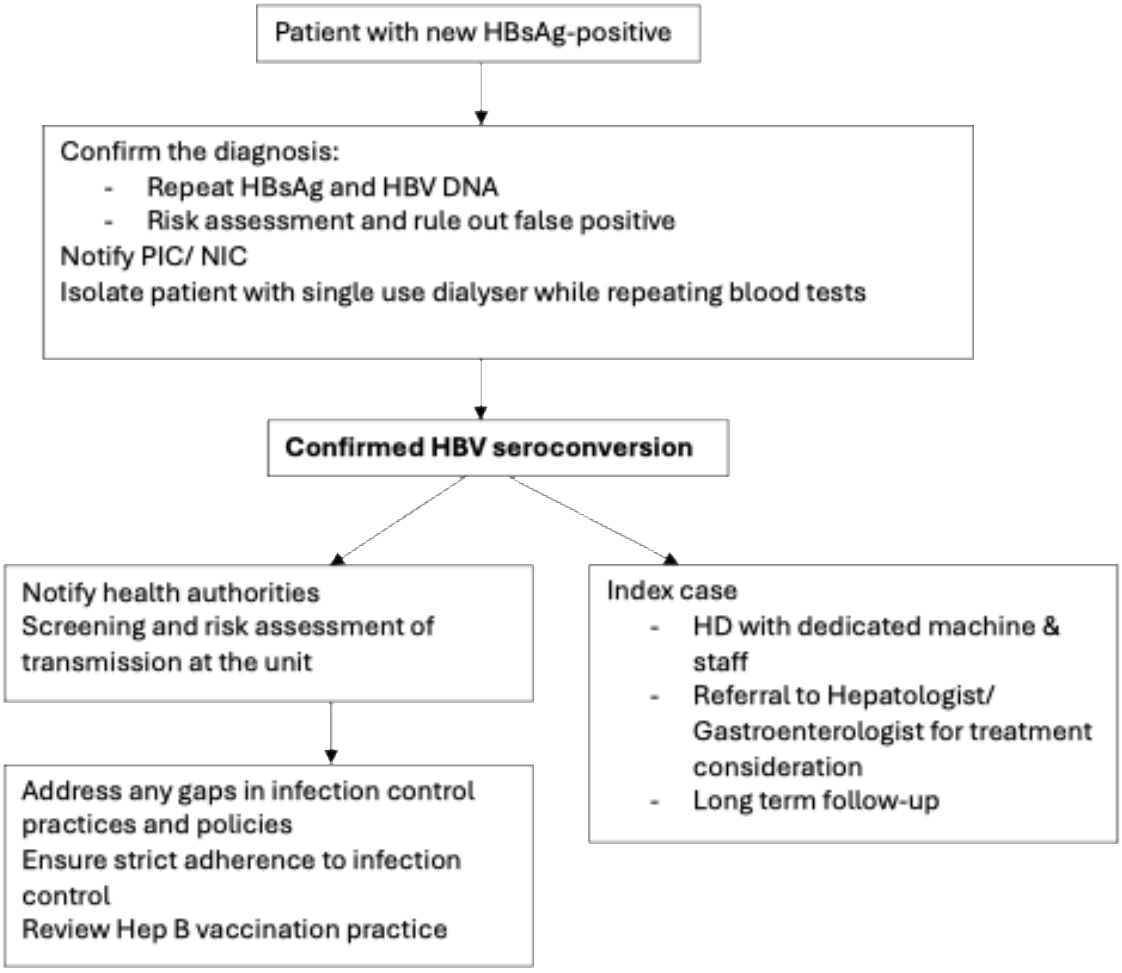
- Is required for patients with active infection (e.g.: MRSA, ESBL producers, VRE, Rotavirus, Clostridium difficile, Adenovirus, Influenza, Parainfluenza, Enterovirus, Hepatitis A) and CRE carrier
- To be dialysed at isolation or cohort area, preferably last shift
- Minimise patient movement within the unit
- Dedicated patient care equipment or disposal equipment
- Terminal cleaning before the next patient use
- The exact duration of isolation for CRE carrier is not known. The recommended duration for isolation is at least 1 year (refer to "Management of Carbapenemase-producing Carbapenem-resistant Enterobacterales (CP-CRE) in Healthcare Setting 5$^{th}$ edition 2025")

**(l) Recommended isolation for patient with pulmonary tuberculosis (TB)**

- Patient shall wear surgical mask; but staff to wear N95 mask
- Patient with active pulmonary TB should preferably be dialysed in an airborne infection isolation room (AIIR) with negative pressure. Where an AIIR is unavailable, dialysis should be performed in a well-ventilated single room or an isolated area, with airborne precautions maintained throughout the session
- The isolation is needed until patient has improved clinically with 3 consecutive negative sputum samples (which usually takes 2 weeks of treatment)
- Following this, the patient can return to general treatment area

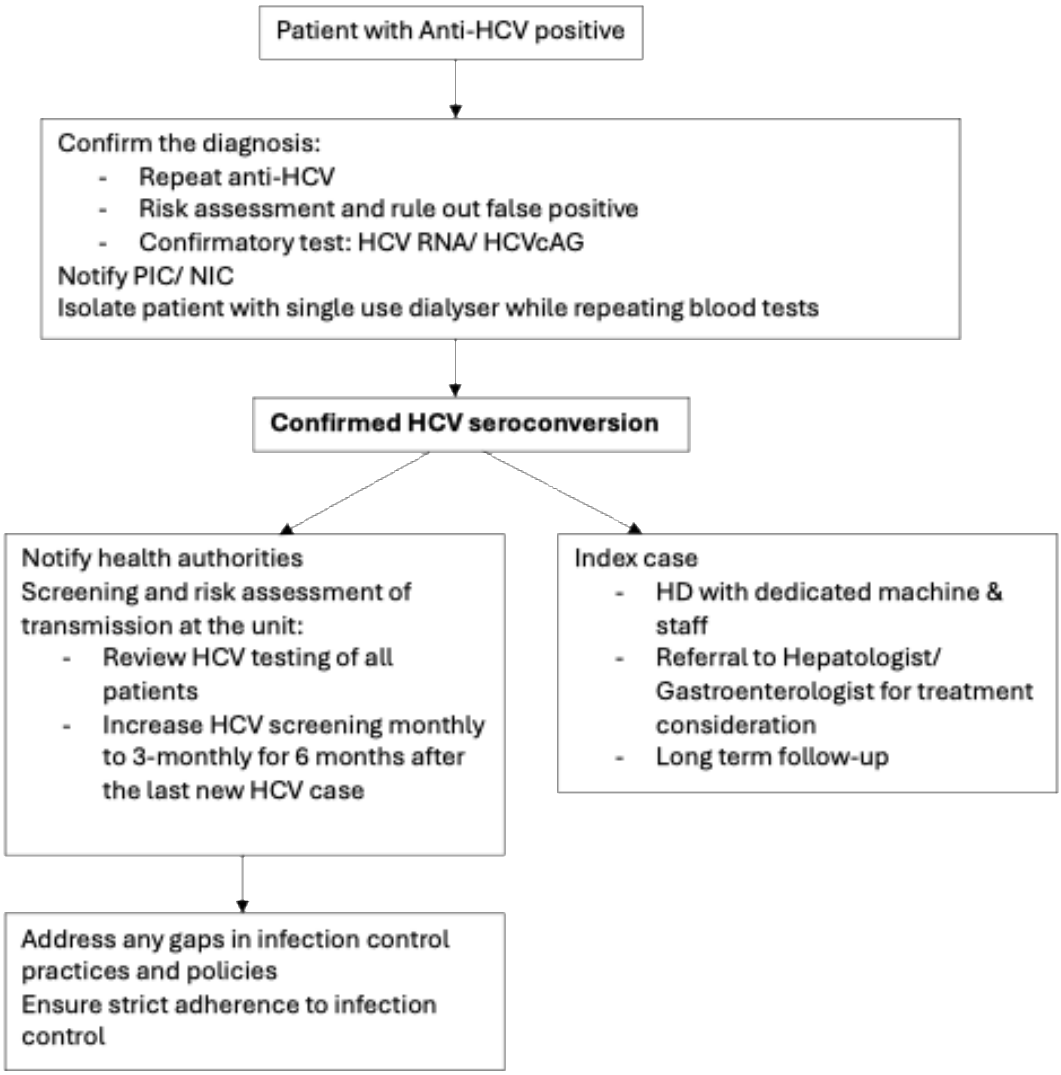
**Appendix 3**

**Clinical pathway of HBV seroconversion (HBsAg-negative to HBsAg-positive)**



**Appendix 4**

**Clinical pathway of HCV seroconversion**



## References


### Chapter 2

1. Private Healthcare Facilities and Services Bill 1998 Part XXII.
2. Setting Up of Haemodialysis Unit. Indian Journal of Nephrology, Volume 30, Supplement 1, July 2020.
3. MSQH Malaysian Hospital Accreditation Standards and Assessment Tools: 6th Edition.
4. CKAPS-ICL-08 Standard for Private Haemodialysis Centre (updated 130116).
5. Handbook of Kidney Replacement Therapy 5th edition.
6. Standard Operational Nephrology Services Operational Policy 3rd edition.
7. The National Haemodialysis Quality Standards 3rd edition, July 2018.

### Chapter 3

1. ISO 23500:2024 Preparation and quality management of fluids for haemodialysis and related therapies. Edition 2, 2024.
2. Goh BL, Bavanandan S, Yahya R, Mushahar L. Handbook of Kidney Replacement Therapy 5th Edition 2023. Post Graduate Renal Society Malaysia.

### Chapter 4

1. MSQH Malaysian Hospital Accreditation Standards and Assessment Tools: 6th Edition.
2. Handbook of Kidney Replacement Therapy 5th edition.
3. Standard Operational Nephrology Services Operational Policy 3rd edition.
4. The National Haemodialysis Quality Standards 3rd edition, July 2018.
5. Guidelines on the Handling & Management of Clinical Waste in Malaysia by Department of Environment, Ministry of Natural Resources and Environment 3rd Edition 2009.

### Chapter 5

1. ISO 23500:2024 Preparation and quality management of fluids for haemodialysis and related therapies. Edition 2, 2024.
2. Goh BL, Bavanandan S, Yahya R, Mushahar L. Handbook of Kidney Replacement Therapy 5th Edition 2023. Post Graduate Renal Society Malaysia

### Chapter 8

1. Kidney Disease: Improving Global Outcomes (KDIGO) Hepatitis C Work Group. KDIGO 2022 Clinical Practice Guideline For the Prevention, Diagnosis, Evaluation, and Treatment of Hepatitis C in Chronic Kidney Disease. Kidney Int. 2022 Dec;102(6S):S129-S205. doi: 10.1016/j.kint.2022.07.013. PMID: 36410841.
2. Malaysia Ministry of Health. Management of Chronic Hepatitis B in Adults. Putrajaya: MoH; 2022.
3. Malaysia Ministry of Health. Handbook of Kidney Replacement Therapy 5th Edition: MOH; 2023.
4. Waheed, Sana et al. Targeting Zero Infections in the Outpatient Dialysis Unit: Core Curriculum 2020. American Journal of Kidney Diseases, Volume 76, Issue 1, 130 – 140.
5. Siegel JD, Rhinehart E, Jackson M, Chiarello L; Health Care Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. Am J Infect Control. 2007 Dec;35(10 Suppl 2):S65-164. doi: 10.1016/j.ajic.2007.10.007.
6. Centres for Disease Control and Prevention (CDC) Recommendations on Hepatitis B Virus (HBV) Screening in Dialysis Patients (2023). https://www.cdc.gov/hepatitis/hbv/index.htm
7. European Renal Best Practice (ERBP) Work Group. European Best Practice Guidelines for Haemodialysis – 2023 Update. Available at: https://www.era-online.org
8. Centers for Disease Control and Prevention. (2023). *Adult Immunization Schedule Notes*. Retrieved from https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-notes.html
9. Centers for Disease Control and Prevention (CDC) – Clinical Screening and Diagnosis for Hepatitis C (2025) https://www.cdc.gov/hepatitis-c/hcp/diagnosis-testing/index.html
10. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C (AASLD/IDSA, 2025).

### Chapter 9

1. McClellan WM, Goldman RS. Continuous quality improvement in dialysis units: basic tools. Adv Ren Replace Ther. 2001 Apr;8(2):95-103.
2. Schiller B. The medical director and quality requirements in the dialysis facility. Clin J Am Soc Nephrol. 2015 Mar 6;10(3):493-9.
3. Guidelines on implementation Incident Reporting & Learning System 2.0 for Ministry of Health Malaysia Hospitals

4. Himmelfarb, J., Vanholder, R., Mehrotra, R. *et al.* The current and future landscape of dialysis. *Nat Rev Nephrol* **16**, 573–585 (2020).
5. Bello, A.K., Okpechi, I.G., Osman, M.A. *et al.* Epidemiology of haemodialysis outcomes. *Nat Rev Nephrol* **18**, 378–395 (2022).
6. Anwar, Choirul, Nursalam, Satriyo D.S., "Hemodialysis Patient Safety Instruments: A Systematic Review", Register: Medical Technology and Public Health Journal, Vol. 8, No. 1, pp. 17-27, 2024.
7. Gelfand et al. Leveraging the End-Stage Renal Disease Patient Life Goals Survey (PaLS) to Improve Quality of Care: Avoiding a "Checkbox Measure". AJKD 2024.
8. Weiner, Daniel E. Aragon, Michael et al. Patient-Centered Quality Measures for Dialysis Care: A Report of a Kidney Disease Outcomes Quality Initiative (KDOQI) Scientific Workshop Sponsored by the National Kidney Foundation. American Journal of Kidney Diseases, Volume 83, Issue 5, 636 – 647, May 2024.
9. Handbook of KRT 5th Edition. 2023.
10. Malaysia CPG: Management of Major Depressive Disorder 2019.
11. Hernán-García Cristina et al. Immunogenicity and predictive factors of hepatitis B vaccination with Fendrix® in chronic kidney disease patients. Frontiers in Public Health. Volume 13 – 2025.
12. Bikbov B, Purcell CA, Levey AS, et al. Global, regional, and national burden of chronic kidney disease, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2020;395:709-733.
13. Alasfar, S., Koubar, S. H., Gautam, S. C., Jaar, B. G., & et al. (2024). Kidney care in times of crises: A review. American Journal of Kidney Diseases, 84(5), 621-631.
14. The National Haemodialysis Quality Standards 2018 ISBN 978-967-217322-9
15. MSN website www.msn.org

eISBN 978-629-94836-1-8




Bahagian Perkembangan Perubatan, Kementerian Kesihatan Malaysia

(online)