Hong Kong College of Physicians

&

Central Renal Committee

(Hospital Authority)

Accreditation of Renal Dialysis Unit

Prepared by the Working Group on Quality Assurance in Renal Services
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Accreditation of Renal Dialysis Unit

(I) Introduction

1. This section contains guidelines leading to accreditation of a renal dialysis unit.
2. A sample of application form for accreditation of renal dialysis unit is attached at the back for reference.

(Standards are categorized as “Recommended” and denoted (R) or as “Desirable” and denoted (D) based on the strength of evidence that such practices will affect the patients’ outcome.)

(II) Design and Space

1. The design of the facility meets the building and fire safety regulations of the government. (R)
2. The treatment area provides safe and comfortable environment for patients receiving haemodialysis. (D)
3. If the renal dialysis unit also provides Continuous Ambulatory Peritoneal Dialysis (CAPD) service, separate rooms are recommended for peritoneal dialysis training and care for complications related to CAPD. (D)

(III) Staffing:

1. Haemodialysis and peritoneal dialysis services are provided in centres with qualified nephrologist(s) and renal nurse(s). (R)
2. Training of CAPD or Automated Peritoneal Dialysis (APD) is done by qualified renal nurses. (R)
3. Hemodialysis procedures are ordered by nephrologists and monitored closely by qualified renal nurses. (R)
4. Medical doctor is available for consultation when needed. (R)
5. Resuscitation guidelines are in place and all medical and nursing staff of the dialysis centres are trained to perform CPR. (R)

(IV) Equipment:

1. All equipment used by a facility, including backup equipment, are operated within manufacturer’s specifications, and maintained free of defects.
Maintenance is performed by qualified staff or contract personnel. (R)

2. Preventive maintenance program to equipment related to patient care is developed and enforced. (R)

3. Staff is trained to identify malfunctioning of equipment and to report to appropriate staff for immediate repair. (R)

4. All maintenance and repair record is kept on file for future reference and inspection. (R)

5. Emergency equipment and supplies include the following: (R)
   - Oxygen
   - Ambu bag and oxygen mask
   - Oximeter
   - Suction equipment
   - Electrocardiograph and ECG monitor.
   - Defibrillator

(V) Water Treatment System:

1. Dual water treatment system is preferred. (D)

2. Each water treatment system includes reverse osmosis membranes or deionization tanks. (R)

3. The water treatment system components are arranged and maintained so that bacterial and chemical contaminant level in the product water do not exceed the standards for hemodialysis water quality. (Please refer to the “Haemodialysis” section for standards) (R)

4. Proper function of water treatment system is continuously monitored during patient treatment and be guarded by audible or visual alarm that can be heard or seen in the dialysis treatment area in case performance of the water treatment system drops below specific parameters. (D)

5. Written logs of the operation of the water treatment system for each treatment day are in place. (R)

6. Procedure guidelines for Disinfection of Reverse Osmosis Machine and Loop as recommended by the manufacturer are in place. (R)

7. No hemodialysis procedure is performed during disinfection of the water treatment system and the loop. (R)

8. Microbiological testing of the treated water from the water treatment system and the loop is done regularly and preferably monthly. (R)

9. For dialysis unit performing HDF, testing of treated water for endotoxin at
regular interval is needed. (R)

10. Written record and results of microbiological and chemical testing of water are in place and reviewed. Corrective action is recorded if indicated. (R)

(Ⅵ) Reuse of haemodialyzers and related devices

1. Procedure guidelines for dialyzer reprocessing are in place. (R)
2. Testing for presence of disinfectant in the reprocessed dialyzer before rinsing and absence of disinfectant after rinsing are performed and documented. (R)
3. Each dialyzer is clearly labeled and identified to be re-used by the same patient. (R)

(VII) Haemodialysis machines

1. At least one unoccupied haemodialysis machine is available on-site as backup for every ten haemodialysis machines. (R)
2. Procedure guidelines on preparation of haemodialysis machine for haemodialysis are in place. (R)
3. Routine disinfection of active and backup dialysis machines are performed according to defined protocol. Documentation of absence of residual disinfectants is required for machines using chemical disinfectant. (R)
4. Samples of dialysate from machines chosen at random are cultured monthly. Microbial count shall not exceed 200 colony forming units per millilitre (cfu/ml) for HD and shall not exceed $10^{-1}$ cfu/ml for online HDF before IV infusion into the patient’s circulation. (R)
5. Testing of dialysate for endotoxin using Limulus amoebocyte lysate (LAL) before IV infusion into patient is performed for dialysis unit performing HDF and documented. Endotoxin level should not exceed 0.03 EU/ml. (R)
6. Testing of inorganic contaminant is desirable. (D)
7. Regular testing of dialysate for electrolytes is suggested to ensure proper function of haemodialysis machines. (D)
8. Repair, maintenance and microbiological testing results of the haemodialysis machine are recorded with corrective actions where indicated. (D)
(VIII) Standards of Equipment, Solutions and Training for Peritoneal Dialysis

1. All automated peritoneal dialysis (APD) machines comply with international standards for electromechanical safety. (R)
2. Fluids for peritoneal dialysis satisfy the current international quality standards. (R)
3. Procedure and guidelines for the use of APD machines are in place. (R)
4. Procedure and guidelines for the training of CAPD and management of its complications are in place. (R)

(IX) Sanitary Conditions, Hygienic Practices and Infection Control

1. All medical and nursing staff are trained to practice universal precautions in the dialysis unit. (R)
2. Universal precautions are followed in the facility for all patient care activities. (R)
3. Hand washing sinks are readily accessible in each patient care area to allow hand washing before and after each patient contact. (R)
4. Gloves, aprons, face-masks, goggles and sharps containers are readily available. (R)
5. All staff including janitorial staff is educated with clear instruction on handling blood spillage on equipment and the floor. (R)
6. All blood stained surface shall be soaked and cleaned with 1:100 sodium hypochlorite if the surface is compatible with this type of chemical treatment. (R)
7. All new dialysis patients or patients who return to the dialysis unit after treatment from high- or unknown-risk areas are tested for HbsAg and Anti-HCV. (R)
8. HBsAg-positive patient is treated in a segregated area with designated haemodialysis machines. (R)
9. Carrier of HCV receives haemodialysis using designated machines. (D)
10. Patient with unknown viral status is dialyzed using designated hemodialysis machines until the status is known. (D)

(X) Other Quality Assurance Activities for patient care
1. Blood chemistry and haematocrit (or haemoglobin) of each dialysis patients are checked at regular interval (preferably every two to three months) to ensure patient’s well being. (R)

2. Contingency plan or procedures are available in case of equipment failure, power outages, or fire so that the patient healthy or safety can be ensured. (R)

3. Drill for CPR and emergency conditions outlined as mentioned in item 2 above are performed regularly. (D)
The Hong Kong College of Physicians
Application for Accreditation of Dialysis Unit

Hospital:  

Address:  

Nephrologist in-charge:  

Tel:  
Fax:  

No. of haemodialysis beds:  
No. of haemodialysis patients:  
No. of peritoneal dialysis patients:  

**Staffing:**

No. of qualified nephrologists:  
No. of qualified renal nurses:  
No. of R.N.:  

Availability of doctor during emergency. (R) yes / no

Formal training of all nursing & medical staff to perform CPR. (R) yes / no

Formal training of all staff to practice universal precautions. (R) yes / no

Formal training of all nursing staff to operate water treatment system. (R) yes / no

Formal training of all nursing staff to operate haemodialysis machine. (R) yes / no

**Space and equipment:**

Cleanliness of the patient treatment area, water treatment plant and haemodialysis machines. (R) yes / no
Separate area for haemodialysis and peritoneal dialysis. (D)  yes / no

Enough hand washing sinks readily accessible to staff. (R)  yes / no

Central water treatment system. (Reverse Osmosis membranes or Deionization tanks) (R)  yes / no

Portable water treatment system. (Reverse Osmosis membranes or Deionization tanks) (R)  yes / no

Backup water treatment system. (D)  yes / no

No. of HD machines: __________  No. of backup HD machines: ________

Designated area and haemodialysis machines for HBsAg positive patient. (R)  yes / no

Designated haemodialysis machines for HCV positive patient. (D)  yes / no

Resuscitation equipment (R): Ambu bag & oxygen mask  yes / no
  Oxygen  yes / no
  Oximeter  yes / no
  Suction equipment  yes / no
  Electrocardiograph  yes / no
  ECG monitor  yes / no
  Defibrillator  yes / no

Quality Assurance Activities:

Audible or visual alarms in patient treatment area for water treatment system monitoring. (D)  yes / no

Preventive maintenance and repair record of hemodialysis machine and water treatment system. (R)  yes / no

Written logs of the operation of the water treatment system for each treatment day. (R)  yes / no
Procedure guidelines for disinfection of water treatment system, product water delivery system and haemodialysis machines. (R) yes / no

Written record on results of microbiological and chemical testing of water. (R) yes / no

Written record on results of dialysate microbiological culture of the haemodialysis machines. (R) yes / no

Written record on results of dialysate microbiological culture and endotoxin level of the HD machines performing HDF. (R) yes/no/NA

Procedure guidelines on preparation of haemodialysis machine for haemodialysis. (R) yes / no

Procedure guidelines for dialyzer re-use. (R) yes/no/NA

Protocols for CAPD, APD training, IPD and management of complications are available. (R) yes/no/NA

Contingency plan to handle fire, power outages, or equipment that may threaten the health of safety of patients and staff. (R) yes / no

Regular drill for CPR and to handle emergency situations. (D) yes / no

Accumulative record of blood tests results of each patient taken at regular interval. (R) yes / no

Presence of clinical audit to monitor quality of patient care. (R) yes / no

Remarks:

__________________________________________  ______________________________________
(Accreditation Team) (Chief, Dialysis Unit)

Date:________________________