

# **GUIDELINES FOR PRIVATE HEALTHCARE INSTITUTIONS PROVIDING RENAL DIALYSIS: - REGULATION 4 OF THE PRIVATE HOSPITALS AND MEDICAL CLINICS REGULATIONS [CAP 248, Rg 1]**

These Guidelines serve as a guide to the management of medical clinics and private hospitals approved by the Ministry of Health to provide renal dialysis, a specialised procedure/special care service listed under the Second/Third Schedule of the Private Hospitals and Medical Clinics (PHMC) Regulations, respectively, on the provision of renal dialysis for the treatment of chronic renal failure.

## **Definition**

Renal dialysis centre means any institution, place or building designed for the primary purpose of providing outpatient dialysis treatment for patients with end stage renal failure.

## **1 Establishment of Dialysis Centres**

1.1 Dialysis centres may be established either as free-standing premises or may be established within the precincts of a hospital.

### **1.2 Application for Setting Up and Licensing of a Renal Dialysis Centre**

1.2.1 Proposals for setting up and licensing of a renal dialysis centre shall be submitted together with the Application Form (Appendix I) to the Director of Medical Services for approval not less than 30 days before the intended commencement of operations of the renal dialysis centre. Application Forms can be down-loaded from website, <http://www.gov.sg/moh/maau/forms.html#app> or obtainable from the Licensing and Accreditation Branch, Ministry of Health (MOH), College of Medicine Building, 16 College Road, Singapore 169854.

### **1.3 Objectives and Range of Services**

1.3.1 The proposal for setting up and licensing of a renal dialysis centre shall specify the objectives of the renal dialysis programme and the range of services to be provided. The proposal shall also stipulate the facilities, and medical and nursing staff who will be providing the service.

### **1.4 Number of Patients to be Treated**

1.4.1 The total number of patients to be treated, number of dialysis stations available and the types of service provided shall be detailed in the Application Form.

## 1.5 Emergency Medical Care

1.5.1 The physician in charge of the dialysis centre shall ensure that there are facilities for emergency resuscitation, as well as documented protocols/procedures to deal with cardiopulmonary collapse and urgent medical treatment as patients may develop hypotension, fits or collapse during dialysis.

1.5.2 In addition, the physician in charge must:

- (a) ensure that there are prior arrangements made for patients receiving dialysis treatment in stand-alone dialysis centre to be admitted to a hospital in Singapore, should the need arise.
- (b) ensure that there are standing arrangements with other medical practitioners to provide immediate medical care in the event that the physician in charge is not available.

## 1.6 Dialysis Equipment

1.6.1 Dialysis machines shall be equipped with monitors and audio-visual alarms to ensure safe dialysis.

1.6.2 The physician in charge is ultimately responsible in ensuring that all dialysis equipment are in proper working condition and that the necessary safety devices are fitted and in working order.

## **2 Staffing and Organisation**

### 2.1 Doctors

2.1.1 The physician in charge of a dialysis centre must be registered with the Singapore Medical Council's Register of Specialists in Renal Medicine and have experience in Nephrology in a recognised centre, including at least 1 year's experience in dialysis.

2.1.2 The physician in charge of the dialysis centre must practise holistic medicine and be responsible for overall management of the patients in the Centre. The responsibility of the physician in charge of the centre must cover dialysis access care (perform or arrange for insertion of vascular catheters, arrange for creation of AVF and insertion of tenckhoff catheters). The physician in charge shall be contactable at all times to render emergency medical care. In the event that the physician in charge is unable to fulfil his full responsibility to the patients of the dialysis centre, he must make arrangements for a similarly qualified physician to be responsible for the total care of the patients in the Centre. He shall ensure that arrangements are made with hospitals for all patients in a stand-alone centre to be expeditiously referred for emergency management.

2.1.3 The physician in charge of the dialysis centre shall in the management of patients, ensure the following:

- (a) that the need for dialysis treatment and choice of modality shall be based on sound clinical principles and a thorough clinical evaluation of medical condition and co-morbidities.
- (b) that the attending renal physician shall clearly recommend to the end-stage renal failure patient the modality that is best suited to him. This shall be based on the patient's renal and other co-morbid conditions, ability to comply with treatment, available family support and other social factors.
- (c) that the patient shall be allowed to make a fully-informed choice of dialysis modality, after receiving adequate counselling from his renal physician on the different modalities available and the modality that is most appropriate for the patient's need

2.1.4 There shall be a 1:150 doctor-dialysis patient ratio at any one time, for total patient care, which includes work in hospital and work related to vascular access problems and medical complications.

2.1.5 There shall be a documented Quality Assurance Programme (QAP) to ensure quality patient care through objective and systematic monitoring, evaluation, identification of problems and action to improve the level and appropriateness of care. The QAP shall include:

- (a) documented policies and procedures related to the safe conduct of all patient care activities.
- (b) documented regular reviews of the policies and procedures.
- (c) documented reviews of deaths, accidents, complications and injuries arising from dialysis treatment.

## 2.2 Nursing Staff

2.2.1 The nurse in charge of a dialysis centre must be a qualified registered nurse:-

- (a) certified in Renal Nursing (or its equivalent) and at least 2 years experience in dialysis nursing in a dialysis unit in a major hospital,  
or
- (b) at least 3 years in an institution based/affiliated dialysis unit if they do not have a course certificate.

2.2.2 A minimum of 1 trained nurse (registered/enrolled nurse) or 1 nurse-aide with at least 6 months training/experience in dialysis is required for every 5 dialysis patients per dialysis shift in a nurse-assisted dialysis facility. For self-dependency dialysis patients, the ratio of trained nurse to patient per shift shall not be less than 1:20. Among these staff, there shall be at least one registered nurse with at least six months training/experience in dialysis to be physically present at each dialysis centre at all times to monitor the patients throughout the dialysis procedure, to be on hand to deal with any emergency that may arise, and also to alert the physician when necessary.

- 2.2.3 The nurse in charge shall possess appropriate training in handling resuscitation equipment and dealing with cardiac emergencies. All nursing staff shall have undergone formal certified training in cardiopulmonary resuscitation. The certified training in basic life support shall be current and up-to-date.

### **3 Physical Facilities: - Construction of Dialysis Centre**

#### **3.1 Building and Plumbing Requirements**

- 3.1.1 The product water distribution system shall not contribute chemicals such as copper, zinc and lead, or bacterial contamination to the treated water.

#### **3.2 The Dialysis Room**

- 3.2.1 The space occupied by each dialysis station shall be at least 5.8 sq. metres, large enough to accommodate the dialysis chair or couch, dialysis machine as well as working room for 2 dialysis personnel. The dialysis station shall be easily accessible in times of emergency and have adequate space for resuscitation to be carried out.

#### **3.3 The Dialyser Room**

- 3.3.1 If reuse of dialyser is practised, there shall be adequate space and facilities to ensure proper cleaning and preparation of dialysers for reuse. There shall be protocols on the cleaning and preparation of dialysers for reuse.

- 3.3.2 The dialyser shall only be reused for the same patient.

#### **3.4 Sluice Room**

- 3.4.1 A small sluice room located within the renal dialysis centre is preferable.

#### **3.5 Treatment Room**

- 3.5.1 A treatment room shall be provided if minor surgery and other sterile procedures are carried out at the centre.

#### **3.6 Washing and Changing Facilities**

- 3.6.1 There shall be adequate allocated space for patients to wash and change.

- 3.6.2 There shall be adequate facilities for staff to wash and change.

## 4 Water Quality

- 4.1 The Centre shall ensure that there is proper treatment of water, which is necessary to rid the water of impurities or to lower the concentration of impurities to within acceptable limits.
- 4.2 The water used for dialysis shall be treated by reverse osmosis and/or deionisers to provide a quality of water which meets with the standards listed below:

(a) <u>Contaminant</u>	<u>Maximal Allowable Level (mg/l)</u>
Fluoride	0.2
Chloramines	0.1
Copper	0.1
Aluminium	0.01
Lead	0.005
Total dissolved solids	5 – 1000

(Extracted from Association for the Advancement of Medical Instrumentation (AAMI) Proposed Standard 1981)

- (b) The water used to prepare the dialysate shall have a bacteriological count of less than 200 per ml after 48 hours of incubation (AAMI, 1981). Total viable counts shall be obtained using conventional microbiological assay procedures (pour plate, spread plate). The calibrated loop technique shall not be used. Alternatively, the water shall have a bacterial lipopolysaccharide concentration of less than 1 ng/ml or 5 Endotoxin units as measured by the Limulus amoebocyte lysate assay.
- 4.3 Regular tests of the quality of the water for (a) and (b) must be carried out, at a minimum of 6-monthly intervals and recorded to ensure that standards are met.
- 4.4 The Physician in charge of the Centre is responsible for ensuring that these tests are carried out by a recognised laboratory registered to perform these assays. The records shall be kept and made available for inspection by Ministry of Health Officials.

## 5 Dialysate Quality

- 5.1 The dialysate fluid shall be a non-sterile aqueous solution with an electrolyte composition near that of normal extracellular fluid.
- 5.2 The water used to prepare the dialysate must have a bacteriological colony count of less than 200/ml using the method as in section 4.2(b).

### 5.3 The composition of the dialysate fluid

5.3.1 The concentration of haemodialysis solutions shall be such that after dilution to the stated volume the final concentrations of the ions expressed as mmol/l are usually in the following ranges:

(a) Cations:

Sodium	135 - 145
Potassium	0 - 3.0
Calcium	1.0 - 2.0
Magnesium	0.25 - 1.0

(b) Anions:

Acetate or lactate expressed as bicarbonate equivalents	32 - 40
Chloride	95 - 110

5.3.2 Sodium concentration may be adjusted to levels outside this range by haemodialysis machines with variable sodium capabilities when prescribed by physician in charge.

5.3.3 The final diluted dialysate shall be analysed every 6 months, with every new batch of dialysate and after each major servicing/repair of dialysis machine.

### 5.4 Bacteriological Requirements

5.4.1 The colony count in dialysate samples collected at the termination of dialysis

a) in a single pass system or

b) in a recirculating single pass system at the periphery of the recirculating chamber containing the dialyser

shall be less than 2000 colony-forming units/ml (AAMI 1981).

5.4.2 Bacteriological analysis of the dialysate shall be carried out at least 2 monthly.

5.5 The physician in charge shall be responsible for arranging for the analysis of the dialysate. Its chemical composition shall be clearly labelled. The results of analysis, bearing the name of the centre and officer analysing the dialysate shall be made available on request as and when required.

## 6 **Equipment**

6.1 The resuscitation equipment shall include, but not be limited to, cardiac monitoring device with defibrillator, air viva or respirator, intubation equipment and oxygen supply, which must be available at the dialysis centre at all times.

- 6.2 The physician in charge is ultimately responsible in ensuring that the monitoring and safety devices and resuscitation equipment are in proper working condition at all times.

## **7 Infection Control Practices**

### **7.1 General Precautions**

- 7.1.1 Standard Precautions<sup>1</sup> shall be used on all patients regardless of whether the Hepatitis B, Hepatitis C and HIV status is known. During dialysis, blood is often spilt. It is therefore vital for staff to be adequately protected using impervious gowns/aprons, gloves and eye protection.
- 7.1.2 Disposable gloves shall be worn by staff members for personal protection when performing procedures which are potentially biohazardous. Staff shall also wash their hands and use a fresh pair of gloves with each patient to prevent cross-transmission. Gloves shall be removed when such procedures are interrupted (e.g. answering telephone calls, called away for other duties) to prevent contamination of surfaces uninvolved with the aforesaid procedure.
- 7.1.3 Hepatitis B vaccination of all staff who have contact with blood and body fluids is strongly recommended. This applies also to helpers of self-care dialysis patients. Routine screening of staff for anti-HCV may be done where necessary.
- 7.1.4 Screening for Methicillin Resistant Staphylococcus Aureus nasal carriers among staff, patients and helpers of self care dialysis patients shall be done in the context of an outbreak in the Centre and appropriate action taken to track carriers and to prevent infection of patients.
- 7.1.5 Blood samples for analysis shall be carefully taken, put in plastic vials and then placed in separate plastic bags. Individual vials shall be labelled and carefully checked after each blood sample is taken.
- 7.1.6 Only blood and blood products screened and found negative for HBsAg, anti-HCV and HIV shall be given.
- 7.1.7 Draining, disinfection and rinsing procedures shall be performed after each dialysis. If a blood leak occurs in a recirculating system, the usual rinsing and disinfection procedure shall be performed twice before the system is used on a different patient.

### **7.2 Acute Haemodialysis**

- 7.2.1 Acute haemodialysis is often done for patients on an emergency or semi-emergency basis. Under these circumstances, it may not be possible to have

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<sup>1</sup> Reference on Standard Precautions  
Infection Control Manual Section 1 (MOH 2000) and Guidelines for Preventing Transmission of Bloodborne Infections in a Health Care Setting, Section One (MOH 2000)

results of tests of blood-borne viruses. Dialysis shall proceed as is required on medical grounds. Isolation facilities are not required unless the patient has concomitant infection with another disease that requires isolation. Disposable dialysers and bloodlines shall be used and the machine shall undergo complete chemical disinfection in accordance to manufacturer's recommendations after each use for patients with unknown HBsAg, anti-HCV and HIV status.

### 7.3 Chronic Haemodialysis

7.3.1 Patients who require chronic haemodialysis at dialysis centres shall be tested for Hepatitis B, Hepatitis C and HIV before they are admitted to the centre. The dialysis centre shall maintain records of patients' latest results.

### 7.4 Hepatitis B

7.4.1 Patients shall be tested for HBsAg and anti-HBs at 6-monthly intervals.

7.4.2 Patients who are seronegative (HBsAg and anti-HBs negative) shall be tested 6-monthly for HBsAg, and anti-HBs. Patients who are anti-HBs positive by 2 consecutive tests and HBsAg negative are considered immune to HBV and need only be tested for anti-HBs annually to verify their immune status.

7.4.3 Patients who are HBsAg positive by 2 consecutive tests shall be tested 6-monthly or as clinically indicated.

7.4.4 Patients who are HBsAg and anti-HBs negative shall receive Hepatitis B vaccination.

7.4.5 Patients who are HBsAg positive shall be isolated in a separate area designated for HBsAg positive patients.

7.4.6 Dedicated dialysis equipment shall be used for HBsAg positive patients. After each dialysis, non-disposable equipment shall be appropriately cleaned and disinfected or sterilised. Dialysers and AV bloodlines must not be shared among patients. Bloodlines shall be used once and discarded. If reuse of dialysers on the same patient is practised, dialysers of HBsAg positive patients must be washed in an area separate from that used for reprocessing of dialysers for HBsAg and anti-HCV negative patients.

### 7.5 Hepatitis C

7.5.1 Patients shall be tested for anti-HCV at 6-monthly intervals.

7.5.2 Testing for HCV using anti-HCV antibody test may not accurately reflect infectivity since patients may be anti-HCV positive and HCV RNA negative or anti-HCV negative and HCV RNA positive.

7.5.3 Dialysers and arterio-venous (AV) bloodlines must not be shared among patients. Bloodlines shall be used once and discarded. If reuse of dialyser on



the same patient is practised, dialysers of HCV positive patients must be washed in an area separate from that used for reprocessing of dialysers for HBsAg and anti-HCV negative patients and HBsAg positive patients.

## 7.6 HIV / AIDS

7.6.1 Patients shall be tested for HIV at 6-monthly intervals.

7.6.2 Patient with HIV/AIDS can be dialysed in any hospital-based or free standing dialysing unit that uses standard infection control precautions. Isolation is not required unless the patient has concomitant illnesses that require isolation e.g. pulmonary tuberculosis, or resistant bacteria as recommended by hospital infection control committees.

7.6.3 The routine infection control precautions used in dialysis centres when dialysing all patients are considered adequate to prevent HIV transmission i.e. blood precautions, routine cleaning and disinfection of dialysis equipment and surfaces that are frequently touched and restriction of non-disposable supplies to individual patients unless they have been sterilised between uses.

7.6.4 Dialysers and AV blood lines of HIV positive patients must not be reused and shall be disposed of in biohazard bags.

7.6.5 Strict adherence to standard infection control practices shall be enforced for all patients regardless of their HIV status since patients can be in the “window” period of seroconversion.

## **8 Dialysis Centre’s Responsibility to Patients**

8.1 The dialysis centre is responsible for the medical care of the patients including the management of complications arising from dialysis and end stage renal failure.

8.2 The physician in charge must ensure adequate monitoring of patients during dialysis, and subsequent outpatient aftercare.

8.3 The dialysis centre is responsible for registering all suitable patients for cadaveric renal transplantation with:

The Transplant Coordinator  
c/o The Department of Renal Medicine  
Singapore General Hospital  
Outram Road  
Singapore 169608

## **9 Safety**

- 9.1 There must be provision for emergency electric power supply for life-saving equipment in case of power failure.
- 9.2 Fire precautions must be taken and fire escapes shall be clearly visible.

## **10 Death of Patient**

- 10.1 All deaths occurring whilst on dialysis or as a consequence of dialysis or any procedure related to dialysis must be reported immediately to the Coroner and MOH.

## **11 Periodic Review of Dialysis Centres**

- 11.1 All dialysis centres will be subject to a regular review by a team appointed by the Ministry of Health, at least one of whom will be a renal physician.

Dated this 1<sup>st</sup> day of June 2001

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