

# **Ministry of Health**

# **POLICY GUIDELINES**

# ON

# **ESTABLISHMENT AND RUNNING**

# OF

# **RENAL DIALYSIS UNITS**

<u>JUNE 2015</u>

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### **ABBREVIATIONS**

ACLS	Advanced Cardiac Life Support
AIDS	Auto Immune Deficiency Syndrome
AAMI	Association for the Advancement of Medical Instrumentation
ART	Anti retroviral therapy
AVF	Arterio-Venous Fistula
AV	Arterio Venous
CKD	Chronic Kidney Disease
HBV	Hepatitis B Virus
HIV	Human Immunodeficiency Virus
KMLTTB	Kenya Medical Laboratory Technicians and Technicians Board
MPBD	Medical Practitioners and Dentists and Board
RRT	Renal Replacement Therapy
SSA	Sub Saharan Africa

#### FOREWORD

It is estimated that 4 million Kenyans suffer from kidney disease and many progress to end stage renal disease unnoticed. At the moment, about 10,000 kidney patients require dialysis as a form of renal replacement therapy. Of this number, only about 10% are currently able to access this service. Dialysis is available in a few centres in Nairobi, Mombasa, Eldoret, Kisumu and Nakuru offered by public, private and faith based health facilities. Some of these centres are stand- alone dialysis units.

In order to provide quality dialysis services to all patients who need it, it is imperative to have standard guidelines to guide the establishment of dialysis units. This will not only ensure that standards are followed, but also discourage setting up of substandard facilities which can endanger the life of patients.

The Policy Guidelines on Establishment of Renal dialysis Units have come at a time when more and more Kenyans require this service. These guidelines have addressed key areas such as physical infrastructure, equipment, human resource in terms of numbers, skills mix and required competencies, infection prevention and control and holistic patient management. Holistic patient management is a very important factor as dialysis should be undertaken with the goal of transplant in mind for patients with end stage kidney disease. For those with acute renal failure, dialysis helps in the short term until the renal function returns to normal. In addition, these guidelines have addressed the area of water quality and routine quality control measures and the need for regular inspections in order to maintain the set standards.

The goal of the ministry is to provide the highest attainable standards of health. The guidelines come at the time when the ministry is scaling up dialysis services by equipping one hospital in each county with dialysis services.

A lot of effort has gone into the development of these guidelines. I therefore urge all the stakeholders involved in provision of renal dialysis services to strictly adhere to the standards set in the guidelines for better treatment outcome.

Dr. Nicholas Muraguri Director of Medical Services.

#### **1.0 BACKGROUND**

Chronic kidney disease (CKD) is an important cause of death and disability worldwide. The estimated prevalence of the disorder is 8-16% worldwide with diabetes mellitus as the most common cause. In some regions, other causes like infections and environmental toxins are more common.

The lack of renal registries means that there are no reliable statistics about the prevalence of chronic kidney disease in the majority of African countries, but it is estimated to affect about 10% of the population. The disease affects mainly young adults aged 20 to 50 years in sub Saharan Africa (SSA) and is primarily due to hypertension and glomerular disease unlike developed countries where it presents in middle aged and elderly patients and is predominantly due to diabetes mellitus and hypertension. Patients mainly present late, with 75% in end stage renal disease (ESRD) requiring dialysis and severely ill with co-morbidities at presentation. The major risk factors for chronic kidney disease in Africa are hypertension, glomerular disease, HIV infection and diabetes mellitus. Hypertension is the leading cause of CKD in sub Saharan Africa affecting about 25% of the adult population, and is the cause of ESRD in 21% of patients on renal replacement therapy (RRT) in South Africa.

Glomerular disease is a major cause of ESRD in Africa. Although epidemiologic data from many areas in Africa are sparse, the incidence of glomerular disease particularly nephrotic syndrome seems to be higher in Africa. It is more prevalent and seems to be of a more severe form than that found in western countries and is characterized by poor response to treatment and progression to renal failure.

Prior to hepatitis B vaccination, hepatitis B virus (HBV) accounted for over 80% of membranous nephropathy in black children in South Africa. Following the introduction HBVC vaccination into the national immunization programme, there were no cases of membranous nephropathy due to HBV reported in the 0-4 year age group. Though data on prevalence of HIV related glomerular disease in Africa is scarce, it is reported that the prevalence of CKD in HIV infected ART-naive patients in SSA ranges from 6-45%. With increasing life expectancy on ART, aging HIV infected populations and nephrotoxicity of the various drugs used, an escalating burden of HIV chronic kidney disease maybe anticipated. Early initiation of ART may impact on the burden of CKD due to HIV.

Diabetes Mellitus affects 9.4 million people in Africa and this figure is expected to rise to 12.7 million, an increase of 140% by 2025. The prevalence of diabetic nephropathy is estimated to be 6-16% in SSA with prevalence of ESRD due to diabetes increasing in some regions.

Renal replacement therapy (RRT) is required for patients with acute renal failure and those with end stage renal disease. The availability of RRT is limited in much of SSA due to the high costs and shortage of skilled personnel and is responsible for the high rates of morbidity and mortality. Most dialysis centers are situated in cities, placing a further burden on patients who often have to frequently travel long distances to a dialysis center. The majority of the people living in SSA need to provide their own funding for RRT and therefore selection for dialysis is determined by personal resources. It's estimated that 4 million Kenyans are affected by chronic kidney disease and the causes are similar to those found in the rest of sub Saharan Africa. Many of these people are unaware of the problem and progress unnoticed to end stage renal disease. An estimated 10,000 Kenyans require dialysis services of whom only about 1200 are currently able to access the service.

The cost to the patient of dialysis excluding tests and medicines can be as high as 108,000 Kenya Shillings per month in the private settings in Kenya. The ultimate goal of the management of end stage renal disease is kidney transplant. About 50 kidney transplants are done annually in Kenya the cost of which is prohibitive to most ordinary Kenyans. Most patients therefore survive on dialysis for an unnecessary long period before undergoing renal transplant.

There are several dialysis units in public, private and faith based facilities including stand alone units. The Ministry of Health is also in the process of supplying 5 dialysis machines, complete with a water treatment plant to one level five hospital in every county, in addition to accelerating training of medical personnel on renal dialysis. There is therefore an urgent need to provide guidelines for the setting up of dialysis services in the country. This will ensure that dialysis, wherever it is offered meets the minimum required standard in terms of infrastructure, equipment and skills mix. Review of these guidelines will be done regularly in order to keep abreast with new developments in this field.

### **SECTION 1: LICENCING OF RENAL DIALYSIS UNITS**

1.1 Dialysis centres may be established either as stand-alone units or be 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 to the Medical Practitioners and Dentists Board for approval not less than 30 days before the intended commencement of operations of the renal dialysis centre. This application must be accompanied by a report from the County Director Health.

#### 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 per session, 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 All dialysis units 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 management of the dialysis unit shall:

(a) Ensure that there are prior arrangements made for patients receiving dialysis treatment in stand-alone dialysis centre to be admitted to a hospital, 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. Review of licensing processes will be done every 2 years by the medical board in conjunction and with the recommendation of the national kidney institute/ relevant stakeholders.

### SECTION 2: STAFFING AND ORGANIZATION OF RENAL DIALYSIS UNITS

#### 2.1 NEPHROLOGIST AND DIALYSIS DOCTORS

#### 2.1.1 Nephrologist

2.1.1.1 The nephrologist(s) in charge of a dialysis centre must be registered with the Kenya Medical Practitioners and Dentists Board to practice as a specialist(s) in internal medicine or paediatrics and sub-specialist(s) in nephrology. (S)he should have 2 year training in Nephrology from a recognized centre or a 2 year working experience from a recognized nephrology centre (including at least 1 year experience in dialysis).

2.1.1.2 The nephrologist in charge of the dialysis centre must practice holistic medicine and be responsible for overall management of the patients in the Centre. The responsibilities of the nephrologist in charge of the centre will include the following:

(a) Overall functioning of the renal/dialysis unit

(b) Dialysis access care (perform or arrange for insertion of vascular catheters, arrange for creation of AVF and insertion of tenckhoff catheters),

(c) Ensuring that arrangements are made with hospitals for all patients in a stand-alone centre to be expeditiously referred for emergency management

(d) Be contactable at all times to render emergency medical care. In the event that the nephrologist in charge is unable to fulfill his full responsibility to the patients of the dialysis centre, (S)he must make arrangements for a similarly qualified physician to be responsible for the total care of the patients in the Centre,

(c) Act as liaison between the hospital management, statutory bodies, dialysis staff and patients.

2.1.1.3 The nephrologist in charge of the dialysis centre shall in the management of patients, ensure that the need for dialysis treatment and choice of modality is based on sound clinical principles. (S)he shall:

(a) Clearly recommend to the end-stage renal failure patient the modality that is best suited to him/her. 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 and economic factors.

(b) Allow the patient to make a fully-informed choice of dialysis modality, after receiving adequate counseling from his renal physician on the different modalities available and the modality that is most appropriate for the patient's need

2.1.1.4 To maintain quality of care, the Nephrologist will ensure the following:

(a) Thorough clinical evaluation of medical condition and co-morbid conditions,

- (b) Periodic review of all patient charts,
- (c) Periodic evaluation of the performance of dialysis doctor(s) and nurses,
- (d) 24-7 hour consultation cover by Him/Her or equivalent,
- (e) Enforcement of patient care and safety rules and regulations
- (f) Supervision of in-house teaching program
- (g) Protection of patient rights
- (h) Supervision of periodic performance audit
- (i) Periodic review of water quality and infection control measures

2.1.1.5 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. A nephrologist can be responsible for up to 150 dialysis patients at any one time.

2.1.1.6 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.

#### 2.1.2 Dialysis doctor(s)

#### 2.1.2.1 Training

- (a) Valid MBCHB with Kenya Medical Practitioners and Dentist Board recognition
- (b) ) At least one-year experience in a recognized dialysis unit after internship
- (c) Experience in central line placement
- (d) Experience in critical care management
- (c) Valid advanced cardiac life support (ACLS) certification
- 2.1.2.2 Job description
- (a) Be involved in day-to-day dialysis patient management,

b) Before starting dialysis: assess hemodynamic status, indication for dialysis, vascular access, and co morbid illnesses,

c) During dialysis and after dialysis, ensure patient safety, dialysis adequacy, access functionality, and compliance to dialysis prescription and other treatments,

d) Institute and lead resuscitation when required,

e) Attend, at least once a year, recognized local (by the East African Kidney Institute or Kenya Renal Association) or international renal Continuous Medical Education (CME) sessions or conference.

f) Act as the team leader during the day to day functioning of the unit

#### 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) The nurse in charge shall be easily accessible at all times for consultation by the other nurses.

2.2.2 A minimum of one nurse per 5 patients per shift shall be required. (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 All nursing staff shall have valid cardiopulmonary resuscitation certification. The certified training in basic life support shall be current and up-to-date.

- 2.2.4 The job description the Nursing Staff shall be:
  - 1. Performing all aspects of the dialysis procedure as per prescription.
  - 2. Conducting discharge assessment.
  - 3. Instituting the recommendations of the dialysis doctors.

4. Conveying to the dialysis doctor/nephrologist any new event/change in patient status and recommending changes in the treatment based on the current needs of the patient.5. Facilitating communication between the patient and patient's family on one side and

- the treating team on the other.
- 6. Keeping an inventory of items in the unit.
- 7. Providing oversight and direction to the trainee technicians/nurses.
- 8. Participating in continuous quality improvement activities.
- 9. Entry and maintenance of records of all patients and producing them for medical auditing

**2.3. Biomedical Technician:** The biomedical technician shall have the relevant training. (s)he will be responsible for care of the equipment, trouble shooting and maintenance.

#### 2.4 Other Staff/Services

The following services shall be available either through a staff attached to the unit or through referral;

(a) Nutrition care: A nutritionist trained in dietetics will be needed to assist patients with Chronic Kidney Disease.

(b) Lab services: A competent lab technologist shall support the unit

(c) Pharmacy services: Where drugs are dispensed in the unit a pharmaceutical technologist shall be required.

(d) Counseling; Counseling services shall be provided by qualified Counselor either on site or through referral

### SECTION 3: PHYSICAL FACILITIES: CONSTRUCTION OF DIALYSIS CENTRE

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

#### **3.1 Water Treatment Plant Details**

Drinking water standards are inadequate for haemodialysis since patients are exposed to many thousands of litres of dialysis fluid annually. Water to be used for dialysis needs to be treated appropriately to remove impurities.

To achieve ultra-pure water standards "double pass reverse osmosis (RO)" may be required, and this will have an effect on the space allocated to the water treatment room. It is also recommended that project teams refer to the Association for the Advancement of Medical Instrumentation's (AAMI) standards.

3.1.1 The specification for the water treatment plant shall be determined by the composition of the water supply. It is therefore important to seek advice of the local water authority and, a renal specialist and the water treatment plant supplier

3.1.2 The plant shall be close to the dialysis area (although not adjacent to it because of noise considerations), as this will shorten the distance covered by the distribution ring. It should also be located close to vehicle access to enable deliveries of chemicals and salt (if softening is required).

3.1.3 There shall be sufficient space to accommodate a maximum of two people to monitor, adjust, service and repair the water treatment plant. Therefore the size shall be least 5 by 4 meters.

3.1.4 The plant room should be adequately lit and ventilated. Mechanical ventilation may be necessary if the heat gain from the water treatment plant cannot be controlled by natural ventilation.

3.1.5 The water treatment plant room shall not house any other equipment (for example calorifiers) other than that which is specific to its function.

3.1.6 The plant room floor shall be sloped to a drain and treated with a chemical-resistant sealant.

3.1.7 The door accesses shall have a lip and ramp to prevent water seeping to the rest of the unit in the event of a large water leak.

31.8 For security reasons there shall be a lockable door.

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

3.1.10 Extra water storage of 10,000 litres shall to be provided for use by the unit.

#### 3.2 The Dialysis Room

3.2.1 The space occupied by each dialysis station shall be 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. Therefore there should be at least one metre between patients undergoing dialysis.

3.2.2 Hand washing facilities shall be provided.

3.2.3 There shall be provision for the privacy of patients.

3.2.4 A nursing station should be sited appropriately where all patients are easily visible.

#### 3.3 Isolation Room

3.3.1 There shall be an isolation room through a separate entrance, with a dialysis machine reserved for patients with Hepatitis B virus infection.

#### 3.4 Room for peritoneal dialysis

A room with at least four beds will be provided for patients who require peritoneal dialysis.

#### 3.5 Dialyser Room

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

3.5.2 The dialyser shall only be reused for the same patient.

#### 3.6 Sluice Room

3.6.1 A small sluice room located within the renal dialysis centre shall be made available.

#### 3.7 Procedure Room

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

#### 3.8 Washing and Changing Facilities

- 3.8.1 There shall be adequate allocated space for patients to wash and change.
- 3.8.2 There shall be adequate facilities for staff to wash and change.

#### 3.9 Maintenance room

3.9.1 There shall be a room for the maintenance and repair of dialysis machines.

3.9.2 The space provision should be sufficient to park and maneuver equipment and accommodate a workbench with integral lockable cupboards.

3.9.3 The floor of the maintenance room shall have an impervious finish with coved skirting.

#### 3.10 Additional infrastructure will include

- Reception office: This is required at the entrance and adjacent to the waiting area for receiving and registering patients upon arrival.
- Waiting rooms: An adequate waiting area is necessary to accommodate patients as they wait their turns on the dialysis stations.
- A doctor's office with couch and chairs.
- An emergency/resuscitation room
- An office for nurse in charge
- A records office
- A restroom for staff
- Toilets for patients and staff
- Stores for drugs, consumables and linen.
- An area for specimen collection

- Pharmacy or access to pharmacy
- Side labs or access to lab facilities.

### **SECTION 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 de-ionisers to provide a quality of water which meets with the standards listed below:

(a)

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

(Extracted from the 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 amebocyte lysate assay.

4.3 Regular tests of the quality of the water for (a) and (b) shall 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 recognized laboratory registered to perform these assays. The records shall be kept and made available for inspection by the Kenya Medical Practitioners and Dentists Board.

### SECTION 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 shall 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 left to the discretion of the nephrologist/physician in charge of the unit.

5.3.2 Electrolytes shall be monitored and adjustments made by the nephrologist/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.

5.5.1 The physician in charge shall be responsible for arranging for the analysis of the dialysate whose chemical composition shall be clearly labeled.

5.5.2 The results of analysis, bearing the name of the centre and officer analyzing the dialysate shall be made available on request as and when required.

### **SECTION 6: EQUIPMENT**

6.1 Dialysis machines shall be equipped with monitors and alarms to ensure safe dialysis.

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

6.3 All dialysis machines and water treatment plant must undergo regular servicing at least once a year by a certified biomedical engineer/ technician.

6.4 The Renal Dialysis Unit shall have a fully equipped resuscitation tray according to the resuscitation guidelines

5 The nephrologist/physician in charge is ultimately responsible for ensuring that the monitoring, safety devices and resuscitation equipment are in proper working condition at all times.

6.6 All Renal Dialysis Units must have easy access to a laboratory for emergency assessment of parameters such as haemoglobin and potassium levels. At the same time there shall be easy access to imaging facilities.

### **SECTION 7: INFECTION CONTROL PRACTICES**

#### 7.1 General Precautions

7.1.1 Infection control measures are applicable at all times as per infection control guidelines

7.1.2 All staff including the Laboratory staff shall be vaccinated against Hepatitis B virus.

7.1.3 Routine screening for Hepatitis C shall be done.

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 handled according to existing guidelines.

7.1.6 Transfusion of blood and blood products shall be as per the National Blood Transfusion guidelines.

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. Dialysis shall proceed as is required on medical grounds.

7.2.2 Isolation facilities are not required unless the patient has concomitant infection with another disease that requires isolation.

7.2.3 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 Haemodialysis

7.3.1 Patients who require chronic haemodialysis shall at least 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 All patients shall be tested for HBsAg and anti-HBs at 6-monthly intervals.

7.4.1.1 Patients who are seronegative (HBsAg and anti-HBs negative) shall be tested 6-monthly for HBsAg, and anti-HBs.

7.4.1.2 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.

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

7.4.2 Patients who are HBsAg positive shall be isolated in a separate room with a separate entrance. A separate nurse and dedicated dialysis equipment shall be used for the HBsAg positive patients.

7.4.3 After each dialysis, non-disposable equipment used on a HBsAg positive patient shall be appropriately cleaned and disinfected or sterilized.

7.4.4 Dialysers and AV bloodlines must not be shared among patients. Bloodlines shall be used once and discarded.

7.4.5 If reuse of dialysers on the same patient is practiced, 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-Hepatitis C Virus (HCV) at 6-monthly intervals.

7.5.2 HCV infection should be confirmed by antibody assays, followed by quantifying the HCV RNA. 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.

7.5.4 If reuse of dialyser on the same patient is practiced, dialysers of HCV positive patients must be washed in a separate area with a separate entrance 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 dialyzed 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 sero conversion.

### **SECTION 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 nephrologist /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 renal transplantation with a recognized transplanting center.

### **SECTION 9: SAFETY**

9.1 There shall be provision for emergency electric power supply for lifesaving equipment in case of power failure.

9.2 Fire precautions shall be taken including clearly labeled fire escape routes.

### **SECTION 10: DEATH OF PATIENT**

10.1 All deaths occurring whilst on dialysis or as a consequence of dialysis or any procedure related to dialysis shall be audited and records kept and availed when required.

# SECTION 11: PERIODIC REVIEW OF DIALYSIS CENTRES BY THE MEDICAL BOARD

11.1 All dialysis centres will be required to renew their licenses annually as required by the Board which is also mandated to inspect the premises during its routine inspections or in special circumstances as necessary.

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