

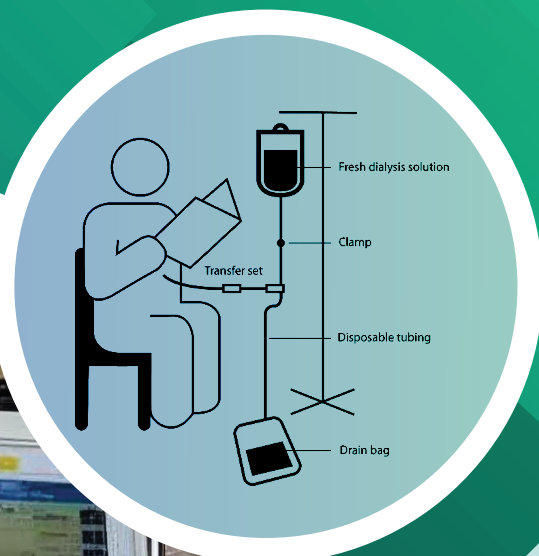


स्वास्थ्य एवं
परिवार कल्याण मंत्रालय
MINISTRY OF
HEALTH AND
FAMILY WELFARE

सत्यमेव जयते



OPERATIONAL GUIDELINES FOR PRADHAN MANTRI NATIONAL DIALYSIS PROGRAMME



Ministry of Health & Family Welfare,
Government of India





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Ministry of Health & Family Welfare,
Government of India



आराधना पटनायक, भा.प्र.से.
अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)
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स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare



MESSAGE

The Pradhan Mantri National Dialysis Programme (PMNDP) reflects the Government's steadfast commitment to ensuring equitable, affordable, and quality healthcare for every citizen. Chronic kidney disease is an emerging public health challenge, and dialysis services are a lifeline for many patients who depend on regular, reliable care for survival and well-being.

Through PMNDP, we are working to strengthen dialysis services across the country by expanding access, improving infrastructure, and building skilled teams capable of delivering safe and compassionate care. Under PMNDP, dialysis services are being provided at District Hospitals to ensure access closer to the community. The effort is not merely about providing treatment, but about restoring dignity, continuity, and hope in the lives of patients and their families.

These Operational Guidelines represent an important step towards standardizing service delivery and supporting states and implementing agencies in improving the quality and efficiency of dialysis care. They will be a useful resource for all stakeholders involved in planning, managing, and providing dialysis services under PMNDP.

I am confident that with continued collaboration, commitment, and adherence to these principles, we will move closer to our goal of ensuring that no individual is denied life-saving dialysis due to lack of access or affordability.

(Aradhana Patnaik)

#StopObesity

टीबी हारेगा देश जीतेगा / TB Harega Desh Jeetega

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Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services



Message

Chronic kidney disease (CKD) is an emerging public health concern in India, closely linked with the increasing prevalence of diabetes and hypertension. According to the Indian Council of Medical Research's report on "India: Health of the Nation's States" (2017), CKD has been identified as the ninth leading cause of mortality in the country. It rose to 20th cause of Disability-Adjusted Life Years (DALYs) in 2016 from 30th in 1990, indicating the rising burden of CKD.

The Pradhan Mantri National Dialysis Programme (PMNDP) was launched to address this growing burden by ensuring equitable access to free and quality dialysis services through public health facilities and Public-Private Partnerships.

These Operational Guidelines provide a comprehensive framework for standardizing dialysis service delivery, strengthening infection prevention and control, ensuring equipment maintenance, rationalizing resource utilization, and improving patient safety and outcomes.

I encourage all healthcare professionals to utilize these guidelines to enhance the quality, safety, and continuity of dialysis care across the country.

(Sunita Sharma)



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Government of India
Ministry of Health & Family Welfare
Kartavya Bhawan-1, New Delhi-110001



Message

The Pradhan Mantri National Dialysis Programme (PMNDP), under the National Health Mission, stands as a vital step towards ensuring that essential and life-saving dialysis services are available and affordable to all who need them. By expanding dialysis facilities across public hospitals and through effective Public-Private Partnerships, the programme has significantly enhanced access to care for patients with chronic kidney disease.

As implementation scales up, maintaining quality, efficiency, and accountability becomes paramount. These Operational Guidelines provide a comprehensive framework to guide states and districts in planning, organizing, and monitoring dialysis services in a systematic and standardized manner. They highlight key aspects such as infrastructure management, human resource development, infection prevention, equipment upkeep, and patient safety.

State and district health authorities are encouraged to adopt these guidelines in their entirety and to integrate the recommended practices within routine programme management processes. Strong coordination, continuous training, and proactive supervision will be essential to ensure consistent and high-quality service delivery.

Through collective effort and commitment, we can ensure that every eligible patient under PMNDP receives dialysis care that upholds the principles of safety, dignity, and equity.



(Sibin C.)

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Ministry of Health and Family Welfare

Government of India

MESSAGE FROM EXECUTIVE DIRECTOR



The Government of India has prioritised the strengthening of non-communicable disease services under the National Health Mission and the Pradhan Mantri National Dialysis Programme (PMNDP) stands as a flagship initiative that has transformed access to dialysis services across the country.

PMNDP was launched in 2016–17 to establish haemodialysis facilities in all district hospitals under the National Health Mission and peritoneal dialysis was subsequently added to the programme in 2019 to further expand treatment options for patients with chronic kidney disease. As the program has expanded, the need for a more structured and comprehensive approach to service delivery has become evident.

The Operational Guidelines for PMNDP represent a significant advancement in our efforts to provide high-quality care to patients suffering from kidney disease. These guidelines address various aspects of dialysis service provision with a strong emphasis on maintaining high standards of patient safety, infection control, and continuous monitoring to ensure optimal outcomes.

I am confident that these guidelines will serve as a valuable resource for all stakeholders involved in the PMNDP, enabling them to deliver the quality of dialysis services. The successful implementation of these guidelines will be a major step forward in our ongoing efforts to improve the health and well-being of our citizens.


19/3/26
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GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
KARTAVYA BHAVAN-1, NEW DELHI-110001



MESSAGE

Ensuring equitable access to affordable and quality healthcare services for patients suffering from chronic kidney disease (CKD) is an important public health priority. With the growing prevalence of diabetes, hypertension, and other non-communicable diseases, the demand for dialysis services is steadily increasing across the country.

The Pradhan Mantri National Dialysis Programme (PMNDP), under the National Health Mission, has been a transformative initiative in addressing this need by expanding access to life-saving dialysis services in public health facilities. Through a combination of in-house services and Public-Private Partnership models, the programme has helped bring dialysis care closer to patients, especially those from poor and vulnerable sections of society, while reducing out-of-pocket expenditure.

The Operational Guidelines on Haemodialysis and Peritoneal Dialysis have been developed to provide States and Union Territories with a comprehensive framework for planning, implementation, and monitoring of dialysis services in a standardized and systematic manner. These guidelines outline key operational, technical, and managerial aspects necessary for ensuring effective service delivery, optimal utilization of resources, and adherence to quality standards across all facilities.

All States and UTs are encouraged to effectively adopt these guidelines and integrate them into routine programme implementation. With sustained commitment and coordinated efforts, we can ensure that every eligible patient receives dialysis care with dignity, safety, and equity, while also reducing the overall burden of kidney disease in the country.


(Saroj Kumar)

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LIST OF ABBREVIATIONS

AAMI	Association for the Advancement of Medical Instrumentation
ABHA	Ayushman Bharat Health Account
ACT	Activated Clotting Time
ALP	Alkaline Phosphatase
ALT	Alanine Transferase
APL	Above Poverty Line
ASAT	Aspartate Transferase
AVF	Arteriovenous Fistula
BIS	Bureau of Indian Standards
BMW	Biomedical Waste
BPL	Below Poverty Line
BSI	Bloodstream Infection
BUN	Blood Urea Nitrogen
CAPD	Continuous Ambulatory Peritoneal Dialysis
CFU	Colony Forming Unit
CKD	Chronic Kidney Disease
CPR	Cardiopulmonary Resuscitation
DG set	Diesel Generator Set
DM	Doctorate of Medicine
ESRD	End-Stage Renal Disease
FDI	Free Drugs Initiative
FDSI	Free Diagnostics Service Initiative
GGT	Gamma-Glutamyl Transpeptidase
GNM	General Nursing and Midwifery
HAI	Healthcare-Associated Infection
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HCW	Healthcare Worker
HD	Haemodialysis
HDF	Hemodiafiltration
HDL	High-Density Lipoprotein
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
IPC	Infection Prevention and Control
IPHS	Indian Public Health Standards
ISO	International Organization for Standardization
LDL	Low-Density Lipoprotein
MBBS	Bachelor of Medicine, Bachelor of Surgery
MD	Doctor of Medicine
MOHFW	Ministry of Health and Family Welfare

MOU	Memorandum of Understanding
NAAT	Nucleic Acid Amplification Test
NHM	National Health Mission
NQAS	National Quality Assurance Standards
PMJAY	Pradhan Mantri Jan Arogya Yojana
PMNDP	Pradhan Mantri National Dialysis Programme
PTH	Parathyroid Hormone
RCH	Reproductive and Child Health
RFP	Record for Proceeding
RO	Reverse Osmosis
RRT	Renal Replacement Therapy
SGOT	Serum Glutamate Oxaloacetate Transaminase
SGPT	Serum Glutamate Pyruvate Transaminase
SpO2	Peripheral Capillary Oxygen Saturation
SRRE	Surveillance, Research, Review & Evaluation
TDS	Total Dissolved Solids
TVC	Total Viable Count

PART 1: HAEMODIALYSIS SERVICES

CHAPTER 1

INTRODUCTION

HAEMODIALYSIS

1. Dialysis removes wastes and excess water from the blood. Haemodialysis (HD) removes wastes and water by circulating blood outside the body through an external filter, called a dialyzer, that contains a semi permeable membrane.
2. Haemodialysis requires a dialysis machine and pure water and is typically done in a health facility (Dialysis centre). One session lasts 4 hours and it needs to be repeated 2-3 times a week. Haemodialysis requires the patient to travel to the centre each time. HD requires repeated access to the blood circulation, which is commonly achieved by creation of Arterio-venous Fistula (AVF), which is initiated at the tertiary care level by a Urology surgeon or reconstructive vascular surgeon.
3. One Haemodialysis machine can be used to dialyse another patient only after disinfection once the previous patient has finished dialysis. Typically, 2-3 dialysis sessions are performed every day. Haemodialysis and Peritoneal dialysis are the two modalities for renal replacement therapy (RRT), till the patient receives kidney transplant. Haemodialysis modality is more accessible (94%) as compared to Peritoneal Dialysis (6%) as per the Global Dialysis Perspective in India report, published on 01 October 2020.
4. Haemodialysis requires trained physicians, nurses, technicians (including those trained to repair HD machines), appropriate physical space, HD machines, accurate scales, the necessary disposable supplies, water processing equipment, dialyzer reprocessing equipment, a reliable electricity supply, and so forth. It is also essential that basic standards of patient care are adhered to in a variety of domains to provide safe and adequate care.

PRADHAN MANTRI NATIONAL DIALYSIS PROGRAMME (PMNDP)

5. Ministry of Health and Family Welfare (MoHFW) had launched the Pradhan Mantri National Dialysis Programme (PMNDP) in the year 2016 with an aim to improve access to Haemodialysis services by setting up one dialysis centre in each district hospital of the country under the National Health Mission. Guidelines of National Dialysis Programme including the Model Request for Proposal (RFP) was developed and released on 7th April 2016. The objective of PMNDP is to provide free of cost dialysis services to BPL (Below Poverty Line) patients at public health facilities and at subsidized rates for the APL patients. Beneficiary of PMNDP will include children from 05 years to 18 years and all adults for haemodialysis.

PMNDP PORTAL

6. The PMNDP portal was launched on 5th May 2022 with the objective of integrating dialysis services under the 'One Nation-One Service' concept. MoHFW undertook the challenge of

ensuring all states provide free dialysis services to any patient when travelling to other state and incorporated the clause in the MoU between NHM and the States/UTs.

7. The PMNDP portal has some unique features like Global Search using ABHA ID, Transfer patient, Vacant slot, waiting list generation, mobile application and patient registration through biometric & demographic authentication for ensuring portability for the patients in availing dialysis services anywhere in the country.

STANDARDS FOR HD FACILITY

8. The standards to be maintained in a dialysis unit are as follows (IPHS-2022 may also be referred to in this regard):
 - A dialysis unit in a HD facility should have an appropriate design and an ideal space of at least 120 square feet per machine (in case space is not available 100 – 110 Sq Ft per machine), with access to cardiac resuscitation equipment.
 - The dialysis unit should have a stable three phase electrical supply with standby DG supply having automatic changeover or Inverter providing uninterrupted electrical supply to the unit.
 - The facility should have the provision for clean potable water supply through a RO water treatment plant adhering to AAMI standards for water quality.
 - Water used for dialysate should meet the AAMI Standards.
 - The facility should have Medical Gas Pipeline System for provision of oxygen near each patient's dialysis bed.
 - Seropositive patients should be dialyzed in a separate area with separate machines.
 - Universal precautions (Head cap, gloves, face mask, apron, shoe covers) should be adhered to by all staff while providing dialysis services at the facility.
 - Dialysis machines should be disinfected internally and externally after every use.
 - Staff should wear gloves when in contact with the dialysis machine and gloves must be changed between patients.
 - Hand hygiene protocols must be prominently displayed and adhered to.
 - Facility for hand washing and disinfection must be available at the unit.
 - Staff should be trained in dealing with dialysis related emergencies, and competent to provide basic life support and resuscitation of patients.
9. Dialyzer reuse - Dialyzer reuse to reduce the costs of disposables is acceptable if proper protocols are followed. Automatic dialysis reprocessing units should be available to clean and disinfect the dialyzer after every use and monitor the bundle volume. Dialyzer can be re-used up to maximum of 5 times or till 80% of bundle volume, whichever is earlier.
10. Vascular access. Ideally, every patient should have permanent vascular access, preferably a native arteriovenous fistula. Complications in maturation, patency and infections are common in arteriovenous fistulas and should be monitored to assess infection rates.

11. Each dialysis session must be of at least 4 hrs duration with appropriate blood flow and should be monitored closely (Kt/V) for adequate removal of uremic toxins. Management of extracellular fluid (volume control) is critically important for all dialysis patients and must be considered as a key component of dialysis adequacy. The goal of fluid removal during dialysis is to maintain the patient's optimal weight and volume status while achieving normal blood pressure (BP) levels.
12. Anaemia in patients can contribute to a variety of symptoms and can be corrected by adequate iron replacement and exogenous supplementation of erythropoietic-stimulating agents. The recommended diagnostic tests to be undertaken is given in Annexure-VIII.
13. Assessment of pulse, BP and weight (Basic vitals) pre-dialysis and post dialysis is important and should be recorded on the PMNDP portal (Patient Health Record Form) during each visit. (Annexure-IX).
14. Many dialysis patients are malnourished, and a careful evaluation of their protein and energy nutritional status should be made with appropriate nutritional counseling. Underlying causes of malnutrition need to be considered carefully, including the problem of inadequate dialysis, underlying inflammation, and undiagnosed infections.
15. The Haemodialysis machine and water treatment system (AAMI Standards) and monitoring protocol is given in Annexure-X.
16. The dialysis facility should comply with the National Quality Assurance Standards (NQAS) for haemodialysis unit. Refer Checklist-20 (Haemodialysis), Page No-129 https://qps.nhsrindia.org/sites/default/files/2024-02/VOLUME-3_final-for-web.pdf

1. INFRASTRUCTURE REQUIREMENTS	
1.1	Signage
1.1.1	The Dialysis Centre shall display appropriate signage which shall be in the local language.
Following informative signage shall be displayed:	
1.1.2	Name of the care provider with contact number
1.1.3	Name of the Head of the Hospital with Contact Number
1.1.4	Timings of the Dialysis center
1.1.5	Patients' rights & responsibilities.
Following safety signage shall be displayed:	
1.1.6	Fire safety and exit plan signage with emergency contact number of nearby Fire Department.
1.1.7	Signage for "No Smoking" in prominent places
1.2.	Other requirements
1.2.1.	Access to the Dialysis Centre shall be comfortable for the patient and/or attendants/visitors.
1.2.2.	The Centre shall be developed and maintained to provide safe, clean and hygienic environment for patients, their attendants, staff and Visitors
Dialysis Service Complex	
1.2.3.	Dialysis station shall be designed to provide adequate space and safe treatment as well as to ensure the privacy of patients.
1.2.4.	Separate haemodialysis areas shall be designated solely for use of Seropositive patients.
1.2.5.	Nursing stations shall be located in an area that allows adequate surveillance of patients on haemodialysis machines.
1.2.6.	Separate storage area for sterile instrument/supplies and other materials should be available.
1.2.7.	The work area should contain a worktable & chair with PC desktop with broadband facility, hand washing sink, storage cabinets.

Non-Treatment Area	
1.2.8	There should be a designated area for water treatment system (RO water plant as per AAMI standards).
1.2.9	The center should have separate male and female toilet facility for the staff & patients with urinal, water closet and lavatory
1.2.10	The centre should have a reception area for information service, procedure room, separate area for dialyzer reprocessing unit and store, and an area for consumables storage.
1.2.11	The centre shall have waiting area with sufficient seats for patients and visitors.
1.2.12	The centre shall have 24-hour provision of portable water for drinking & hand hygiene. It shall also have 24-hour uninterrupted supply of electricity, either through direct supply or from other sources (DG set/inverter).
1.2.13	The centre shall have provision for analysis of water used for haemodialysis purposes (Pre & Post RO TDS on daily basis, chemical purity (every 03 month), endotoxin (monthly), bacteriological & fungal growth (monthly).
1.2.14	The water pipe system connecting the treated water supply to HD machines should not have bends to avoid growth of bacteria. All plumbing shall be installed in such a manner as to prevent back flow or cross-contamination between other water supply pipeline.
1.2.15	The Dialysis centre shall be provided with effective and suitable ventilation (AC) to maintain comfortable room temperature.
1.2.16	The centre shall be provided with sufficient intensity of illumination to provide effective nursing care.
1.2.17	The centre shall have appropriate internal and external communication facilities.
1.2.18	Furniture and fixtures shall be available in accordance with the activities and workload of the centre. They shall be functional and properly maintained. Indicative list of furniture and fixtures is as per Annexure-I

2. MEDICAL EQUIPMENT AND INSTRUMENTS	
2.1	The Centre shall have adequate medical equipment and instruments, commensurate to the scope of service and number of beds.
2.2	There shall be established system for maintenance of critical Equipment
2.3	All equipment shall be kept in good working condition through a process of periodic inspection, cleaning and maintenance. An equipment log- book shall be maintained for all the major equipment. Indicative list of medical equipment and instruments is as given in Annexure-II.

3. DRUGS, MEDICAL DEVICES AND CONSUMABLES	
3.1	The centre shall have adequate drugs and consumables commensurate to the scope of services and number of beds
3.2	Emergency drugs and consumables shall be available at all times.
3.3	Drug storage shall be in a clean, well lit, and safe environment and shall be in consonance with applicable laws and regulations. Indicative list of drugs and consumables is as given in Annexure-III.

4. HUMAN RESOURCE REQUIREMENTS	
4.1.	A Qualified Nephrologist, having DM or DNB in nephrology or its equivalent degree shall visit the dialysis facility fortnightly/monthly and available for review of patients. In areas where there is no Qualified Nephrologist, a certified trained dialysis physician (MD Medicine) (as per local law and regulation) shall provide the services of the Nephrologist or may engage Nephrologists from private facilities on visit basis. For PPP Mode- Service Provider will provide 01 Nephrologist for 10 dialysis facilities for undertaking physical fortnightly/monthly visits and review patients.
4.2.	The centre shall have qualified and/or trained medical staff as per the scope of service provided and the medical care shall be provided as per the requirements of professional and regulatory bodies
4.3.	The centre shall have qualified and/or trained nursing staff as per the scope of service provided and the nursing care shall be provided as per the requirements of professional and regulatory bodies
4.4.	The support/paramedical staff shall be qualified and/or trained as per the scope of services provided, and as per the requirement of the respective professional or regulatory bodies.
4.5.	For every member of staff (including contractual staff), there shall be personal record containing the appointment order, documentary evidence of qualification and/or training (and professional registration where applicable).
4.6.	Periodic skill enhancement/refresher training on renal care and basic life support resuscitation procedures shall be provided for all categories of the staff as relevant to their job profile, as prescribed by professional bodies and as per local law/regulations. Details of HR requirement are as given in Annexure-IV

5. SUPPORT SERVICES	
Registration/Help desk:	
5.1.	The Centre shall have a Registration/ Helpdesk and the scope of this shall also include provision of patient guidance/diet counselling and training in use of PMNDP mobile application.
Linen management:	

5.2.	The center should use disposable linen. In case of unavailability of disposable linen, soiled linen shall be collected, transported and washed separately in clean and hygienic environment.
5.3.	Where linen is contaminated, appropriate decontamination shall be carried prior to dispatch for washing.
Waste Management Services:	
5.4.	Segregation, collection, transportation, storage and disposal of biomedical waste shall be as per Bio medical waste handling rules.
5.5.	Segregation, collection, transportation, storage and disposal of general waste shall be as per applicable local laws
Medical Gas	
5.6.	The centre should have medical gas pipeline system for supply of oxygen at the bed point. State/UT shall provide medical gas pipe system for delivery of oxygen at the bedside delivery points.
5.7.	In case of unavailability of MGPS, oxygen cylinder shall be stored and handled in a safe manner.
5.8.	All applicable legal requirements shall be complied.
5.9.	Appropriate back-up and safety measures shall be in place to ensure patient safety at all times.
Ambulance services	
5.10.	The Centre shall have provision of transporting patients using the 102 ambulances for unwell dialysis patients using the existing facility available for transporting pregnant women. The transfer/referral/investigations etc in safe manner.
5.11	The ambulance service shall be in-house and shall comply with the applicable local laws.
5.12	Critical patients shall be transported under supervision of trained and qualified staff.

6. RECORD MAINTENANCE AND REPORTING	
6.1	The centre should use the PMNDP portal for registration of new patients using ABHA ID and biometrics. ABHA ID should be used for every subsequent visit and for proving dialysis session.
6.2	Medical Records should be maintained in both physical and digital format patient health record (PMNDP portal).
6.3	Confidentiality, security and integrity of records shall be ensured at all times. For records a Dialysis Centre shall maintain please refer to Annexure-V .

7. BASIC PROCESS

Informed Consent Procedure

7.1.	Informed consent shall be obtained from the patient/ next of kin/ legal guardian as and when required as per the prevailing Guidelines / Rules and regulations in the language patient can understand. Please refer to Annexure-VI & VII
7.2.	Patient and/or families shall be educated on preventive, curative, promotive and rehabilitative aspects of care either verbally, or through printed materials.
7.3.	All the relevant documents pertaining to the procedures performed shall be maintained in the record, including the procedure safety checklist.
7.4.	Monitoring of patients' intradialytic clinical parameters like pulse, blood pressure and SpO2 shall be done during and after the procedures and same shall be documented.
7.5.	Staff involved in direct patient care shall receive basic training in CPR
7.6.	The centre shall follow standard precautions like practicing hand hygiene, use of personal protection equipment, etc to reduce the risk of healthcare associated infections.
7.7	Regular cleaning of all areas with disinfectant shall be done as per prescribed & documented procedure.
7.8	Housekeeping/sanitary services shall ensure appropriate hygiene and sanitation in the hospital.
7.9	Security and safety of patients, staff, visitors and relatives shall be ensured by provision of appropriate safety installations and adoption of appropriate safety measures.
7.10	The Hospital shall undertake all necessary measures, including demonstration of preparedness for fire and non-fire emergencies, to ensure the safety of patients, attendants, staff and visitors.
7.11	All applicable fire safety measures as per local law shall be adopted. This includes fire prevention, detection, mitigation, evacuation and containment measures. Periodic training of the staff and mock drills shall be conducted. The same shall be documented and is desirable.

Infection is the most common cause of hospitalization and the second most common cause of mortality among haemodialysis (HD) patients, after cardiovascular disease. HD patients are exposed to different types of infection, which include BSI and localized infections of the vascular access, blood-borne infections (HBV, HCV and/ or HIV) and airborne infections such as tuberculosis.

Outbreaks of HCV infections in HD facilities, which occur frequently, have often been due to poor infection control practices. Sources of infections could be contaminated water, equipment and environmental surfaces in the treatment area and patients with infections who pose a risk to other nearby patients.

1. IPC programme in the dialysis unit

Patients undergoing haemodialysis are at increased risk of HAIs. Therefore, the IPC programme is essential for HD units. It includes multiple interventions which are designed to reduce the risk of infection.

A doctor or a senior nurse working in the unit should be given responsibilities of IPC activities. The role of this link person includes:

- Monitoring of IPC practices
- Training of new staff and ongoing training of all staff
- Periodic surveillance to assess risk
- Implementation of preventive bundles

It is important that this link person communicates and networks with the facility IPC team and all members of the HD team including nurses, technicians, physicians, housekeeping staff, and the patient/ family. It is important that all members of the HD team understand their role and are held accountable for compliance with IPC practices.

2. Measures to reduce risk of infection in HD patients

In the haemodialysis setting, contact transmission plays a major role in transmission of blood-borne pathogens. Transmission occurs via hands of HCWs, contaminated with infected blood directly or indirectly from contaminated surfaces and equipment.

- Standard precautions are to be used routinely on all patients and include use of gloves, disposable plastic aprons or gown, mask (whenever needed), to prevent contact of HCWs

with blood, secretions, excretions, or contaminated items.

- Respiratory etiquette should be observed routinely.
- Patient identified with an airborne illness should be masked immediately and separated from other patients in a single room which is preferably under negative pressure.
- Staff should be vaccinated as per the recommendations of the national immunization programme.
- The patient and nurse must wear a mask when a catheter (not fistula or graft) is connected or disconnected from the blood lines during dialysis.

3. IPC for patients with blood-borne infections

Besides standard precautions, the following points should be kept in mind.

- HBsAg-positive patients should undergo dialysis in a separate room using separate machines, equipment, instruments, and supplies.
- Dialysers are discarded in biomedical waste after treatment and cannot be reprocessed or reused.
- Staff caring for HBV patients should be HBV-immune and cannot care for HBV-positive and -negative patients at the same time.
- Care of patients with HCV and HIV requires strict adherence to environmental IPC practices including equipment disinfection.

4. Dialysis water

The patient is exposed to more than 100 litres of water during each session of dialysis. Therefore, water must be purified and filtered. Contaminants must be removed by deionization and reverse osmosis.

Perform bacterial culture and endotoxin assay on dialysate and reverse osmosis water at least monthly and during outbreaks using standard quantitative methods, as per available guidelines. Dialysate should be tested at the end of the treatment day.

5. Reprocessing and reuse of dialyser sets

Reprocessing is performed outside of the dialysis treatment area in a dedicated room. It is the act of cleaning, testing, and filling the dialyser with disinfectant solution.

Reuse is performed in the treatment area. It refers to verification of disinfection, rinsing and testing to ensure the complete removal of all disinfectants, and “reusing” the reprocessed dialyser for the designated (same) patient.

Reuse and reprocessing must follow all applicable standards (**Refer Annexure-X, Part-E**) and for sero-positive cases, only single use disposable dialyser is recommended.

1. Capacity Building for the Healthcare staff providing dialysis care

Capacity building, or development, is the process by which individuals and organisations obtain, improve, and retain the skills, knowledge, tools and other resources needed to do their jobs competently or to a greater capacity to obtain better results.

The training methodology is suggested as 'On Job Training' with short orientation training for healthcare providers at the nearest Medical College or Dialysis facility under the supervision of MO/nephrologist. Refresher training can be provided under distance coaching & mentoring by the designated in-house Nephrologist or through private service provider. Webinars and workshop as per need can also be conducted.

Patient education for taking care of the AV fistula site is important while on haemodialysis. The same is discussed in the subsequent paragraphs.

2. Patient Education

Patient Education particularly in taking care of the vascular/ catheter access site is very important. Infections are common among people receiving dialysis and can be very serious. It is important to remember that germs can spread between people through direct contact when someone is sick or by breathing in respiratory droplets after a sick person coughs or sneezes. Germs can also spread within the dialysis facility through the surfaces of equipment or through the unclean hands.

3. Taking Care of AV Fistula

Caring for AV Fistula or graft one must learn how to take care of the arterio-venous access.

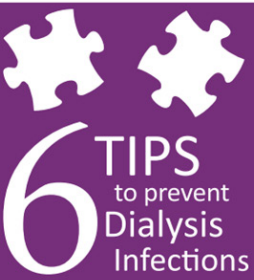
- Check the access site every day for a pulse. Watch for any redness, pus or unusual drainage or swelling. This may be sign of infection and must be informed to the health care provider/ Nurse.
- To feel for a pulse: – Put your fingers over the thumb side of your wrist. – Gently push down. – You should feel a pulsing sensation.
- If you have a fistula, you will need to feel for a thrill. To feel for a thrill:
 - Put your fingers on the top of your access.
 - You should feel a “purr” or pulsing sensation (thrill).

It is important to educate patient for keeping the access site clean to lower the chance of infection.

Patient should be educated for :

- Washing hands often or use hand sanitizer.
- Covering nose and mouth when coughing or sneezing.
- Learn about the dialysis process and know what to expect during treatment.
- Wash the access arm with soap and warm water every day and before going to the dialysis centre.
- Protect the dialysis access site from trauma, pressure or cut or wound.
- Avoid dressing that puts pressure on the access site.
- Avoid wearing tight clothing or jewellery around the access arm.
- Avoid sleeping on the access arm side.
- Avoid lifting heavy objects with the fistula arm.
- Do not let anyone use your access arm to draw blood, take blood pressure or place IV's in the access arm.

Informed consent shall be obtained from the patient/ next of kin/ legal guardian as and when required as per the prevailing Guidelines / Rules and regulations in the language patient can understand. Patient and/or families shall be educated on preventive, curative, promotive and rehabilitative aspects of care either verbally, or through printed materials.

Patients with Fistulas or Grafts	 TIP 1	 TIP 2	 TIP 3
 6 TIPS to prevent Dialysis Infections U.S. Department of Health and Human Services Centers for Disease Control and Prevention www.cdc.gov/ckd www.cdc.gov/dialysis/patient	TIP 1 Take care of your dialysis access site at home. Avoid scratching or picking it.	TIP 2 Wash your hands often, especially before and after dialysis treatment.	TIP 3 Wash or cleanse your dialysis access site prior to treatment.
	 TIP 4	 TIP 5	 TIP 6
	TIP 4 Know the steps your healthcare providers should take when using your dialysis access for treatment.	TIP 5 Know the signs and symptoms of infection and what to do if you think you might have an infection.	TIP 6 Know what to do if you have any problem with your dialysis access site.

MONITORING OF HAEMODIALYSIS QUALITY OF CARE INDICATORS

Haemodialysis patients have high morbidity and mortality rates, in spite of the promising technical advances developed over the last 15 years. CKD is associated with increased mortality, mainly attributable to cardiovascular events. In ESRD patients, optimization of dialysis quality and cardiovascular risk factors is consequently a major issue and monitoring of specific indicators is therefore mandatory.

Table 1: Quality of care Indicators and Targets

(Source: <https://bmcnephrol.biomedcentral.com/articles/10.1186/1471-2369-14-109>)

Field	Clinical Indicator	Frequency	Clinical Performance Measures	Remarks
Anemia	Hemoglobin (Hb, g/dl)	Monthly	% of patients with $10 < \text{Hb} < 12$	Monitoring of erythropoietin and iron sucrose doses.
Vascular Access	Arteriovenous Fistula	-	% of patients with catheters $< 7\%$	Early AVF making and avoiding catheter use
Dialysis Dose	Kt/VBCM (single pool)	Values collected for each dialysis session	% of patients with Kt/VBCM > 1.4	Monitoring of Kt/V
Hemodynamics	Blood Pressure	Values collected for each dialysis session	% of patients with pre-dialysis BP $< 140/90$ mmHg	Pre & post dialysis BP goals should be $< 140/90$ mm Hg and $< 130/80$ mm Hg respectively and it should be monitored.
Nutrition	Albumin (g/l)	Monthly	% of patients with albumin > 35	Albumin level showed the strongest association with mortality compared with other predictor variables.

Field	Clinical Indicator	Frequency	Clinical Performance Measures	Remarks
	Serum Bicarbonate (mEq/L)	Monthly	% of patients with $20 < \text{HCO}_3 < 24$	Patients with serum bicarbonate levels higher than the upper target range can be treated by lowering the bicarbonate dialysate concentration, bearing in mind that intradialytic alkalosis is poorly tolerated with more hypotensive episodes during the dialysis session.
Bone Metabolism	Phosphorus (mg/dL)	Monthly	% of patients with range between 2.5 to 4.5 mg/dL	More aggressive strategies to be adopted to lower serum phosphorus, such as adding a convective component to clearance with hemodiafiltration, lengthening dialysis session time or increasing dialysis frequency.
	Calcium (mg/dL)	Monthly	% of patients with $8.5 < \text{Ca} < 10.5$	Calcium level should be monitored.
	PTH (pg/ml)	Every 06 Month	% of patients with $150 < \text{PTH} < 300$	PTH levels should be maintained in the range of approximately two to nine times the upper normal limit for the assay (45 to 490 pg/ml).

Field	Clinical Indicator	Frequency	Clinical Performance Measures	Remarks
	25 (OH)vitD (ng/mL)	Every 06 Month	% of patients with 28.8 <vitD<80	Vitamin D deficiency is an independent risk factor for cardiovascular events and all cause mortality in haemodialysis patients. Vitamin D may become an important quality of care indicator in the near future.
Complete KFT	Blood Urea Nitrogen (BUN)	Quarterly	7 - 20 mg/dL	Monitoring of Kidney function parameters.
	Blood Urea		10 - 50 mg/dL	
	Creatinine		Male: 0.6-1.2 mg/dL, Female: 0.5-1.1 mg/dL	
	Uric Acid		3.4-7.0 mg/dL	
Complete LFT	Alanine Transaminase (ALT)/SGPT	Quarterly	4-36 IU/L	Monitoring of liver function parameters.
	Aspartate Transaminase (AST)/SGOT		5 to 30 IU/L	
	Alkaline Phosphatase (ALP)		30-120 IU/L	
	Bilirubin (total)		2-17 µmol/L	
	Direct Bilirubin		0-6 µmol/L	
	Albumin		35-50 g/L	
	Total Protein		60-80 g/L	
	Gamma-Glutamyl Transpeptidase (GGT)		6-50 IU/L	
Viral Marker	(HIV/HCV/ HBsAg)	Quarterly	-	Monitoring of viral markers status.

NORMS UNDER INDIAN PUBLIC HEALTH STANDARDS (IPHS-2022)

The dialysis station should be designed to provide an adequate space area and safe treatment as well as to ensure the privacy of patients. The nursing station should be located in an area that allows adequate surveillance of patients on haemodialysis machines. The facilities such as observation rooms, recovery rooms, isolation rooms, RO room should be provisioned. There should also be a designated area for continuous ambulatory peritoneal dialysis (CAPD) training for the patient and her/his family member. The number of dialysis machines required at different levels of District Hospitals are as under:

Type of Hospital	SDH 100 beds	DH 50 beds	DH 100 beds	DH 200 beds	DH 300 beds	DH 400 beds	DH 500 beds
Number of Dialysis Beds including seropositive Isolation bed	5	5	5	5	10	10	10

Population Based Dialysis Demand Estimation:

In India, the approximate prevalence of Chronic Kidney Diseases (CKD) is 800 per million population (Source: Chronic Kidney Diseases in India: Challenges & solution published in 2009 SK Agarwal & RK Srivastava)

The incidence of ESRD 150-200 pmp (15-20 per lakh population).

Type of Hospital	SDH 100 beds	DH 100 beds	DH 200 beds	DH 300 beds	DH 400 beds	DH 500 beds
Population Norm	Less than 2 lakh	2 to 5 lakh	5 to 10 lakh	10 to 20 lakh	20 to 30 lakh	More than 30 lakh
Number of anticipated patients requiring dialysis as per the incidence rate of ESRD (20 per lakh population)	40	100	200	400	600	600

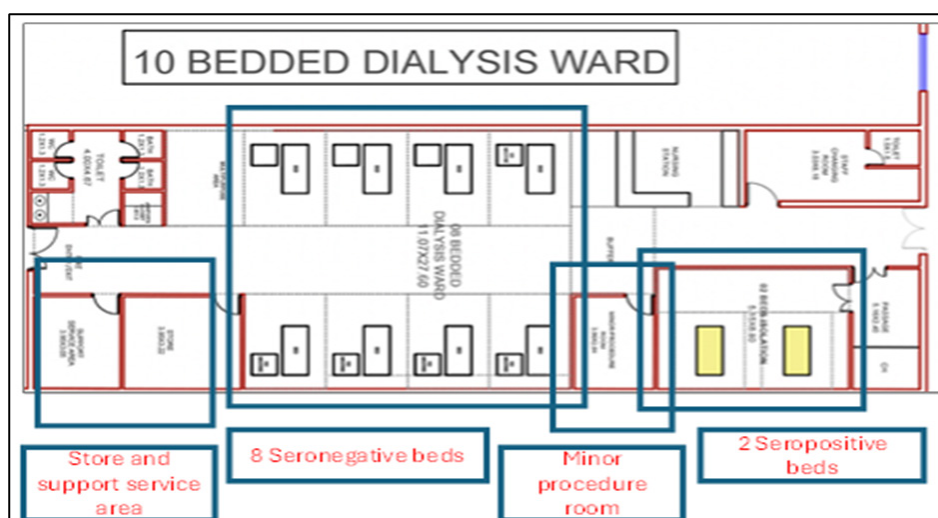
Type of Hospital	SDH 100 beds	DH 100 beds	DH 200 beds	DH 300 beds	DH 400 beds	DH 500 beds
Estimated number of HD machines required (03 patients per HD machine) Rounded Off	13	33	66	133	200	200
Number of Recommended Dialysis Beds (IPHS Recommended Beds + 10% of the estimated HD machines)	07 (5+2)	09((5+4)	12 (5+7)	23 (10+13)	30 (10+20)	30 (10+20)

Note: The demand estimation should be as per requirement based on availability and gap assessment of dialysis beds in the facility.

Suggested plan for scaling up dialysis services

1. Establish dialysis centre in all district hospitals. As on 31st March 2026, a total of 751 (45 linked) districts has the dialysis centres. The 45 linked district have population less than 50,000 and the dialysis demand is not known. State/UTs are required to undertake gap assessment and establish dialysis centres in a phased manner.
2. Establish dialysis centre at Sub-district hospital/ Area hospital/ Rural Hospital and Community Health Centre. This shall ensure availability of dialysis centre closer to the community.
3. The State/UTs having less than 05 HD machines in the centre and having dialysis load are required to augment the facilities with more number of HD machines.
4. The average machine utilisation should be between 3-4 sessions per day.

Layout of Dialysis Facility:



Ministry of Health & Family Welfare (MoHFW) provides financial support under National Health Mission (NHM) to States/UTs in establishing dialysis centres at the district hospitals and down below up to community health centres based on the gap assessment undertaken by respective State/UT through the State Annual Program Implementation Plan (PIP).

States/UTs can budget the fund required under FMR Code-NCD.6 (S. No-112) for the following activities:

Sl. No	Budget Head	Remarks
1.	Equipment including Furniture (INR 54 Lakhs for 5-Bed Dialysis Unit including RO Plant)	Cost of HD Machines, RO plant, Dialyzer Reprocessing Machine and emergency equipment as mentioned in guideline.
2.	Drugs & Supplies including Erythropoietin, Iron Sucrose and other emergency drugs as per Annexure-III	Health facility should provide the drugs & supplies through Free Drugs Initiative (FDI). In case of non-availability, the cost can be budgeted.
3.	Diagnostics Tests as mentioned in the guidelines	Health facility should conduct diagnostic tests through in-house Free Diagnostic Services Initiative (FDSI). In case of non-availability, the cost can be budgeted.
4.	Training & Capacity Building (As per State proposal)	As per MoHFW approved revised RCH training financial norms (D.O. No. A-110033/101/07-Trg dated 28th January 2015) Training of Surgeon, Dialysis Technicians and staff nurse (short-term) as per actuals state training plan to be submitted.
5.	IEC & Printing	INR 1 Lakh per district (Including Printing posters, flex, signages, patient health record booklet, audio/ video development).
6.	IT system (Desktop/Laptop) and peripherals, Biometric, QR code reader, Printer, Workstation (Table & Chair) and high speed internet (Broadband), UPS	INR 1 Lakh per HD centre & INR 1000 per month recurring cost for internet services.

Sl. No	Budget Head	Remarks
7.	Other Operational Costs (As per State actual expenses) for in-house mode	Cost of consumables, tubing, dialyzer, disposable bedsheets, waste management, Consultation fee for Nephrologist, Dialysis session cost in case of dialysis services are outsourced.
8.	Planning, Monitoring & Evaluation	INR 10 Lakhs (mobility support, Monitoring and evaluation charges)
9.	Surveillance Research Review & Evaluation (SRRE)	INR 5 lakh for conducting study on dialysis outcome and related subject.
10.	AV Fistula Charges	INR 6000 per patient as one-time support for successful AV fistula (without prosthesis) making charges for the below poverty line patients not covered under PMJAY scheme.

FURNITURE AND FIXTURES

Sl. No	Articles
1.	Examination Table
2.	Writing tables
3.	Chairs
4.	Almirah
5.	Waiting Benches
6.	Medical Beds
7.	Wheelchair/Stretcher
8.	Medicine Trolley, Instrument Trolley
9.	Screens/curtains
10.	Footstep
11.	Bed Side Table
12.	Stool
13.	Examination Lamp
14.	View box
15.	Fans
16.	Tube Light/ lighting fixtures
17.	Wash Basin
18.	IV Stand
19.	Color coded bins for BMW

*This is an indicative list, and the items shall be provided as per the size of the hospital and scope of service.

EQUIPMENT LIST

Emergency equipment: The following equipment should be available:

1. Haemodialysis machine with open access for PC interface.
2. Resuscitation equipment including Laryngoscope, endotracheal tubes, suction equipment, xylocaine spray, oropharyngeal and nasopharyngeal airways, Ambu Bag- Adult & Paediatric (neonatal if indicated)
3. Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs
4. Suction Apparatus
5. Defibrillator with accessories
6. Equipment for dressing/bandaging/suturing
7. Basic diagnostic equipment- Blood Pressure Apparatus, Stethoscope, weighing machine, thermometer
8. ECG Machine
9. Pulse Oximeter
10. Nebulizer with accessories
11. Dialyzer reprocessing unit
12. ACT machine
13. Cardiac monitors
14. Vein finder
15. All required consumables for adult and paediatric patients

CRASH CART MEDICINES

Sl. No	Medicine*
1.	INJ. Atropine
2.	INJ. Adrenaline
3.	INJ. Avil
4.	INJ. Buscopan
5.	INJ. Deriphyllin
6.	INJ. Emeset
7.	INJ. Lasix
8.	INJ. Noradrenaline
9.	INJ. Xylocaine
10.	INJ. Epsoline
11.	INJ. Hydrocortisone
12.	INJ. Calcium gluconate
13.	INJ. Soda bicarbonate
14.	Laryngoscope
15.	Airway (size 2 and 3)
16.	Suction catheter
17.	Feeding tube
18.	Dyna plaster
19.	Xylocane jelly
20.	IV Cannula 18 g
21.	IV Cannula 20 g
22.	IV Cannula 22 g
23.	IV Cannula 24 g
24.	Sterile water
25.	INJ. Dextrose 25%
26.	INJ. Dextrose 50%
27.	Ambu bag
28.	Nebuliser Mask

Sl. No	Medicine*
29.	O2 mask
30.	Neb. Asthalin, Duolin, Budecort
31.	Ringer's lactate (RS); Normal saline (NS); Dextrose normal saline (DNS)
32.	ECG electrodes
33.	Syringes- 2,5,10,20,50 ml
34.	Gloves

* Consumables/medicines should be refilled and expiry date should be checked by the staff on the daily basis.

STAFFING REQUIREMENT FOR DIALYSIS UNIT

The following minimum staffing pattern standard should be maintained at the dialysis unit:

S.N	Human Resource	Numbers	Qualification	Availability	Role
1.	Nephrologist	1 Nephrologist per 10 Dialysis Facility (1:10)	DM (Nephrology)	Fortnightly / Monthly physical visit depending upon the number of dialysis facilities in the State/ UT.	▪ The nephrologist shall conduct physical consultation fortnightly / Monthly for all dialysis patients at the dialysis facility. ▪ The nephrologist shall provide advisory role ▪ The observations/ remarks of Nephrologists provided after consultation shall be incorporated in the patient records
2.	Physician	01 per co-located facility (DH/ SDH/CHC)	MD (Medicine) trained in renal care	Should be available during dialysis hours for attending any emergency.	▪ In case non-availability of Nephrologist, physician trained in renal care will undertake the role of Nephrologist as given above. ▪ Will be available in the co-located health facility (DH/SDH/CHC) during dialysis hours for attending any emergency.
3.	Medical Officer	1 per Facility	MBBS	Should be available during dialysis hours	▪ The Medical Officer to be the intermediary contact between the patient and the nephrologist

S.N	Human Resource	Numbers	Qualification	Availability	Role
4.	Staff Nurse trained in renal care	1 per Facility	Staff nurse: GNM/ BSc. Nursing with training experience of 6 months in a dialysis unit. Should be registered with the local state nursing council.	Per Facility	▪ The staff nurse would be accountable for monitoring, scheduling and assisting administrative activities in the dialysis unit. ▪ Responsible to the Nephrologist and MO for reporting progress/ status of patient condition.
5.	Dialysis Technician (DT)	One each for every 03 HD machines (1:3) and facility having beyond 06 HD machine the requirement will be 01 DT per 04 HD machines (1:4) with one dedicated DT for every sero-positive patient, if any.	Dialysis Technicians Post intermediate/ life science graduate and should have passed at least 2-year certificate course in dialysis technique certified by a government authority and registered with paramedical board	Per shift per day	▪ Operate haemodialysis units ▪ Maintenance of records and analyze readings ▪ Dialyzer care ▪ Patient care ▪ Maintenance of RO plant
6.	Dietician	01 dietician for providing diet counselling services to the patients, in case not available in the co-located hospital.			
7.	Housekeeper	1 per shift	-	Per shift per day	Cleaning activities within the haemodialysis unit

RECORDS & DOCUMENTATION

A dialysis centre shall maintain a record system to provide readily available information on:

1. Patient care
 - a. Haemodialysis charts
 - b. Standing order for haemodialysis – updated quarterly
 - c. Physician's order with signature
 - d. Completed consent form
 - e. Patient's monitoring sheet
 - f. Standing order for medication
 - g. Laboratory results
 - h. Confinements with corresponding date and name of hospital
 - i. History and physical examination
 - j. Complication list
 - k. Transfer/referral slip (for patients that will be transferred or referred to another health facility)
2. Incident and accident (in logbooks)
 - a. Complications related to haemodialysis procedure
 - b. Complications related to vascular access
 - c. Complications related to disease process
3. Haemodialysis adequacy of patients and outcomes reported on monthly basis (in logbooks)
 - a. Haemodialysis adequacy of patients
 - b. Outcomes- Patient's intra dialytic complications, Mortality and hospitalization rates
 - c. Staff/patient's hepatitis status
4. Staff and patient vaccination and antibody titer status as applicable
 - a. Hepatitis B (double dose) – 0, 1,2,6 months
 - b. Influenza – annually
 - c. Pneumococcal – every 5 years
5. Water treatment as per ISO 23500/AAMI 2020/BIS 17646
 - a. Bacteriological

- b. Endotoxin
 - c. Chemical
- 6. Facility and equipment maintenance schedule
 - a. Preventive maintenance
 - b. Corrective measures

PATIENTS' RIGHTS AND RESPONSIBILITIES

PATIENTS' RIGHTS

A patient and his/her representative have the following rights with respect to the Dialysis Centre-

- To adequate relevant information about the nature, cause of illness, proposed investigations and care, expected results of treatment, possible complications and expected costs;
- Rate of services provided by the Dialysis Centre would be displayed prominently.
- To access a copy of case papers, patient records, investigations reports and detailed bill
- To informed consent prior to specific tests/treatment (e.g. surgery, chemotherapy)
- To seek second opinion from an appropriate clinician of patients' choice, with records and information being provided by treating hospital
- To confidentiality, human dignity and privacy during treatment.
- To have ensured presence of a female person, during physical examination of a female patient by a male practitioner
- To non-discrimination about treatment and behaviour on the basis of HIV status
- To choose registered pharmacy or registered diagnostic centre/laboratory with qualified personnel from which to avail service
- To choose alternative treatment if options are available
- To seek redressal in case of grievance related to services provided by the establishment
- Rate of services provided by the Dialysis Centre would be displayed prominently.

PATIENTS' RESPONSIBILITIES

- Provide health related information
- Cooperate with Doctors during examination, treatment
- Follow all instructions
- Pay hospitals agreed fees on time
- Respect dignity of doctors and other hospital staff
- No smoking, spitting or littering in the hospital premises
- Never resort to violence

INFORMED CONSENT / CONSENT GUIDELINES

The informed consent shall at the least contain the following information in an understandable language and format.

Sl. No.	Content
1.	Name of the patient/ guardian (in case of minor/mentally disabled).
2.	ABHA ID of patient
3.	Date of admission
4.	Name & Registration number of treating doctor
5.	Name of procedure/operation/investigation/blood transfusion /anesthesia/ potential complications
6.	Signature of patient/guardian with date and time

DIAGNOSTIC TESTS

1. Hemoglobin (HB) (Monthly)
2. Complete LFT (03 Months)
3. Complete KFT (03 Months)
4. Pre & Post haemodialysis urea
5. Viral Marker Tests (HIV/HBsAg/HCV) – Every 03 month
6. iPTH (Intact Parathyroid hormone) test- Every 06 Month
7. Vitamin D test – Every 06 month
8. Iron Profile (Serum Ferritin & transferrin saturation) – Every 03 month
9. TB screening through chest X-ray, sputum examination and NAAT testing for newly registered patients.

Note: Diagnostic tests should be done under Free Diagnostic Services initiative program at the co-located DH/SDH/CHC.

PATIENT HEALTH RECORD

Facility Name:

Address:

Contact No:

NIN ID:

Facility In charge Name

Patient Dialysis Report

Patient Name:

ABHA ID:

Age:

Mobile No.:

Test	Value (Pre-Dialysis)	Value (Post Dialysis)
Blood Pressure		
Weight		
Kt/V		
Serum Creatinine		
Hemoglobin		

Doctor Name & Signature:

Date:

HAEMODIALYSIS MACHINE & WATER TREATMENT SYSTEMS AND MONITORING PROTOCOLS

A. HD machine: Mandatory

1. Blood pump to achieve a unidirectional flow up to 400ml/min
2. Heparin pump
3. Arterial line and venous line pressure monitors
4. Functional air bubble detector
5. Mixing proportion unit with bicarbonate dialysis facility, with the rate of dialysate delivery from 300 to 500 ml/min or more.
6. Conductivity meter
7. Functional blood leak detector
8. Dialysate temperature regulator that has a range of temperature 35 to 39 deg C
9. Volumetric UF control
10. Safety devices functioning alarms, venous blood clamp
11. Dialysate filter
12. The HD machines should be with open access for PC interface.
13. The HD machine should be FDA/CDSCO approved, or BIS compliant/European CE marked.

At least one machine with dialysate flow rate of 100 ml/min to 500ml/min for paediatric haemodialysis.

B. HD machine: Optional

1. Online blood volume monitor
2. Online urea clearance
3. Sodium profiling of dialysate
4. Single needle dialysis facility
5. Hemodiafiltration

6. Optical detector

C. Monitoring and Evaluation of HD machine

1. Conductivity of the final dialysate being delivered to the dialyzer should be checked before every treatment. According to manufacturers' instructions, the conductivity should be checked with an independent reference meter which is known to be properly calibrated. Conductivity must be within the manufacturer's stated specifics. The frequency of checking with independent reference meter should be as per manufacturer's guideline and also every time the machine is calibrated and repaired.
2. When used, the pH of bicarbonate dialysate should also be confirmed before each treatment. If the pH is below 6.5 or above 7.5, dialysis should not be started, even when conductivity within limits acceptable. The pH can be checked with a similar pH meter.
3. Temperature should also be within the manufacturer's specifications. Temperature may be checked with an independent reference meter or with a reference thermometer.
4. Absence of residual germicide should be verified on all delivery systems connected to a single water treatment "loop" before dialysis begins. Such testing must be performed with an assay known to detect the minimum standard level.
5. A test of proper functioning of the air/foam detector should be performed before dialysis is initiated. This test should be a direct test of function of the alarm, causing interruption of the blood pump an actuation of the blood line clamp, either by introducing air into the venous level detector or by removing the tubing so that air is sensed by the detector as recommended by the device manufacturer.
6. The blood detector must be checked for proper armed status according to the method recommended by the manufacturer.
7. The user should perform applicable tests of the UF control system as prescribed by the manufacturer.
8. All other alarms must be tested according to the manufacturer's instructions for use before every treatment including low and high conductivity alarm, low and high temperature alarm, dialysate pressure alarm, water pressure alarm, etc. Documentation of that testing should be performed. If the delivery system is equipped with a "self-alarm check" mode, it is important that the user understands that, most often, it is a check of the electronic circuitry, and not a confirmation of some of the vital functions of specific alarms.
9. Observation of dialysate flow should be made while the machine is in a "dialyzing" mode. Absence of dialysate flow should be confirmed when the machine is in "bypass" mode actuated by both manual setting of the machine to bypass or via any of the alarm functions that will cause the machine to enter a bypass mode.
10. The automatic "self-test" should be performed if this facility is available prior to each HD treatment to confirm proper performance of operative and protective functions of the machine and should never be bypassed.

11. Periodic Microbiological monitoring: water for production of dialysate and actual dialysate proportioned and exiting the dialyzer should be monitored for bacterial levels on no less than a monthly basis. Microbiological monitoring is performed to establish ongoing validation of proper disinfection protocols. The sampling should be done at the termination of dialysis at the point where dialysate exits the dialyzer. Results for total microbial counts in dialysis water or dialysis fluid, should be less than 100 CFU/mL as per ISO 23500/AAMI 2020/BIS 17646 standard.
12. Assessing trends: Pertinent information, i.e., bacterial levels, conductivity and pH readings, etc., should be logged on a chart across a page so that readings can be examined and compared over an extended period of time. This tool makes it possible to compare current readings to those taken during the past several days/weeks/months.

D. Dialyzer (filter) specifications:

The hollow fiber dialyzer forms the central component of dialysis delivery system, where in actual process of transfer of solutes and water occurs across a semi-permeable membrane. A large array of dialyzers is available for clinical use with several permutations and combinations based on biocompatibility, flux and surface area of the dialyzer. Most often a single type of dialyzer may be sufficient in most patients in a dialysis unit. However, some patients may have specific needs and may require change in the dialyzer specifications. Hence, dialyzers with specifications other than that generally used in the dialysis unit may also be routinely stocked or should be made available at a short notice when the need arises. Paediatric specific consumables (Dialyzers 0.7 m² and pediatric tubing (40-50 ml) will be available for paediatric haemodialysis.

E. Recommendations for dialyzer use in HD:

1. Biocompatible, synthetic (e.g., polysulfone, polyacrylonitrile, polymethylmethacrylate) or modified cellulose membrane (e.g., cellulose acetate) should be preferred over unmodified cellulose membranes (e.g., Cuprophane). Cuprophane membranes should only be used when a patient is intolerant to other biocompatible membranes.
2. Either low flux or high flux biocompatible membrane may be used for regular HD.
3. An allergic reaction to a specific dialyzer is rarely encountered in some patients. In such situations, the dialyzer should be avoided, and this should be specifically written in bold letters on the dialysis folder of the patient to prevent its inadvertent use.
4. Dialyzer may be used for not more than 05 times or till the bundle volume is more than 80% of original capacity, whichever is earlier (Availability of Dialyzer reprocessing unit is mandatory for cleaning the dialyser and assessment of bundle volume) and in such cases reused only for the same patient after due sterilization using dialyzer reprocessing unit. Dialyzer should not be reused for seropositive cases in any situation, and the patient should be dialysed on a separate isolated machine. In such cases, single use dialyzer is recommended.
5. Blood line, Transducer Protectors, IV sets, Catheters any other disposables should not be should not be reused.

F. Dialysis fluid specifications:

1. Dialysate, or dialysis fluid, is a non-sterile aqueous solution with an electrolyte composition near that of normal extracellular fluid. Its electrolyte composition is designed to correct the metabolic imbalance that occurs as a result of azotemia. Dialysate concentrates are manufactured commercially in liquid or powder form. The chemicals present in the dialysate have access, via the dialyzer, to the bloodstream of patients undergoing dialysis. Hence, the proper concentration of all of these chemicals as well as the quality of the concentrate and the water used to dilute the concentrate is critical. The following is to be ensured:
2. Electrolyte content of dialysate includes sodium, potassium, chloride, magnesium, calcium, glucose (optional), and bicarbonate as a buffer. The concentration of HD solutions should 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: Sodium 135-145, Potassium 2-4, Calcium 1.0-2.0, Magnesium 0.25-1.0, bicarbonate 32-40, Chloride 95-110. Sodium concentration may be adjusted to levels outside the range of 135-140 mmol/L by HD machines with variable sodium capabilities only when prescribed by physician in charge.
3. Commercially produced concentrates are classified as medical devices and should be approved for clinical use by appropriate authority. The dialysate should contain bicarbonate as the buffer.
4. Water used to prepare the dialysate must have a bacteriological colony count of 100 CFU/ml as per AAMI 2020/ISO 23500/BIS 17646. Bacteriological and fungal growth in the dialysate shall be checked at least once monthly (depending upon the raw water condition) (as per Standard Treatment Guidelines for haemodialysis, Indian Society of Nephrology). The colony count in dialysate samples collected at the termination of dialysis a) in a single pass system or b) in a re-circulating single pass system at the periphery of the re-circulating chamber containing the dialyzer should be 100 CFU/ml as per AAMI 2020/ISO 23500/BIS 17646. Dialysate containing glucose at 100- 200 mg/dl concentration should be used.

G. Recommendations for storing and mixing dialysis concentrate:

1. Store and dispense dialysate concentrate as though they were drugs. Ensure that all personnel in the facility are aware of the types of dialysates concentrates available, even if currently only one type is being used.
2. Develop a policy, management, and storage system that will effectively control the mixing and dispensing of all concentrates. Storing concentrates according to type, composition, and proportioning ratios should reduce the risk of mismatching concentrates. Prohibit access to storage areas and allow only authorized, specially trained personnel to mix and dispense concentrates. The concentrate should be prepared/consumed same day and there should not be overnight storage to prevent bacterial colonization in the bicarbonate concentrate.
3. Double-check and record concentrate formulas on the patient's record. Consider a procedure for countersigning patient and storage records. Do not dispense concentrates from large containers into smaller ones without a "keyed" dispensing system. Whenever possible, purchase concentrates in single-treatment (21/2-4 gallon) containers (optional).

4. Always dispose of concentrates remaining from the previous treatment. Do not pour remaining concentrate into another container or use in the next treatment. Replace empty or partially full containers with full ones. Whenever possible, standardize equipment so that only one bicarbonate concentrate system is used.

H. Water Treatment System:

1. Water treatment system is mandatory which consists of pretreatment system and main RO system. Pretreatment should consist of - Filtration for suspended particles, Activated carbon filtration, Softener or deionizers
2. The main water treatment system should have reverse osmosis membranes.
3. The water treatment system components are arranged and maintained so that bacterial and chemical contaminant level in the product water does not exceed the standards for Haemodialysis water quality, as stated in AAMI 2020/ISO 23500/BIS 17646.

- a. Monitoring - Chemical purity: Online conductivity meters are mandatory after deionizers & reverse osmosis. There should be visible & audible alarm for improper conductivity in the dialysis technician's station. The alarm should lead to stoppage of water beyond reverse osmosis. The water should re-start only after adequate conductivity is achieved.

Once in 3 months treated water sample must be sent for detailed chemical analysis to an independent laboratory having adequate instrumentation for testing as per AAMI 2020/ISO 23500/BIS 17646 standards. The results should be a mandatory part of the record system.

- b. Microbiological purity: This should be checked at least once monthly (depending upon the raw water condition) to achieve the standards as per AAMI 2020/ISO 23500/BIS 17646 standards. It is strongly recommended that pour plate method on nutrient poor medium should be used for cultures of treated water.
- c. Endotoxin levels: should be checked at least once monthly or earlier depending upon the raw water condition, to achieve the standard as per AAMI 2020/ISO 23500/BIS 17646 standards.

Maximum allowable levels for total viable microbial count (TVC) and endotoxins in dialysis water, in standard and ultrapure dialysis fluid (dialysate) and online-prepared substitution fluid.

Fluid category	Application	TVC (CFU/ml)	Endotoxin (EU/ml)
Dialysis Water	Basis for all fluid preparation-used in water treatment system	<100 (Action level 50)	<0.25 (Action level 0.125)
Standard dialysis fluid	Maximum acceptable quality for routine HD- used in HD concentrates	<100 (Action level 50)	<0.5 (Action level 0.25)
Ultrapure dialysis fluid	Recommended for routine HD-used in dialysate ultrafilters	<0.1	<0.03

Fluid category	Application	TVC (CFU/ml)	Endotoxin (EU/ml)
Online- prepared substitution fluid	HF and HDF: priming solution, bolus administration- used in dialysis machines	Sterile	Non-pyrogenic

1. Sterilization- it is recommended that each component of the water treatment system must be thoroughly cleaned & sterilized as per the manufacturer's recommendation. The process of sterilization should be carried out once in every 15 days. After sterilization it is essential that the sterilant is completely removed before the treated water is used for dialysis.
2. 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.
3. A log should be maintained documenting the performance of the water treatment system components and indicating the maintenance done on each component.
4. Procedure guidelines for Disinfection of Reverse Osmosis Machine and Loop as recommended by the manufacturer are in place.
5. No Haemodialysis procedure is performed during disinfection of the water treatment system and the loop.
6. Microbiological testing of the treated water from the water treatment system and the loop is done regularly and preferably monthly
7. For dialysis unit performing HDF, testing of treated water for endotoxin at regular interval is needed.
8. Written record and results of microbiological and chemical testing of water are in place and reviewed. Corrective action is recorded if indicated.

I. Reuse of Hemodialyzers and related devices

1. Procedure guidelines for dialyzer reprocessing are in place. Dialyzers should be re-processed & sterilized using a dialyzer re-processing machine and not done manually.
2. Testing for presence of disinfectant in the reprocessed dialyzer before rinsing and absence of disinfectant after rinsing are performed and documented.
3. Each dialyzer is clearly labeled and identified to be re-used by the same patient.
4. Routine disinfection of active and backup dialysis machines are performed according to defined protocol. i.e HD Machine shall be disinfected after every dialysis session with 20 minutes of Citric Acid, to avoid cross contamination. Also end of the day 1hour of Citric and thermal dis-infection shall be done to all HD machines. The same shall be documented.

J. Other Activities for patient care and staff working in the dialysis unit

1. Blood chemistry and haematocrit (or haemoglobin) of each dialysis patients are checked at regular Interval (preferably every month) to ensure patient's well-being and viral markers be tested every 03 months (HIV/HBsAg/HCV), Hb (monthly), Complete LFT and KFT (03 months), iPTH (intact Parathyroid hormone), iron studies (06 monthly) and vitamin-D should be done every 6 monthly.
2. Contingency plan or procedures are available in case of equipment failure, power outages, or fire so that the patient safety is not compromised.
3. Drill for CPR and emergency conditions outlined are performed regularly.
4. All staff including janitorial staff is educated with clear instruction on handling blood spillage on equipment and the floor.
5. All blood-stained surfaces shall be soaked and cleaned with freshly prepared 1 percent sodium hypochlorite solution if the surface is compatible with this type of chemical treatment.
6. 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 etc.
7. HBsAg/HCV-positive patients should be treated in a segregated area with designated haemodialysis machines.
8. Carrier of HCV receives haemodialysis using designated machines.
9. Patient with unknown viral status is dialyzed using designated haemodialysis machines until the status is known.

**PART 2 :
PERITONEAL DIALYSIS
SERVICES**

SERVICE DELIVERY FRAMEWORK

BACKGROUND

1. Dialysis still remains hard to access for large number of patients specially for those living in remote rural areas and thus introduction of home-based peritoneal dialysis (PD) is beneficial for such population. PD allows greater flexibility & freedom in treatment schedule for chronic kidney disease (CKD) patients.
2. Under Pradhan Mantri National Dialysis Programme (PMNDP), 'Peritoneal Dialysis' was introduced and guidelines for PD was rolled out on 10th October 2019. National Health Mission supports implementation of PD services in States/UTs. Financial support is provided based on the State/UTs requirement on the basis of per patient cost per month including supply of CAPD bags and training cost.
3. Peritoneal dialysis is a way to remove waste products from blood when kidneys can't adequately do the job any longer. This procedure filters the blood in a different way than does the more common blood-filtering procedure called haemodialysis. During peritoneal dialysis, peritoneal dialysis fluid flows through a tube (catheter) into the abdominal cavity. The lining of abdomen (peritoneum) acts as a filter and removes waste products from blood to peritoneal dialysis fluid. After a set period, the fluid with the filtered waste products flows out of abdomen and is discarded. These treatments can be done at home, at work or while traveling in a clean environment.
4. Peritoneal dialysis (PD) is a home-based cost-effective standard dialysis therapy offering patient autonomy and treatment with minimal supervision and less disruption to normal lifestyle. PD does not put additional incremental burden on the existing healthcare infrastructure and has the potential to benefit large number of end stage kidney failure patients living in remote rural areas. PD also reduces travel to the dialysis centers for treatment and allows greater flexibility and freedom in treatment schedule.

CONTINUOUS AMBULATORY PERITONEAL DIALYSIS

1. The permanent access for peritoneal dialysis (CAPD catheter) is a soft, thin, flexible silicon rubber tube with numerous side holes. It is inserted into the patient's abdomen through the abdominal wall, about an inch below and to the side of the navel or belly button. The insertion technique may be surgical, percutaneous or laparoscopic. The CAPD catheter is inserted about 10 to 14 days before CAPD starts. The PD catheter is the "lifeline" of CAPD patients, just like the AV fistula for a haemodialysis patient. A titanium adaptor is attached to the PD catheter to which is connected the Transfer set.
2. In CAPD, hyperosmolar fluid (dialysate) is infused into the abdominal cavity and is kept there for a while, after which it is drained. This process of fill, dwell and drain is called an exchange.

Fill: For the last several years the double-bag system is used for performing an exchange.

In this system there is a sealed package with one bag containing 2 litres of the PD fluid, while the other bag is empty. The double-bag system is connected to the Transfer set and the previous exchange remaining fluid (dwell volume plus ultrafiltered volume) in the peritoneal cavity is first drained out into the empty bag. Thereafter a small amount of fresh fluid from the new bag is drained out into the empty bag. Finally, two litres of fluid is instilled into the peritoneal cavity

Dwell: The period in which PD fluid remains inside the abdominal cavity is called the dwell time. This lasts for about 4 to 6 hours per exchange during the day and 6 to 8 hours at night. The process of cleaning the blood (solute removal) and ultrafiltration (removal of extra fluid) takes place during dwell time. The peritoneal membrane works like a filter allowing waste products, unwanted substances, and excess fluid to pass from the blood into the PD fluid. The patient can walk around during this time (hence the term ambulatory).

Drain: When the dwell time is completed, the PD fluid is drained into the empty collection bag. The bag with the drained fluid is weighed and discarded (biomedical waste); the weight is recorded. The drained fluid should be clear. Drainage and replacement with fresh solution take about 30 to 40 minutes. Exchanges may be done 2 to 3 times during the day and once at night. Fluid for the night exchange is left in the abdomen overnight and drained in the morning. Strict aseptic precautions should be observed when performing CAPD.

3. Three or four such exchanges are done in a day seven days a week. The process is ambulatory since patients can walk around and perform routine activities. CAPD is a form of dialysis that a kidney failure patient can carry out at home without using a machine. As CAPD provides convenience and independence, it is a popular dialysis modality. CAPD must be carried out meticulously every day at a fixed times with no holidays

AUTOMATED PERITONEAL DIALYSIS (APD)

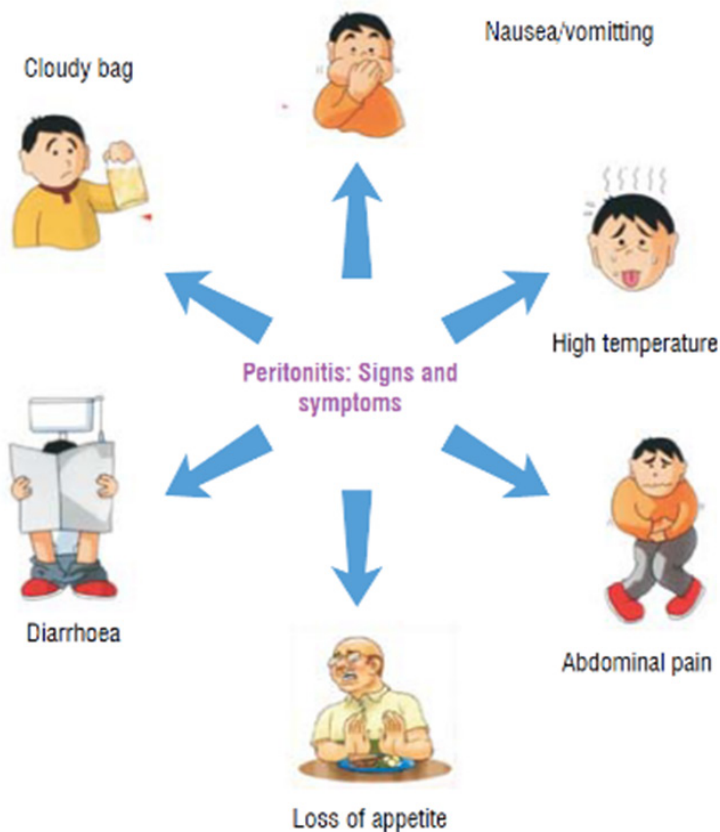
Automated peritoneal dialysis (APD) or continuous cycling peritoneal dialysis (CCPD) is a form of PD treatment done at home using an automated cycler machine. The machine automatically fills and drains the PD fluid from the abdomen. The usual prescription for adult is 10 Litres of PD fluid (2 bags of 5 litres), and the treatment lasts about 8 to 10 hours, usually at night, while the patient is asleep. In the morning, the machine is disconnected. Some amount of PD fluid may be left in the abdominal cavity (Tidal PD volume), or a patient may be advised for an extra day exchange depending on the requirement and residual kidney function of the patient. This fluid is drained in the following evening before the subsequent treatment is started. APD is advantageous since it allows the patient to do daily activities. APD is especially indicated in patients with a fast peritoneal transport status, leading to low values of ultrafiltration on CAPD. It is also the preferred modality for children and patients needing assistance. Also, since the PD bag is connected and detached from the catheter only once a day, the procedure is more comfortable and carries less risk of peritonitis. However, APD is expensive since it requires the additional use of an automated cycler and might be a complex procedure for some patients.

COMPLICATIONS

The most common infection is peritonitis. Pain abdomen, nausea/vomiting, fever, chills, loss of appetite, diarrhoea and cloudy/turbid outflow of PD fluid (effluent) are common presentations of peritonitis. CAPD should be done under strict aseptic precautions to avoid peritonitis. Infection at the exit site of the PD catheter and tunnel infection are another common source of infection. Peritonitis can be quite serious. If the patients have any of the following symptoms, the patient should seek medical help right away.

CLEANING OF EXIT SITE AFTER TAKING BATH

The exit site should be cleaned every day, and an antibiotic agent must be applied to the new dressing to reduce the risk of getting an infection. Patients taking bath or shower should change the dressing of the exit site immediately after the bath to minimize the risk of getting an infection from a wet dressing. After taking bath, the exit site should be dried with the special sterile gauze but not with a towel.



ADVANTAGES OF CAPD

The advantages of Continuous Ambulatory Peritoneal Dialysis are as follows:

- Lifeline for many adult patients who cannot undergo haemodialysis due to lack of vascular access or cardio-vascular complications.
- Patients living in remote areas (hilly areas or islands) when they have to travel long distances

to access HD.

- c. More freedom since PD can be done at home, work or travelling. The patient can perform CAPD independently, and there is no need for a machine, technician, or another person to help. Other activities may be done while dialysis is taking place.
- d. The fixed schedule of hospital or dialysis centre visits, travel time and needle pricks associated with HD are avoided.
- e. Hypertension and Anaemia may be better controlled.
- f. Chances of blood borne infection like Hepatitis C and HIV is minimised
- g. Suitable for children with kidney failure, as vascular access for haemodialysis is often difficult. The use of automated peritoneal dialysis and adjusting PD prescription may allow regular school attendance and participation in sports and extracurricular activities.

LIMITATIONS & CHALLENGES OF CAPD

The challenges of Continuous Ambulatory Peritoneal Dialysis are as follows:

- a. Infection of the peritoneum (Peritonitis) and catheter exit site can happen
- b. Inflow and/ outflow failures may occur
- c. Can be stressful. Patients should perform CAPD regularly every day, without fail, meticulously following instructions and strict cleanliness.
- d. Weight gain, elevated blood sugar and hypertriglyceridemia may develop due to glucose absorption in the PD solution. However, these can be managed with lifestyle measure
- e. PD solution bags require storage at home.

PATIENT SELECTION FOR CAPD

All ESRD patients are suitable for PD, with few exceptions. The success of PD depends significantly on careful patient selection and repeated patient education and training. Generally acceptable patients are:

- a. Any ESKD patients who opt for PD as modality of renal replacement therapy.
- b. Senior citizens without any major contraindications are acceptable for CAPD preferably with family support.
- c. Children of any age with adequate home-support, who require moderate to long-term dialysis therapy.
- d. With residual renal function
- e. Patients with a functional peritoneum and no recent history of major abdominal surgery.

- f. Patients with steady dexterity, vision, and mental acuity.

Contraindications	
Documented Type II Ultrafiltration Failure	Severe malnutrition
Severe Inflammatory Bowel Disease	Multiple abdominal adhesions
Acute Active Diverticulitis	Ostomy
Abdominal Abscess	Upper limb amputation with no help at home
Active Ischemic Bowel Disease	Poor personal hygiene
Severe Active Psychotic Disorder	Dementia
Marked Intellectual Disability	Homelessness
Third Trimester of Pregnancy	

PERITONEAL DIALYSIS SERVICES DELIVERY FRAMEWORK

- Based on the States/UTs experience in undertaking limited peritoneal dialysis services, it is envisaged that peritoneal dialysis services need to be scaled up in the country as an alternative option benefitting the population residing in remote and difficult locations under the Pradhan Mantri National Dialysis programme.
- In order to increase the reach of CAPD, a **HUB and SPOKE model** is recommended wherein the patient can get the **catheter insertion** done at the nearest **Medical Institutes/ Medical College Hospital / District Hospital** acting as '**HUB**' for PD service delivery under the supervision of a Nephrologist/Physician trained in dialysis. The Block Primary Health Centres/ CHCs will serve as the **Spokes and same can be progressed to AAM-PHCs and AAM-SHCs for service delivery in phase wise manner**. CAPD is suitable for children with kidney failure and availability of paediatric double cuff catheters 31 centimetre, and 37.5 centimetre will be ensured along with CAPD bags (2 litre).
- One staff nurse in the Block PHC/CHC shall be designated as **PD nurse** for PD service delivery. The PD Nurses, CHOs and ANMs, patients and family members will be trained to provide information, education and limited care after training at the nearest District Hospital/Medical College. The roles and responsibilities of the functionaries at different levels of healthcare is as follows:

S.N	Level of Healthcare	Role	Responsibility
1.	Medical Institutes/ Govt Medical Colleges Hospital / District Hospital	- Selection of patients - Registration of patients for CAPD with ABHA ID on PMNDP Portal. - Placement of catheter - Initial Orientation and training on CAPD patients and caregivers - Treatment of complications including peritonitis - PET test and assessing dialysis adequacy - Follow-up once in 2-3 months for assessment of peritoneal dialysis and treatment of CKD related complications - Re-training of the patients - ABHA ID generation and sharing the patient details to the respective Block PHCs/CHCs.	Nephrologist / Physician treating the patients.
2.	Block PHC/ Community Healthcare Centre	- Monitoring of CAPD patients - Raising indents for CAPD bags, drugs and consumables for PD beneficiaries on monthly basis with a float/reserve stock of 2 weeks for each patient - Raising of Pre-auth for CAPD patients as required by Insurance Schemes (PMJAY/State Insurance Scheme) - Line listing in PMNDP dashboard. - Procurement & storage of bags for CAPD - Distribution of CAPD bags to beneficiaries through PD Nurses, ANMs and CHOs - Give weekly/ twice weekly Injections of Erythropoietin at the health facility (patient can take EPO at home if trained)	Block Medical Officer PD Nurse (Designated from the existing pool) ANMs

S.N	Level of Healthcare	Role	Responsibility
3.	Community Level AAM-PHC & SHC	- Visit PD patient at his/her home - Look for signs of any complications - Guide patients for collection of CAPD bags from the nearest health facility/Block PHC/CHC - Maintain line listing of patients - Referral to higher centres in case of any emergency	CHO AAM-SHC ANM ASHA

WHO CAN PRESCRIBE PD?

The initial decision to start a patient on peritoneal dialysis can be made by a nephrologist or a physician with appropriate training in nephrology.

REQUIREMENTS FOR CAPD IN A HOME SETTING

The essential minimum requirements for CAPD services in a home setting is as follows:

- A caregiver, usually a family member, will be required to provide assistance with the CAPD technique, check the exit site, blood pressure and weight, and communicate with the PD nurse. A stable ESKD patient with good cognitive function can do all the activities themselves, after advice from the physician.
- The room should be well lit, with good ventilation through windows and doors and preferably with an attached bathroom/washbasin with clean running water.
- There should be no disruptions during the exchange process.
- The house should have clean, dry space to store CAPD supplies.

SUPPLY CHAIN OF CAPD BAGS

State/UT will be required to enter into a **rate contract** with the L1 vendor (after competitive bidding) for supply and maintaining **uninterrupted supply chain of CAPD bags and mini caps/ clips**. States/UTs may designate the Block PHC/CHC and below health facility as per the need of the patient and the distances involved for collection of bags due to the non-availability of space at the patient's home. The contract may also consider the supply of bags directly at the doorstep of the PD patients for a period of 30 days in case of availability of storage area in patient home. Stocking of CAPD bags at the health facility should cater for minimum 3 months' stock to avoid stock outs. The indenting periodicity is suggested for 2 months cycle with 1 month of stock kept as reserve.

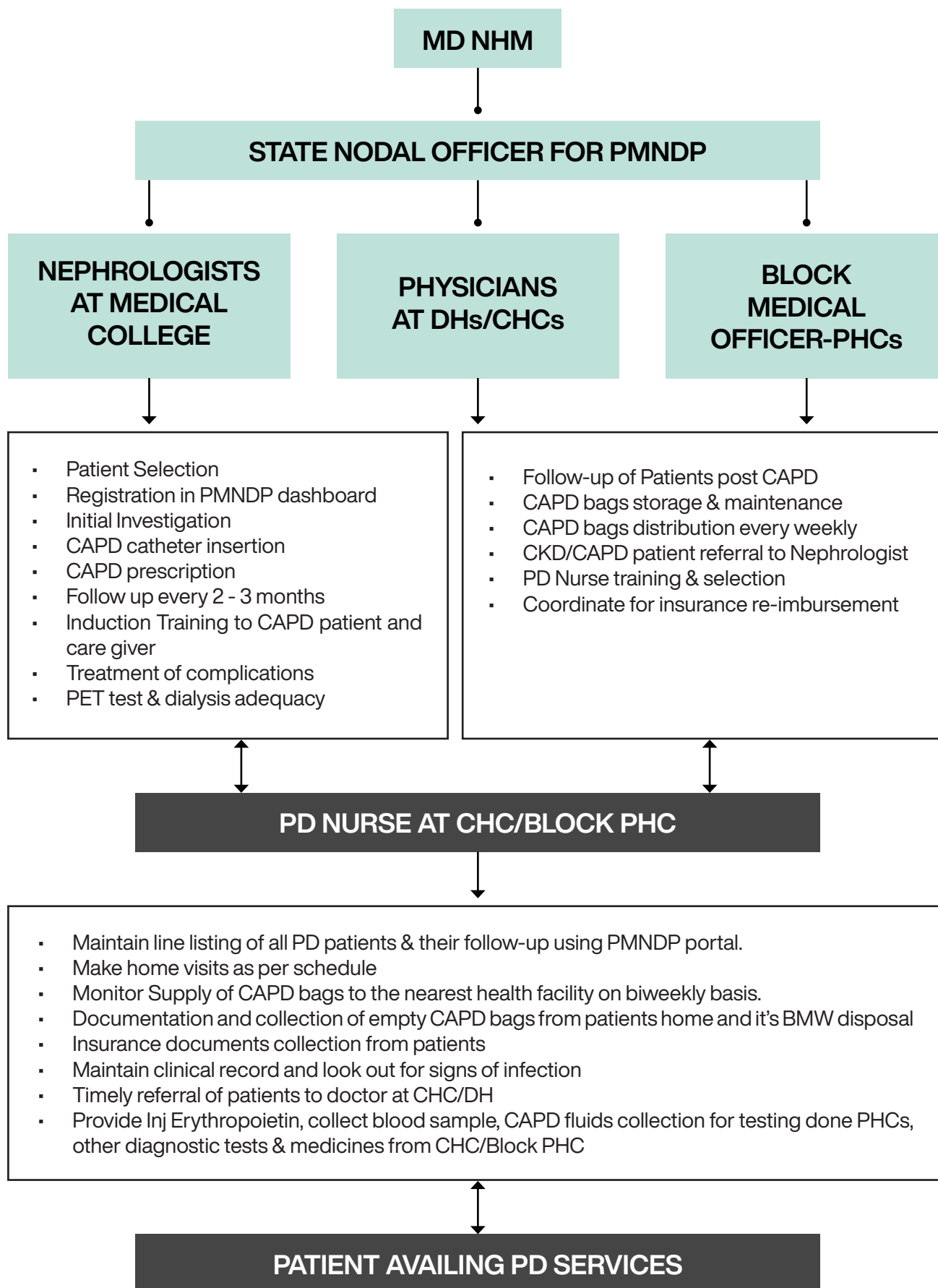
MONITORING AND SUPPORT

The following is suggested for monitoring and providing support to the PD patients at home:

- a. The **PD Nurse** will be at the center of **systematic care delivery** mechanism to a patient on CAPD.
- b. The PD Nurse shall register the PD patient on the PMNDP portal after initial stabilization at the Medical College/DH. She will maintain the line listing and update records in the PMNDP portal.
- c. The PD Nurse shall visit the patient in his/her home environment at the following time points after dialysis initiation: (i) immediately after discharge from hospital; (ii) 1-month; (iii) 3-months; (iv) 6 months; and (v) follow-up visits every 30 days.
- d. The PD Nurse shall also visit the health facility near patient's residence and appraise the CHO/MO of the patient progress and supervise the stock status of CAPD bags for the patient.
- e. The CHO & ANM from AAM-SHC will visit the patient's home on weekly basis in consultation with PD nurse.
- f. **States/UTs shall designate Block Primary Health Centres/ CHCs to act as SPOKES** for distribution of bags, patient management and training based on the distance involved from the designated Hubs usually Government Medical College/District Hospital.
- g. The counselling for dialysis patients on PD and their family members will be provided at the nearest Medical College/District Hospital.
- h. The PD Nurse should maintain the line list of patients in the Blocks level PHF /CHCs and ensure timely distribution of the bags. She will also make home visits once in a fortnight to follow up the PD patients. The PD Nurse would be assisted by CHOs/ANMs as needed.
- i. The PD Nurse will perform all responsibilities as mentioned in Para 16 (2). She will provide training to patients and caregivers and be the first contact point for all clinical queries and act as PD Coordinator & facilitator.
- j. On stabilization of the PD programme, AAM-SHC & PHC can be included as spokes with MO & CHO trained to treat and follow-up of PD complications and make home visits to follow-up PD patients.
- k. The PD Nurse would screen for signs of infection like fever, pain, discoloration at the site, sepsis etc. during every visit and raise referral to the Medical Officer of CHC or AAM-PHC if needed.
- l. When a CAPD patient wants to restock CAPD bags, used CAPD bags issued should be returned to the PD Nurse or in the issuing health facility. The empty bags must be sealed in a disposable BMW bag and treated as infectious waste.
- m. Block PHC/CHC is responsible for disposing of used CAPD bags as per government notified biomedical waste (management & handling) act & rules.

REFERRAL LINKAGES

1. The Nephrologist/Physician should share the details of the patients with the Block Medical Officers concerned and there should be a **bi-directional flow of information**. The ABHA ID shall be generated at the first consultation at the Medical College/District hospital level. The same can be updated on Pradhan Mantri National Dialysis Programme Portal at the time of registration of patient from CAPD.
2. On discharge from Medical College/DH after catheterization, the patient is required to get re-admitted after 10-14 days of PD catheter insertion, a break in period. The patient may get admitted to Medical College/DH where the catheterisation was done, for training on the PD process which usually takes 4-5 days. The patient must be educated on following the aseptic precaution during the PD filling and draining process. The patients must be educated on the signs and symptoms of significant complications to ensure they avail treatment for them without delay. If the situation permits, the caregiver and patient may be trained during the break in period.
3. **The District Level Nephrologists/Physician at Medical College/Medical Institute/ District hospital** will coordinate the activity with the support of State Nodal Officer & District Programme officer PMDNP. The **Block Medical Officer** will inform the PD nurse on any new CAPD Patients in liaison with the treating Nephrologist and District Programme Officer for further follow up of the patients. Detailed Referral Linkage has been given in the chart below.



INSURANCE AND CLAIMS

1. States/UTs may also establish linkages with their state-run insurance schemes or PMJAY for the proposed PD service delivery framework.
2. PD Nurse will raise the preauthorization and upload the documents of the patients that are necessary for insurance claims under PMJAY.
3. The amount claimed will be utilized for meeting out the recurrent costs and procurement of PD Bags through State Medical Corporation or DHS/ State Health Society (Procurement Cell).
4. The PD service delivery has to be meticulously planned and monitored by Block Medical Officer at CHC/Block PHC to ensure that supply chain is maintained, and the patient is not affected.

LOGISTICS & DISTRIBUTION

1. The procurement and supply of the CAPD Bags will be done through State Medical Services Corporation or the Directorate of Health Services/State Health Society (Procurement Cell) under Rate Contract.
2. The Procurement agency shall ensure the terms and conditions in procurement agreement for supplies of different size PD bags and also include clauses of training & monitoring of the PD patients.
3. The Procurement agency shall ensure stocking for 90 days' supply of PD bags in advance and supply to the health facility/ doorstep delivery. Indent will be placed by the Block MO/PD Nurse for all the PD patients on monthly basis with keeping minimum 1 month stock as float to avoid stock outs.
4. The indent for the bags shall be raised by the Block MO/PD nurse/Pharmacist based on the line list and requirement generated by the patients.
5. The CAPD bags will be initially supplied to the Block PHCs/CHCs and will be stored at room temperature securely. Storage of CAPD bags lower down at the AAM-SHC & PHC will be undertaken on stabilization of the supply chain as it would involve transportation /monitoring issues. CAPD bags can also be stocked at the AAM-SHC & PHC for patients not having storage space at their home and on recommendation of Block MO/PD Nurse on case to case basis.
6. The Block PD Nurse will be in charge of maintaining the Stock of the CAPD bags supplied to the Block PHC/CHCs, maintain records and ensure that there is no pilferage.
7. From the Block PHCs/CHCs the CAPD bags for the patients would be delivered to their home by the PD Staff Nurse using the Patient Transport Vehicle or to the nearest health facility, in case there is shortage of space in the patient's residence.
8. The PD Nurse will supply CAPD bags to the beneficiaries on fortnightly basis on the recommendations of the Nephrologists/Physicians.

9. PD Nurse will fill the patient's home visit record book during each visit for recording clinical details and also collect empty bags prior issue of fresh supply.

MONITORING AND EVALUATION

For Cases that end up having peritonitis, an audit should be conducted at District and State Level regularly to minimize such events in the future.

Level of Management	Monitoring Officer	Responsibilities
State Level	State Nodal Officer – PMNDP	1. State Nodal Officer for PMNDP shall monitor the functioning of programme across the State including coordination with all Directorates 2. The SNO will monitor the daily activities of the service delivery under PMNDP and ensure timely update of daily reports/data to the HOD/ Government. 3. The SNO will work in close coordination with the other Directorates of the state and the treating Nephrologist/Physician and the PD Nurse. 4. The SNO will monitor the referral services and facilitate the PD Nurse in providing transport & other supplies. 5. The SNO will analyze the reports and take necessary steps for the successful implementation of the programme. 6. The SNO will conduct regular meetings/ trainings with their Directorate staff and to attend the review meetings/trainings at the State/National Level. 7. The SNO will make periodical field visits to ensure the effective implementation of the programme. 8. The SNO will provide technical and administrative support to the State and District authorities.
District Level	Deputy Director Health Services / CMO	District level Nodal Officer for the implementation of the CAPD Component of the PMNDP in the district.

Level of Management	Monitoring Officer	Responsibilities
District Level	District Nephrologist/ Physician	Will be nominated for each District by State Nodal Officers to coordinate the scheme in 'Hub & Spoke' model, ensuring continuum of care. Will be in touch with the Block PD Nurse and the SNO PMNDP
	District Programme Officer PMNDP	Coordinate with the SNO and facilitate supplies and transportation to the PD Nurse, CHOs and ANMs in the field.

FAMILY SUPPORT FOR PERITONEAL DIALYSIS

A major challenge to the growth of PD, and home dialysis in general, is the fact that the majority of dialysis patients are elderly and have barriers to self-care. Family support was associated with an increase in PD eligibility and PD choice and leads to increased incidence PD utilization. When family support was available the patients are also able to continue with PD. The family supports the patient in:

- PD preparation and exchange.
- Exit-site care, dressing, hand wash, general hygiene.
- Measurement of blood-pressure, weight and continuous filling the logbook with ultrafiltration measure.
- Ability to identify any complication, including the infections and instillation of medications in the PD fluid if needed.
- Ability to communicate with caregivers and ensure supplies

FINANCIAL SUPPORT

The components that will require budgeting under PMNDP (FMR-NCD.6 PMNDP Sl. No. 113) include the following. However, PD services will be offered free of cost to the BPL beneficiary as per PMNDP Guidelines.

One Time Cost		Recurring Cost	
Budget Head Cost (INR)	Cost (INR)	Budget Head Cost (INR)	Cost (INR)
One time Catheter, Initial Kit including Transfer Set & Adapter	Rs. 11000/-	Quarterly replacement of Transfer sets (04 per year)	Rs. 2000/-
One-time Patient Support for Monitoring Tools (BP apparatus, IV Stand, Weighing scale)	Rs. 3000/-	PD Bags (including training support) (Monthly requirement 90 to 120 per patient)	As per rate contract Approx. (Rs. 18000 – Rs. 26400)

One Time Cost		Recurring Cost	
Total Expense	Rs. 14000/-	Total Expense	Rs.26000 (18000 + 8000)
Total Estimated Budget Per Patient/year = Rs. 238000/- (INR 14000 + 8000 + 216000)			

The additional cost for transportation & PD Nurse home visit will be budgeted under FMR NCD.6 S.NO.113- Peritoneal Dialysis (others including operating cost)

PPP MODEL OF SERVICE DELIVERY

1. States/UTs may explore the feasibility of engaging a service provider for the provisioning of CAPD Fluid (bags) and other medical supplies/consumables. The service provider shall provide the PD Bags and maintain inventory with patient details. The public health facility in turn will provide space wherever it exists for the service provider to stock the PD supplies and issue them to patients.
2. The Service Provider shall be responsible for arranging skill-development training for medical personnel, nursing staff, dietician, social worker and pharmacy staff as identified by the designated hospital. The training shall include but not limited to:
 - a. Pre-dialysis counselling tools and training modules including counselling kits, and data management software and a mobile based downloadable app.
 - b. Peritoneal equilibration test (PET) and adequacy of dialysis through software.
 - c. Training on management of infectious and non-infectious complications.
 - d. Nutritional management
 - e. Stock inventory management software for peritoneal dialysis fluids and other consumables.

BIOMEDICAL WASTE DISPOSAL

Each patient is generally prescribed between 90-120 bags, each containing 2L of PD fluid. This generates 90-120 sets of empty waste bags. The guideline for discarding the drained-out PD fluid is to flush it out in the toilet or pour it in the Indian toilet. Empty waste bags should be placed and packed in another bag (double bagging) and should be deposited and exchanged with fresh/new PD bags at the co-located health facility. Proper disposal of the empty waste bags will be the responsibility of the health facility as per the Biomedical Waste Management Rules-2016 and amendments thereafter.

PERITONEAL DIALYSIS TRAINING

1. **'Patient training'** is a key element in implementation of the peritoneal dialysis programme and a dedicated training team is essential to provide training to patients so that they are able to take care of themselves. The patient accepted for peritoneal dialysis, will have to be trained in techniques to help in reducing infection and prevent other PD related complications. The treating nephrologist at the Medical College (First Contact) will initiate peritoneal dialysis after informed consent and train the patient and family caregiver. Training will be given on the signs for infection, care of the exit site, Fill-Dwell-Drain technique and personal hygiene.

2. Training will include Handwashing, infection prevention, CAPD procedure, Catheter, exit site care, Peritonitis - prevention and detection, Diet, Exercise, monitoring supplies of CAPD bags and consumables.

LINKAGES WITH HEALTHCARE FACILITY AND CONTINUUM OF CARE

1. The PD catheter insertion and patient training will be initiated at the Medical College level by nephrologist. On discharge from Medical College, the patient is admitted at the Block PHC/ CHC level for registration and review by the physician/PD Nurse before patient undertakes PD exchange sessions at home. The PD Nurse will be the first point of contact for any query or emergency requirement at home for the PD patient.
2. The PD patient will require linkages with the nearest health care facility for timely referral in case of emergency and to ensure uninterrupted supply of CAPD bags. The expanded package of care (12 services) includes provision of NCD care and incentive for ASHA workers in the field. ASHA will undertake home visit of the PD patient once a week. CHO shall monitor/supervise the activity of ANM and ASHA periodically and ensure availability of CAPD bags. CHO may also visit the PD patients as and when required.
3. The ASHA worker will look out for the following during the patient home visit.
 - Look for signs of infection- fever, diarrhoea, nausea, vomiting, abdominal pain or bloating, loss of appetite and cloudiness of drained PD fluid
 - Exit-site care- soaked dressing, hand washing, personal hygiene
 - Enquire well-being, check body temperature and BP
4. The ANM will undertake home visit once in 15 days and interact with the PD patient and check availability of PD bags, record pulse, BP and signs of infection if any and visually inspect the catheter exit site for any complications. The ANM will record the observation/findings as per the reporting format given in **Annexure A** and submit it to CHO/MO and PD Nurse.

TRAINING

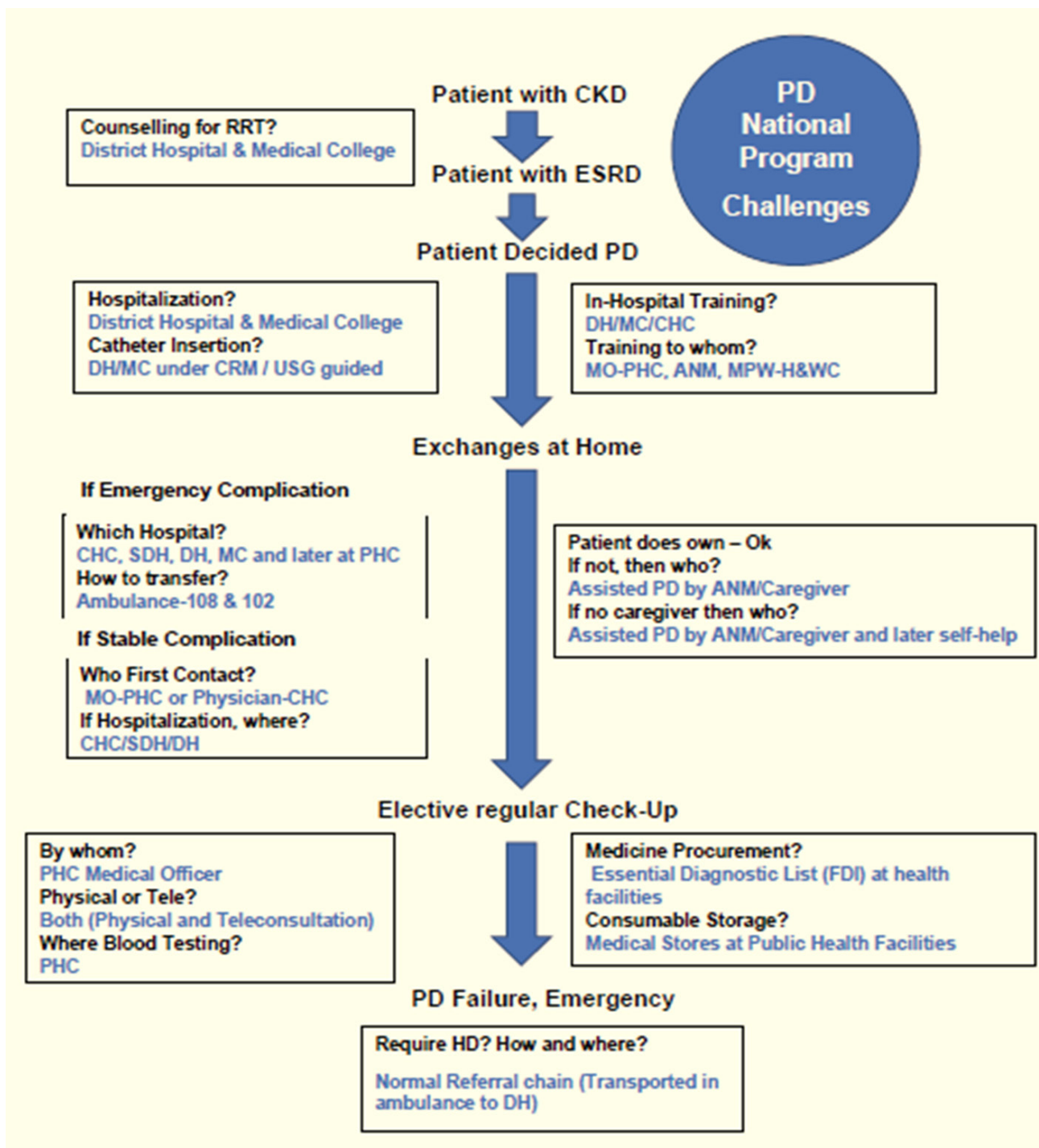
The PD component will be integrated into the CHO induction module, ASHA induction module and ANM training as part of NCD care.

ASHA INCENTIVE

The existing incentive of INR 1000 per month for Expanded package care will include the incentive for follow up care of PD component (INR 10 per patient per visit)

LOGISTICS AND TRANSPORTATION OF CAPD BAGS

A dedicated vehicle (outsourced) by the block PHC/ CHC will be used to deliver the CAPD bags to the patient home or to the nearest health facility in case the storage condition at the patient home is inadequate. The PD nurse will send the requisition for the transportation of supplies as per the schedule well in advance to the SNO and Medical Officer in-charge (MOIC). The expense for outsourcing the vehicle will be included in the State Program Implementation Plan (PIP) under FMR NCD.6 S.NO.113- Peritoneal Dialysis.



ANNEXURE A: PATIENT CLINICAL STATUS MONITROING RECORD BY ANM/CHO/PD NURSE

Name of the Patient:

Age:

Sex:

Address:

ABHA ID:

REMARKS	CLINICAL SIGNS/SYMTOMS OF PERITONITIS												
	FOLLOW UP WITH MO/NEPHROLOGIST WITH DATE	ANY OTHER COMPLAINT	CLOUDY DRAIN BAG	DIARRHOEA	LOSS OF APETITE	ABDOMINAL PAIN	NAUSEA / VOMITING	WEIGHT	TEMPERATURE	PULSE RATE	BLOOD PRESSURE	DATE OF VISIT	



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