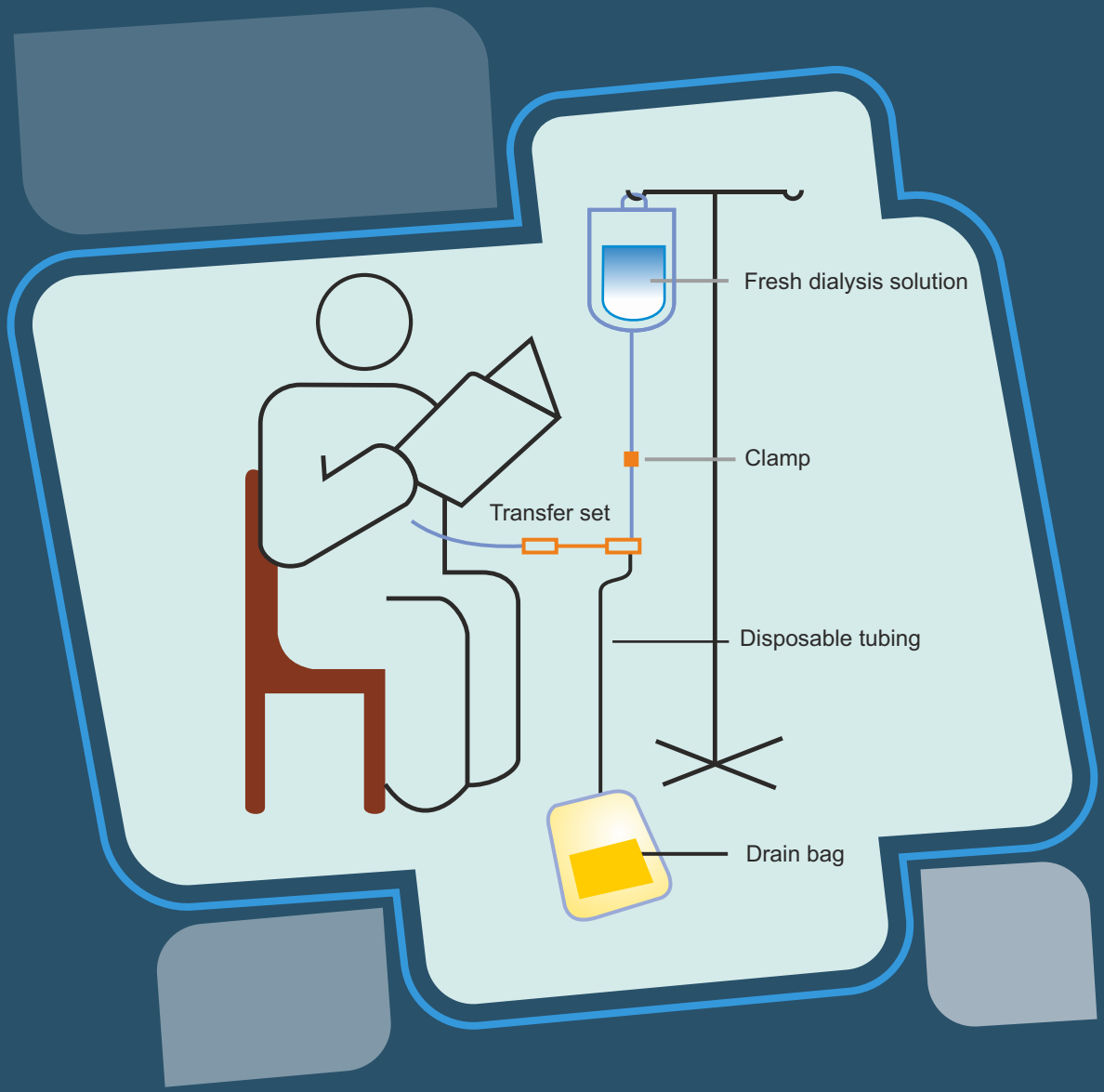
सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Pradhan Mantri National Dialysis Programme

GUIDELINES FOR ESTABLISHING PERITONEAL DIALYSIS SERVICES



Ministry of Health & Family Welfare
Government of India

प्रधानमंत्री जन आरोग्य योजना
आयुष्मान भारत
PM-JAY

जय विज्ञान
जय अनुसंधान

सबका साथ, सबका विकास, सबका विश्वास
Sabka Saath, Sabka Vikas, Sabka Vishwas

सत्यमेव जयते

डॉ हर्ष वर्धन
Dr. Harsh Vardhan

स्वास्थ्य एवं परिवार कल्याण, विज्ञान और प्रौद्योगिकी
व पृथ्वी विज्ञान मंत्री, भारत सरकार
Union Minister for Health & Family Welfare,
Science & Technology and Earth Sciences
Government of India

Message

Chronic Kidney Disease (CKD) is a condition characterized by a gradual loss of kidney function over time CKD is recognized as a health crisis globally as 10% of the world's population is affected by it, and millions die each year because they do not have access to affordable treatment. Prior to availability of dialysis, total kidney failure meant death. OVer 2 million people worldwide receive treatment with dialysis or a kidney transplant, yet this number only represents less than half of persons who actually require treatment to stay alive. Dialysis programmes world over include a combination of Hemodialysis and Peritoneal dialysis.

Due to increase in loss of kidney function across the world, the demand for dialysis is bound to increase. Thus there is an urgent need for cost-effective and scalable solutions. Peritoneal dialysis, an important treatment modality, can be done at home, is cheaper and does not have much infrastructure and technical manpower requirements. It has been adopted as the preferred modality by many countries - Thailand, Hong Kong, New Zealand and Australia, being the latest examples. Other countries like USA are pushing to increase the share of patients on peritoneal dialysis. It ensures better productivity and quality of life for patients and that too, at a relatively lower cost.

On 7th April 2016, Ministry of Health and Family Welfare, Govt. of India launched programme guidelines for haemodialysis under PM National Dialysis Programme for implementation at District Level. Now, as a subsequent step of the programme, this initiative to roll out Peritoneal Dialysis is being taken to provide respite to kidney patients particularly to those who are living in remote areas and enable them to have a better quality of lie. I request all the State/UT governments to implement this programme urgently and in full earnest.

I am confident that this initiative will improve the equity in patients' access to dialysis services and reduce the overall cost of care to the system by focusing on efficient leveraging of resources.

Harsh

(Dr. Harsh Vardhan)

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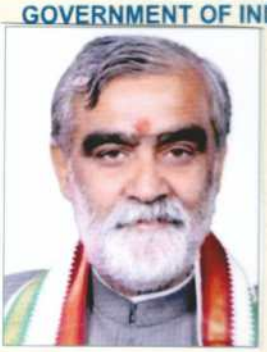
Ashwini Kumar Choubey

सत्यमेव जयते

सर्वेसन्तु निरामया

स्वच्छ भारत
एक कदम स्वच्छता की ओर

स्वास्थ्य एवं परिवार कल्याण राज्य मंत्री
भारत सरकार
MINISTER OF STATE FOR
HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA



संदेश

जिला स्तर पर जन स्वास्थ्य केंद्रों में हीमोडायलिसिस सेवाएं दीर्घकालीन गुर्दों के रोग से ग्रस्त रोगियों को उपलब्ध कराने के लिए स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के द्वारा राष्ट्रीय स्वास्थ्य मिशन के अंतर्गत वर्ष 2016 में प्रधान मंत्री राष्ट्रीय डायलिसिस कार्यक्रम प्रारंभ की गयी हैं। वर्तमान में, भारत में कुल 32 राज्यों/केंद्र शासित प्रदेश में राष्ट्रीय डायलिसिस कार्यक्रम के अंतर्गत रोगियों को जिला स्तर पर हीमोडायलिसिस सेवाएं दी जा रही हैं। 18 राज्य/केंद्र शासित प्रदेश डायलिसिस सेवाएं पीपीपी पद्धति पर दे रहे हैं, जबकि 14 राज्य/केंद्र शासित प्रदेश ये सेवाएं विभागीय पद्धति पर दे रहे हैं और शेष 04 राज्यों/केंद्र शासित प्रदेश में यह कार्यक्रम स्थापित करने का कार्य प्रगति पर है।

प्रधान मंत्री नेशनल डायलिसिस प्रोग्राम (पीएमएनडीपी) की पहुंच और प्रभाव को बढ़ाने हेतु, हीमोडायलिसिस को राष्ट्रीय रूप में सफलतापूर्वक चलाने के बाद दूसरी डायलिसिस सेवा पद्धति अर्थात् पेरिटोनियल डायलिसिस की सेवाएं शुरू की जा रही हैं। मैं आशा करता हूँ कि पेरिटोनियल डायलिसिस रोगी के उपचार की पहुंच को बढ़ाएगा और दीर्घकालीन गुर्दों के रोग से ग्रस्त रोगियों के जीवन की गुणवत्ता में सुधार होगा। राज्यों/केंद्र शासित प्रदेशो से मेरा अनुरोध है कि इस कार्यक्रम को निष्ठापूर्वक कार्यान्वित करें और जीर्ण कडनी रोग से ग्रस्त रोगियों के जीवन की गुणवत्ता में सुधार लाने में योगदान करें।

(अश्विनी कुमार चौबे)

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सत्यमेव जयते

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स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

Dated : 2nd July, 2019

Message

In India, the proportion of Chronic Kidney Disease (CKD) patients amount to 8-17% of the total population. The number of cases of kidney failure is expected to increase disproportionately in developing countries, such as India, where the number of elderly people and the NCD risk factors are increasing. CKD is associated with increased risk of complications and mortality at all stages in its natural course. End Stage Kidney Failure (ESKF) is the most advanced stage of kidney failure when survival without some form of renal replacement therapy, such as kidney transplant or maintenance dialysis is not possible. About 10-20% of those with CKD are expected to develop ESKF.

Every year about 2.2 Lakh new patients of End Stage Renal Disease (ESRD) get added in India resulting in additional demand for 3.4 Crore dialysis every year. Moreover, treatment with dialysis or kidney transplantation creates a huge financial burden on the majority of the people who need it. In view of this gigantic demand and financial catastrophe, Ministry of Health and Family Welfare, Government of India introduced haemodialysis under PM National Dialysis Programme in 2016; the scope of which is now further extended by inclusion of Peritoneal Dialysis in the programme. We are hopeful that inclusion of peritoneal dialysis will reduce out of pocket expenditure by offering dialysis services at home and avoid the need to travel to and fro to district hospital or higher level facilities for treatment.

(Preeti Sudan)
2.7.19

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MINISTRY OF HEALTH & FAMILY WELFARE
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MESSAGE

In India, about 2.2 Lakh new patients of End Stage Renal Disease (ESRD) get added each year which results in additional demand for 3.4 Crore dialysis session every year. Even about 70-80% of kidney patients who actually start dialysis, resource limitations force about two-thirds of them to withdraw and be condemned to death. To resolve the issues of ESRD patients like financial constraints, low service accessibility and prolonged dependency for survival on Dialysis, Ministry of Health & Family Welfare, Government of India launched National Dialysis Program (NDP) in 2016. Hemodialysis services under NDP is currently available at district hospital level in 444 Districts in 765 Centres by deploying 4471 machines. Furthermore, PMNDP has already rolled out in 32 States/UTs and is in implementation phase in 04 States. PMNDP is supported by National Health Mission and is providing free of cost heamodialysis services to BPL patients.

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 would be beneficial for such population. Introduction of peritoneal dialysis would be beneficial for such population. Introduction of peritoneal dialysis will reduce travel to the haemodialysis centres for treatment and allow greater flexibility and freedom in treatment schedule. I kindly request the States/UTs to include Peritoneal dialysis proposals under National Dialysis Programme in their NHM Programme Implementation Plan.

(Manoj Jhalani)

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List of Contents

ABBREVIATIONS

ANM	Auxiliary Nurse Midwifery
APD	Automated Peritoneal Dialysis
ASHA	Accredited Social Health Activist
AV	Arteriovenous
BP	Blood Pressure
BPL	Below Poverty Line
CAPD	Continuous Ambulatory Peritoneal Dialysis
CAPEX	Capital Expenditures
CARI	Caring for Australasians with Renal Impairment
CC	Clinical Coordinator
CCPD	Continuous Cycling Peritoneal Dialysis
CHC	Community Health Centre
CKD	Chronic Kidney Disease
CPHC	Comprehensive Primary Health Care
CVD	CardioVascular Disease
DH	District Hospital
ESA	Erythropoiesis Stimulating Agent
ESKD	End Stage Kidney Disease
ESKF	End Stage Kidney Failure
ESRD	End Stage Renal Disease
GFR	Glomerular Filtration Rate
GoI	Government of India
HD	Hemo-dialysis
IT	Information Technology
IV	Intravenous
KPI	Key Performance Indicators
MPW	Multipurpose Health Worker

NatCom	National Oversight Committee
NCD	Non- Communicable Disease
NDP	National Dialysis Programme
NHM	National Health Mission
NHP	National Health Programme
NPCDCS	National Programme for Prevention & Control of Cancer, Diabetes, CVD & Stroke
NPHCE	National Programme for Healthcare of Elderly
NTCP	National Tobacco Control Programme
OEM	Original Equipment Manufacturer
OPEX	Operating Expenses
OT	Operation Theatre
PD	Peritoneal Dialysis
PHC	Primary Health Centre
PMNDP	Pradhan Mantra National Dialysis Programme
RRF	Residual Renal Function
RRT	Renal Replacement Therapy
S.aureus	Staphylococcus aureus
SC	Sub Centre
SDG	Sustainable Development Goals
SOP	Standard Operating Procedure
StateCom	State Committee
UHC	Universal Health Coverage
VARK	Visual, Aural, Read-Write & Kinesthetic
WBC	White Blood Cell

INTRODUCTION

In the 2016 Union Budget, the Government of India announced the National Dialysis Programme. The first phase of this programme envisaged setting up of haemodialysis (HD) centres in all districts, which is being implemented. Peritoneal dialysis (PD), which is another form of standard dialysis therapy, was not included in this phase. However, alleviating the expected increase in the growth in the prevalent end-stage kidney failure (ESKF) population will necessitate capitalizing on treatments beyond in-centre haemodialysis. Dialysis programmes around the world are developed on a combination of haemodialysis and peritoneal dialysis. Given that peritoneal dialysis avoids the substantial costs of infrastructure set up and maintenance and staffing, reduces the demand on healthcare system and offers patient autonomy, a decision was made to include peritoneal dialysis in the ambit of the National Dialysis Programme.

This document will serve as a guide to states that intend to set up peritoneal dialysis in their states, and for providers of peritoneal dialysis as a best practice document for ensuring delivery of high quality, cost-effective service and supplies to develop a clinically safe and effective programme for children, young people and adult women and men. It aims to achieve equity in patient access to home-based peritoneal dialysis, reduce the overall cost of care to the system by focusing on efficient leveraging of resources, and bring in consistency of practice, pricing and a full range of product availability.

Chapter - I

BACKGROUND

1. Chronic kidney disease (CKD) and End-Stage Kidney Failure (ESKF)

Chronic kidney disease (CKD) had been recognised as an important public health problem. The 2016 Global Burden of Disease Report had documented a massive rise in the number of deaths due to this condition around the world, and called for its specific inclusion in the United Nation's Sustainable Development Goals (SDG) agenda. In India, the population prevalence of CKD has been shown to be 8-17% in different surveys (Kumar and Jha, Clin Nephrol 2016, Jha et al, Lancet 2015). CKD is associated with increased risk of complications and mortality at all stages in its natural history. ESKF is the most advanced stage of kidney failure when survival without some form of renal replacement therapy, such as kidney transplant or maintenance dialysis is not possible. About 10-20% of those with CKD are expected to develop ESKF.

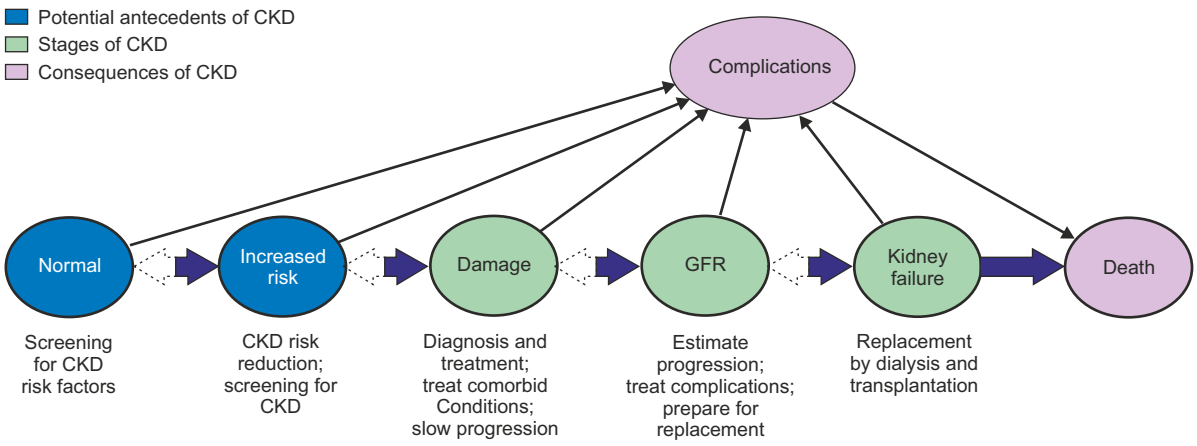


Fig 1: A conceptual model of chronic kidney disease

2. End-stage kidney failure (ESKF) in India

A population-based study determined the age-standardised incidence of ESKF in India to be 226 per million of the population(Modi and Jha, Kidney Int 2006). This roughly translates to an estimated 225,000 people, developing ESKF annually, at the current rates of CKD. Annexure No. 1 provides a projection of the number of individuals with ESKF in different Indian states for whom provision will need to be made in the first year of setting up programmes, and the projected number on dialysis over 5-6 year period. Most individuals diagnosed with ESKF are between the ages of 30 and 60, which are the most productive years of life and hence their death has major consequences for families, society and national productivity. Patients with ESKF also report feeling less independent, unable to participate in activities they enjoy and an overall decline in functional status and quality of life. The number of deaths due to kidney failure in India

rose by 50% over a 10-year period between 2001-03 and 2010-13, with an age-standardized death rate of 40 per lakh population amongst the 45-69 year olds (Dare et al, Lancet Global Health 2017). Kidney disease was the ninth most common cause of death in India in the 2016 Global Burden of Disease report.

3. What are treatment options for patients with ESKF?

Advances in kidney transplantation and dialysis have permitted millions of people with ESKF around the world to stay healthy and active and enjoy an improved quality of life. Some patients may have limited life expectancy because of other reasons (like old age, presence of debilitating comorbid conditions) in which case they are not candidates for Renal Replacement Therapy (RRT), and are offered conservative therapy only. In suitable candidates, kidney transplantation is clearly superior in terms of cost-effectiveness, improved quality of life, survival and societal economic benefit. However, kidney transplant availability is limited by lack of donor organs and expertise. Lack of alternatives to living donors promotes commercialization in the form of transplant tourism and organ trafficking that target the most impoverished members of our populations. Dialysis is needed for all those who are either not suitable for kidney transplant, or have no available kidney donor or as a bridge until they can get a transplant. In a mature healthcare system, all three RRT modalities (HD, PD and transplant) are integrated, and patients can undergo transition from one to another.

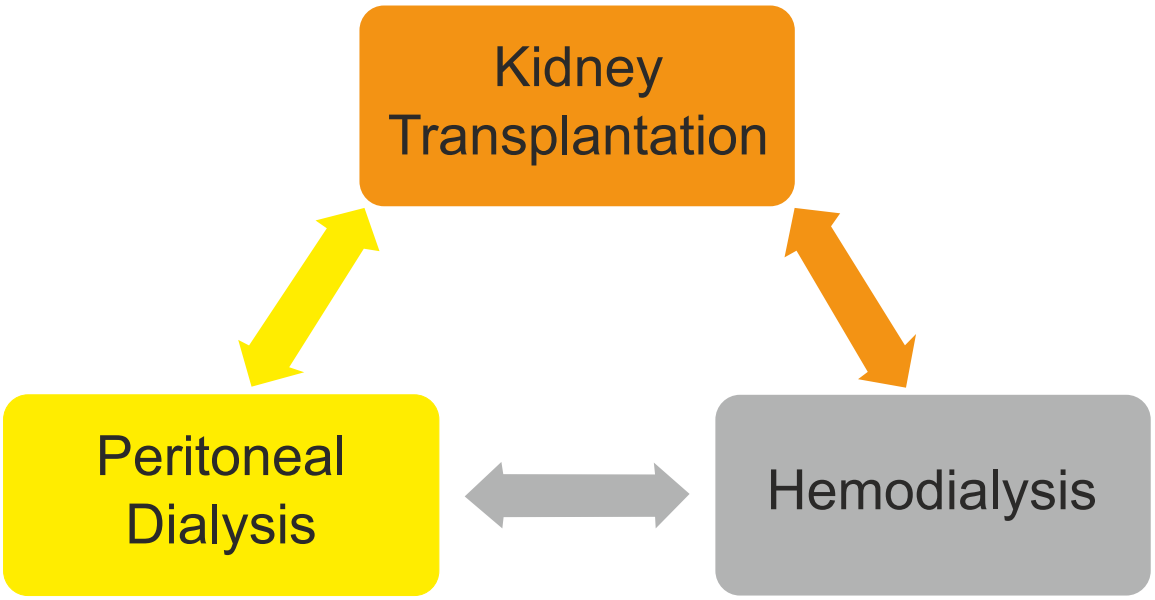


Fig 2: Integrated treatment options for patients with ESKF

4. Dialysis in India

The exact number of patients on dialysis in India is not known, but according to some estimates, this number was between 75,000 to 1 lakh in 2012, and is increasing rapidly. Even using modest prevalence estimates, the number of patients on dialysis in India is soon likely to grow to over 1 million. According to a 2013 market survey, the value of the Indian dialysis market increased from $100 million in 2007 to $150 million in 2012. India's demand for dialysis was reported to be growing at a rate of 31 percent, compared to 6 percent in the US and 8 percent in the rest of the world. Changing disease epidemiology, in particular increase in the prevalence of diabetes and hypertension could make these figures an underestimate.

In-centre HD is the most prevalent type of dialysis in India, but until recently has been concentrated in large cities. Over the last few years, dialysis has been making inroads into Tier 2 and even Tier 3 cities. Still, dialysis remains hard to access for large number of patients living in remote rural areas. They can benefit more from home-based dialysis like PD.

According to current estimates, there are about 6,500 patients on PD in India. The reasons for low utilisation of PD are multiple, and include the high cost of PD supplies, which are exacerbated by application of taxes and duties. Another important reason is physician and provider bias, in part due to financial incentives to physicians from frequent HD unit visits, resulting in higher professional earnings. For the provider organization, the initial fixed cost creates an incentive to fill each HD station to maximum capacity because per capita cost increases when dialysis stations are left unused. Finally, there are two widespread but unfounded impressions: 1. PD is associated with higher complication rates, in particular, infection, and 2. low socio-economic group patients will not be suitable for PD.

5. Why should dialysis be funded by the government?

It was estimated that about 2.7 million people were on dialysis throughout the world in 2010. An equal number, however, needed dialysis but could not get it due to financial reasons. Long-term dialysis is expensive, and leads to catastrophic healthcare expenditure. About 63 million Indians land in debt due to expenditure related to health. And, nearly a third of the population is driven below poverty line due to expenditure related to health.

6. Best Practices Examples

Dialysis is expensive. The annual costs of providing dialysis to one patient is US$ 89,900 in USA, AU$65,000 in Australia, US$12,100 in Thailand and US$9,112 in Brazil. It was decided by the United States Congress that in view of such high recurrent costs, dialysis must be funded by the government. This led to passage of legislation creating the publicly funded Medicare End-Stage Renal Disease Program in the US, which eventually shaped the scope of funding for dialysis throughout the developed world. In almost all developed countries, dialysis is publicly funded and provided free to all eligible citizens. According to the Ethical Considerations section of the Caring for Australasians with Renal Impairment (CARI) Guidelines: “Availability of resources should not be a reason to deny a patient access onto dialysis. Decisions to recommend or not to recommend dialysis should not be influenced by either availability of resources or potential litigation.” Access to dialysis is now used globally as a surrogate for societal willingness to pay for medical care.

Over recent years, countries with relatively less developed healthcare systems have started including dialysis under ambit of coverage by public finding. The inclusion of renal dialysis is considered aligned with the objectives of UHC, viz. protecting people from health impoverishment and improving equity in health across socioeconomic groups. At least 60 countries currently provide universal access to maintenance dialysis to its citizens.

Experience from around the world shows that elimination of cost barrier leads to a rapid increase in demand for dialysis. There was a 170% increase in prevalence of patients treated with maintenance dialysis in countries that provided universal access and a 154% increase in the last two decades for countries still working toward universal access. According to the recently published Global Kidney Health Atlas, out of the 124 countries surveyed, more provided free PD (51%) than HD (42%) from public funds.

Example from Thailand

Thailand's universal coverage has been widely recognised as a successful model for tax-based health benefit schemes in the developing world. It has adopted a dialysis programme primarily based on PD. This decision was made after a thorough evaluation of cost, outcome and acceptability of the competing technologies. Under the current policy, PD is offered as the default dialysis modality unless contraindicated on medical grounds. According to the "negative list approach", only those patients who have medical reasons like non-functional peritoneal membrane or have extensive adhesions or catheter failure, have suffered severe peritonitis, have skin lesions that do not support exit site, have conditions that make PD unfeasible, like visual impairment, infirmity due to old age, absence of social support or neurological complications are excluded from getting PD. The indications for shifting to HD are set up by the Nephrology Society of Thailand and regional committees are authorized to make the decision. Over time, the policy has been revised and patients who started HD before launching this policy now also are fully reimbursed, but those who elect to start HD since the launch of the policy must pay out of pocket.

The objectives of this policy are to increase access to dialysis and transplantation, to provide financial risk protection to patients, and to minimize the impact on the overall national health care budget. Experiences from Thailand (and Hong Kong) demonstrate that PD has relatively lower cost for providers (including capital investment), less need for healthcare provider staff, reduced travel time and cost for patients, reduced erythropoietin costs and increased patient autonomy and satisfaction. In Thailand, rural hospitals have successfully implemented PD services at home for patients living in remote areas. Nephrologists initially opposed this because of their poor experience with peritoneal dialysis, and fear of lost income; they accepted it because it was the only way that poorer patients would be able to obtain dialysis, and their income was ensured by the inclusion of incentive for PD. In the initial years, a reimbursement of THB 4000 per patient per month was provided to the Centre and another THB 2000 per patient was provided to the nephrologist. Subsequently, these amounts were reduced to their current level of THB 3000 per patient per month per centre (including in-patient treatment, added later) and nil to the healthcare professional.

The following approach was adopted to facilitate the success of this approach -

1. Cost Containment by central purchasing of PD solutions, erythropoietin and PD catheters
2. Incentive schemes to drive the health care system toward PD rather than HD
3. Increase the number and capacity of PD Centres by co-operation between government and professional societies - Nephrology Society of Thailand, the Thai Nephrology Nursing Association, and the Thai Dietetic Association
4. Encourage New PD centres, most of which are in public provincial hospitals, to create local satellite kidney patient clubs

Chapter - II

PRINCIPLES AND MODALITY CHOICES

1. Dialysis modality choice

Globally, technologies such as HD have been advocated by privileged groups, such as politicians, health professionals and the industry. Other stakeholders with less power, such as patient groups and civil society organizations, generally are left behind in decision making. This led to risk of neglecting some essential interventions, such as those that provide less incentive to the stakeholders and those intended for health promotion and disease prevention. Competition between the relative value assigned to cost-effectiveness, affordability, feasibility, equity and ethics, makes coverage decisions complex. In the overall context of the healthcare system, the values that should be applied for decision making include transparency, accountability and participation. Technologies which offer value for money and/or enhance equity and solidarity should receive priority. Dialysis modality choice should take into account patient motivation and desire after evaluation of all available choices. Currently, many patients are not even offered PD before beginning dialysis. (Refer Annexure 1a and 1b)

With few exceptions, all ESKF patients are suitable for either HD or PD. Overall, the number of patients on HD vastly outnumber those on PD. Irrespective of what policy is decided, guidelines for its implementation should be based on a transparent decision making, taking into account the individual patient's circumstances, to optimize use of this limited resource.

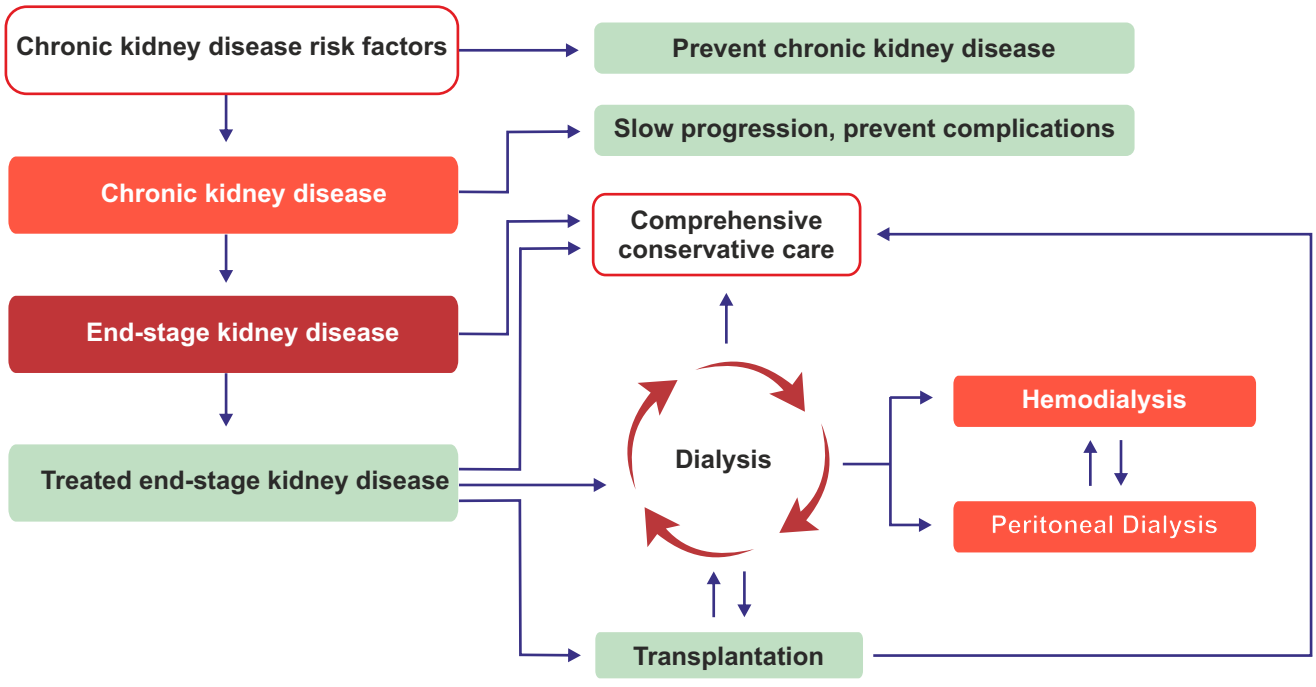


Fig 3: ESKD Pathways

According to the International Society of Nephrology Ethical Dialysis Task Force “To achieve equity in treatment when inequalities of access are unavoidable, fair and transparent criteria and procedures governing access must be established. Although the goals, values, and principles that should govern access to dialysis in a particular society might vary, a number of considerations will be common to all societies seeking to promote health equity.

Procedural justice requires that decisions about access policies be made by legitimate authorities who are accountable to those affected by the decisions. Such decision making should be transparent, informed by relevant evidence and ethical principles, and consistent in the application of principles or rules. Procedures should be established to engage stakeholders and experts in decision making and to provide opportunities for appeal and revision of individual decisions. Distributive justice requires the development of frameworks to guide allocation of limited resources. Access criteria and policies must therefore be informed by an understanding of broader access issues relating to prevention and management of chronic kidney disease, supportive care, management of co morbidities and complications, and general health-care services.

2. Comparing Hemo-dialysis and Peritoneal Dialysis

Although the efficiency of the two dialysis modalities in terms of per unit of operation time is different, over a prolonged period, the net effect in terms of removal of waste products, salt and water are similar. Both types of dialysis broadly are similar in terms of their effect on patient outcomes and longevity/survivals. Most patients are suitable for either HD or PD, but a small number may be unsuitable for one form of dialysis (Table 1). Young children especially those below 5 years of age are often unsuitable for HD. Such patients are preferably initiated on PD. Additional considerations that come into play include living circumstances, employment and education, support from family members and community networks, distance between patients’ residences and dialysis facilities and convenience in transportation.

a. Haemodialysis

Dialysis removes wastes and excess water from the blood. HD removes wastes and water by circulating blood outside the body through an external filter, called a dialyzer, that contains a semi permeable membrane. HD requires a dialysis machine and pure water, and is typically done in a dialysis centre. One session lasts 4 hours and it needs to be repeated 2-3 times a week. HD requires the patient to travel to the centre each time. Need for pure water requires installation of a water treatment system. Operation of the unit depends on the availability of trained nurses and/or technicians. Haemofiltration, and variations of HD can increase the clearance of solutes. Long-term HD requires repeated access to high-flow circulation, which is most commonly achieved by creation of an arteriovenous fistula on the arm. In some patients, access is gained by placing a catheter into one of the large veins. Long term HD access is difficult to achieve especially in children and adolescents.

One HD 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. HD can be done at home, but requires availability of a dedicated machine for the patient and installation of a water treatment system at home which is a difficult and expensive alternative.

b. Peritoneal Dialysis

In PD, wastes and water are removed from the blood inside the body using the peritoneum (natural membrane lining the inside of abdominal cavity) as a natural semi permeable

membrane. Wastes and excess water move from the blood, across the peritoneal membrane, and into a special dialysis solution, called dialysate, that is instilled cyclically in the abdominal cavity of the patient. After the dialysate is saturated with solutes removed from the blood vessels it is drained out. This exchange is repeated 3-4 times per day; automatic systems can run more frequent exchange cycles overnight. Access to abdominal cavity is obtained by placing a catheter in the peritoneal cavity. PD is carried out at home by the patient, often without help. However children require assistance from parents or caregivers for performing PD. PD frees patients from the routine of having to go to dialysis clinics multiple times per week, and can be performed with little to no specialized equipment (other than bags of fresh pharmaceutical grade sterile dialysate).

Table 1: A comparative account of Hemo-dialysis and Peritoneal Dialysis

Haemodialysis	Peritoneal	Dialysis
Location	Patient needs to travel to a dialysis centre 2-3 times a week, typically with a caregiver	Usually done at home
Method	Access to circulation by needles or catheter. Blood circulated through a filter in a dialysis machine in which an artificial semi permeable membrane allows movement of toxins and excess water out of blood stream.	Dialysate instilled into peritoneal cavity through a catheter, allowed to stay for some time to allow movement of toxins and excess water out of blood stream across natural peritoneal membrane.
Frequency	2-3 times every week for 4-hour session each time	3-4 exchanges a day, 20-30 minute each time for filling and draining the abdominal cavity
Requirement	Setting up dialysis unit, dialysis machines, water treatment system, dialysis-grade plumbing, availability of doctor, trained technicians and nurses (1 for 3 patients).	No infrastructure or machines needed. Trained PD nurses (1 for 25-30 patients). Doctor for supervision.
Technical difficulty	High, requires supervision by experienced personnel and use of monitoring devices	Simple, done by patient or caregiver. No technology required. Steady supply of PD fluid and some consumables
What is needed before starting	Gaining access to vascular system by creating an arterio-venous fistula or placing a vascular catheter	Gaining access to peritoneal cavity by placing a peritoneal catheter.
Patient-related factors	No requirement for self-care, allows more frequent contact with healthcare system, but can reduce freedom to work and travel.	Supports flexible lifestyle and freedom to work and travel, better quality of life, particularly suitable for children. Needs a suitable home environment.
Risk of infection	more frequent	less frequent
Impact on environment	Consumes high quantity of water and electricity and travel	Disposing of PD bags is a concern
Cost to health care system	CAPEX- High OPEX- High ₹₹₹₹	CAPEX – Negligible OPEX - Less ₹₹₹₹

The Risk of infections

There is a common perception that patients on PD are at an increased risk of infection. In fact, both PD and HD increase the infection risk. Because of the difference in the way the two treatments are provided, the most important type of infection in PD patients is related to PD catheter - peritonitis and exit site infection, whereas those in HD are at risk of developing vascular catheter related sepsis – bloodstream infections (bacteremia), infective endocarditis and pneumonia. Overall, however, infections are seen more frequently in patients on HD, particularly if they do not have an AV fistula and use a vascular catheter. In comparative studies, hospital admission rates for HD patients for bacteremia, sepsis and pneumonia are 2-fold higher than they are for PD patients, which increased the risk of death in the HD patients. Moreover, with proper technique, PD infection rates can be brought down, as has been shown in several parts of the world. The International Society for Peritoneal Dialysis has established a unit level benchmark of 1 infection episode for every 18 patient-month. Most PD centres/ dialysis units offering regular PD programmes in India already report much better results than this threshold.

PD saves water and is environmentally responsible

Water security is emerging as an increasingly vital issue for India. Many Indian cities experience moderate to severe water shortages. HD is water-intensive, one 4-hour session requires about 250 L of water (used plus discarded). A theoretical construct would produce a water saving of over a million litres of water per 100 patients treated with HD and PD each per month.

Comparison of the cost of providing HD and PD

There are a number of studies on the comparative cost-effectiveness of HD and PD from many parts of the world. These studies show that when provided at equal level of quality and standard, PD is consistently more cost-effective to the healthcare system (Chang et al, Scientific Reports 2016). A position statement issued by opinion leaders from Hong Kong, Australia, China, Italy, France, Japan, Korea, Macau, Malaysia, Singapore, Spain, Taiwan, Thailand, and the United States reiterated that in-centre HD is more expensive than PD (Li et al, Nephrology 2011).

In India, PD has been labelled as being more expensive than HD. Part of the reason for this impression is the failure to consider many hidden costs in delivery of HD, and cost-cutting by omitting several measures needed to deliver HD of a reasonable standard. No formal comparative health technology assessment of various RRT options has been done. Recent data suggest that the actual cost of HD is at least 4-8 times higher than estimated previously. In a public-sector tertiary hospital, the mean out-of-pocket expenditure on HD was estimated to be INR 2,230. Another study reported median direct costs for HD at INR 2,628. In a private tertiary care hospital in South India, the cost per HD session borne by the patient was found to be INR 4,428. In the most comprehensive study carried out in a public-sector hospital using rigorous methodology, the overall average cost incurred by the health system per HD session was INR 4,148.

Chapter - III

SERVICE DELIVERY FRAMEWORK

1. Principles of providing Peritoneal Dialysis

The following principles will ensure an efficient and cost-effective PD programme without compromising quality –

(i) Reducing procurement costs –

a. local production of PD solution bags (already exists in India)

b. abolition of statutory duties on PD supplies and

c. bulk procurement of PD supplies (solutions, catheters).

(ii) Improving patient and technique survival on PD so that patients are not forced to transition to HD –

a. developing a trained cadre of PD providers at all levels (physicians, nurses, clinical coordinators, etc),

b. training nephrologists to insert PD catheters,

c. providing continuum of care to patients on PD, and

d. measuring and monitoring quality indices and implementing corrective steps in a timely manner.

2. Managing entry of patients towards Peritoneal dialysis

Patients will approach PD by the following pathways-

(i) Planned - CKD under care of a nephrologist who has been prepared

(ii) Planned - transitioning from another RRT, e.g. failed transplant, switch from HD

(iii) Unplanned - including those presenting with ESKF for the first time directly to emergency (crash landers)

(iv) From primary care - under medical care but not prepared for dialysis

3. Patient selection for PD

As mentioned before, with rare exceptions, all ESKF patients are suitable for PD. Generally acceptable patients are:

- Age <= 60; however with family support senior citizens might benefit more by reduced ambulation needs
- With residual renal function,
- Adults without significant associated co-morbidities,
- Patients with a functional peritoneum and no recent history of major abdominal surgery.

- Patients with steady dexterity, vision and mental acuity
- Children with adequate home-support
- Adults with ability to undertake PD at home or those with family support for PD.
- House with space to store PD supplies, adequate water supply and dedicated space for undergoing PD.

4. Who can prescribe PD?

The initial decision to start a patient on dialysis can be made by a nephrologist or a physician with appropriate training. In case the initial decision has been made by a non-nephrologist,it should be confirmed by a nephrologist within a 4-week period. This is being suggested to make sure that patients are evaluated to exclude all reversible causes of kidney failure so that the patient is not denied appropriate curative therapy.

5. How to prescribe PD?

The daily regimen of four 2 L exchanges has long been the standardized, accepted continuous peritoneal dialysis standard prescription. However, physicians started to use three 2L exchanges for patients of “small body size with residual renal function”, as a strategy of making PD therapy affordable, and accessible. Small-volume dialysis (6 L daily) was used to address financial constraints and as an acceptable compromise in some populations with a smaller body size and significant residual renal function.

The strategy of starting with fewer exchanges in patients who have small amount of residual kidney function has been used successfully in many countries. Patients are started on 3exchanges, and as residual kidney function declines over time, the number of exchanges is increased. All patients with residual kidney function <2 ml/min or body weight >75 kg should be started on 4 exchanges daily, whereas others can be started on 3 exchanges. All patients should be assessed every 6 months for adequacy of dialysis and the need to modify prescription. It is suggested that residual renal function should be assessed in all patients at initiation, at 6 monthly intervals or as needed.

6. PD network structure

In order to increase the reach of PD, a mixed model could be created depending upon the context. States could consider either providing PD in SC, PHC CHC and DH, for those who live close to these facilities. Home based PD could be considered for those who meet the criteria

As PD reaches remote communities, opportunities to co-opt non-physician health workers (ANM, MPW), village volunteers (ASHA), patients and family members could be trained to provide information, education and limited care.

PD centres could be established in SC, PHC, CHCs, district hospitals and government medical colleges. These organizations have the advantage of being well connected with comprehensive primary care networks at all levels.

Opportunities for treatment partnerships with private facilities to overcome the limited capacity in the government sector should be explored, with the principle of setting fixed prices for reimbursement.

A dialysis unit should be able to provide the following services:

- Infrastructure able to offer all PD modalities
- PD catheter insertion
- Capacity for home visits and review of home circumstances when PD is being undertaken at home
- A pathway to accommodate crashlanders (who present acutely and require urgent unplanned dialysis)
- Protocols supported by IT to guide all aspects of care of PD patient
- Balanced education about kidney disease, dialysis, treatment choices, nutrition, lifestyle adjustments etc.
- Ability to respond to patient needs at all times either in person or through IT

Most frequent barriers to PD

- Place of residence does not permit PD
- Previous major abdominal surgeries
- Morbid obesity
- Large abdominal wall hernias
- Active diverticulitis
- Abdominal walls ostomies or conduits
- Large abdominal aortic aneurysms
- Severe visual impairment or poor manual dexterity
- Lack of caregivers at home

7. Infrastructure (when provided in a facility)

- PD Centre or Service Area: The service area should be designed to provide integrated PD service, including education area, training area, treatment room, consultation room and waiting area.
- The size should be adequate to the PD population
- The area should be friendly for differently abled people.
- There should be space to manage acutely ill patient or an attached health care facility
- An Operating Theater should be available for PD catheter insertion (or removal)

8. Size (Pt Volumes per PD Centre rather than size) of a PD centre:

Various studies have shown a relationship between the size of the PD centre and the risk of technique failure. Technique failure is high in centres that have less than 20 PD patients.

9. Human Resources

- Nurses/ANM/Clinical coordinator (CC) who can provide PD education including dietary counselling to PD patients - and are able to evaluate and solve basic medical issues related to PD, and co-ordinate care with nephrologist as needed.
- One trained PD nurse/CC to be provided for 20 PD patients, total strength should account for 24x7 coverage, leaves etc.

- Nephrologist/ Physician with appropriate dialysis training to decide need for PD, write PD prescription, medical treatment, access planning and PD catheter insertion
- Primary care physician/nephrologist to provide follow up advice and make treatment changes if triggered by Nurse/ANM.In Thailand, linkage of every patient to a physician reduced the risk of technique failure by 2%.
- Access to trained nephrologist/surgeon for PD catheter placement.
- Pharmacists/storekeeper to maintain/disburse PD supplies and other medicines
- Data entry person to ensure up-to-date documentation.
- Support staff to keep the centre clean, maintain equipment etc.
- Psychologists/social workers/nutritionists - where available.
- Volunteer community members - including patient-to-patient peer groups

Details of training are at Annexure 2 and 3

10. Information Technology

- IT support to trigger referral, follow progress, provide audit trail and quality parameters.
- IT-based clinical decision support to patients and carers and if possible telemedicine or real time audiovisual support.
- IT-based inventory procurement, monitoring, ordering pharmacy supplies, authorisation and billing.
- IT literature, websites and decision aids of acceptable standard in terms of content
- Printed literature on environmentally preferred materials that patients can take home (avoid duplication with IT-based content).
- Computer and handheld devices for documentation and decision aid.
- PD adequacy software.
- Dialysis registry software.
- All data to be captured electronically.
- Advance care planning to include recognition of changes in the patient.
- Planned transfer to HD or supportive therapy (end of life care) as needed.
- Efficient patient transport arrangements should be established (use 108/102 service).

11. Equipment

- OT infrastructure including C-arm, OT light and cautery.
- Beds and chairs for dedicated PD area.
- PD catheters with accessories (adapter, transfer set).
- Full range of dialysis fluids in all bag sizes, strengths and special fluids.
- All needed medications and surgical supplies including but not limited to - bag scales, bag warmer, weighing scales, Blood Pressure (BP) machine, cleaning solutions, dressings, towels, dressing packs.
- PD Cycler in district hospitals/medical colleges, especially for children and for acute start PD.
- Microscope for bedside examination PD effluent for infection.

12. Drugs

The drugs and diagnostics mentioned below are to be provided free of cost to the patients under Free drugs programme and Free diagnostic service initiative. Currently all drugs listed below are neither included in national list of essential medicine 2011 nor included in all States/UT's list of essential medicines. But these are mandatory requirements and non-negotiable, without this states are not advised to initiate the dialysis programme.

- Anti-hypertensives.
- Loop diuretics.
- Antidiabetic agents including insulin.
- Phosphate binders: calcium carbonate, calcium acetate, sevelamer*.
- Erythropoietin*.
- Vitamin D analogues: cholecalciferol, calcitriol, alfacalcidol.
- Aspirin*.
- Antibiotics (Injectables for peritonitis)*.

13. Diagnostics

- Blood counts.
- Routine biochemistry – blood urea, serum creatinine, albumin, calcium, phosphate.
- Microscopy for counting cells in PD fluid.
- Fluid and blood culture facility (culture bottles with transport medium should be available).
- Chest X-ray.

The following best practices are suggested to improve outcomes on PD -

1. *Patient selection:* Patients <60 years without co-morbidity should be considered for PD. Select motivated patients with support (if required) from a family member or friend.

2. *Prophylaxis and timely treatment of infectious complications:* All PD units must establish a protocol for PD catheter insertion, Staphylococcus aureus (S. aureus) should be eradicated to reduce exit-site infection, catheter should have a downward-facing exit site, a single dose of prophylactic antibiotic should be administered at the time of catheter insertion, catheter exit site should be kept clean and topical antimicrobial (mupirocin) should be applied, units must follow infection control protocols, treatment should be immediate with antibiotic(s) as per protocol, and changed if necessary once culture and sensitivity is available, antifungal prophylaxis should be given in centres with high rates of fungal peritonitis, PD catheter should be removed early in the event of inadequate response to treatment.

3. *Investigation of social causes of technique failure:* All units must record infection rates and outcomes for benchmarking against national and international registries and guidelines, deviations from current best practice should be identified, social causes of technique failure should be investigated.

4. *Patient education and continuous support:* Centralized training practices based upon adult-learning principles should be applied, there should be oversight for infection control, hand hygiene etc.

5. *Clinical governance and professional standards:* There should be clinical oversight in every unit with clear lines of responsibility and mandatory continuous quality assurance processes.

6. National key performance indicators should be established and used for benchmarking PD practice and clinical outcomes on a quarterly basis.

7. System for ongoing surveillance of PD practice and patient outcomes should be in place

8. Indian Society of Nephrology and the National Board of Examination should establish minimum professional standards and education programmes for nephrology trainees, support PD Registry, identify evidence gaps and undertake more PD research. All trainees must be involved in the care of at least 50 PD patients - both in inpatient and outpatient settings, and have placed 5 PD catheters.

14. Follow-up care for patients on PD

The PD Nurse should be in the centre of systematic care delivery mechanism to a patient on PD. (S)he should assess suitability for PD at home or in PHC, provide training, and be the first contact point for all clinical queries. (S)he would be assisted by ANM/ASHA as needed. She would monitor and document the technique and quality parameters every month, and raise referral to a nephrologist/trained physician if needed. A nephrologist should see the patient once every 3 months (or more frequently if needed), and review the overall medical care of the patient. We suggest that the nephrologist-physician/hospital (as appropriate) be reimbursed at a fixed rate for each visit.

15. Requirements for PD in a home setting:

Peritoneal dialysis is a home-based treatment. Many patients would prefer PD, but are unable to carry out the technique on their own. In this situation, the carer, usually a family member, provides assistance with the PD technique, check the exit site, blood pressure and weight, and communicates with the treating team.

Since PD is self-administered and at home, the room setting requirements are not required to be modified. The room like any other room should be well-lit, with good ventilation through windows and doors (both need to be closed during exchange) and preferably with an attached bathroom with regular running water. The room should have minimum furniture. Pets are not allowed into the room where PD exchange would be done. Any linen in the room like any other living room, PD room has regularhouse-keeping requirements like change of bedsheet, pillow covers should be cleaned frequently and all surfaces swabbed daily with an antiseptic. , cleaning and if possible, a daily dry-wash. There should be no disruptions during exchange process. The house should have clean, dry space for storage of PD supplies. Total space required for storing 120 PD bags (20 bags per case) may not be more than 32 cu ft (appx 1 cu m).

Process

- PD education and preparation should be appropriately timed.
- Suitability for modality (PD), and patient expectation of treatment should be documented.
- Identify family members or carers who will need to be involved in education/training.
- PD education should include at least one dedicated 1:1 session, with further group or single sessions as needed.

- Training to be flexible as per patient/family needs.
- Staff should be able to undertake home visits to recognise and fix health and safety risks.
- An identified nurse/ANM educator should be assigned to each patient for resolving queries.
- Where available, patient volunteers should be involved in education.
- PD catheter insertion should be available such that a routine catheter insertion can be performed within two weeks and an urgent catheter insertion can be done within 24 hours.
- Home delivery of required supplies and waste collection should be done.
- Individual care plan for each patient should be developed.
- Home visit, peritoneal equilibration test, adequacy test, should be done as per guidelines.

16. Family Support and PD

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 increases 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 log-book 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.

17. Home Visits and limited troubleshooting through use of technology interface.

The government already has a large network of trained ASHA/ANM network that can with requisite training be engaged in patient care, identification of medical intervention and immediate trouble shooting. Using technology interface, allows patients and caregivers to perform routine adjustments in treatment, gives them the ability to communicate with providers allows the non-physician health workers to track compliance and efficiency of care and does additional tasks like inventory management will be enablers in this endeavor.

18. Support to Home based PD.

ANM/ASHA shall perform monthly home visit to the patient and provide home-based training to the patients. Identified Government Hospitals/Community Health Centres will act the nodal Centre for catheterization and patient training.

When a PD patient wants to restock PD bags, used PD bags issued initially should be returned to the PHC, ensuring that the bag is sealed. PHC/Sub centre is responsible for disposing used PD bags as per government notified biomedical waste (management & handling) act & rules.

19. Monitoring of PD patients: periodicity, parameters, expertise of personnel at each level

All PD patients have to necessarily report to their assigned PD centre/CHC for follow-up once in every two months. The supplies would be provided at patient home or PHC as indicated. PD patients would have to carry their log- book for each centre visit.

20. Refresher training – at what interval?

All patients should undergo at least one re-training every 6 months or a quarter to ensure technical skill does not wane with time. Such a re-training would act as a reinforce PD technique refresher training and would also pick up topical subject like fluid warming (prior to winters), exit-site care and routine dressing (prior to the monsoons) or fluid balance (prior to the summers) etc. Other topics would include general guidance and collective learning importance of blood pressure monitoring or regular weight measurement.

21. Logistics: Distribution and storage

The suppliers/bidders should ensure efficient and time bound supply logistics and would be required to supply up to the sub-centre/health and wellness centre/provider hospital. The average turn-around-time should not exceed one two-weeks from the receipt of composite order at their end, and there should be a penalty cause in the contract to cover this point. There should be absolutely no break in supply since the patient faces imminent mortality if dialysis interrupted. This may need adequate buffer stocks to be kept by respective members of the supply chain.

An inventory and procurement system that connects the PD providers with suppliers of medicines and materials should be set up to ensure inventory control and timely delivery of drugs, erythropoietin, dialysates for peritoneal dialysis, and catheters. The supplier/bidder would be responsible to deliver the total bags to patient homes upon raising indent (within 72 hours) or upto the level of the Sub-centre/PHC as the case may be.

The total number of PD bags have to be recorded at the end of purchaser (eg: government tendering authority) and transferred along the supply chain till it reaches the PD patient. Tracking of PD bags is essential to safeguard patient in the event of an adverse event associated with PD bag manufacturing and to ensure PD bags reach patients or to avoid spillage to open market for sale.

No specific storage conditions are required except a cool, dry place and with a limitation of stacking not more than twenty boxes of PD fluids. Not more than six boxes should be stackedontop of eachother. On an average each patient would require between 90-120 PD bags for monthly maintenance. Every patient should have a buffer stock for 2 weeks. Hence, the initial supply should be for 6 weeks after which 30 day supply should be given every month.

22. PD Catheter insertion

There is overwhelming evidence from around the world including India that PD insertion by nephrologists is associated with lower or similar complication rate compared to a surgeon. Benefits of this approach include better continuity of care, reduced waiting times, and the creation of a committed team with a keen interest in catheter placement. Use of PD increases when nephrologists insert catheters.

23. Urgent start PD

Late referral is considered a major barrier to PD. A large number of patients start dialysis unexpectedly, mostly on HD with central venous dialysis catheters. Such patients receive no education about choice of modality. Except those with severely metabolically disturbed acute presentation of ESKF, other patients could not be started directly on PD. There is evidence that outcomes are identical for late presenting patients starting on PD or HD. The main factor limiting the use of acute PD is the difficulty of getting a PD inserted. This may be overcome by developing nephrology competencies in catheter insertion. Several models of urgent start PD have been developed in which PD can be started soon after catheter insertion, either through a cycler on an outpatient basis, or manual exchanges in supine position.

24. Care of children and adolescents with ESKF

Children and adolescents with ESKF face the additional challenge of living with renal disease along with the usual pressures of childhood and growing up. These needs should be addressed comprehensively by developing a special cadre of appropriately trained staff. This is of particular importance in India where about 41% of the population (472 million in 2013) is under the age of 18. Specialised equipment is needed to provide HD to small children, hence currently they have been almost completely excluded from HD programmes in India. Wide availability of PD will remove this disadvantage. Moreover, home-based PD is better suited to their flexible lifestyle, including education, schooling and other childhood activities. The technical simplicity of the procedure allows for performance at home in all but the most exceptional circumstances. Many children will move from paediatric to adult units, a process that will need to be managed efficiently.

25. Care of women with ESKF

While men on dialysis consistently outnumber women all over the world, this different is particularly noticeable in India. In the state funded dialysis programme in the Andhra Pradesh, this ratio was 3:1. Moreover, the survival was poorer amongst women. Biological differences are unlikely to explain this difference, and social structures and limited resources likely play a role in limiting access of women to HD. PD has the potential in achieving equity in delivery of dialysis to women with ESKF, by providing this treatment at homes, and understanding their needs by co-opting the community non-physician work force like ANMs and ASHA in improving access of women to HD.

26. Cost

In India 2.2 lakh new ESRD patients are added every year, assuming 50 % of the patients are prescribed PD, 10,000 sub centres/ PHC may be identified as the last mile service and supply delivery point.

Treatment cost can be brought down substantially by developing a creative procurement process. The Thai experience suggests that central procurement allows price negotiation and quality assurance. At this time, there are 3 PD fluid manufacturers/suppliers in India - Baxter, Fresenius and J Mitra. It is unlikely that any one of them will be able to cater for the entire or even a majority of PD population in India. It is therefore desirable that a rate contract mechanism be developed, and more than one provider could be contracted to provide supplies. Even though superficially manufacturing PD fluid bags seems simple, past experience indicates that having

a robust manufacturing process with transparent quality control mechanisms is essential. Developing the technical specifications should take into account the capabilities of the bidders to meet with these criteria. The supplier should also support the government system through their clinical-coordinators, and expertise in this area should be a technical requirement.

The catheter, adaptor and transfer set may be included in the Essential Drug List and be provided to the patient for free or a subsidized cost. Since the catheterization is expected to be completed in government facility 'procedure charges' may be waived off.

The components that will require budgeting (either in this programme or under other pre-existing programmes) include -

1. Nephrologist fee - diagnosis and routine follow up
2. One time -
    - PD catheter insertion procedure.
    - PD catheter, adapter.
    - Surgical supplies.
3. Recurring costs
    - PD fluid bags.
    - Drugs for routine medical management.
    - Drugs needed for peritonitis management – antibiotics.
    - Erythropoietin.
    - Transfer set (once every 3-6 months).
    - Investigations.

The national PD programme can be budgeted on the basis of per patient cost per month including a supply of between 90-120 bags per month and all the allied training to the staff.

Estimated cost for peritoneal dialysis per patient (as during year 2019)

Catheter Initial kit including transfer set and adaptor: Rs. 11,000.00

One time Patient Support for Monitoring tools (BP apparatus, IV stand, weighing scale): 3000/-

Quarterly replacement of transfer set: 2000/-(Three per year)

PD bag (including training support): Between Rs.200.00-Rs. 220.00

Monthly requirement: 90-120 bags per patient

Monthly per patient cost (range) INR 18,000-INR26,400

Chapter - IV

QUALITY AND CLINICAL GOVERNANCE

In order to ensure delivery of high quality service, all staff needs to be appropriately trained. A minimum competence framework is designed to enable the practitioners to enhance knowledge underpinning practice, to gain confidence by perfecting practice and to optimise care for the patient receiving peritoneal dialysis. The International Society for Peritoneal Dialysis has developed a set of guidelines for training which have been adapted for this purpose after appropriate modification. Practitioners and units who have developed curricula and standards should share their good work to ensure the quality of care they for patients on PD is optimised and consistent.

There should be a Nodal person for PD in each district who will be responsible for quality supervision, will be notified immediately of any incidents relating to the PD service and will be responsible for deciding on appropriate action. All incidents/complaints should be logged and resolved expeditiously, at the most 4 working days.

Delivery of a successful RRT programme requires involvement of multiple stakeholders including professional medical associations, industries, civil societies, community groups and networks, and family members. National Dialysis Program should develop relations with equivalent organisations in India and other countries, multilateral and non-governmentalorganizations for sharing experiences, good practices and problem-solving for policy implementation.

1. National Oversight Committee

A national programme has the responsibility of creating support systems that would ensure that the goals of treatment are achieved in a time-bound manner, are replicable in the and can be continually improved, both upstream and downstream.

A National Oversight Committee (NatCom) should be set up as the overall owner of the National Peritoneal Dialysis Programme. The NatCom would be assisted by State Committees (StateCom). The structure of the NatCom would be as follows:

The NatCom shall establish an overall policy-framework, set up processes, develop guidelines, set therapy related targets, assess progress, identify areas of improvement and guide StateCom in implementation of policy. NatCom will also formulate the standards of professional conduct and maintain an oversight on the overall conduct of the participating Provider Hospitals.

The NatCom would support and promote human resource and academic development of Provider Hospitals and coordinate with Bidders (Suppliers) to organize and deliver such activities. In addition, the NatCom would commission committees or working groups, conduct meetings and seminars for disseminating knowledge or campaigning for awareness about kidney disease, its causes and strategies for prevention and mitigation of co-morbidities.

The NatCom would function under the overall supervision of the Chair, National PD Programme and shall include members of PD Committee, invited members of stakeholder societies and patient representatives.

2. Dialysis Registry

Registries are an organized and standardized method to systematically collect observational data about specific groups of patients managed in routine clinical practice for a predetermined objective. Such data are held in a central database and typically include information on longitudinal follow-up and outcomes. Registries describe the natural history, epidemiology, and burden of a disease; capture regional or national variations in treatment and outcomes; evaluate safety and quality of care; track cost of care, assess patient, economic and provider-driven demands; and help in budgetary allocations. By impacting health care procedures, registries influence policy and thus population health.

End-stage renal disease (ESRD) and its current standard of care, renal replacement therapy (RRT - dialysis and/or kidney transplantation) result in substantial economic and societal costs. In developed countries, ESRD affects about 0.03% of the total population, but RRT costs consumes up to 3% of annual healthcare budgets. Most developed countries have renal registries that provide critical information to support the planning, delivery and evaluation of dialysis and transplantation services. The lack of a renal registry means that there are few reliable statistics on RRT from India.

The GOI, in the NHP 2017 has pledged on establishing “registries for the diseases of public importance”. From such registries would emerge information that may become integral to developing evidence based treatment guidelines, another pledge of the NHP 2017. Therefore, the proposed National Dialysis Service should include a registry:

Purpose and scope - To generate information on the prevalence, incidence and causes of ESRD in patients on RRT and information on treatments and outcomes by collecting well-defined epidemiological data over many years.

Defining patients to be included - All patients who receive dialysis.

What data should be recorded - There should be core items that will be collected for the lifetime of the registry and provision for additional items of time-limited interest. This lowers the costs and time requirements and improves compliance. This process should be supported by a data dictionary, and SOPs for collecting and cleaning data and ensuring quality, confidentiality and ethics.

Dissemination of findings - annual reports, presentations at academic meetings, media releases, publications in medical journals and the release of datasets.

3. Key Performance Indicators (KPI) : Peritonitis rate

Rationale: Peritonitis is a leading cause of morbidity and has been associated with mortality and the reason for ceasing Peritoneal Dialysis (PD) treatments. Peritonitis is also the biggest barrier to uptake and success of PD as a therapy. Finally, peritonitis prevention provides an overview of the management of the centre and is a good surrogate of the overall function of the hub.

Definition: Peritonitisis inflammation of the peritoneum. Diagnostic criteria for PD peritonitis is at least two of the following:

- Signs and symptoms of peritoneal inflammation.
- Cloudy peritoneal fluid with and the effluent white blood cell count is greater than 100/mm^3 and at least 50% of the WBCs are polymorphonuclear leucocytes.
- Demonstration of bacteria in the peritoneal effluent by gram stain or culture.

Peritonitis rate is calculated as number of episodes of peritonitis (i.e. total number of peritonitis episodes experienced by all patients in a unit) divided by, months of peritoneal dialysis at risk (i.e. total number of months all patients have spent on dialysis), and expressed as rate per person-year and inverse (in months between episodes, e.g. 1 per 20 patients months)

Relapsing peritonitis - Peritonitis that occurs within 4 weeks of completion of therapy of a prior episode with same organism or culture negative episode. Should be counted as a single episode of peritonitis.

Recurrent peritonitis – Peritonitis that occurs within 4 weeks of completion of therapy of a prior episode but with a different organism. Should be counted as an episode.

Repeat peritonitis – Peritonitis that occurs more than 4 weeks after completion of therapy of a prior episode with the same organism. Should be counted as an episode.

Inclusions:

- Patients on PD at any time during the reporting period.
- Patients on PD at commencement of a reporting period.
- Patients that have transferred into a hospital part-way through the reporting period.
- Patient that have transferred out of a hospital part-way through the reporting period.

Exclusions:

- Peritonitis episodes before or at the start of or after the reporting period (e.g. after Tenckhoff catheter insertion but before commencement of dialysis.

Numerator: Number of peritonitis episodes in all patients while receiving peritoneal dialysis.

Denominator: Total number of patient months on PD during the relevant period. Patient count included when they start PD (not just when they have the catheter insitu) or the transfer in to a centre during the reporting period. Episodes are only relevant if they occur during the reporting period.

*Target :*Peritonitis rate should be no more than 1 episode every 18 months.

Data reporting: Data should be reported at the end of each month and submitted. It will be reported as follows

Centre	PD Patients	Episodes	Person- Year	Rate (95 % CI)	Months per Episode	Previous Year Episodes Quarterly Average

Other KPIs

- *PD penetration*- Proportion of patients out of the overall ESRD population of the assigned area that opt for/are maintained on PD. (expressed as percentage).
- *Catheter Survival* – Expressed in months, it is a measure of the duration that a catheter remained in use.
- *Technique survival* - Expressed in months, it is a measure of the duration that a patient was on PD before (s)he received a renal transplant or had therapy withdrawn for any reason.
- *Resolution of peritonitis and catheter re-implantation rates*- Indicates the number of patients who recovered from peritonitis completely and the number of patients whose catheter were removed due to peritonitis or other complications but re-implanted after being withdrawn due to peritonitis or other complications (expressed as % of total episodes of peritonitis).
- *Culture positivity rates*- Indicate in how many samples of PDperitoneal dialysis fluid were the microbiologists able to identify the causative micro-organism.
- *Drop-out rates (with cause)* - Proportion of patients who withdrew from therapy and reasons thereof (expressed as percentage).

The said indicators for individual patients shall be entered into the PD Registry and would be reported in the national outcomes.

Chapter - V

LINKAGES WITH EXISTING PROGRAMMES IN THE PUBLIC HEALTH SYSTEM

1. NCD screening, NPCDCS, CPHC, UHC:

The National Program for Prevention and Control of Cancer, Diabetes, CVD and Stroke (NPCDCS) aims at integration of non-communicable diseases (NCD) Interventions in the NHM framework for optimization of scarce resources and provision of seamless services to the citizens. Since, NPCDCS is institutionalized at district level within the District Health Society; the NCD cell at various levels will ensure implementation and supervision of the Peritoneal Dialysis (PD) programme activities. Simultaneously w.r.t. to the PD programme, NPCDS will attempt to create a wider knowledge base in the community through convergence with the ongoing interventions of National Health Mission (NHM), National Tobacco Control Programme (NTCP), and National Programme for Health Care of Elderly (NPHCE) etc and build a strong monitoring and evaluation system through the public health system of India.

2. Screening and prevention of CKD progression

All countries that have implemented universal dialysis have recognised that screening and prevention of progression must accompany this programme. Targeted screening of high risk individuals with serum creatinine-based GFR and proteinuria testing followed by use of effective interventions (lifestyle changes, blood sugar and blood pressure control, use of statins and angiotensin blocking agents) has led to reduction in the number of new patients developing ESKF. The recently implemented universal NCD screening provides opportunity to implement such a programme in Indian communities. This can be done through community health workers who are empowered with clinical decision tools and point of care devices.

3. Pre-dialysis care of CKD

Although the focus of this document is on dialysis, it is important to emphasise that the dialysis modality choice and outcome depend to a large extent on pre-dialysis care. The UK NSF recommends 1 year of pre-dialysis preparation. This period is necessary to

1. Educate patient about life after ESKF,
2. Exploring all RRT choices and help the patient make a decision,
3. Facilitating pre-emptive transplant where possible,
4. Guiding patient to conservative care if dialysis is not feasible, creation of access for dialysis,
5. Providing psychosocial counselling to the family, nutritional advice and optimising medical therapy,
6. Timely initiation of dialysis.

Tools for education of pre-dialysis patients should be available in all district hospitals. Patient support groups including volunteers from amongst the local population on dialysis should be developed.

4. Supportive/palliative care

The option to receive supportive or palliative care should be available to those who choose not to receive PD or HD, such as those that are terminally ill or very old, or have voluntarily withdrawn from dialysis. Supportive care is defined as patient- and family-centred care that optimizes quality of life by anticipating, preventing and treating suffering. It is important to ensure that patients are not abandoned but receive all medical, physical, and mental support to ensure that patients at the terminal stage receive humane care.

5. Referral Transport

Linking the PD programme with a strong referral transport network across the country is necessary for improving physical access to PD centres. Most of the states have been providing such referral services for free to pregnant women, victims of road side accident, patients belonging to below poverty line households, post-natal cases, etc. Through these guidelines it is advised that these free services are also extended for transporting the dialysis patients to public health facility or from a public facility to a higher referral centre, or back home after discharge.

6. Non-Medical Challenges in rolling-out National PD Programme

Peritoneal dialysis is used to treat an estimated 250,000 individuals worldwide.

Despite being an easy-to-use home therapy, its roll out as a National Programme in India is likely to have its own challenges. We are a large country spread through mountains, desert, plains, plateau, and much geographical diversity.

Logistics related challenges

Such diversity is a challenge for logistics- both forward and reverse logistics. Monsoon, landslides and severe winters in some parts of the country lead to frequent and long disruptions- large parts of India may get cutoff due to severe flooding or snow or both.

The critical input for a successful PD programme is the timely and adequate availability of prescription-specific quantity of PD fluids, and an ability to manage timely swap of PD fluids according to the changed prescription.

Another issue to be addressed is the ability of efficient reverse logistics that addresses the requirement of timely pick-up. The need for a such a reverse-pick up arises on two counts- one, because of changes in prescription and two, the cessation of PD therapy due to drop-out.

Selected service provider/OEM of PD bags may be tasked to make last mile delivery or the option of partnering with a credible, reliable logistics provider to overcome the challenges associated with forward and reverse logistics. This should be included in the procurement bid.

Environmental concerns

Each patient is generally prescribed between 90-120 bags, each containing 2L of PD fluid. This generates 90-120 sets of waste including 90-120 2L fluid filled bags.

The guideline for discarding the PD fluid is to drain it into the toilet flush with the addition of 1:10 dilution of household bleach. Used bags should be placed and packed in another bag (double bagging), and be mandatorily be exchanged with fresh/new PD bags at the health facility. Proper disposing of the bags shall remain the responsibility of the health facility or its outsourced agency as per Biomedical Waste Management Rules.

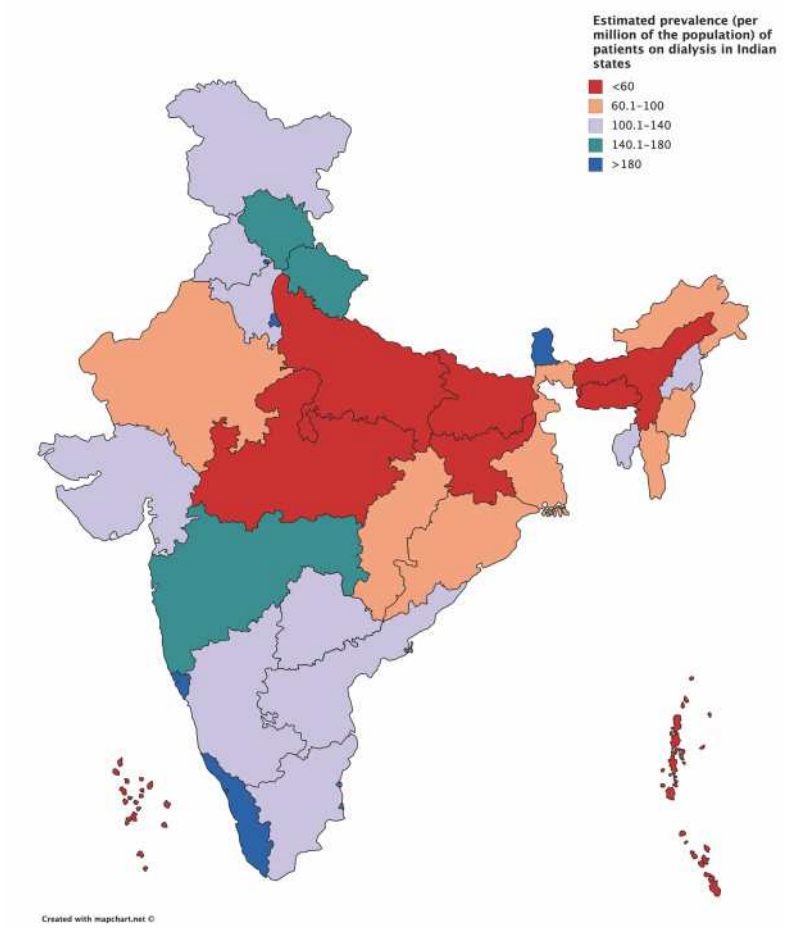
Annexure 1: ESKF in India

Estimated number of patients on dialysis in different Indian states

State	Number of patients on dialysis
Andamans	22
Andhra Pradesh	5057
Arunachal Pradesh	99
Assam	1511
Bihar	5215
Chandigarh	208
Chhattisgarh	1579
Delhi	3995
Goa	356
Gujarat	6708
Haryana	3288
Himachal Pradesh	998
Jammu and Kashmir	1436
Jharkhand	1895
Karnataka	7665
Kerala	6305
Madhya Pradesh	4122

State	Number of patients on dialysis
Maharashtra	16342
Manipur	200
Meghalaya	139
Mizoram	95
Nagaland	241
Odisha	2594
Puducherry	207
Punjab	3702
Rajasthan	5707
Sikkim	129
Tamil Nadu	9885
Telangana	4289
Tripura	416
Uttar Pradesh	9260
Uttarakhand	1536
West Bengal	8645

Calculations based on the formula in Liyanage T, Ninomiya T, Jha V, et al. Worldwide access to treatment for end-stage kidney disease: a systematic review. Lancet. 2015 May 16;385(9981):1975-82.



Annexure 1a: Clinical Pathway for choice of dialysis mode

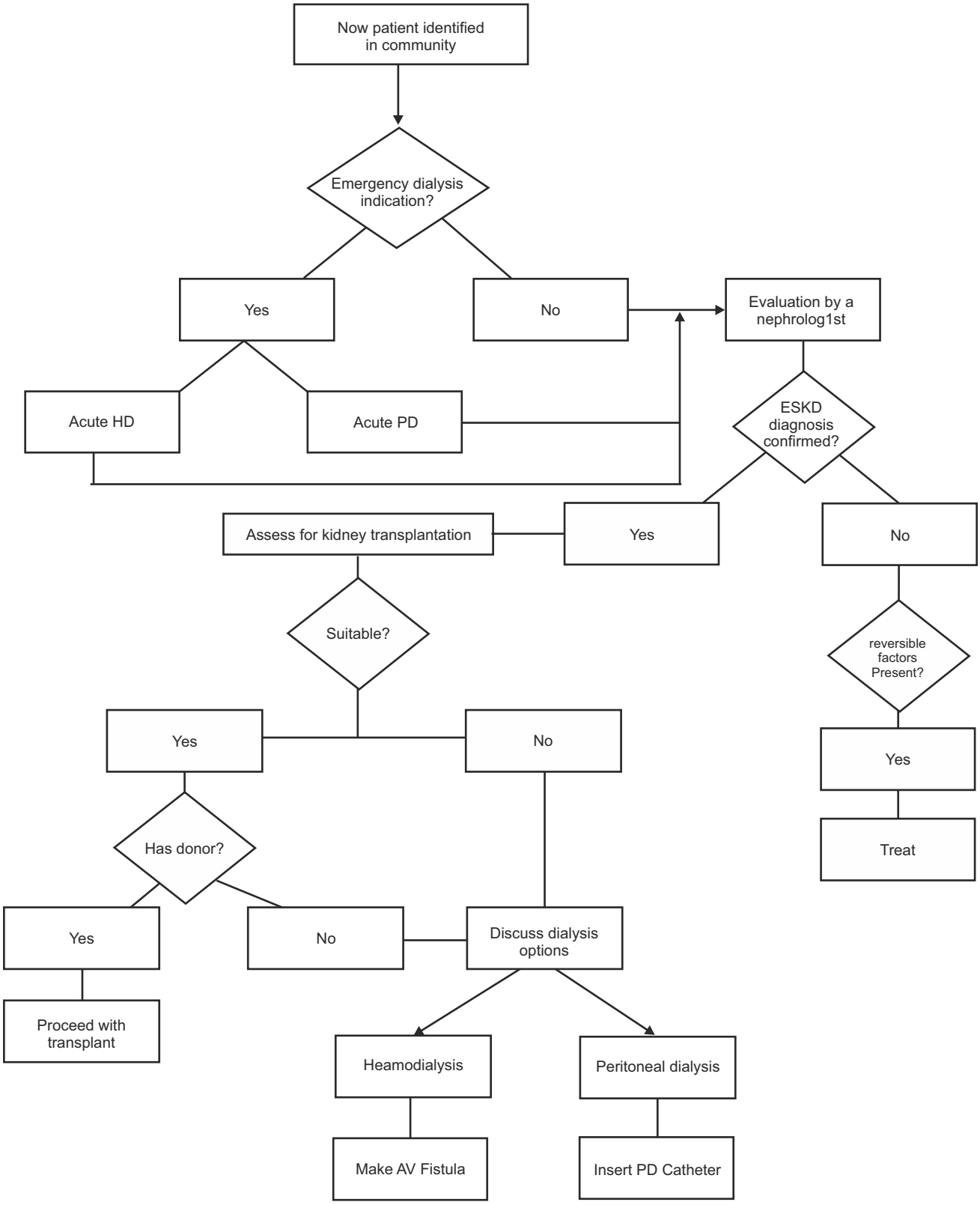


Fig 4

Annexure 1b: PD Pathway

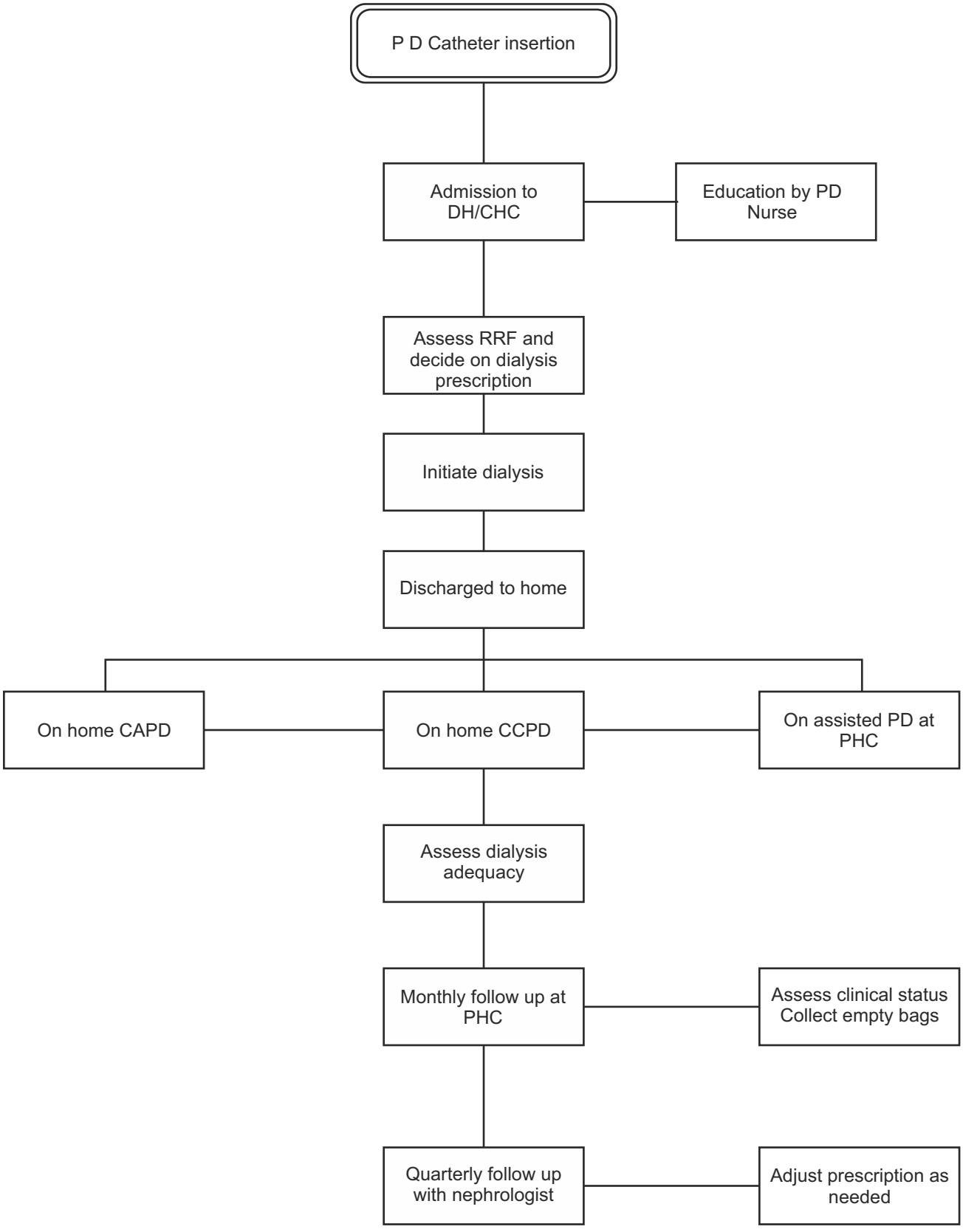


Fig 5

Annexure 2: Peritoneal Dialysis Training Specifications

Introduction

Patient training is a key element in any peritoneal dialysis programme and a dedicated training team is essential to provide well-educated patients who are able to care for themselves. The competent patient will have been trained in techniques to help reduce infection and prevent other PD related complications. PD nurses are the owner of the PD training programme. The recommended training format the adult learning VARK format-Visual, Aural, Read-write and Kinesthetic. The treating nephrologist or a designated member of the treating team may be assigned the responsibility of assessing the learning of the patient/care-giver trained. Training may be held before or after PD catheter implantation, in part or in whole. Since the learning speeds of the patient/care-givers may be different additional time and attention should be provided to the 'slow learners'. Ideally, the nurse will introduce a series of procedures and concepts, alternating demonstrations with discussions and questions. The practice of skills and procedures will begin only after the patient has learned the steps of each (cognitive learning) phase.

- *Pre-dialysis training essential from modality choice until the start of dialysis.*
- *Multi disciplinary team involvement with social worker support.*
- *Centralized and standardized training practices based on adult-learing principles*
- *Dedicated training space with adequate hygiene and area for equipment.*
- *Training tailored to individual's learning capacity, native language and specific needs.*
- *Practical training - preferably with home-based instruction.*
- *Appropriate duration spread over a number of days.*
- *Dedicated trainers with nursing qualification and experience in education techniques.*
- *One-on-one trainer to patient ratio.*
- *24 hour telephone support.*
- *Continuous retraining of patients and PD staff.*

PD, Peritoneal Dialysis.

Fig 6: Requirement for PD Training and Support

Types of PD Training

- Continuous ambulatory peritoneal dialysis (CAPD).
- Automated peritoneal dialysis (APD).
- Post infection technique reviews.

Trainer

- They should be a trained and certified nurse or clinical co-ordinator.
- They should be part of a designated PD team.
- Should be available to teach on a 1:1 basis with the patient throughout training.

Trainee

- If capable, the individual patient should be taught how to perform the procedure themselves.
- A carer may be trained if the patient is incapable or a child.

Location of Training

- Designated training area in PD centre.
- Home –wherever possible.

Training Programme

- Handwashing and infection prevention.
- CAPD/ APD procedure.
- Catheter and Exit site care.
- Peritonitis - prevention and detection.
- Fluid balance monitoring.
- Problem solving.
- Diet.
- Exercise.
- Sexual relationships.
- Ordering supplies.

Training Aids

Training resources should be available to suit all learning needs, including physical disability, language and cultural needs, limited literacy and cognitive impairment. A variety of different resources should be used to suit the learners' needs.

Completion of Training

Training will be considered complete when as a minimum the patient or carer:

- Is able to perform the CAPD / APD procedure safely?
- Is able to recognise contamination and infection?
- Is able to list appropriate responses?

On-going training

- Education should be an on-going process throughout the patient's PD experience.
- Technique should be reviewed every 6 months or after any infection episode.
- Regular "Patient workshops" should be organised for addressing answer questions which may have arisen from time to time. It also provides the opportunity to reinforce good practice.

Annexure 3: CAPD Patient Training Record

Principles of PD	Discussed or demonstrated	Observed	Competent	Signature
How toxins are removed?				
How fluid is controlled?				
Importance of hygiene				
Importance of hygiene and general cleanliness				
Hand washing technique				
Importance of keeping equipment clean				
Advice on infection control and control/care of pets				
Waste disposal				
Exchange Procedure				
Correct methods of heating bags				
Checking solution				
- Type of fluid				
- Expiry date				
- Check for faults				
Exchange procedure				
Explain rationale for 15 second flush				
Record information				
Dispose of fluid				
Exit Site Care				
Exit site dressing and immobilization				
Bathing and showering				
Recognising infection and taking appropriate action				
Fluid balance				
Record weight and understand significance				
Understand use of different fluid strengths				
Demonstrate understanding of fluid overload				
Demonstrate understanding of dehydration				
Problem solving				
State action to take if:				
Not draining in or out				
Fibrin in line				
Contamination of line				

Split/cut in catheter or line				
Blood in effluent				
Develop hernia				
Develop leak				
Constipation				
Sickness or diarrhea				
Medication				
State significance of ESA				
State significance of PO4 binders and vitamin D				
State significance of antihypertensives				
State significance of laxatives in PD				
Specify use of each of their own drugs				
Diet				
Demonstrate an understanding of reason for increasing protein intake.				
Discuss fibre and constipation				
Refer to dietician if appropriate				
Peritonitis				
Understand how to prevent				
Understand how to detect				
Discuss action to be taken				
Ordering supplies				
Demonstrate how to order PD supplies				
Discuss where to store supplies				
Demonstrate what to do if supplies run out				
General Health				
Discuss regular exercise				
If smoker, discuss smoke cessation initiatives				
Lifestyle				
Sexual relationships/body image - give opportunity to discuss				
Employment issues				
Holidays and travel				
Offer opportunity to meet social worker				
Diabetic Patients				
Advice to use appropriate blood sugar monitor				
Ensure patient is having regular diabetic check-ups				

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