



Dialysis delivery in  
India: demand,  
challenges and policy  
insights

EY - NATHEALTH

November 2022

A lighthouse silhouette is positioned on the left side of the frame, with the sun setting directly behind it, creating a bright glow. The sky transitions from a deep orange near the horizon to a dark blue at the top. The ocean in the foreground is dark with some ripples. The text 'Fore word' is overlaid on the image, with 'Fore' in white and 'word' in yellow. A yellow horizontal line extends from the end of the word 'word' across the bottom of the image.

# Fore word

This report is a product of a detailed study by EY in collaboration with the Healthcare Federation of India (NATHEALTH) based on insights provided by key stakeholders in the Dialysis Ecosystem of India. We are grateful for our collaboration with NATHEALTH and its stakeholders, who provided us with timely support and guidance in the form of primary data, sectoral and medical knowledge and industry reports. These insights have been critical in formulating the analysis presented in the whitepaper, along with drafting the recommendations and vision for the future of the Dialysis Industry in India.

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Name	Designation	Organisation
<b>Government Stakeholders</b>		
Mr Rajesh Bhushan	Union Health Secretary	Ministry of Health & Family Welfare (MoHFW)
Dr. Atul Mohan Kocchar	Chief Executive Officer	National Accreditation Board for Hospitals and Healthcare Providers (NABH)
Dr. Ranjan. Kumar Choudhury	Advisor, Health Care Technology, National	National Health Systems Resource Centre (NHSRC)
<b>NATHEALTH Secretariat</b>		
Mr. Siddhartha Bhattacharya	Secretary-General	NATHEALTH - Healthcare Federation of India
Ms. Anugrah William	Government Partnership Specialist and Northern Region Chapter Lead	NATHEALTH - Healthcare Federation of India
<b>Dialysis Core Group - Key stakeholders</b>		
Mr. Vikram Vuppala	Founder and CEO	NephroPlus
Dr. Suresh Sankar	Nephrologist & Senior Vice President, Clinical Affairs	NephroPlus
Mr. Rohit Singh	Senior Vice President - Strategic Initiatives and Business Development	NephroPlus
Mr. Dharma Rajagopalan	Head - Government Affairs and Policy Advocacy	NephroPlus
Dr. Aashish Sharma	Senior Consultant Nephrologist and Director-Medical Affairs	Fresenius Medical Care India
Mr. Indranil Roy Choudhury	Group Chief Executive Officer	Apex Kidney Care Pvt. Ltd.
Mr. M Sudhakar Rao	Head- Apollo Dialysis	Apollo Hospitals Enterprise Limited (AHEL)
Dr. Narayan Pendse	Vice President - Medical Strategy & Operations	Fortis Healthcare Ltd.
Mr. Manish Sardana	President	PolyMedicare
Mr. Parveen Jain, RAC (Devices)	Head, Regulatory Affairs, Quality and Government Affairs	Fresenius Medical Care India Pvt. Ltd.
Mr. Shaurya A Tayal	CEO and MD	RahiCare Pvt. Ltd.
Dr. Aseem Garg	CEO	DCDC Pvt. Ltd.
Mr. Prabhat Shrivastava	Co- Founder and CEO	VitusCare
Mr. Harish Natarajan	Director	HxCo India

**EY TEAM**

Rajnish Gupta  
Associate Partner

Deepraj Pathak  
Senior Manager

Shambhavi Sharan  
Manager

# Executive summary

*Dialysis: The popular treatment of ESRD disease requires policy focus to build access and capacity, thereby helping reduce mortality rates*

## Dialysis Overview

- ▶ Renal failure is an important public health problem. However, it remains a mostly undocumented cause of premature death in developing countries, like India.
- ▶ As per government estimates, nearly 220,000 patients develop end stage renal disease (ESRD) annually in India, leading to an additional annual dialysis demand of 34 million treatment sessions.
- ▶ With nearly 5,000 existing dialysis centers and 3,340 nephrologists (based on industry estimates), this may be inadequate to meet the upcoming demand of dialysis as this disease gains traction due to various sociological and environmental factors.
- ▶ There are majorly two types of complementary treatments offered to ESRD Patients in India: Hemodialysis (HD) Treatment and Peritoneal Dialysis (PD).
- ▶ 94% of dialysis patients in India are on HD treatment

## Key Challenges

- ▶ Lack of access to dialysis centers and machines across districts, lead to low frequency of treatment, impacting health of patients
- ▶ Erratic and low rate of reimbursements for dialysis sessions affects operation of dialysis centers
- ▶ Lack of skilled workforce including dialysis technicians and renal nurses.
- ▶ Low uptake of PD in India due to high cost and low clinical adoption.

### Need for Clinical Outcome Monitoring

- ▶ An essential component of quality delivery of dialysis services is recording and monitoring clinical outcome of ESRD patients for improving their safety and clinical care.
- ▶ There are several important clinical outcomes which are considered critical for dialysis patients; however, the four key indicators are mortality, anemia, seroconversions and dialysis access.
- ▶ Monitoring and tracking these outcomes helps improve the understanding of the effect of dialysis treatment on patients and thereby helps the service providers in turn to improve their services in order to increase the lifespan of patients and enhance their quality of life.

### Human resource requirement In dialysis

India needs to address several gaps in terms of training healthcare professionals and building a skilled workforce to deliver quality dialysis services. Few of the gaps identified by the industry in the dialysis ecosystem are the following:

1. Addressing shortage of Dialysis Technicians (DTs) and ensuring employability of DTs in the country
2. Need for short-duration courses to accelerate the upskilling of existing pool of nurses, doctors and allied professionals.
3. Addressing the requirement of training centers available in the country



### Need for standalone dialysis centers

Higher safety: Patients in standalone centers have lesser chances of developing hospital-acquired infections

Convenient and patient-friendly solution: A convenient and patient friendly solution for patients accessing services in multiple locations rather than hospitals for service billing, dialysis service, laboratory tests, cafeteria, etc.

Proximity to Patient: These centers will reduce travel cost and hassle for patients who live far away from the district hospitals; especially as dialysis sessions are required three times a week.

### Short-term recommendations

- ▶ Improving access of standalone dialysis centers through both PPP and non-PPP channels
- ▶ Optimal use of Human Resource, maintaining standards and mitigating other costs
- ▶ Resolving Empanelment Delays through provision of default "deemed approved status"
- ▶ Reimbursement rates to be increased considering the overall cost of treatment to providers

### Medium-term recommendations

- ▶ On the job trainings and internship opportunities for DTs
- ▶ Short-term trainings for nurses on both HD and PD
- ▶ Short-duration training courses for Ayush, BAMS, BHMS, MBBS doctors to be formulated.
- ▶ To address infrastructure challenge, PPP model is to be used to conduct training
- ▶ Specific trainings required for surgeons, nurses and patients for PD.

### Key recommendations for peritoneal dialysis

- ▶ PPP mode for PD treatment delivery with private service providers providing consumables and public sector providing care
- ▶ Building awareness amongst patients through information and education campaigns
- ▶ Establishing supply side channels by enabling reduction in cost of consumables
- ▶ Clinical support infrastructure through establishing and monitoring clinical outcomes
- ▶ Promoting PD treatment through community healthcare

# Table of contents

1. Dialysis landscape of India	07
2. Need for standalone dialysis centers	13
3. Human resource required for dialysis	16
4. Key challenges in the dialysis ecosystem	19
5. Global perspective for dialysis	22
6. Focus on clinical outcomes and standards	25
7. Key recommendations	28



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# Dialysis **landscape** of India

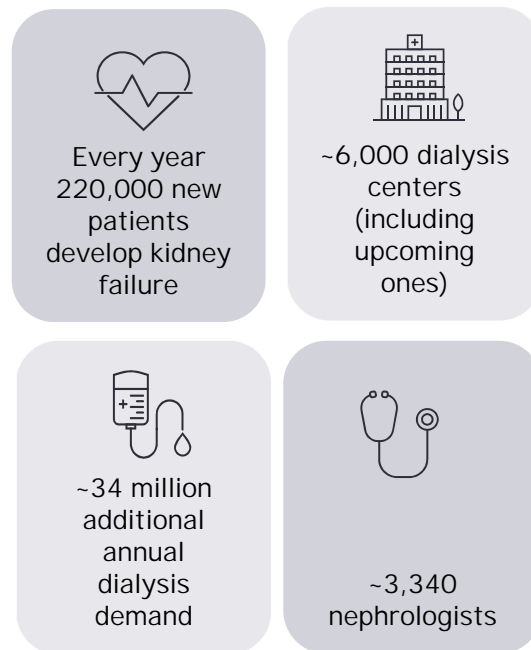
# Introduction:

## Understanding the need for dialysis in India

Renal failure is an important public health problem, however, it remains a mostly undocumented cause of premature death in developing countries, like India. Scientifically known as Chronic Kidney Disease (CKD), it is characterized by a gradual loss of kidney function over time. The final stage of this disease, known as the end-stage renal disease (ESRD) requires kidney or renal replacement therapy (RRT) such as dialysis or kidney transplant.

As per the Million Deaths study, from 2001 to 2003, 2.1% of total deaths among 15 to 69-year-olds were from renal failure, which increased to 2.9% by 2010-13. On an aggregate level, there were 136,000 renal failure deaths in 2015. Another study published in the Statesman estimates that more than 3% of the total deaths in India between the age group 15-69 occur every year due to renal failure or kidney diseases.

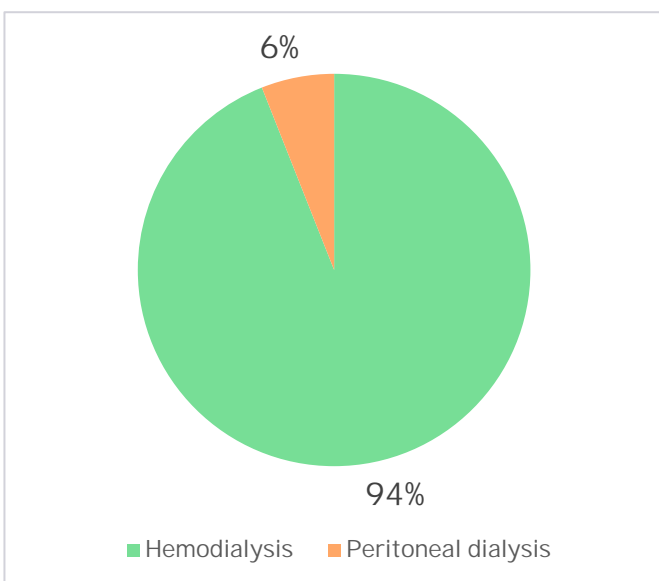
As per government estimates, nearly 220,000 patients develop ESRD in India, leading to an additional annual additional dialysis demand of 34 million treatment sessions. With nearly 5,000 existing dialysis centers (6,000, if including upcoming) and 3,340 nephrologists, this will prove to not meet the upcoming demand of dialysis as this disease gains traction due to various sociological and environmental factors.



Source: Industry Inputs

*This whitepaper provides detailed analysis of the dialysis landscape in India, determining India's readiness to meet the dialysis demand, while also improving the quality of services to maintain international standards. An important component lies in promoting and resolving challenges in standalone dialysis centers, which will prove essential in meeting district level demand. Meanwhile, future policy is necessary to be centered around building human resource including dialysis technicians and nurses, while also building an ecosystem for peritoneal dialysis in Indian patients.*

### Available treatment modalities in India: HD vs. PD



Source: Global Dialysis Perspective: India: Joyita Bharati and Vivekanand Jha, 2020

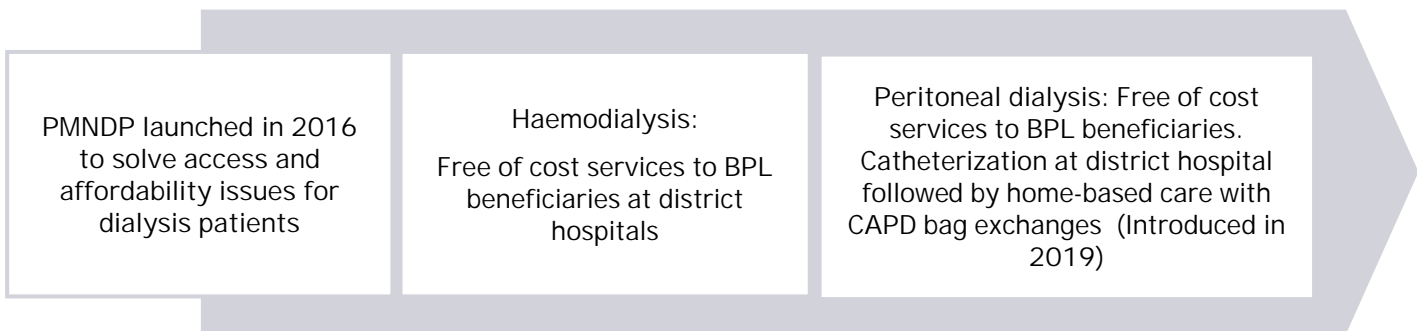
- ▶ There are majorly two types of complementary treatments offered to ESRD Patients in India: Hemodialysis (HD) Treatment and Peritoneal Dialysis (PD). In HD treatment, blood is pumped out of the body to an artificial kidney machine and returned to the body by tubes that are connected to the machine.
- ▶ Meanwhile, in PD treatment, a cleansing fluid flows through a tube (catheter) into part of the abdomen while the lining of the abdomen (peritoneum) acts as a filter and removes waste products from the blood.
- ▶ It is possible to perform PD at home using CAPD bags, while HD services are offered mainly at centers and also at homes.
- ▶ 94% of dialysis patients in India are on HD treatment
- ▶ Kidney Transplant is considered the most effective treatment modality. However, due to issues of high cost and delay in procuring transplant, dialysis treatment is commonly used.



# Health profile of Indians: Government support provided in dialysis

*Diabetes and Hypertension are leading causes of ESRD in India*

- ▶ Scientific studies indicate that the leading cause of ESRD disease in India are diabetes (high blood sugar) and hypertension (high blood pressure). The health profile of Indians can be tracked through the National Family Health Surveys (NFHS).
- ▶ In India, NFHS 2019-21 data indicates that on an average nearly 14.5% to 15% population suffer from high blood sugar levels or are taking medication for controlling blood sugar levels. In addition, on an average, nearly 22% of the Indian population suffers from hypertension or high blood pressure levels. Both these populations may have overlapping patients, which are at risk of developing renal diseases.
- ▶ These indicate a significant Indian population is at risk of suffering ESRD condition and may require dialysis treatment. Therefore, there is a need for national level policy support and guidance for managing the Indian dialysis population.



Dialysis Coverage

14.37 lakh

Number of patients that availed dialysis services under PMNDP since 2016

Government Spending for Dialysis Sessions

INR 2,283 Cr

Estimated at INR 1,500 for 152.2 lakh hemodialysis sessions held under PMNDP since 2016

**Pradhan Mantri National Dialysis Program (PMNDP) coverage**

*PMNDP program covers 36 States and Union Territories, and the program has spread to 603 districts. There are 1,121 centers under the program which have 7,721 HD machines.*

Ayushman Bharat- Pradhan Mantri Jan Arogya Yojana (PMJAY)

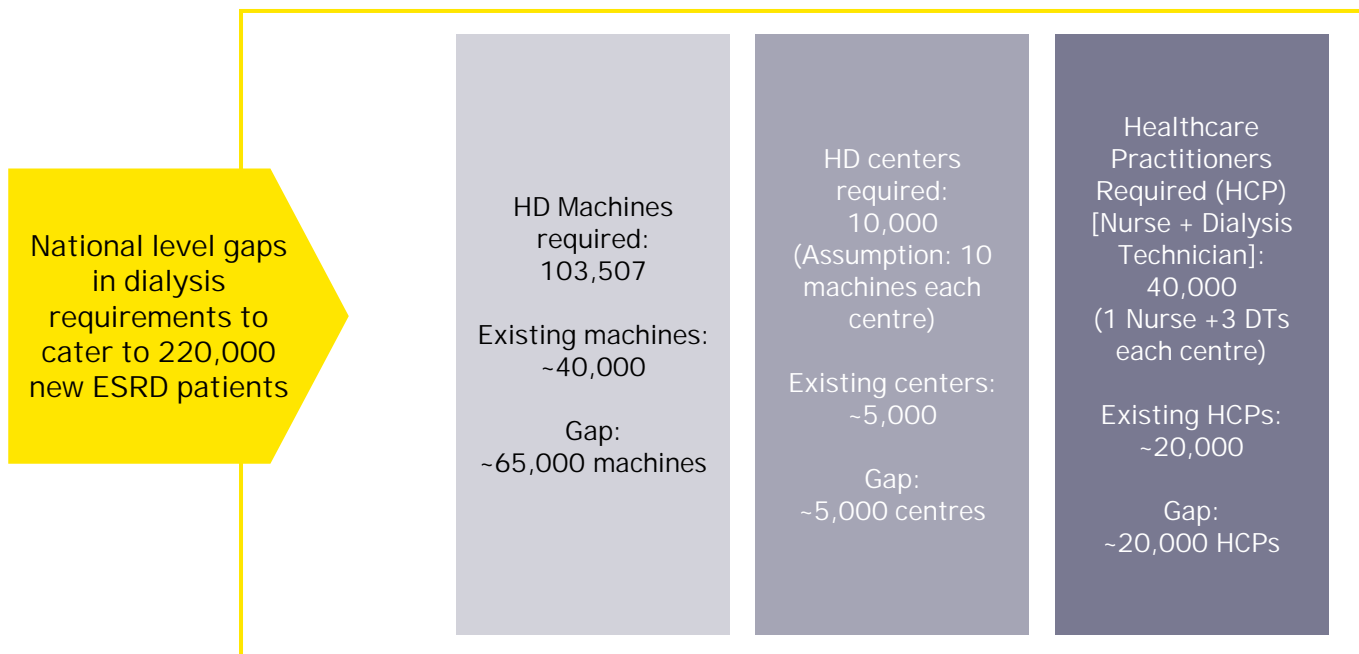
Other legacy schemes used for dialysis payment reimbursements

Rashtriya Swasthya Bima Yojana (RSBY)

Central Government Health Scheme (CGHS); Ex-Servicemen Contributory Health Scheme (ECHS)

Employees State Insurance Scheme (ESIS)

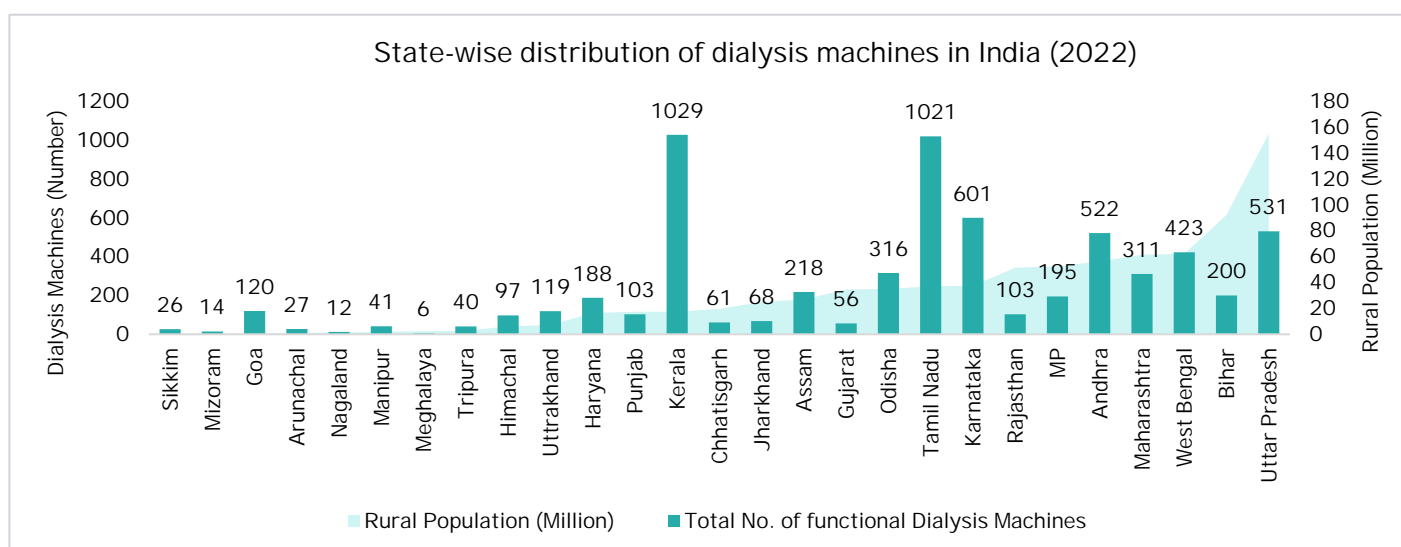
## Access issues which plague dialysis treatment delivered to rural patients



Source: Industry estimates

Various research studies reiterate that large inequalities exist in accessing dialysis services in India, with the rural areas being a disadvantage. As per industry experts, around 90% of the dialysis facilities in India are in urban India (i.e., metro cities and tier I and tier II cities). Thus, more than 60% of patients on dialysis travel about 50 km to access HD treatment while nearly 25% lived more than 100 kms away from the facility .

Access issues can also be understood by mapping the availability of dialysis machines under the PMNDP program, against the rural population across various states. The following figure shows the state-wise variations and disparities in accessibility of dialysis services. For instance, states like Kerala and Tamil Nadu have a much higher number of dialysis machines, even though they have a lower rural population. In contrast, Bihar and Uttar Pradesh have a greater rural population suffers from inadequate dialysis access. Thus, access to dialysis machines remains a key concern in several states of India.



Source: PMNDP, RBI Statistics

Note: Rural data for Delhi and Telangana unavailable on RBI Statistics

# State-wise Dialysis demand: Large variations

## New ESRD Patients added across states every year

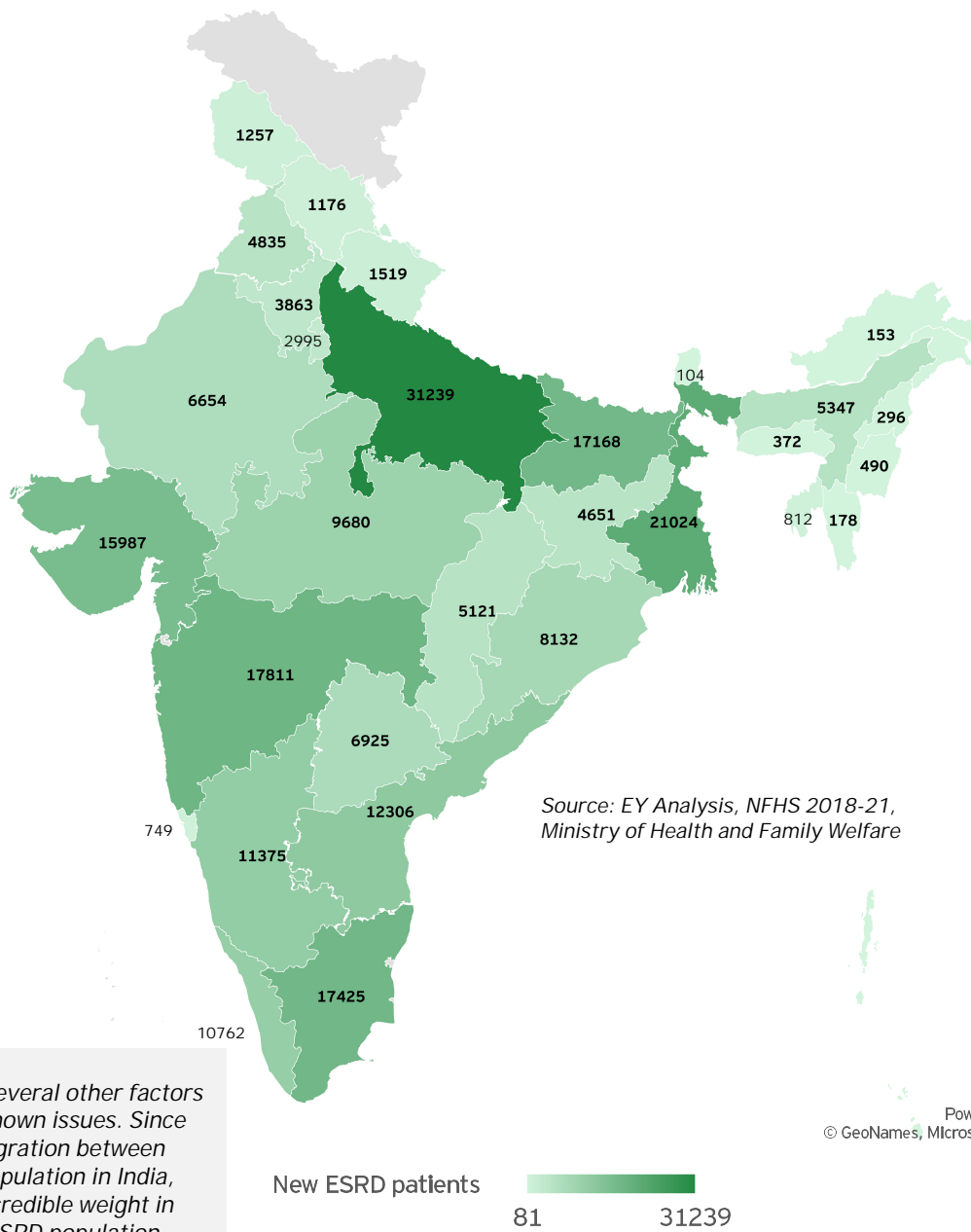
As 220,000 new ESRD patients are added every year, state-wise distribution of new patients requiring dialysis can be estimated.

For representation purposes, the weight of each state has been taken to be the share of diabetic persons in that state in total population suffering from diabetes. This weight has been taken as diabetes is the leading known cause of ESRD.

However, there is a mismatch between the demand arising out of every state and the number of the dialysis centres set up under the PMNDP program.

Note: Data from UT of Ladakh unavailable

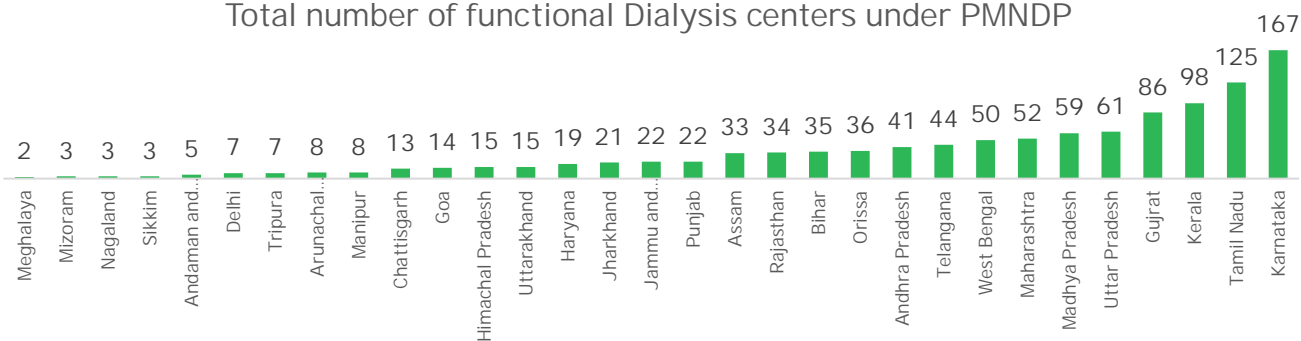
Note: ESRD is also caused due several other factors such as hypertension and unknown issues. Since there is no statistical disintegration between diabetes and hypertension population in India, diabetes has been used as a credible weight in determining the state-wise ESRD population.



Source: EY Analysis, NFHS 2018-21, Ministry of Health and Family Welfare

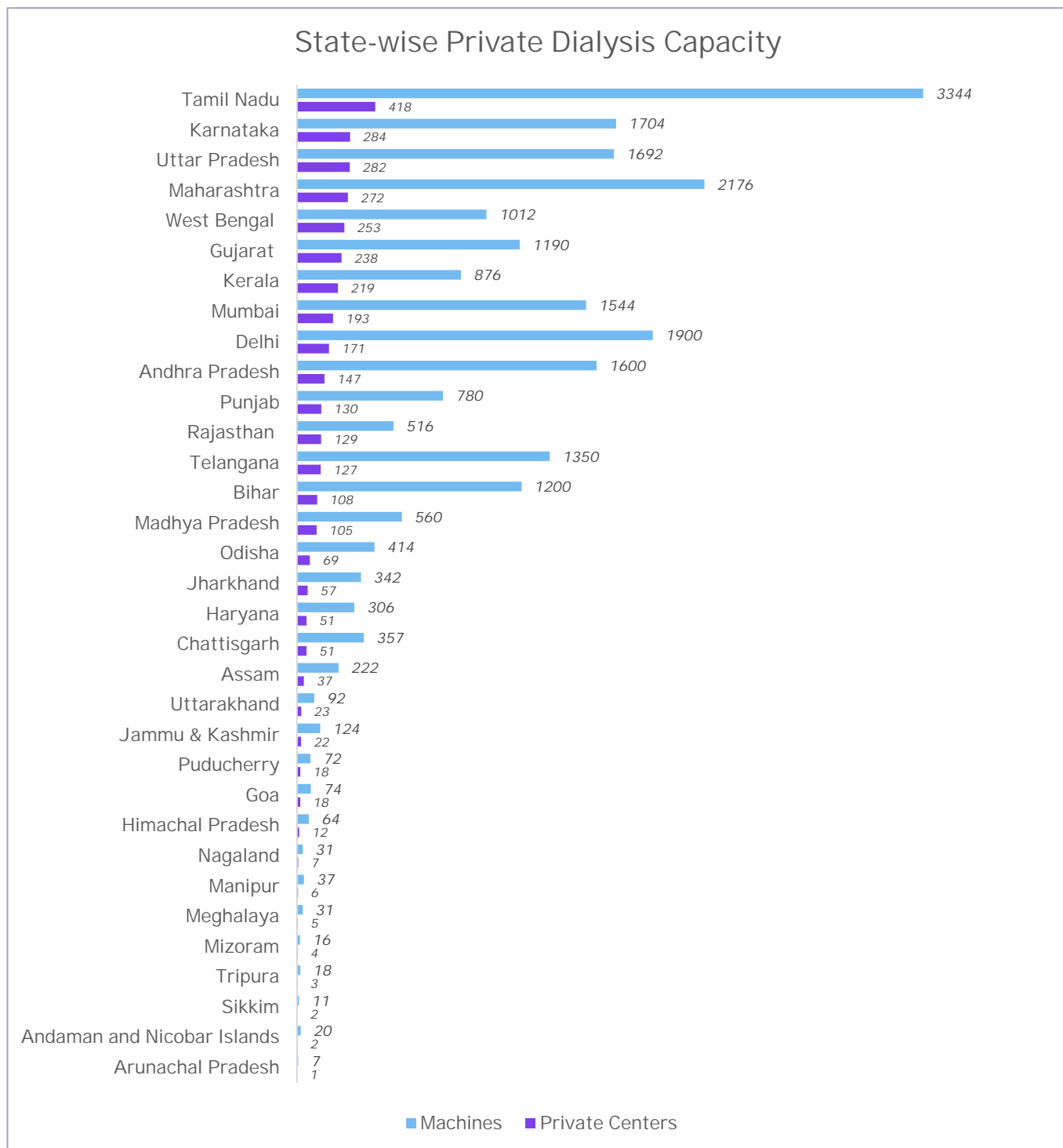
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## Total number of functional Dialysis centers under PMNDP



Source: Ministry of Health and Family Welfare

# Private Dialysis Capacity: Tamil Nadu leads in Dialysis Coverage



Source: Industry estimates



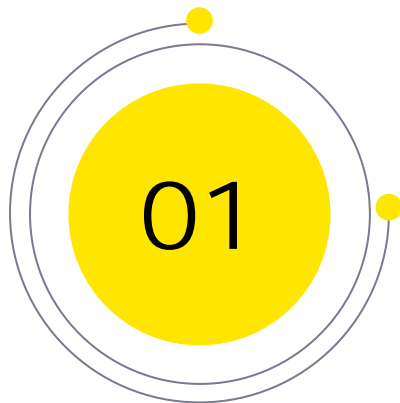


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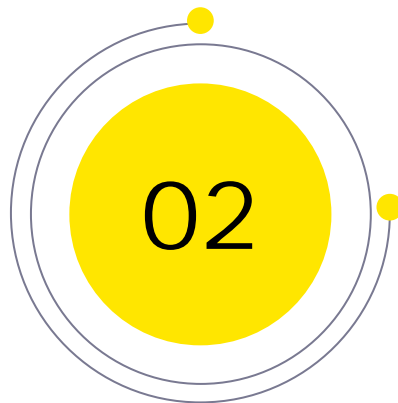
## Need for **standalone** **dialysis** centres

Standalone dialysis center:  
Key solution to Indian dialysis demand



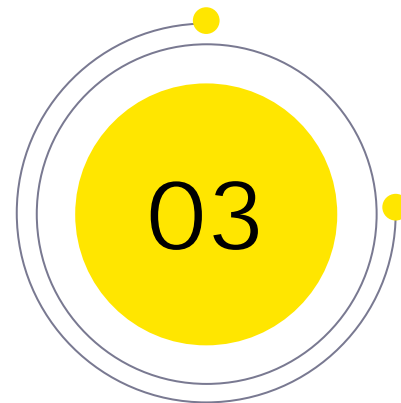
**Higher safety**

Patients in standalone centers have lesser chances of developing hospital-acquired infections



**Convenient and patient-friendly**

A convenient and patient friendly solution for patients accessing services in multiple locations rather than hospitals for service billing, dialysis service, laboratory tests, cafeteria, etc.



**Proximity to patient**

These centers will reduce travel cost and hassle for patients who live far away from the district hospitals; especially as dialysis sessions are required three times a week

Key features of a standalone center

Infrastructure

- ▶ Proposed standalone center to have a minimum 90 to 100 sq. feet area
- ▶ Minimum number of dialysis machines: 5 to 6 HD machines
- ▶ RO water treatment plant with output water provision as per AAMI standards for hemodialysis
- ▶ Dialyzer reprocessing machine for reuse of dialyzers after due disinfection
- ▶ 24x7 ambulance connectivity to the nearest hospital
- ▶ Availability of emergency medical equipment
- ▶ Provision for tele-consultation

Human Resource

- ▶ Lead dialysis nurse/BAMS/ BHMS/Ayush/MBBS
- ▶ Nephrologist visit once or twice a month
- ▶ Lead dialysis technician with five or more years of dialysis experience
- ▶ Ratio of 1 Renal Nurse/1 Technician per 5 occupied beds

Quality Assessment & Performance Improvement (QAPI)

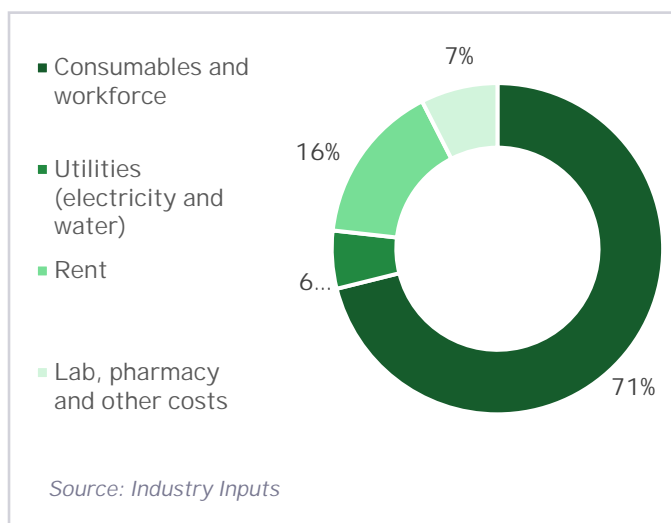
- ▶ Centers must develop, implement, and maintain an effective QAPI program that documents, measures, analyzes, and tracks quality indicators related to providing Quality Dialysis Treatments
- ▶ Clinical outcomes should be measured and analyzed

# Cost components of dialysis treatment in India: Manpower and consumables drive costs

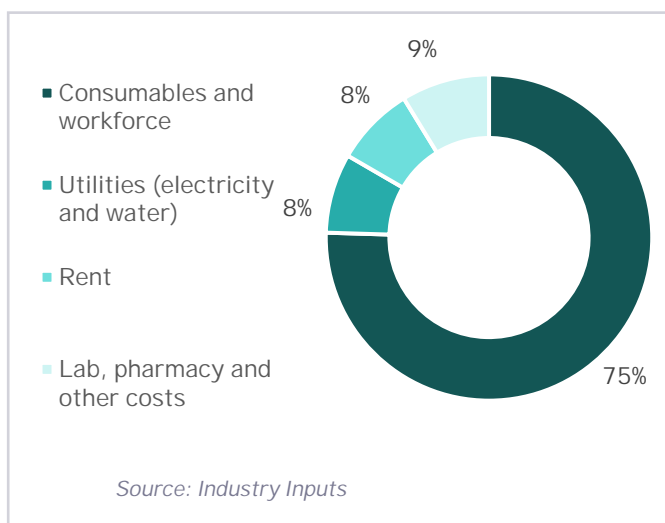
## Case for standalone dialysis centers in India

- ▶ India needs to catch up with the rest of the world and leverage standalone dialysis centers to improve access, affordability and safety.
- ▶ The broader acceptance of standalone dialysis centers in the world because of their low set-up costs and their scalability to penetrate rural and semi-urban areas is a proven example of improving accessibility in the Indian dialysis ecosystem.
- ▶ With the growing number of patients requiring dialysis in India, hospital-centric dialysis units are getting fully saturated and hence standalone dialysis centers can be utilized to meet the growing demand for an affordable model.

Cost break-up of single-use dialyser in Tier 1/Tier 2 cities



Cost break-up of single-use dialyser in Tier 3 cities



### Key challenges to be addressed

**Location:** As per the present PMNDP guidelines, standalone dialysis units can be set up within 3 kms of the district hospitals. However, this clause restricts the service providers from choosing an optimal location based on their assessment and evaluation of the real estate and thereby discourages them from making investments.

**High attrition of MBBS doctors:** The other major concern that the dialysis service providers face pertains to the human resources element such as the high attrition of MBBS doctors deployed at the dialysis centers, along with inadequate availability of dialysis technicians (DTs) and Nurses. This leads to a drastic impact on the operations of the standalone units and also puts patients' safety at risk.

**Delay in empanelment:** The delay in empanelment under the Ayushman Bharat and other health schemes of the government, which impacts financial viability of the dialysis service providers. Meanwhile, delay in empanelment at state level and subsequent delay in patient referrals affect driving sustainability of dialysis centers.

Standalone centers may be decoupled out of the PMNDP Standard Bidding document proposed in the National Health Mission.

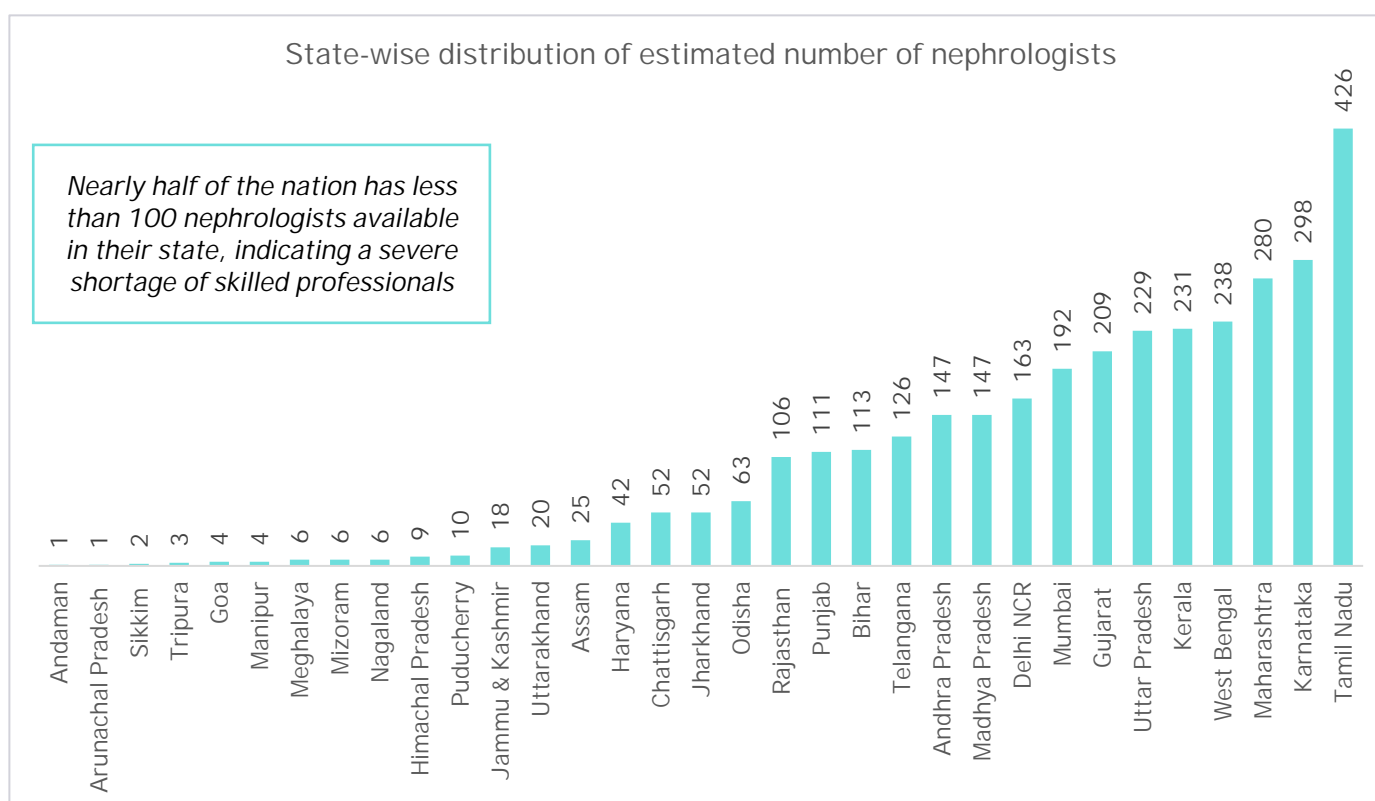
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## Human resource required for dialysis



## Human resource for dialysis delivery: Shortage of skilled manpower varies across states

Currently, India suffers from a shortage of nephrologists, thereby having a very low nephrology workforce density. As per the Global Dialysis Perspective: India (2020) study, there were about 2600 nephrologists, or 1.9 nephrologists per million population, as of 2020. Recent industry estimates indicate that the total number of nephrologists in India has increased to 3340 in 2022. However, there is a state-wise disparity in the availability of these nephrologists. Population dense states such as Rajasthan, Punjab, Bihar and Telangana have less than 150 nephrologists in the state. Meanwhile, Tamil Nadu is leading the country in its human resource availability with over 400 nephrologists. The other two key healthcare professionals for dialysis are trained renal nurses and dialysis technicians. The dialysis industry reports a severe shortage of both these skilled professionals, along with lack of registries of such professionals.



Source: Industry estimates

The report titled "Rural Health Statistics", published by the Ministry of Health and Family Welfare, also reflects shortage of skilled medical professionals in India. This report provides the shortfall in terms of specialists such as surgeons, physicians and pediatricians required at community healthcare centers. In aggregate terms, there is an unmet demand of 17,519 specialized healthcare professionals, such as physicians and surgeons, in rural areas of India.

Other multipurpose workers engaged in the dialysis ecosystem include sanitation workers, machine cleaning, and dialyzer reprocessing services. In addition, only a few standalone dialysis centres have access to renal dieticians. As per the WHO estimates, India will face a severe shortage of public health professionals in the near future. This demand-supply gap may increase from 45,000 professionals to a scarcity of 64,000 professionals by 2026, thereby reemphasizing the urgent need to undertake training of healthcare professionals in order to meet the human resource requirements.

# Training requirements in dialysis ecosystem: Understanding gaps in the system

India needs to address several gaps in terms of training healthcare professionals and building a skilled workforce to deliver quality dialysis services. Few of the gaps identified by the industry in the dialysis ecosystem are the following:

1. Dialysis Technicians
  - ▶ Addressing shortage of Dialysis Technicians (DTs) in the country
  - ▶ Ensuring employability of DTs in the country
  - ▶ Need for training curriculum where HD technicians can be trained for PD treatment as well.
2. Need for short-duration courses to accelerate the upskilling of existing pool of nurses, doctors and allied professionals. These courses are to be provided with universal accreditation and recognition.
3. Addressing the requirement of training centers available in the country

Apart from these, for the long-term vision of building adequate human resource capacity for Dialysis Treatment in India, longer duration programs are required for each key healthcare professional. While such programs may already exist, the following table provides key features of training program features, which may be adopted as part of dialysis policy in India.

Program	Eligibility	Curriculum	Assessment	Training facility
Dialysis Nursing training program	Bachelor of Science (B.Sc.) in Nursing, General Nursing and Midwifery (GNM), Diploma	6 months training program –3 months of theory, practical and field visits+3 months of internship in a dialysis unit under supervision	3 monthly assessments followed by final exam of theory, practical and viva by a clinical trainer and nephrologist.	Lecture room, skill lab – fully equipped with all renal replacement modalities, including water treatment system, mannequins for access training and emergency management crash cart.
Dialysis Duty doctor training program	Candidate should be minimum Ayush, BAMS, BHMS, MBBS with basic knowledge and registered with the respective medical council.	3 months of training (1 month is classroom training and 2 months on the job)	Same as above	
Dialysis technician training program	Candidates should be 12th pass, preferably from science	24 months training (theory, practical and field visit training followed by an internship in a dialysis unit under supervision)	6 monthly assessment done Final exam would be theory, practical and viva by a senior trainer and a nephrologist.	

## Specific Training Requirements in PD Treatment

**Home-care manual:** A patient home care manual (paper and online) where patients can record daily therapy information – exchanges, fluid status, diet, exercise and medication. Essential training tools and schedule to include a 6-step hand-washing, maintaining a safe environment for exchanges, safe disposal, what to watch out for, patient help-line etc.

**Training Nurses:** To expand the reachability of PD treatment, nurses could be encouraged may be trained about the nuances of PD (along with HD). This includes emphasis on homecare trainings to ensure safety of patients.

**Training Surgeons:** Besides training of paramedical staff, surgeons needs to be trained for catheter insertion.

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Key **challenges** in the dialysis ecosystem

## Major challenges in dialysis ecosystem: A summary



### Lack of access to dialysis centers and machines leads to low frequency of treatment

HD treatment is conducted thrice in a week in established countries. However, in India, only 20% of patients are dialyzed three times a week (R. Chauhan and S. Mendonca, 2015) and balance undergo HD either once or twice a week. The cause of low frequency of visits in India are various reasons, such as the lack of access to dialysis center in the district, lack of availability of attendants to accompany them for dialysis, traveling from far of distances to the dialysis centers and having limited finances. Further, central health schemes such as CGHS, ESIC, ECHS don't recognize empanelment of standalone dialysis centers further adding to lack of access to dialysis services



### Erratic and low price of reimbursements affects operation of dialysis centers

Service provider's experience under several government schemes such as under CGHS, ESIC and ECHS schemes, along with PMNDP program is such that the reimbursements received are erratic, which impacts the operations of service providers that undertake large capital expenditure in establishing dialysis centers. Meanwhile, ensuring low price per dialysis treatment makes the market less attractive for many private players who incur heavy capex for setting up the center. There is a lack of uniformity in state tenders, which leads to varying state-level experience. In addition, there is a lack of necessary price escalation clause to account for inflation. This may help service providers avoid quoting higher prices from the project initiation date to ensure project sustainability over the tender tenure.



### Lack of skilled workforce

Under the domain of training and technical requirements, a key issue grappling with the dialysis delivery in India is the shortage of DTs in the country. There is a lack of any kind of incentive or assurance of employability of DTs in the country, which deters the youth from entering this domain. In addition, there is a need for training curriculum where HD technicians can be trained for PD treatment as well. Meanwhile, for the trained professionals, such as the existing pool of nurses, doctors, and allied professionals, there is a requirement for short-duration courses to accelerate the upskilling and meet the demand on the ground. Along with this, training centers need to be identified to deliver dialysis-related trainings in India.



### PD treatment yet to take off

The key reason for a low update of PD in India is the high cost and low clinical adoption as compared to HD treatment. In addition, low level of awareness of PD services in the country amongst the patients causes low adoption. On the delivery side, lack of established supply side channels for provisioning and storage of CAPD bags leads to higher costs and inconvenience for PD patients.

In terms of clinical concerns, reducing infection rates and health complications arising out of PD treatment is of key importance. There is a need for defining clinical outcomes, improving access to care for PD patients, monitoring the status of patients, and providing emergency care.

## Import dependence on key dialysis consumables

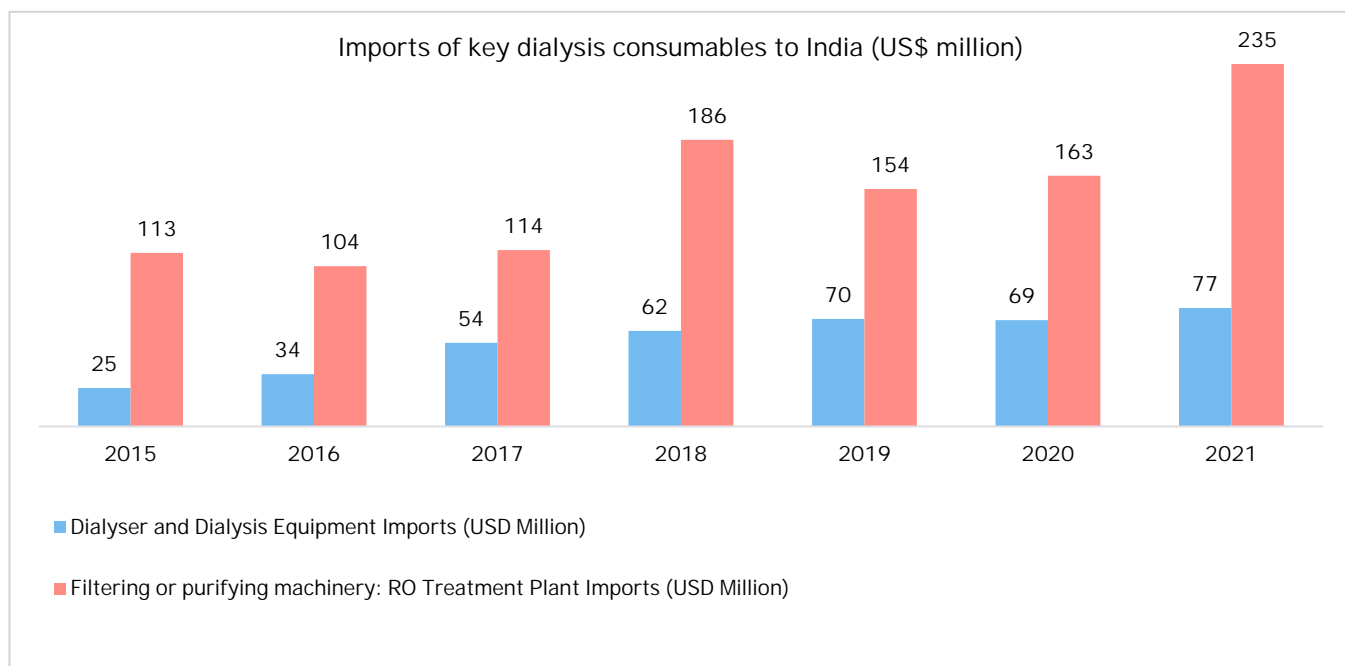
- ▶ Dialysis machines are essential components for dialysis treatment and the present quantity of these machines and equipment in India are not sufficient to meet the dialysis demand. Hence, service providers look to import the equipment from outside India to provide the highest quality service to dialysis patients. Any customs duty levied on these inputs to dialysis service is an additional burden on the patient.
- ▶ Custom duties and additional taxes levied on the import of these consumables required for dialysis treatment are in turn passed on by the importers to their customers, such as dialysis centres and hospitals, thereby making the treatment even more expensive for patients in India.
- ▶ For hemodialysis treatment, there is a clear indication of import dependence on two of the critical components- the dialysis machines (HD) and dialyzers and the RO treatment plant, which adds to the cost of services. While the PLI scheme exists to encourage domestic manufacturing of the dialysis equipment in India, domestic manufacturing is yet to catch up to the domestic demand for dialysis equipment.

Custom duty levied on key dialysis consumables imported in India

HSN Code	Description	Basic Custom Duty
90189031	Artificial kidney (dialysis) apparatus	7.5%
84212900	Filtering or purifying machinery and apparatus for gases	10%
38089400	Disinfectants	10%
30019091	Heparin and its salts	10%

*Import of dialyzer and RO plants add to overall HD treatment costs*

The following figure indicates the growing level of imports of products of two HSN codes: 90189031 (Artificial kidney (dialysis) apparatus: Dialysis Machine and Dialyzers) and 84212900 (Filtering or purifying machinery: Reverse Osmosis (RO) Treatment plants), indicating added costs due to custom duties and goods and services tax (GST) levies.



Source: WITS, World Bank, Ministry of Commerce



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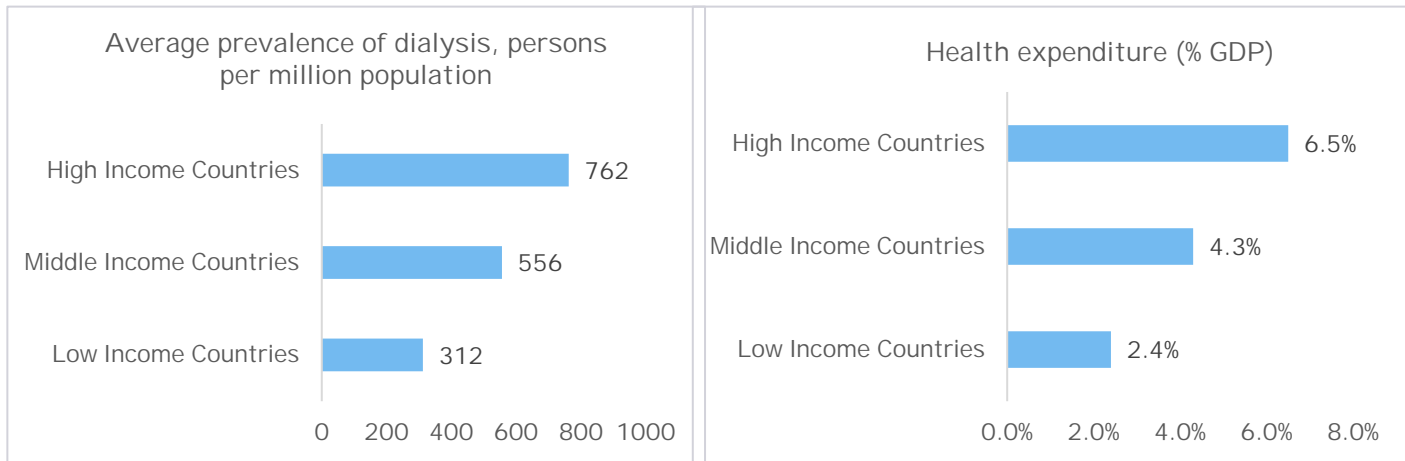
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# Global perspective for dialysis

## Global trends:

# Countries with higher income have strong focus on dialysis

Higher Income countries dedicate a higher share of their GDP on health expenditure, allowing a greater number of people accessing dialysis services



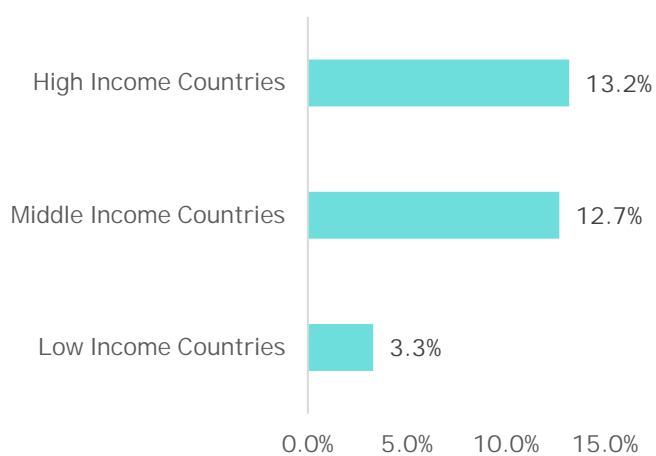
Source: An International Analysis of Dialysis Services Reimbursement, CJASN, Multiple Authors, 2018

Source: An International Analysis of Dialysis Services Reimbursement, CJASN, Multiple Authors, 2018

- ▶ In low-income countries such as India, the average number of persons on dialysis per million population is about 312.
- ▶ The global discourse indicates that the government's support and reimbursement under dialysis services is influenced by economic factors.
- ▶ Thus, in-center HD services, which require incurring labor costs, are promoted in countries where labor costs are low. In contrast, expenditure in PD treatment is over various consumables, such as CAPD bags and tubing.
- ▶ In low- and middle-income countries these consumables are mostly imported, and thereafter transported over long distances which adds to overall costs of PD services. Consequently, the prevalence of PD in these countries is low.

### PD prevalent in countries with PD first policy

Peritoneal dialysis in overall dialysis population (%)

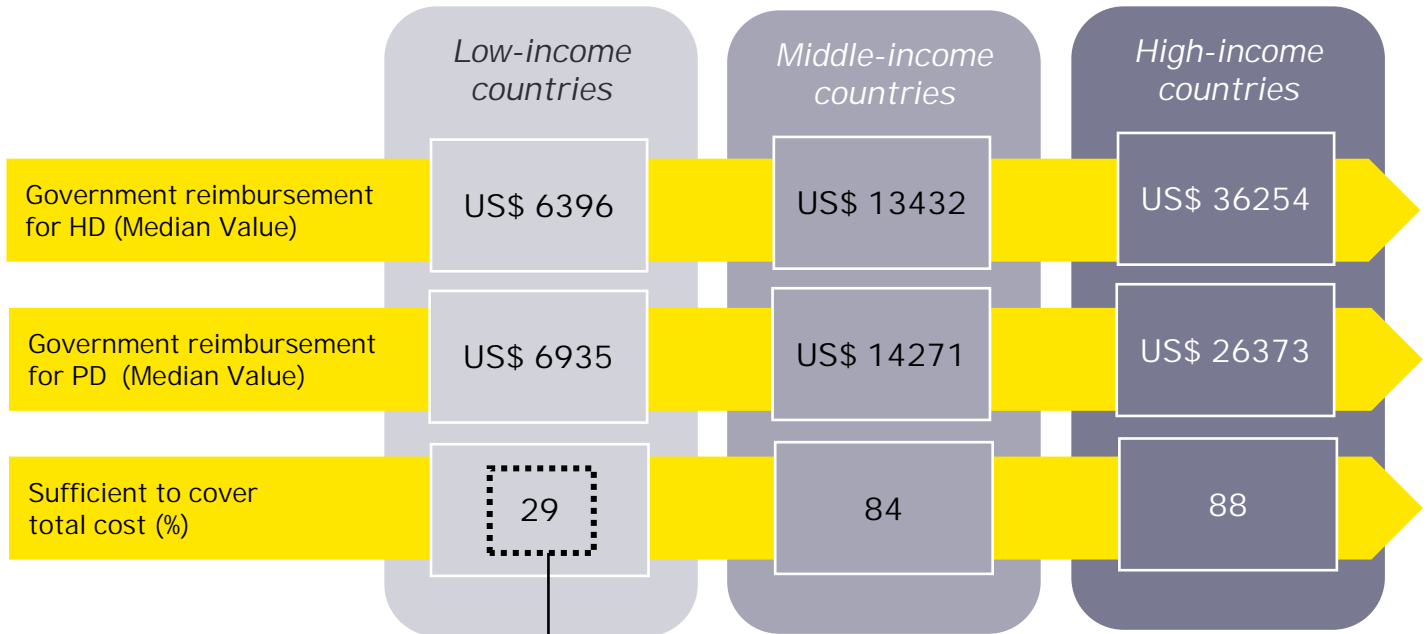


- ▶ The prevalence of patients on PD is much lower than that of patients on HD worldwide.
- ▶ Countries that have a non-financial PD-first policy such as Denmark, Hong Kong, Latvia, Malaysia, Mexico, Philippines, South Africa, and Thailand have a higher percentage of patients on PD.
- ▶ Studies suggest that financial incentives aimed solely at hospitals or care providers are not sufficient to increase use of PD
- ▶ To increase use of PD, costs of PD need to be reduced by local production and supply of PD fluids, or reduced taxes on imported fluids.

Source: An International Analysis of Dialysis Services Reimbursement, CJASN, Multiple Authors, 2018

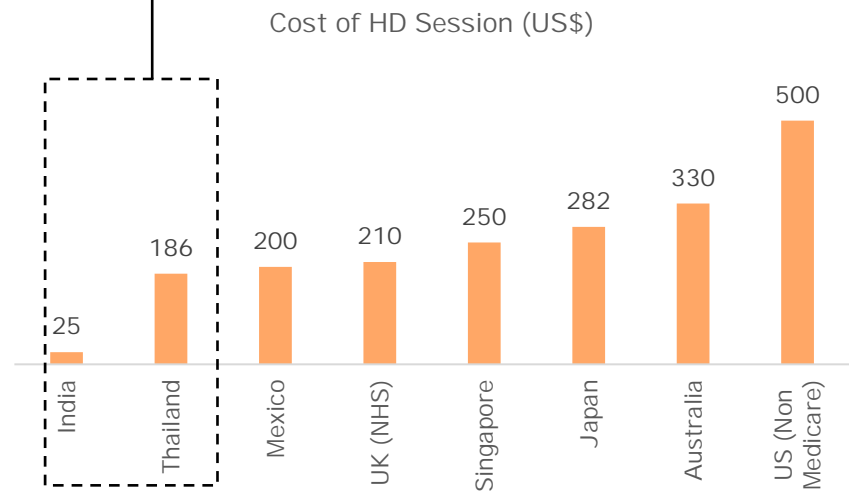
# India's standing in the global landscape: Insufficient reimbursement to cover overall costs

India's cost of an HD session is much lower than that of comparable countries. In the same measure, the government reimbursement for HD treatment per patient is also the lowest in India.

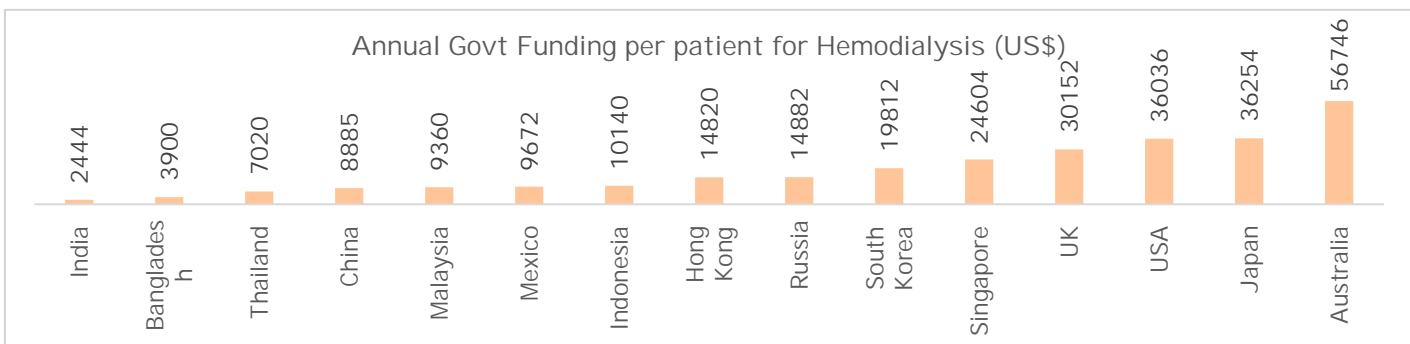


Source: An International Analysis of Dialysis Services Reimbursement, CJASN, Multiple Authors, 2018

- ▶ Even though cost of one HD session is lower in comparison to other key countries, the government reimbursement provided is not sufficient to cover total cost.
- ▶ Cost of HD sessions in developed countries may be higher due to real estate cost, latest equipment and workforce deployed. Meanwhile in India, to deliver at the lowest price point at the same level of international quality, Indian private dialysis service providers operations remain stressed.
- ▶ Developed countries spend a significant share of their government expenditure into medical programs, especially that of end stage renal care. This, in turn, helps reduce mortality and improve quality of life of ESRD patients.



Source: EY Analysis



Source: An International Analysis of Dialysis Services Reimbursement, CJASN, Multiple Authors, 2018



6

Focus on **Clinical Outcomes**  
and Standards

# Clinical outcomes monitoring: Essential to quality dialysis delivery

- ▶ An essential component of quality delivery of dialysis services is recording and monitoring clinical outcome of ESRD patients for improving their safety and clinical care. There are several important clinical outcomes which are considered critical for dialysis patients; however, the four key indicators are mortality, anemia, seroconversions and dialysis access.
- ▶ Monitoring and tracking these outcomes helps improve the understanding of the effect of dialysis treatment on patients and thereby helps the service providers in turn to improve their services in order to increase the lifespan of patients and enhance their quality of life. Service providers may play a key role in educating the patients on the utility of proper dialysis access (AVF/AVG/Perm Cath) thereby improving clinical outcomes.
- ▶ Presently, there is a lack of record keeping of the clinical outcomes of ESRD patients, which also severely impacts patient safety and quality of service delivery.

## 01 Mortality

Share of patients died at least three months/one year after they started dialysis in a year (%)

Mortality among patients with ESRD remains high. So, measuring mortality is important to ensure that the quality of dialysis being provided is as per the clinical standards.

## 02 Anemia

Share of patients who have their HB measured once a month and % of those tested who are in the recommended range (9.5 to 11.5 g/dL) (%)

Anemia is one of the most common problems faced by dialysis patients, resulting in several side effects like fatigue, lack of energy, increased risk of infection, etc. It is important to measure and correct anemia to ensure improved longevity, reduced mortality and morbidity and a Better Quality of Life.

## 03 Seroconversions

Share of patients who have seroconverted with Hepatitis C in a year (%)

Seroconversions are a huge problem in dialysis centers. The very nature of hemodialysis makes it susceptible to seroconversions. However, following proper protocols can reduce the incidence of seroconversions significantly.

## 04 Dialysis Vascular Access

Share of patients who have an Arteriovenous Fistula (AVF) or an Arteriovenous Graft (AVG) within 3 months of initiating Hemodialysis (%)

AVF is associated with the best Clinical Outcomes in hemodialysis patients, followed by AVG. Temporary accesses such as non-tunneled and tunneled catheters are known to worsen outcomes due to their inherent nature of being external accesses compared to AVFs and AVGs which reside under the skin. Providers must strive to ensure their patients get an AVF or an AVG as soon as possible.

# Maintaining standards: Dialysis-centered requirements

Any policy guideline for dialysis must be centered toward ensuring patient safety and quality treatment. This is why, it is extremely important to have universal Dialysis service standards under NABH. The majority of Asia-pacific countries, including Malaysia, Philippines, Hong Kong, Taiwan, Singapore, Australia, Indonesia, China, and Thailand, have published mandatory Dialysis Service Standards. Following are standards recommended by Indian dialysis stakeholders:

Facility	<ul style="list-style-type: none"><li>▶ Dialysis Clinics including standalone centers should have tie-ups with nearby healthcare facilities to treat/handle emergency complications.</li><li>▶ Infra and space should be adequate as per ISN recommendations</li><li>▶ Mandate to have dedicated machines to treat isolation cases (HCV/HbSAg/HIV)</li></ul>
Manpower	<ul style="list-style-type: none"><li>▶ Standalone dialysis center to be managed by certified renal nurse/ MBBS/ BAMS/ BHMS/ BUMS doctor</li><li>▶ Manpower should be adequate as per machine ratio (one staff per three occupied machines)</li><li>▶ All staff including technicians should be certified in BLS</li><li>▶ Clinic must have dedicated staff to treat isolation and suspected cases</li><li>▶ Regular nephrologist visit: once in a fortnight</li></ul>
Products and consumables	<ul style="list-style-type: none"><li>▶ Reuse of dialyzer for Hepatitis B and HIV, and such suspect cases, should be avoided strictly.</li></ul>
Diagnostics	<ul style="list-style-type: none"><li>▶ Virology testing of patients, through HCV RNA and HBV DNA method, should be preferred over Antibodies/ Rapid Kit method, where these tests are available in the facility</li><li>▶ No refurbished machines to be allowed</li></ul>
RO/Water treatment unit	<ul style="list-style-type: none"><li>▶ TDS of RO water to be recorded every day by provider to ensure AAMI standards are met</li><li>▶ Loop line disinfection to be done monthly</li><li>▶ Dialysate Endotoxins to be measured on a six months basis and Dialysate CFU (Colony Forming Unit) test to be done on a monthly basis</li><li>▶ Complete chemical analysis (23 parameters) to be done annually</li></ul>

Source: Compiled Industry Inputs



7

## Key Recommendations

## Short-term recommendation: Promoting standalone centers for HD Treatment

Issue	Key recommendations
Improving access	<p>Access to dialysis can be improved by allowing flexibility to service providers in choosing the location for setting up of standalone dialysis units if space not provided in the district hospitals. Two types of models can be adopted:</p> <ul style="list-style-type: none"> <li>▶ PPP Model: Setting up of standalone dialysis center at the district hospital level or other primary healthcare centers under PPP Model.</li> <li>▶ Non-PPP Model: Private entities may set up centers under a private-lease model. However, this standalone center may be empaneled under Ayushman Bharat, to serve to patients under Ayushman Bharat, any other health schemes, insurance schemes and also other private patients</li> </ul> <p>Access creation: In few apex hospitals (may be medical colleges/referral hospitals) in a state, government may create necessary infrastructure for free dialysis access creation for patients. This must include access to Arteriovenous Fistulas (AVF), arteriovenous graft (AVG) and Perm Cath creation for patients.</p>
Optimal use of human resource, maintaining standards and mitigating other costs	<p>Human Resource: As witnessed in successful countries like the US, the UK, Singapore, Philippines, China and others, trained Dialysis/renal care nurses may be allowed to manage the standalone centers. The nephrologists may visit the facility once or twice a month. If a Renal/Dialysis nurse is not available, any of the BAMS, BHMS, Ayush or MBBS with basic knowledge and registered with the respective medical council can be considered for managing the standalone centers.</p> <p>Maintaining Standards: Dialysis quality and RO water quality to be maintained as per AAMI standards.</p> <p>Reducing cost of equipment: Equipment incurring high custom duties may be considered for relaxation/exemptions to reduce overall costs of equipment and thereby facilitating affordability.</p>
Resolving empanelment delays	<ul style="list-style-type: none"> <li>▶ Guidelines for empanelment of standalone centers under Ayushman Bharat scheme to be simplified and made uniform across the country.</li> <li>▶ To ensure empanelment process concludes in a time bound manner, provision of "deemed approved", or an automated approval process at state level could be considered under central schemes and centrally supported schemes. Here, minimum infrastructure, consumables and human resource compliance need to be met.</li> <li>▶ Auto/Default-approval for specialized dialysis networks with significant years of experience with dialysis services and PMJAY empanelment: For e.g., those with over 3 years of experience; 100 dialysis machines; 3 PMJAY empaneled units operational for one year, auto approval to be given in 30 days while an in person visit/audit can happen in three to six months to ensure compliance so that access is not compromised for needy patients during the usual waiting period.</li> </ul>
Maintaining price point and reimbursements	<ul style="list-style-type: none"> <li>▶ Reimbursement rates to be increased considering the overall cost of treatment to providers in NHA, CGHS and other government reimbursement scheme.</li> <li>▶ The final price point for dialysis services at the standalone center may be linked to the Wholesale Price Index (WPI) with the provision of an annual revision of price to manage rising costs arising due to inflation.</li> </ul>

Source: Compiled Industry Inputs

## Medium-term recommendation: Building human resource for dialysis

Issue	Key recommendations
Scarcity of Dialysis Technicians	<ul style="list-style-type: none"> <li>▶ To address shortage of dialysis technicians (DTs), a broad set of candidates with minimum qualification of higher secondary, preferably from science, biology background, can be trained. In addition, there should be a qualifying entrance test to maintain the quality of trainees. These technicians can be trained on both HD and PD treatments. This training may be provided with accreditation and universal recognition.</li> <li>▶ On the job trainings and internship opportunities: Promoting sponsored internships/sponsorships in partnership with the private sector. This will encourage interested youth to be involved in the dialysis ecosystem. A key feature of this model must be on-the-job training at standalone centers.</li> </ul>
Accelerated learning for trained professionals	<ul style="list-style-type: none"> <li>▶ Nurses play a critical role in dialysis treatment, and therefore short-term trainings may be formulated for nurses on both HD and PD treatments. This may be provided with accreditation and universal recognition.</li> <li>▶ Short-duration training courses for Ayush, BAMS, BHMS, MBBS doctors to be formulated. This may be provided with accreditation and universal recognition.</li> <li>▶ In addition, Train the Trainers program can be introduced to help reduce the turnaround time and making a balance between quality and quantity of the allied professionals.</li> </ul>
Infrastructure requirements: training centers	<p>To address infrastructure challenge, state governments can engage in public private partnerships (PPP) with service providers. Here, two types of PPP models can be used:</p> <ul style="list-style-type: none"> <li>▶ Any public hospital meeting a minimum benchmark of infrastructure requirement can be used to deliver training sessions, whereas the training material and equipment will be provided by the service providers.</li> <li>▶ The state government can directly engage with service providers to set up facilities wherein the existing pool of nurses and doctors can be trained on the equipment provided by service providers.</li> </ul>
Specific human resource requirements for PD	<ul style="list-style-type: none"> <li>▶ Home-care manual: A patient home care manual (paper and online) where patients can record daily therapy information – exchanges, fluid status, diet, exercise and medication. Essential training tools and schedule to include a 6-step handwashing, maintaining a safe environment for exchanges, safe disposal, what to watch out for, patient helpline, etc.</li> <li>▶ Training nurses: To expand the reachability of PD treatment, nurses could be encouraged to be trained about the nuances of PD (along with HD). This includes emphasis on home care trainings to ensure safety of patients.</li> <li>▶ Training surgeons: Besides training of paramedical staff, surgeons need to be trained for catheter insertion.</li> </ul>

Source: Compiled Industry Inputs

# Recommended Standards for Standalone Dialysis Centres

Standard	
1	Patient requiring continuous monitoring beyond scope of care shall be referred to identified facility
2	Assessment is done in all patients before procedure
3	Informed consent is taken before the procedure
4	Procedural safety checklist is implemented
5	Written guidance governs procedural sedation
6	Written guidance governs administration of anaesthesia
7	The operative procedure note is documented
8	Patients are monitored for adverse events before discharge and Documented
9	Nursing Care is provided to patients in the centre in consonance with clinical protocols.
10	The written guidance governs equipment and engineering controls
11	The dialysis centre develops appropriate key performance indicators suitable to monitor clinical structures, processes and outcomes.
12	Emergency readiness of the standalone dialysis centre to be insured
13	Reduction in infection rate to be insured

Source: Compiled Industry Inputs



# Recommendations for peritoneal dialysis: Making PD treatment an accessible and viable alternative

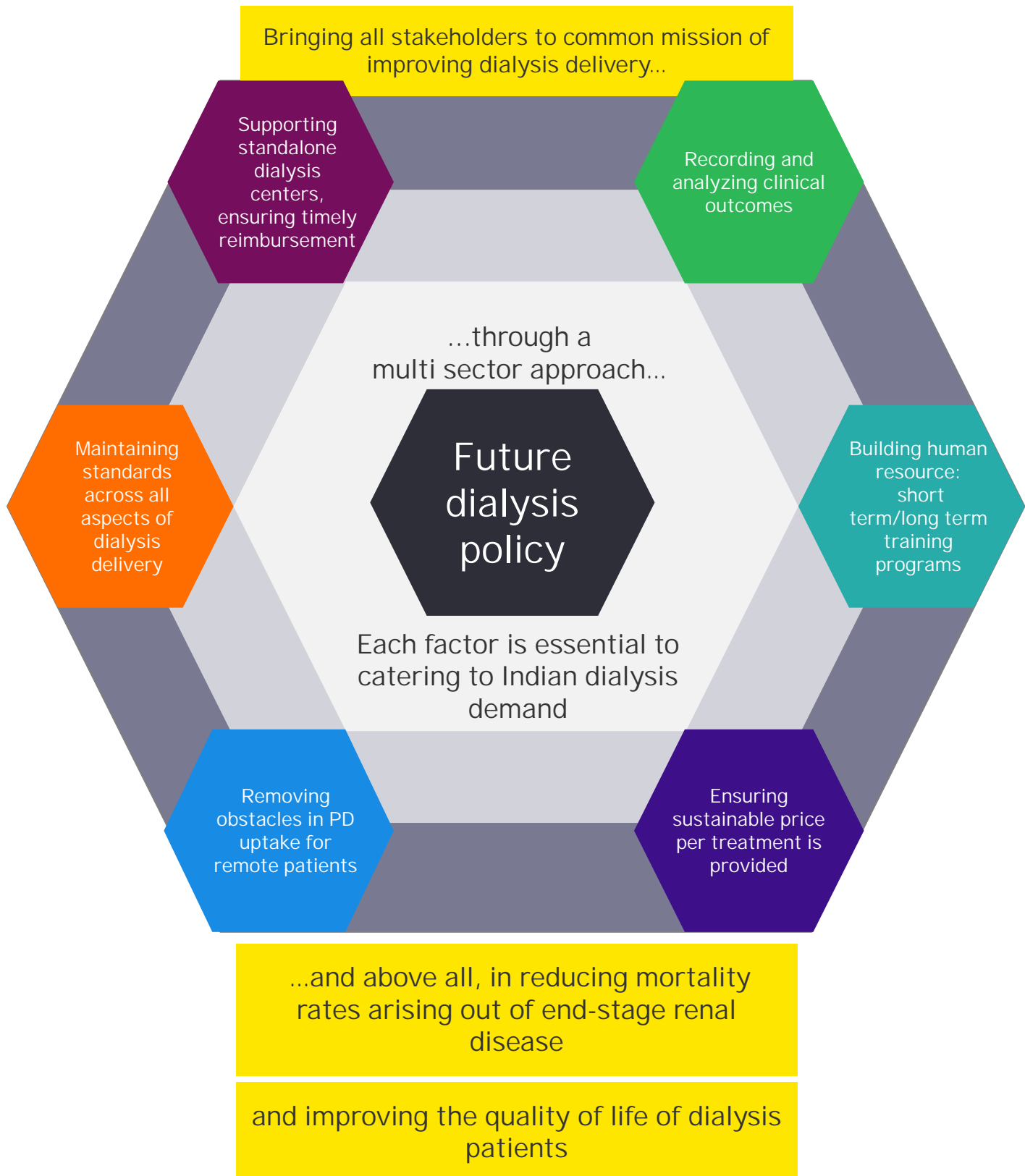
Issue	Key recommendations
PPP Model for PD treatment	This treatment may be offered under a PPP model wherein the consumables (including the delivery of CAPD bags) may be provided by the private entities to the district level healthcare center, while the care and delivery to the patient may be handled by the states in their existing healthcare facilities such as district hospitals, standalone centers.
Building Awareness amongst patients	Promoting awareness of PD treatment for ESRD patients through mass campaigns. Lack of awareness is a barrier to PD penetration, which could be addressed through information and education campaigns. These educative campaigns may be organized at the state/district level (along with service providers) to improve the penetration of this treatment. This should also include aspects of safety and hygiene to be taught to the patients.
Making PD treatment cost competitive	<p>Custom Duty reduction on CAPD Bags: CAPD bags being imported in India may be considered for Custom Duty reduction to make bulk buying of bags more affordable to service providers.</p> <p>Encouraging domestic manufacturing: The domestic production of CAPD bags can be promoted under the existing PLI scheme for medical devices in line with the government's Make in India agenda.</p>
Clinical support infrastructure	<p>Defining clinical outcomes: Central government can decide a specific list of clinical outcomes to be monitored in PD patients in consultation with nephrologists, service providers and professionals with field experience.</p> <p>Encouraging clinical outcomes monitoring for PD: specific clinical outcomes measures for PD treatment, such as incidents of fluid overload, cardiovascular events and malnutrition indicators, be recommended to be monitored by district and state level hospitals having patients on PD treatment. This will help improve the quality of care provided to the patients.</p> <p>Allocating PD Rooms: States can allocate a specific percentage of all standalone dialysis centers to have PD rooms. This will ease the process of initial PD sessions under guided supervision to improve clinical outcomes for patients.</p>
Promoting community healthcare	<p>PD can be promoted in India under community healthcare model. This may include the following:</p> <ul style="list-style-type: none"> <li>▶ Engage Asha workers or social workers to provide first point of assistance to PD patients.</li> <li>▶ Engage PD Coordinators, who may record the patient status – through scheduled video and in-person evaluations.</li> <li>▶ Evaluations may include indicators of clinical condition such as fluid status, compliance with therapy, nutrition status, fatigue assessment and complications that will need escalation</li> <li>▶ Registry of PD patient with the nearest district hospital, standalone center; practicing nephrologist may provide services in critical conditions.</li> </ul>

Source: Compiled Industry Inputs



Summary:

# Dialysis policy to be centered around critical sectors



## List of Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
AVF	Arteriovenous Fistula
AVG	Arteriovenous Graft
BAMS	Bachelor of Ayurvedic Medicine and Surgery
BHMS	Bachelor of Homeopathic Medicine and Surgery
BPL	Below poverty line
BUMS	Bachelor of Unani Medicine & Surgery
CAPD	Continuous ambulatory peritoneal dialysis
CFU	Colony Forming Unit
CGHS	Central Government Health Scheme
CKD	Chronic Kidney Disease
DNA	Deoxyribonucleic acid
DT	Dialysis Technician
ECHS	Ex-Servicemen Contributory Health Scheme
ESIS	Employees State Insurance Scheme
ESRD	End Stage Renal Disease
GDP	Gross Domestic Product
GNM	General Nursing and Midwifery
GST	Goods and Services Tax
HCP	Healthcare Practitioners
HCV	Hepatitis C virus
HD	Haemodialysis
HIV	Human immunodeficiency virus
MBBS	Bachelor of Medicine and Bachelor of Surgery
NABH	National Accreditation Board for Hospitals
NFHS	National Family Health Surveys
PD	Peritoneal Dialysis
PLI	Product Linked Incentive
PMJAY	Ayushman Bharat- Pradhan Mantri Jan Arogya Yojana
PMNDP	Pradhan Mantri National Dialysis Program
PPP	Public private partnership
QAPI	Quality Assessment & Performance Improvement
RNA	Ribonucleic acid
RO	Reverse Osmosis
RRT	Renal replacement therapy
RSBY	Rashtriya Swasthya Bima Yojana
WPI	Wholesale Price Index





# Notes

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# Our offices



## Ahmedabad

22<sup>nd</sup> Floor, B Wing, Privilon  
Ambli BRT Road, Behind Iskcon  
Temple, Off SG Highway  
Ahmedabad - 380 059  
Tel: + 91 79 6608 3800

## Bengaluru

12<sup>th</sup> & 13<sup>th</sup> floor  
"UB City", Canberra Block  
No. 24, Vittal Mallya Road  
Bengaluru - 560 001  
Tel: + 91 80 6727 5000

Ground Floor, 'A' wing  
Divyasree Chambers  
Langford Gardens  
Bengaluru - 560 025  
Tel: + 91 80 6727 5000

## Chandigarh

Elante offices, Unit No. B-613 & 614  
6<sup>th</sup> Floor, Plot No- 178-178A  
Industrial & Business Park, Phase-I  
Chandigarh - 160 002  
Tel: + 91 172 6717800

## Chennai

Tidel Park, 6<sup>th</sup> & 7<sup>th</sup> Floor  
A Block, No.4, Rajiv Gandhi Salai  
Taramani, Chennai - 600 113  
Tel: + 91 44 6654 8100

## Delhi NCR

Golf View Corporate Tower B  
Sector 42, Sector Road  
Gurugram - 122 002  
Tel: + 91 124 443 4000

3<sup>rd</sup> & 6<sup>th</sup> Floor, Worldmark-1  
IGI Airport Hospitality District  
Aerocity, New Delhi - 110 037  
Tel: + 91 11 4731 8000

4<sup>th</sup> & 5<sup>th</sup> Floor, Plot No 2B  
Tower 2, Sector 126  
Gautam Budh Nagar, U.P.  
Noida - 201 304  
Tel: + 91 120 671 7000

## Hyderabad

THE SKYVIEW 10  
18<sup>th</sup> Floor, "SOUTH LOBBY"  
Survey No 83/1, Raidurgam  
Hyderabad - 500 032  
Tel: + 91 40 6736 2000

## Jamshedpur

1<sup>st</sup> Floor, Shantiniketan  
Building, Holding No. 1  
SB Shop Area, Bistupur  
Jamshedpur - 831 001  
Tel: + 91 657 663 1000

## Jaipur

Level 6, Regus Radiant  
Centres Jaipur Centre  
Building, B2 Bypass, Tonk  
Road Sector B-4, Near Airport  
Jaipur - 302018  
Tel +91 141 673 3245

## Kochi

9<sup>th</sup> Floor, ABAD Nucleus  
NH-49, Maradu PO  
Kochi - 682 304  
Tel: + 91 484 433 4000

## Kolkata

22 Camac Street  
3<sup>rd</sup> Floor, Block 'C'  
Kolkata - 700 016  
Tel: + 91 33 6615 3400

## Mumbai

14<sup>th</sup> Floor, The Ruby  
29 Senapati Bapat Marg  
Dadar (W), Mumbai - 400 028  
Tel: + 91 22 6192 0000

5<sup>th</sup> Floor, Block B-2  
Nirlon Knowledge Park  
Off. Western Express Highway  
Goregaon (E)  
Mumbai - 400 063  
Tel: + 91 22 6192 0000

## Pune

C-401, 4<sup>th</sup> floor  
Panchshil Tech Park, Yerwada  
(Near Don Bosco School)  
Pune - 411 006  
Tel: + 91 20 4912 6000

For further information, kindly contact:

**Shambhavi Sharan**  
Manager, Tax and Economic Policy Group  
Golf View Corporate Tower B  
Sector 42, Sector Road  
Gurugram - 122 002  
Email: shambhavi.sharan@in.ey.com

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