INTERNATIONAL SOCIETY OF NEPHROLOGY

The ISN framework for developing dialysis programs in low-resource settings

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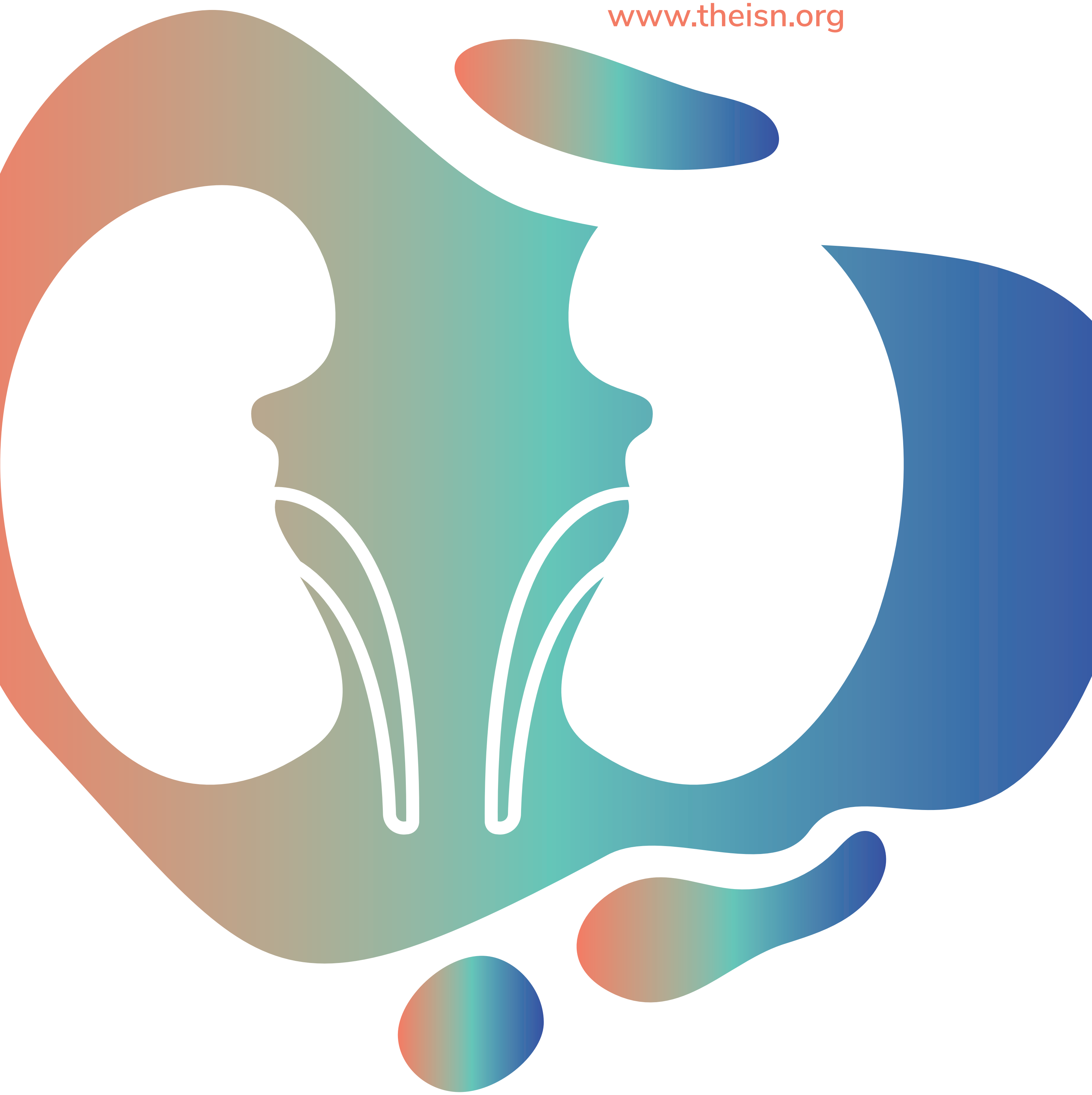

Advancing Kidney Health Worldwide. Together.

FOREWORD

Chronic kidney disease (CKD) is an important contributor to mortality from noncommunicable diseases. No decrease has been seen for CKD mortality contrary to many other important non-communicable diseases (e.g., cardiovascular disease). The prevalence of CKD and kidney failure are increasing all over the world – and thereby also the need for dialysis. Unfortunately, the prevalence increases most rapidly in low- and middle-income countries. Globally, there are great inequities in access and quality of management of kidney failure. Many low- and middle-income countries cannot meet the increased need for dialysis. If the patients receive dialysis, it might only be for a limited period due to the out-of-pocket expenses. There are global disparities in CKD mortality reflecting the disparities in access to care. Lack of access to dialysis is an important cause of the increased CKD mortality in low- and middle-income countries.

Two major risk factors for CKD - diabetes and hypertension - are increasing burdens in low- and middle-income countries. Therefore, the pressure on the health care systems to manage CKD, therein dialysis will increase further. The World Health Organization (WHO) has started initiatives to halt the rise in both diabetes and hypertension - the WHO Global Diabetes Compact and WHO HEARTS Technical package. These initiatives aim to facilitate prevention and care of these conditions.

The framework for dialysis by ISN will be a major resource for the management of CKD and we hope that this will be used widely.

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ABBREVIATIONS AND DEFINITIONS

AKI	Acute Kidney Injury – kidney injury that is present for less than 3 months, and frequently reversible.
AV	Arteriovenous
CAPD	Continuous Ambulatory Peritoneal Dialysis: continuous ambulatory peritoneal dialysis – peritoneal dialysis done without the help of a cycler using manual exchanges with patients going about their normal daily activities.
CARI	Caring for Australian and New Zealanders with Kidney Impairment
CKD	Chronic kidney disease – kidney disease that is present for 3 months or more, and frequently progressive.
CKD-MBD	Chronic kidney disease – mineral bone density
CKM	Conservative kidney management – care for patients with kidney failure other than dialysis or kidney transplantation.
DALY	Disability-Adjusted Life Year: Disability Adjusted Life Years – The sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability. One DALY represents the loss of the equivalent of one year of full health.
Dialyzer reuse	The same hemodialyzer (filter) is used more than once for the same patient, generally to reduce cost of care. When dialyzers are reused, they are cleaned and disinfected after each treatment.
ERBP	European Renal Best Practice
eGFR	Estimated glomerular filtration rate
ESKD	End-stage Kidney Disease
ESPN	European Society of Pediatric Nephrology
GDP	Gross domestic product
GFR	Glomerular filtration rate: glomerular filtration rate - is a test of the filtration function of the kidneys and measures how much blood passes through the glomeruli each minute.
GKHA	Global Kidney Health Atlas
HD	Hemodialysis: blood is pumped out of the body to an artificial kidney machine and returned to the body by tubes that connect the person to the machine.
HDI	Human development index
HIC	High-income countries
HITAP	Health Intervention and Technology Assessment Program
HIV	Human immunodeficiency virus
HKKF	Hong Kong Kidney Foundation
HTA	Health technology assessment: A systematic multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology to define its properties, effects, and/or impacts.
IPNA	International Pediatric Nephrology Association
ISHD	International Society for Hemodialysis
ISN	International Society of Nephrology
KDIGO	Kidney Disease: Improving Global Outcomes

KDOQI	Kidney Disease Outcomes Quality Initiative
KRT	Kidney replacement therapy: dialysis or kidney transplantation.
KSC	Kidney supportive care: services aimed at improving quality of life of patients with CKD or kidney failure, whether they are receiving KRT or not.
LIC	Low-income countries
LMIC	Low- and middle-income countries
MOH	Ministry of Health
NCDs	Non-communicable diseases: diseases that are not directly caused by an infectious agent. They tend to be of long duration and are the result of a combination of genetic, physiological, environmental, and behavioral factors.
NGOs	Non-governmental organizations
NICE	National Institute for Health and Care Excellence
NPHW	Non-physician health care workers: nurses, physician extenders, technologists, community health workers.
PD	Peritoneal dialysis: blood vessels in the stomach's abdominal lining filter much like the kidneys with the help of a dialysate fluid that goes in and out in cycles through a catheter in the abdomen.
Pmp	Per million population
PPP	Public-private partnership: A long-term cooperative arrangement between government and private sectors. The private partner finances, builds, and operates the dialysis service, bears initial financial risk and owns management responsibility whereas the government (public sector) monitors the service and pays as per performance.
QALY	Quality adjusted life year
SDGs	Sustainable Development Goals: A collection of 17 interlinked global goals designed to be a "blueprint to achieve a better and more sustainable future for all" in 2015 by the United Nations General Assembly and are intended to be achieved by the year 2030.
SDI	Socio-demographic Index: A summary measure developed by the Global burden of disease study that identifies where countries or other geographic areas sit on the spectrum of development. SDI is a composite average of the rankings of the incomes per capita, average educational attainment, and total fertility rate.
SharE-RR	Sharing Expertise in establishing Renal Registries
SOCSO	Social Security Organization
SOPs	Standardized operating procedures
SWOT	Strengths, weaknesses, opportunities, threats
TTS	The Transplantation Society
UHC	Universal health coverage
USD	United States Dollars
USRDS	United States Renal Data System
Vertical program	Health programs with specific, defined objectives, relating to a single condition or small group of health problems.
WHO	World Health Organization

EXECUTIVE SUMMARY

The prevalence of chronic kidney disease (CKD) and kidney failure are increasing worldwide. Kidney replacement therapy (KRT), through either peritoneal dialysis (PD), hemodialysis (HD), or kidney transplantation, is a lifesaving yet high-cost treatment for people with kidney failure. The number of people receiving KRT is about 3 million and is projected to grow to 5.4 million by 2030. However, in many low- and middle-income countries (LMIC), there is a huge gap between the total number of patients with kidney failure and the number of patients who have access to KRT services.

Dialysis is the commonest KRT worldwide. Dialysis services are being set up throughout the world, either supported by governments, or in the private sector. However, there are great inequities in provision of KRT, with poor access, affordability, range and quality of different domains of KRT in low-income countries (LIC) and LMIC where growth in kidney failure incidence is greatest. Many of these countries are ill-prepared to meet this challenge and many patients who commence KRT are able to continue it for only a short period of time given the reliance on out-of-pocket payment.

Recognizing the urgent global need for more accessible and quality KRT, the International Society of Nephrology (ISN) has developed this framework to guide the establishment or expansion of chronic dialysis programs in low-resource settings as part of the ISN's work in relation with the World Health Organization (WHO). Improving care for patients with kidney failure is necessary to achieve Sustainable Development Goal (SDG) 3.4 – 'by 2030, reduce the premature mortality due to NCDs by one third' and to be consistent with the WHO's commitment to accelerate action in tackling non-communicable diseases (NCDs).

The document highlights the need of adopting multisectoral policies that reduce the main risk factors common to all NCDs as well as taking an integrated approach to developing KRT programs that include kidney transplantation and conservative kidney management, within the health system and other disease programs. The framework recognizes the need for LIC and LMIC with a largely young population with kidney failure to prioritize kidney transplantation and emphasizes conservative kidney management and kidney supportive care as an integral component of KRT. Between the two dialysis modalities (PD and HD), the ISN recommends that health systems in low-resource settings prioritize setting up PD services .

Provision of dialysis is a health system intervention rather than just delivery of a service and requires considerations of other components identified in the WHO Health Systems Building Blocks – such as financing, human resource, information systems, access to essential medicines and governance. The framework has addressed all these aspects.

With focus on affordability, sustainability, scalability and equity, the framework takes into account clinical contexts, technical requirements related to service distribution, infrastructure, human resources, patient management (starting from pre-kidney failure care), shared decision-making for choice of modality of KRT, protocols for different aspects of dialysis delivery, quality assurance, monitoring and crisis preparedness.

Guidance is provided around different ways to finance KRT services to ensure investments in basic medicines and diagnostics needed for care of a patient with kidney failure and develop appropriate delivery models. Public-private partnerships (PPP) can offer opportunities to scale up services, and efficiencies in terms of human resource training and implementation of quality control protocols but require strong governance and oversight. The document recognizes that efficiencies gained by using the most appropriate modality of KRT, return of eligible patients to job markets and gains through new jobs created by the dialysis industry, and skills, trade, and knowledge generated can lead to significant returns on investment.

The ongoing COVID-19 crisis has highlighted the need to rethink the future practice of all medical care, including that of kidney failure. Large scale disruptions have been reported in the care of patients with kidney failure in many countries, both due to the pandemic and the administrative response to the contagion. COVID-19 has highlighted logistic and administrative challenges associated with in-center HD in such situations as a result of shifting health care priorities, interruption of supply chains and transportation, enforced isolation of at-risk or infected patients and staff, cancellation of elective procedures, and increased need of acute dialysis. The pandemic also brought into sharp focus the multiple advantages with home-based PD both for the patients and the health care system. The document also provides guidance to prepare dialysis units for future pandemics and other disasters – both natural (e.g. earthquake, tsunami) or man-made (wars, conflicts).

The ISN has provided the broad guiding principles for setting up dialysis services and intends for this framework to serve as a guiding document, rather than a prescriptive one-size-fits-all solution. Decisions should be made on the basis of high-quality evidence on the costs and consequences of the various options in different jurisdictions, guided by the local disease burden and evaluation of the readiness of the health system to deliver the different components of a coordinated kidney care program of an acceptable quality.

Implementation of components of this framework in different parts of the world will require global co-operation. The ISN will work with the WHO to develop toolkits to help implementation of the various elements of this framework and a monitoring mechanism that tracks the progress of countries towards their goal of providing equitable kidney care to their citizens. This work supports and complements WHO's initiatives towards controlling diabetes and hypertension, two of the most important drivers of the rising need of KRT through the WHO Global Diabetes Compact and WHO HEARTS technical package.

THE DIALYSIS FRAMEWORK: PURPOSE AND TARGET AUDIENCE

The International Society of Nephrology (ISN), a global society with members representing 164 countries, has developed this framework in collaboration with the World Health Organization (WHO) in the context of a non-government organization with official relation with WHO. This framework outlines the requirements and operational considerations for setting up or expanding dialysis programs and is intended as a tool to support the WHO member states in developing sustainable strategies for the treatment of patients with kidney failure.

The development of this framework is in line with the WHO's commitment to accelerate action on tackling non-communicable diseases (NCDs)[1] as highlighted in the 13th Programme of Work for 2019-2020. The WHO Impact Framework establishes the treatment of kidney failure as a trace indicator of the implementation of the 13th Programme of Work by member states.

The chief purpose of this framework is to provide guidance to countries in their planning and operationalizing of dialysis services in resource-constrained settings. While maintaining a primary focus on dialysis, we strongly emphasize the importance of developing an integrated kidney replacement therapy (KRT) program that includes kidney transplantation and conservative kidney management in addition to dialysis. Such a program should be developed alongside a broader approach to prevention, early detection, and timely treatment of all stages of chronic kidney disease (CKD).

This framework's guidance covers human resource needs, infrastructure requirements, processes (for peritoneal dialysis [PD] and hemodialysis [HD]), quality assurance for dialysis as well as ancillary care for patients with kidney failure. Guidance has also been provided for setting up kidney supportive care and comprehensive kidney care services as part of integrated KRT programs.

The target audience for this framework includes policymakers, health system managers, hospital directors, program managers, dialysis service providers, dialysis equipment and supplies manufacturers, health care workers, patients, and civil society stakeholders.

This framework was developed by a Working Group, composed of selected leaders of the different themes covered in the 2018 ISN End-stage Kidney Disease (ESKD) Summit, selected members of the ISN Dialysis Working Group, and those professionals with extensive on-ground experience in delivering KRT services in low-resource settings, and/or who supported the development of dialysis in their own countries and are key opinion leaders (members of the Working Group are included in Annex 2). Guidance was derived from a range of peer-reviewed manuscripts and technical documents, including guidelines, developed by professional societies and/or regulatory organizations around the world, such as global dialysis delivery guidelines and standards developed by Guideline development groups such as Kidney Disease: Improving Global Outcomes (KDIGO), Kidney Disease

Outcomes Quality Initiative (KDOQI), European Renal Best Practice (ERBP), National Institute for Health and Care Excellence (NICE), Caring for Australian and New Zealanders with Kidney Impairment (CARI) and Centers for Disease Control and Prevention (CDC), USA.

The document was first reviewed by the ISN Dialysis Working Group, ISN Kidney Health Professionals Working Group, and the ISN Young Nephrologists Committee, all comprised of ISN members from around the globe. The revised document was then reviewed by the 10 ISN Regional Boards: Africa, Eastern and Central Europe, Latin America, The Middle East, Newly Independent States and Russia, North America and the Caribbean, North and East Asia, Oceania and South East Asia, South Asia, and Western Europe. Each Regional Board consists of nephrology experts, including members of the pediatric and transplant community, and representatives of the affiliated nephrology (national and regional) societies of nephrology. In addition, the framework was reviewed by The Transplantation Society (TTS), International Pediatric Nephrology Association (IPNA), International Society of Peritoneal Dialysis (ISPD), International Society for Hemodialysis (ISHD), and experts in Renal disaster preparedness, kidney supportive care, and conservative kidney management (see Contributors in Annex 2).

ISN did not liaise with, nor involve, pharmaceutical and corporate entities for the development of the dialysis framework. This project was funded solely by ISN. The Working Group members are ISN volunteers. The project was coordinated by ISN Headquarters Staff.

CHAPTER 1

THE GLOBAL BURDEN OF CHRONIC KIDNEY DISEASE

Kidney disease is an increasingly important public health concern because of the large numbers of patients affected, the low levels of awareness, interaction with other diseases, the associated diagnostic and management challenges, and the high cost of care.[2] These challenges are particularly concerning in low-resource settings, where decision-makers must make difficult choices about how to ensure equitable access to treatments despite scarce resources and many competing priorities.[3] Recent estimates suggest that around 850 million people worldwide have some form of kidney disease.[4]

Kidney diseases can be acute or chronic. Acute kidney injury (AKI) may occur following a range of insults, including but not limited to infections, use of nephrotoxic medicines (often available over the counter) and traditional remedies, complications of pregnancy such as preeclampsia, environmental hazards, or trauma. In addition to its short-term consequences, AKI is an important risk factor for chronic kidney disease (CKD).[5]

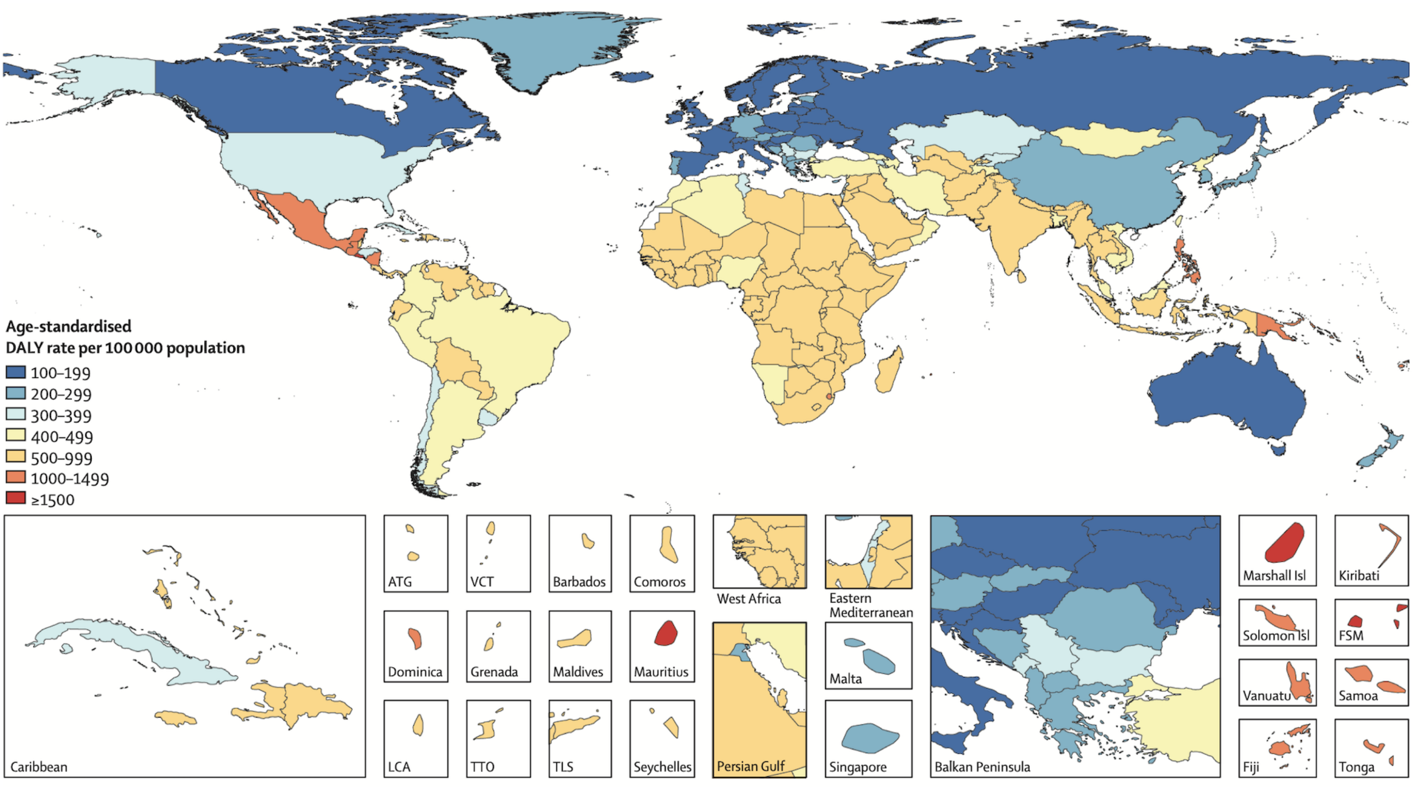
About 700 million people worldwide have CKD.[6] CKD has many causes, both inherited and acquired. Some causes and risk factors for CKD, particularly diabetes, hypertension, and glomerulonephritis, are well known. Others, such as preeclampsia, infections, use of traditional remedies, and environmental causes, have been recognized recently.[6-8] Congenital anomalies of the kidney and urinary tract, hereditary nephropathies, and glomerulonephritis are important causes of CKD in children.[9]

Although the best-known consequence of CKD is kidney failure, CKD is a major risk factor for hypertension, heart disease, and stroke,[10-12] and is independently associated with premature death and disability. CKD is more prevalent among populations who are underserved and ethnic minorities worldwide.[13] In low- and middle-income countries (LMIC), kidney diseases occur at a relatively young age and amongst the economically active population.[2,14]

Over the past three decades, declines in the global age-standardized mortality rates observed for cardiovascular disease, chronic lung disease, and cancer have not been observed for CKD, in part because of disparities in access to diagnosis and care.[6] CKD is the third fastest growing cause of death around the world, and is projected to become the 5th most common cause of years of life lost worldwide by 2040.[15]

The burden of CKD is not uniform around the world. Data from the Global Burden of Disease Study showed most of the current and future burden of CKD to be concentrated in the countries within the three lowest quintiles of Socio-demographic Index (SDI), where there is a larger gap between CKD burden and provision of adequate health care.[6] Population aging and the rising burden of diabetes and hypertension are the major factors responsible for the global rise in the CKD burden. The lack of a coordinated and systematized health care policy precludes the establishment or access to effective case finding and preventative therapies for patients with CKD, and opportunities for timely access to appropriate kidney replacement therapy (KRT) to those with kidney failure, resulting in the continued increase in the burden of CKD-related morbidities and mortality and societal costs, especially in the low SDI countries. Effective action on CKD is therefore essential for improvement of overall health as well as health equity worldwide.[14,16] Figure 1 shows the age-standardized Disability-Adjusted Life Year (DALY) rates for CKD in different countries.[6]

Figure 1. Age standardized DALYs for chronic kidney disease in 2017



Reproduced from GBD Chronic Kidney Disease Collaboration, Figure 1. From Global, regional, and national burden of chronic kidney disease, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2020;395(10225):709-733.(6) Creative Commons CC-BY license.

Abbreviations: DALYs = Disability-Adjusted Life Years; ATG = Antigua and Barbuda; FSM = Federated States of Micronesia; LCA = Saint Lucia; TLS = Timor-Leste; TTO = Trinidad and Tobago; VCT = Saint Vincent and the Grenadines

CKD is classified into 5 stages for uniformity of definition and clinical risk stratification (Figure 2).[17] Accurate diagnosis and classification require the ability to estimate glomerular filtration rate (GFR) by measuring serum creatinine and testing for urine albumin excretion.

Figure 2. Composite Ranking for Relative Risks by glomerular filtration rate (GFR) and albuminuria categories

Guide to Frequency of Monitoring (number of times per year) by GFR and Albuminuria Category				Persistent albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30–300 mg/g 3–30 mg/mmol	>300 mg/g >30mg/mmol
GFR categories (ml/min/1.73 m²) Description and range	G1	Normal or high	≥90	1 if CKD	1	2
	G2	Mildly decreased	60–89	1 if CKD	1	2
	G3a	Mildly to moderately decreased	45–59	1	2	3
	G3b	Moderately to severely decreased	30–44	2	3	3
	G4	Severely decreased	15–29	3	3	4+
	G5	Kidney failure	<15	4+	4+	4+

GFR and albuminuria grid to reflect the risk of progression by intensity of coloring (green, yellow, orange, red, deep red). The numbers in the boxes are a guide to the frequency of monitoring (number of times per year). Green reflects stable disease, with follow-up measurements annually if CKD is present; yellow requires caution and measurements at least once per year; orange requires measurements twice per year; red requires measurements at 3 times per year while deep red may require closest monitoring approximately 4 times or more per year (at least every 1–-3 months). These are general parameters only based on expert opinion and must take into account underlying comorbid conditions and disease state, as well as the likelihood of impacting a change in management for any individual patient. Reproduced with permission from The International Society of Nephrology and Kidney Disease: Improving Global Outcomes. Figure 17. From KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int Suppl. 2013;3:1-150; https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf.[17]

Abbreviations: CKD = chronic kidney disease; GFR = glomerular filtration rate; KDIGO = Kidney Disease: Improving Global Outcomes; G = Grade

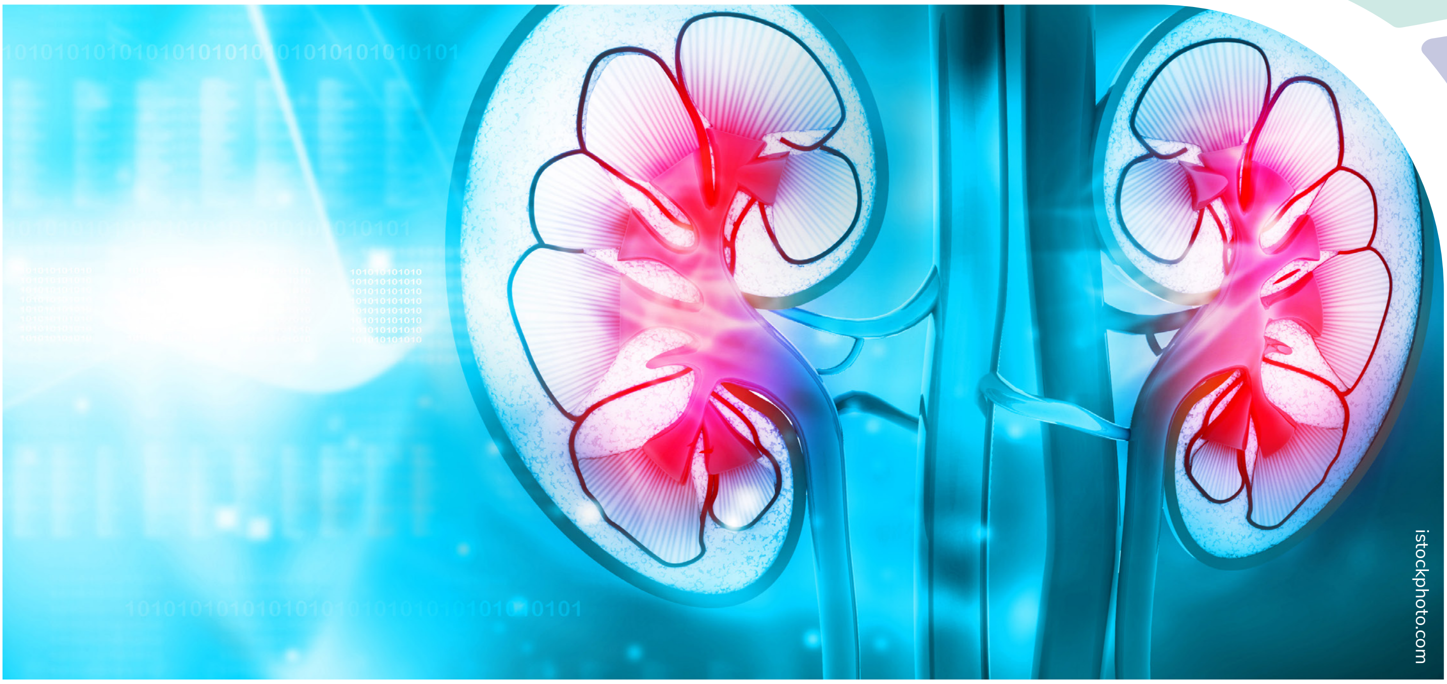
Only a minority of patients with progressive CKD develop symptoms in early stages of the disease. The onset and progression of CKD in early stages can often only be detected by laboratory tests. Once kidney function deteriorates below around 30% of normal, [Kidney Disease: Improving Global Outcomes (KDIGO) stage G4, affecting 13 million people in 2016[18]][17] complications (e.g. anemia, hyperparathyroidism, worsening blood pressure, fluid retention, cognitive decline and cardiovascular complications) become more frequent. Symptoms typically associated with advanced kidney failure (poor appetite, tiredness, shortness of breath, body swelling, leg cramps, itching, bleeding, hiccups) develop late, once estimated GFR (eGFR) is <15% of normal (KDIGO stage G5, 10 million people in 2016).[18] Once eGFR falls below 10% of normal, prolonged survival is not usually possible without KRT.

If detected early, the progression of CKD can be slowed down and even halted through simple and inexpensive treatments. Since CKD often coexists with other non-communicable diseases (NCDs) such as diabetes, hypertension, and vascular disease, and because treatments for CKD also improve outcomes for other NCDs, there are tremendous potential benefits for integrating the detection and management of CKD with existing national programs for NCD detection and control, as recommended by the two work-umbrellas specified in the World Health Organization (WHO) NCD Cluster - Primary Prevention and Integrated Management.[19] Realizing benefits on kidney health will require ensuring access to these beneficial treatments as well as increasing the timely detection of CKD in at-risk subjects ("case-finding"). If kidney disease is not detected at its earlier stages, patients will present with more advanced kidney disease, especially in low-income countries (LIC) and LMIC with weak health systems.

Patients with kidney disease are especially vulnerable when universal health coverage (UHC) and consistent primary care are not in place (Box 1). Kidney diseases are associated with an estimated 188 million cases of catastrophic health expenditure in LIC and LMIC, mostly related to the high cost of KRT.[20]

Box 1. Why patients with CKD in LMIC are especially vulnerable in absence of UHC

- CKD is often asymptomatic in its early stages and may not be detected until very late.
- If detected at an early stage, progression of CKD can be prevented or delayed with simple treatments. However, these are not all universally available.
- To effectively delay progression and prevent complications, medications need to be taken every day. Access to good quality medicines must therefore be both affordable and sustainable, with traditional remedies being avoided.
- Prevention and treatment of CKD also requires adherence to a healthy diet, regular physical activity, and smoking cessation, which are more challenging for the most vulnerable sections of society.
- Treatment of kidney failure leads to catastrophic out-of-pocket health expenditure.



Proposed solutions

The principles of UHC, as well as the policies and initiatives aimed at achieving the Sustainable Development Goals (SDGs), offer many opportunities for policymakers to improve kidney health. All 17 SDGs have implications for patients with kidney disease, or for providers and policymakers involved in providing its treatment.[21] Annex 1, Table A provides examples of the interdependent links between kidney disease and the SDGs.[21] Annex 1, Table B offers 12 recommendations for addressing the global challenge of kidney disease, leveraging the momentum behind the SDGs, consistent with the 2030 Sustainable Development Agenda.[22]

A holistic approach to prevention and management of kidney diseases requires the consideration of several components (Box 2).

Box 2. Holistic approach to the prevention and management of kidney diseases

- Undertake a 'whole of system' and 'whole of government' approach to the development and implementation of public health measures, including the implementation of evidence-based measures for prevention and treatment across the spectrum of kidney disease.
- Prioritize the establishment of comprehensive programs for the prevention of CKD over the development or expansion of KRT.
- Institute programs for the identification and management of preventable AKI.
- Promote the integration of diagnosis and treatment across chronic NCDs to create economic synergies and reduce silos.
- Promote case-finding for CKD amongst people with kidney risk factors being treated in other NCD management programs.
- Use appropriate measures of kidney function for case-finding in children a nd adults.
- Ensure the availability of equitable access to essential diagnostics and medications for the detection and treatment of kidney disease.
- Develop the full range of treatment options (dialysis, kidney transplantation, and conservative kidney management) for patients with kidney failure.

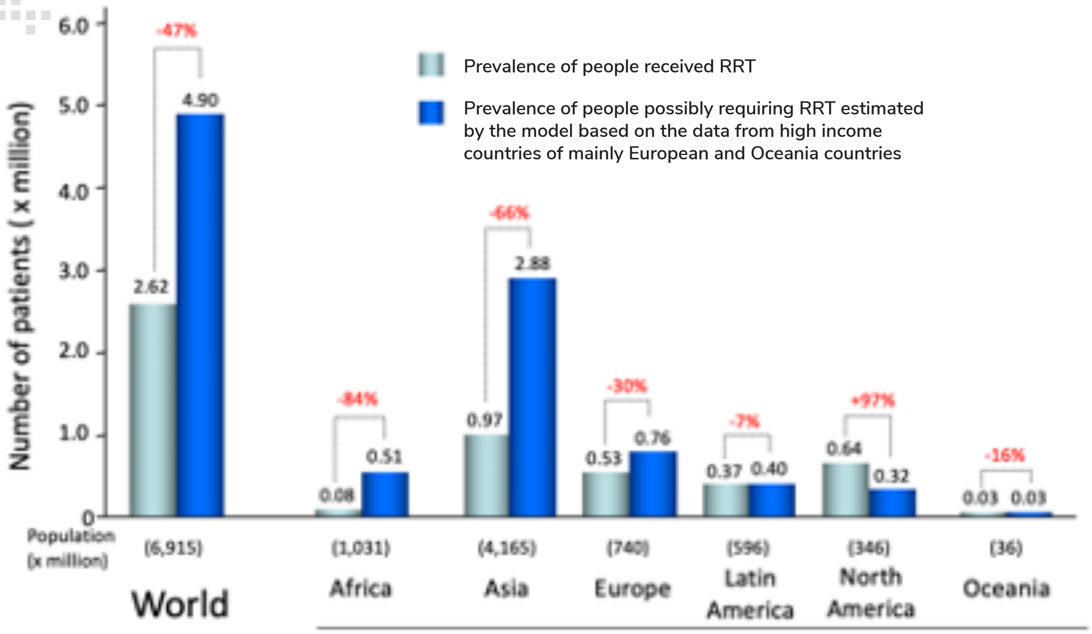
2

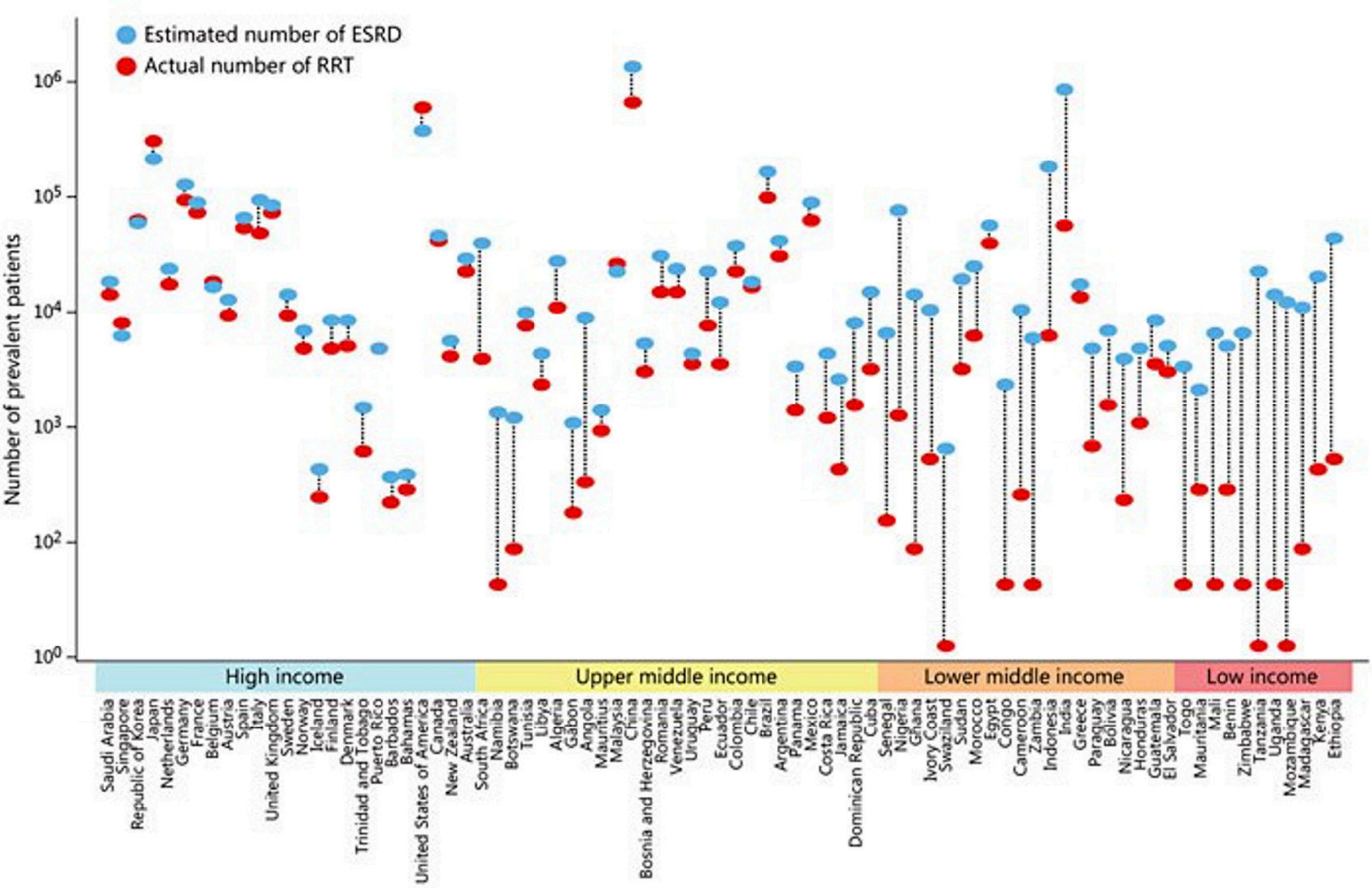
CHAPTER 2

KIDNEY FAILURE AND KIDNEY REPLACEMENT THERAPIES AROUND THE WORLD

The number of people who develop kidney failure and require KRT for survival is increasing worldwide. The number of people receiving KRT stands currently at about 3 million. Estimates suggest that another 2.3 - 7.1 million die annually *because of lack of access to KRT,*[23] *predominantly in LIC and LMIC* (Figures 3a and 3b). With increasing awareness and access to diagnosis and treatment, the number of people on KRT is projected to grow to 5.4 million by 2030, and will pose challenges for health systems.[24,25]

Figure 3. (a) Regional prevalence of people receiving KRT compared with the estimated prevalence of those who require KRT in 2010. (b) Gap between the number of people requiring and receiving treatment for kidney failure around the world in 2010



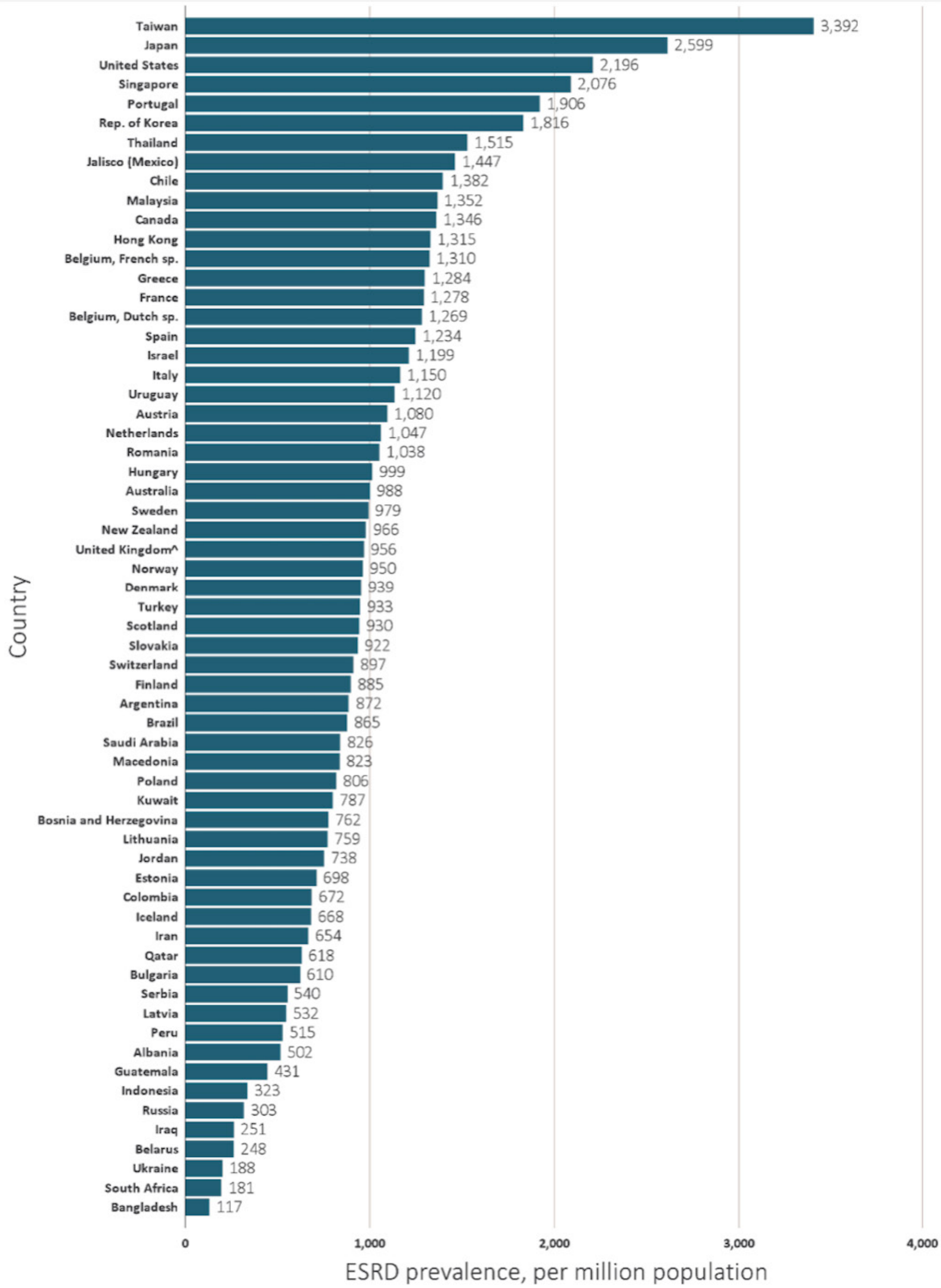


Data from Liyanage et al. Lancet. 2015;385(9981):1975-1982.[23]

Abbreviations: RRT = renal replacement therapy; Oceania = Australasia, Melanesia, Micronesia, and Polynesia; ESRD = end-stage renal disease

The current prevalence of patients who are receiving KRT in different countries varies from < 1 per million population (pmp) to over 2,000 pmp (Figure 4).[26] These between-country differences in KRT prevalence rates are likely to be related to variable access caused by social and structural barriers to care, rather than reflecting genuine differences in either the incidence of kidney failure.[23] Of all the people receiving KRT in 2010, 92.3% resided in high- or upper-middle-income countries.

Figure 4. Prevalence of treated ESRD per million population, by country, 2016

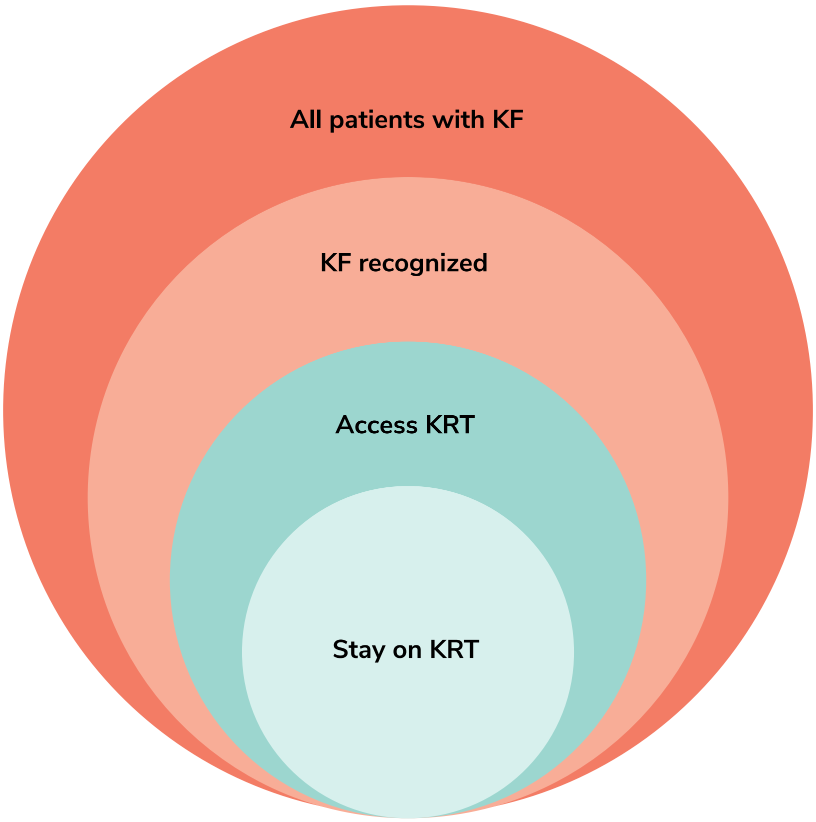


Reprinted from United States Renal Data System, vol 2 Figure 11.9. From 2018 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.[26] The date reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. Government.

Abbreviations: ESRD = end-stage renal disease; Rep = Republic; sp =speaking

Data from LMIC show that even when patients are able to access KRT, they often drop out and are unable to continue treatment in the long-term.[27,28,29] Poor and inequitable access, high burden of comorbidities, faster disease progression because of lack of access to preventive treatments and financial burden of treatment are common barriers to KRT in LIC and LMIC. Patients are lost to the health care system at each stage of health care delivery either because they cannot access care, or are unable to continue because of financial hardships (Figure 5).

Figure 5. Global burden of kidney failure – progressive attrition in patients who are able to have sustainable access to KRT



KF = kidney failure; KRT = kidney replacement therapy

Even in high- or upper-middle-income countries, access to treatment is more limited for certain groups, such as children, women, the poor, the indigenous, migrant and tribal communities, those without health care insurance, and those living in rural areas.[9,30] Particularly notable are gender disparities – while the prevalence of CKD is higher amongst women throughout the world, the treatment rates, in particular for KRT are lower in women, perhaps related to a combination of biological factors (higher rates of disease progression in men), as well as the de-prioritization of expensive care for women in some patriarchal low-income societies.[18]

3

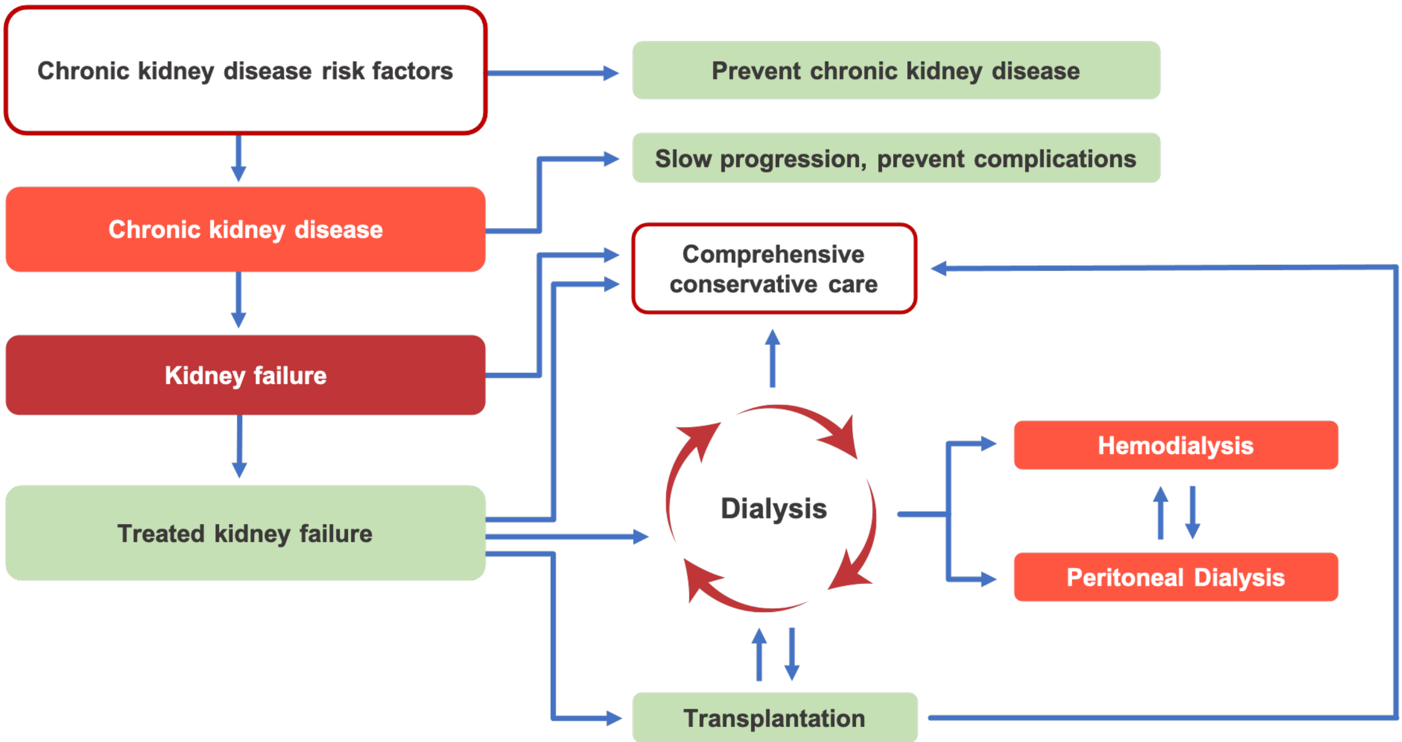
CHAPTER 3

RATIONALE AND STRATEGIC APPROACH TO PROVIDING DIALYSIS IN THE CONTEXT OF INTEGRATED KIDNEY CARE

Integrated kidney care considers locally relevant issues and resources, and suggests a sustainable approach to improving the health of people with kidney failure in line with the values and preferences of the society rather than focusing on one or more of its components.

Among people with established or imminent kidney failure, there are three key treatment strategies: dialysis, kidney transplantation, and conservative kidney management. Joining up effective preventive care for people with milder forms of CKD, with therapies for kidney failure and developing synergistic links between the different treatment options is called "integrated kidney care" (see Figure 6).[3] Integrated kidney care has benefits for patients, families, communities, and the health care system.

Figure 6. Kidney failure pathways as part of integrated kidney care



Reproduced from Harris DCH et al., Figure 1. Increasing access to integrated ESKD care as part of universal health coverage. Kidney Int. 2019;95(4S):S1-S33.[3] Creative Commons CC-BY-NC-ND license.

A. NATIONAL RESPONSES TO THE GROWING BURDEN OF KIDNEY FAILURE

Countries are responding to the challenges of kidney failure in different ways.[31] In most high-income countries (HIC), any decision to provide KRT is based on the likely benefit to be derived from treatment, rather than availability of resources.[32] In recent years, it has been recognized that KRT may not be appropriate for all patients, and a subset (such as the elderly and the frail, or those with multiple comorbidities) are more appropriately managed with non-dialytic conservative kidney management.[33] In many lower income countries, in contrast, access to KRT is often restricted by finances (ability to pay for all or some of the treatment costs), geography, lack of infrastructure, lack of knowledge, or patients presenting too late to be rescued.[27]

There is heterogeneity between and within countries in terms of the relative investment devoted to the prevention, early diagnosis and treatment of CKD, and management of kidney failure. This variability may be due to differences in the structures of health systems, values and preferences, political context, available human or financial resources, cost structures (e.g. relative cost of labor vs. supplies), and competing interests from stakeholders (governments, other payers, patients/families, drug and device companies, dialysis providers, nephrologists, and other health care workers).[34]

Given that preventive care provides markedly more favorable returns in terms of cost per quality adjusted life year (QALY) than dialysis care,[16] arguments have been made to not support KRT from public funding until the majority of citizens have access to publicly funded preventive care.[35] The ISN recommends investment in integrated kidney care rather than focusing on individual components of KRT as a more sustainable approach for improving the health of populations with kidney failure.[36] Decisions to establish dialysis services without adequate consideration of other components of integrated kidney care are of particular concern.

Data from ISN's Global Kidney Health Atlas show that dialysis is already available and growing in all countries.[37] If not supported by public funding, services will expand within the private sector, will not be integrated into the health system and may not be subject to adequate oversight, thereby exacerbating already existing inequities in access to care and increasing catastrophic health expenditure.

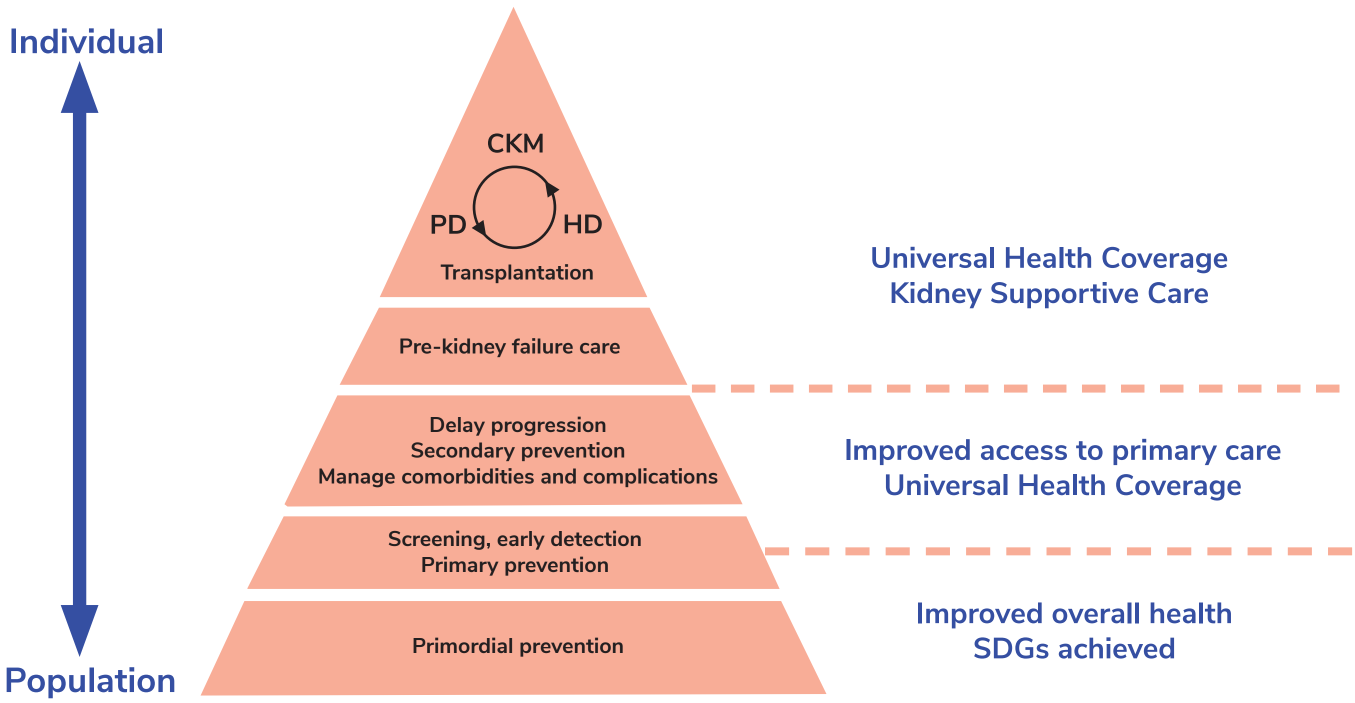
B. FRAMEWORK FOR ESTABLISHING INTEGRATED KIDNEY CARE PROGRAMS IN LMIC

Priority setting

Priority setting is the process of making decisions about how best to allocate limited resources to improve population health and may involve making trade-offs about which services should be provided and to whom. Such decisions should ideally be supported by high-quality evidence on the costs and consequences of the various options. Decisions may need to be made to withhold some services (e.g. dialysis) in order to allocate specific resources to other services that might benefit more people (e.g. kidney disease prevention),[38,39] or prioritize some forms of KRT because overall they provide more value for money.

The principles and components of integrated kidney care[40] are illustrated in Figure 7.

Figure 7. Framework to support decision makers in promoting kidney health and implementing integrated kidney care



Based on Tonelli M et al. Framework for establishing integrated kidney care programs in low- and middle-income countries. Kidney Int Suppl. 2020;10(1):e19–e23.[40]

Abbreviations: CKM = conservative kidney management; PD = peritoneal dialysis; HD = hemodialysis; SDGs = Sustainable Development Goals

Primordial prevention involves the reduction of risk factors by improving overall population health through universal system-wide interventions that have long-term benefits, e.g. improved nutrition, improved infrastructure, clean water, universal immunization, etc.[41] In this model, kidney disease prevention progresses alongside an overall improvement in population health. Interventions to prevent kidney disease (*primary prevention*) include identification of those at risk of developing kidney disease and optimal management of these conditions (for example, diabetes and hypertension).[7] *Secondary prevention* involves early detection of kidney diseases through targeted case-finding, and institution of treatments that delay or prevent progression from early stages of kidney disease to kidney failure.[42]

Some people will develop kidney failure despite the best prevention efforts, and possibly even as a result of adverse structural factors that have been tolerated by the state (e.g. lack of access to primary care), and have a justifiable right to expect health care protection from financial risk.[43]

In suitable patients, kidney transplantation, especially from living donors, offers the best rates of survival and quality of life whilst also offering the best outcomes at lower cost.[44] LMIC with relatively young populations should be encouraged to prioritize sustainable transplant programs, preferably in the public sector, so that it is available to all suitable patients with kidney failure.

Except for those who can get a pre-emptive transplant, patients with kidney failure may need to be on dialysis for variable and often extended periods. Between the two forms of dialysis, the ISN recommends prioritizing peritoneal dialysis (PD) on the basis of overwhelming evidence that PD is more cost-effective (offers similar or better outcomes at potentially lower costs) and scalable (can be expanded more easily including to remote areas).[45-49] PD also helps preserve kidney function and is associated with greater autonomy and independence which increases ability to remain employed.[45-47] Finally, PD is the only form of dialysis suitable for children in low-resource settings. As a result, PD has been prioritized by several countries seeking to develop or expand publicly funded dialysis services under the rubric of 'PD first' or 'PD preferred' policies. These decisions have been supported by country-specific health technology assessment (HTA).[50-53]

However, PD may be more expensive than hemodialysis (HD) in some countries, for example where PD supplies need to be imported from HIC (high production costs and import taxes increase PD costs, which require out-of-pocket payment),[54] or where skilled labor is relatively cheap (reducing HD costs).[47] Even when costs of PD are lower, PD programs may not be easy to establish. For example, in some jurisdictions, PD is deprioritized by nephrologists because of financial disincentives (more reimbursement for center-based HD leading to loss of income associated with growth in PD). These barriers can be removed by promoting local manufacturing of PD solutions, and reimbursement reforms to remove disincentives for use of PD (as is the norm in many developed countries like Canada, United Kingdom, and Australia and recently introduced in the United States). Medical staff can be paid to train patients in using PD. These reforms may be necessary to ensure that the potential economic benefits of PD are realized in all settings.

Attention must also be paid to logistical, social, and ethical challenges so that if KRT is provided, benefits can be maximized for both individuals and society. Therefore, even though PD is the preferred form of dialysis treatment overall, it may not be the best choice of dialysis modality in all settings. Principles and considerations related to the provision of integrated kidney care are outlined in Box 3.[40]

Box 3. Principles of KRT in an integrated kidney care framework

1. All countries should develop a sustainable model to organize and fund kidney care programs.
2. Treatments to slow or prevent progression of kidney disease are effective, cost-efficient, and easily integrated within national NCD programs. Such preventive care should always be prioritized.
3. KRT programs should be developed progressively such that kidney transplant could be offered to all suitable patients.
4. Criteria for eligibility for access to KRT should be clear, aligned with social values, and must be applied in a transparent, consistent, and equitable manner.
5. Patients with kidney failure who do not have access to, or prefer not to receive KRT, should be able to benefit from conservative kidney management.
6. PD should be prioritized by LIC and LMIC contemplating setting up or expanding chronic dialysis programs.
7. A health technology assessment or other systematic assessment of the costs and consequences of PD vs HD could be considered in some jurisdictions where barriers to implementing a PD program are unexpectedly significant.

Finally, where dialysis is not available or accessible, conservative kidney management can provide comfort, even if not prolonging life, and should be made available when considering setting up dialysis services.

All choices about the funding of health services should be supported by high quality evidence on the costs and consequences of the various options.[16] These include accurate information about local disease burdens, and an evaluation of the readiness of the health system to deliver the different components of an acceptably high-quality coordinated kidney care program.

Examples of strategies for developing an integrated kidney care program are listed in Table 1.

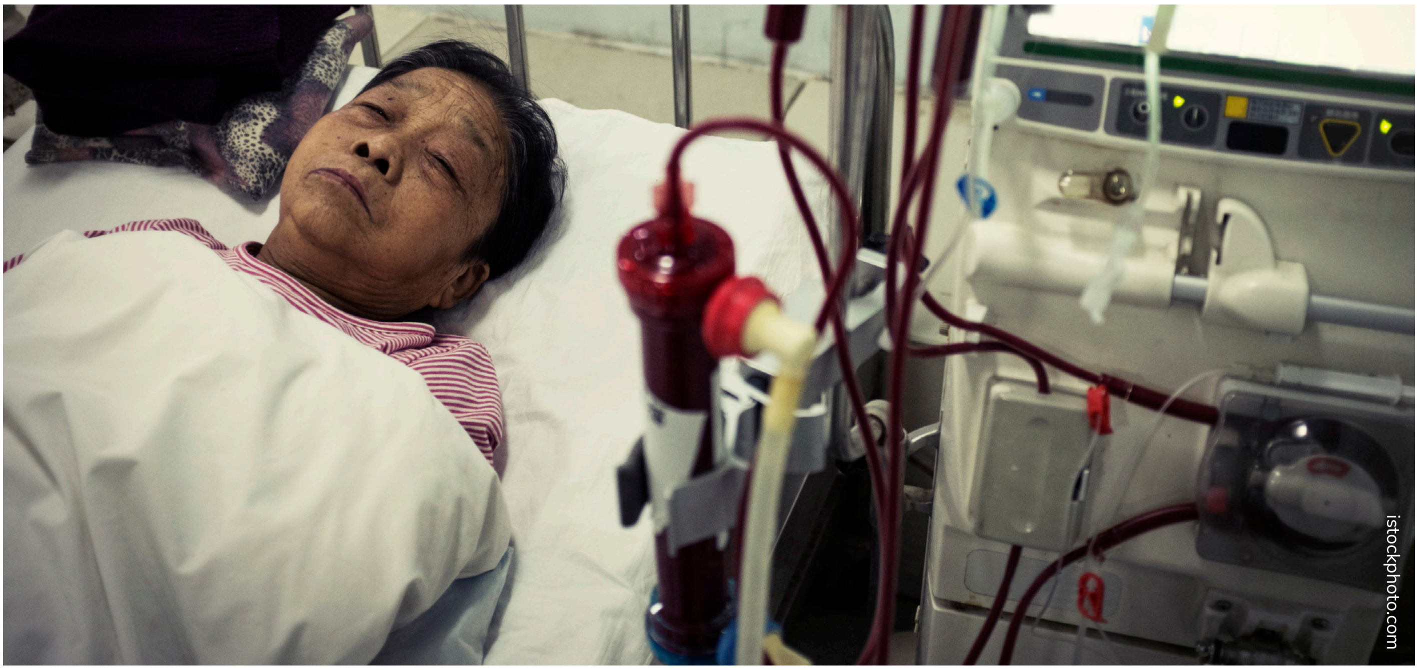

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Table 1. Examples of strategies for developing an integrated kidney care program

What?	Who?	How?	Links and Examples
Understand the burden of acute and chronic kidney disease and kidney failure	• National health administration • National nephrology societies • Hospitals • Dialysis providers	• CKD/kidney failure registry • Health Surveys • Epidemiologic studies, risk factor identification • Determine at-risk population (for case-finding)	• Australia and New Zealand Dialysis and Transplant Registry. https://www.anzdata.org.au/anzdata/ • Canadian Organ Replacement Register. https://www.cihi.ca/en/canadian-organ-replacement-register-corr • Dialysis Outcomes and Practice Patterns Study (DOPPS) (Australia, Belgium, Canada, France, Germany, Japan, Italy, New Zealand, Spain, Sweden, United Kingdom, United States). https://www.dopps.org/ • European Renal Association - European Dialysis and Transplant Association (ERA-EDTA), Europe. https://www.era-edta.org/en/ • Finnish Registry for Kidney Diseases Finland. https://www.muma.fi/liitto/suomen_munuaistautirekisteri/finnish_registry_for_kidney_diseases • Scottish Renal Registry. https://www.srr.scot.nhs.uk/ • United Kingdom Renal Registry. https://www.renalreg.org/ • United States Renal Data System (USRDS) USA. https://www.usrds.org/ Centers for Disease Control (CDC) Surveillance system. https://nccd.cdc.gov/CKD/help.aspx?section=D • Registro Uruguayo de Diálisis. http://nefrouruguay.org.uy/rud-datos-2016/ • Registro Argentino de Diálisis Crónica. https://www.cadradialisis.org.ar/registro.php • Registro Colombiano de la Enfermedad Crónica. Cuenta de Alto Costo. https://cuentadealtocosto.org/site/erc/ • African Renal Registry. http://sa-renalsociety.org/registry/ • Overview of the burden of chronic kidney disease in Mexico: secondary data analysis based on the Global Burden of Disease Study 2017. https://bmjopen.bmj.com/content/10/3/e035285.info • The need for kidney transplantation in low- and middle-income countries in 2012: an epidemiological perspective. https://journals.lww.com/transplantjournal/Fulltext/2015/03000/The_Need_for_Kidney_Transplantation_in_Low__and.8.aspx • Global Burden of chronic kidney disease. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32977-0/fulltext • Risk factors for chronic kidney disease: an update. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4089662/ • The burden of chronic kidney disease and its major risk factors in Jamaica. https://www.kidney-international.org/article/S0085-2538(18)30602-1/fulltext • Identifying High-Risk Individuals for Chronic Kidney Disease: Results of the CHERISH Community Demonstration Project. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6624836/ • The Utility of a National Surveillance Network to Estimate CKD Prevalence and Identify High-Risk Populations in Primary Care. https://www.kireports.org/article/S2468-0249(19)30044-0/fulltext • Vassalotti JA, Fox CH, Becker BN. Risk factors and screening for chronic kidney disease. Adv Chronic Kidney Dis. 2010;17(3):237-245. DOI: 10.1053/j.ackd.2010.03.003 • Cuenta de Alto Costo. Situation of chronic kidney disease, high blood pressure and diabetes mellitus in Colombia 2019 (Situación de la enfermedad renal crónica, la hipertensión arterial y la diabetes mellitus en Colombia). https://cuentadealtocosto.org/site/erc/ • China Kidney Disease Network (CK-NET) 2015 Annual Data Report. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6382959/ • Kidney Health Program (Programa de Salud Renal). Uruguay. http://www.fnr.gub.uy/home_psaludrenal • Ministerio de Salud de Chile. Chronic Kidney Disease (Enfermedad Renal Crónica.). https://redcronicas.minsal.cl/temas-de-salud/enfermedad-renal-cronica-2/

Table 1. (Continued)

What?	Who?	How?	Links and Examples
Setting up national strategy and oversight of integrated kidney care	• National health administration • National nephrology societies • HTA agencies • Planning bodies, health economists • Insurance organizations • Provincial governments, hospitals, health programs	• NCD/CKD prevention program, use ention program, use multidisciplinary teams • Ensure availability of essential diagnostics and medications • Determine the feasibility and sustainability of KRT • HTA to determine best strategy for KRT delivery • Promotion of kidney transplantation • Advocacy for local production of dialysis supplies • Oversight and gatekeeping of KRT programs	• Health Intervention and Technology Assessment Program: http://www.hitap.net/en?s=dialysis • Increasing access to integrated ESKD care as part of universal health coverage. https://pubmed.ncbi.nlm.nih.gov/30904051/ • Framework for establishing integrated kidney care programs in low- and middle-income countries. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7031683/ • Regional Renal Models of Care. https://www.ontariorenalnetwork.ca/sites/renalnetwork/files/assets/regionalrenalmodelsofcare.pdf • A Scoping Review for Strategies to Increase Living Kidney Donation. https://cjasn.asnjournals.org/content/12/9/1518 • Renal replacement therapy and conservative management. https://www.nice.org.uk/guidance/ng107
Standardization of integrated kidney care	• National health administration • Regulatory agencies • National nephrology society • International Societies (ISN, etc.) • Multilateral Organizations (WHO) • Consumer organizations	• Guidelines – either national or suitably adapted global (e.g. KDIGO) guidelines • CKD detection and management • Eligibility for KRT • Setting up dialysis programs • Optimal management of patients on dialysis • Management of kidney transplant donors and recipients • Kidney supportive care	• See Table 5 • KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf • Kidney Health Australia-Caring for Australasians with Renal Impairment (KHA-CARI) guideline: Early chronic kidney disease: detection, prevention and management. https://onlinelibrary.wiley.com/doi/full/10.1111/nep.12052 • Pradhan Mantri National Dialysis Programme. https://nhm.gov.in/New_Updates_2018/PMNDP/Guidelines_for_PMNDP.pdf • Renal association clinical practice guideline in post-operative care in the kidney transplant recipient. https://bmcnephrol.biomedcentral.com/articles/10.1186/s12882-017-0553-2. • NICE Guidelines - Chronic kidney disease in adults: assessment and management. https://www.nice.org.uk/guidance/cg182 • Prevención, diagnóstico y tratamiento de la enfermedad renal crónica temprana. Consejo de Salubridad General. Mexico. http://www.cenetec.salud.gob.mx/descargas/gpc/CatalogoMaestro/335_IMSS_09_Enfermedad_Renal_Cronica_Temprana/GRR_IMSS_335_09.pdf • Prevención, diagnóstico y tratamiento y referencia oportuna de la enfermedad renal crónica temprana en pacientes menores de 18 años. Consejo de Salubridad General. http://www.cenetec.salud.gob.mx/descargas/gpc/CatalogoMaestro/SS_188_13_PxDxyTxERCMenores_de_18a/GRR188.pdf • Renal Health Program Standards (Normas de Programas de Salud Renal). Ministerio de Salud de Bolivia. https://www.minsalud.gob.bo/8-institucional/679-normas-programa-de-salud-renal • Official Mexican Standard NOM-003-SSA3-2010, for the Practice of Hemodialisis. Secretaria de Salud. Mexico. http://www.dof.gob.mx/normasOficiales/4093/Salud/Salud.htm • Certificación de Unidades de Hemodiálisis. Consejo de Salubridad General. Mexico. http://www.csg.gob.mx/descargas/pdf/certificacion-establecimientos/modelo_de_seguridad/uhemodialisis/ED2017-2015-EstandaresHemodialisis-v2.pdf

Table 1. (Continued)

What?	Who?	How?	Links and Examples
Implementation of integrated kidney care	• Policymakers • Regulatory agencies • Insurance providers • Primary and secondary care physicians • Multidisciplinary health care professions	• Training of health care workers • Developing locally appropriate kidney care models • Multidisciplinary and multi-professional care approaches including NPHW involvement as appropriate • Sustainable use of technology • Continuous quality monitoring	• Preparing the Nephrology Workforce for the Transformation to Value-Based Kidney Care-Needs Assessment for Advancing American Kidney Health. https://cjasn.asnjournals.org/content/14/12/1802 • Ong SW, KaushalA, Pariser P, et al. An Integrated Kidney Care eConsult Practice Model: Results from the iKinect Project. Am J Nephrol. 2019; 50(4):262-271. DOI:10.1159/000502602 • Multidisciplinary Team Care May Slow the Rate of Decline in Renal Function. https://cjasn.asnjournals.org/content/6/4/704.long • Interdisciplinary care clinics in chronic kidney disease. https://bmcnephrol.biomedcentral.com/articles/10.1186/s12882-015-0158-6
Sustainability and quality improvement	• National health administration • Budgeting agencies • Insurance providers • Nephrology societies • Patient/ civil society organizations	• Funding assurance and health care coverage • Review mechanisms • Set performance targets and measuring performance • Set up registries • Independent program audits and reiterative refinement • Civil society feedback	• Pradesh A. (2017, June 15). State govt. mulling pension for kidney patients. The Hindu. Retrieved from https://www.thehindu.com • Universal health coverage and chronic kidney disease in India. https://www.who.int/bulletin/volumes/96/7/18-208207/en/ • Toussaint ND, McMahon LP, Dowling G, et al. Implementation of renal key performance indicators: promoting improved clinical practice. Nephrology (Carlton). 2015 Mar;20(3):184-93. doi: 10.1111/nep.12366 • Performance Measurement in Chronic Kidney Disease. https://jasn.asnjournals.org/content/22/2/225 • Mapping outcomes in quality improvement and system design activities: the outcome identification loop and system impact model. https://bmjopenquality.bmj.com/content/bmjqir/8/3/e000439.full.pdf • A Multifaceted Quality Improvement Programme to Improve Acute Kidney Injury Care and Outcomes in a Large Teaching Hospital. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5457974/ • Optimizing patient involvement in quality improvement. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3883095/ • Continuous quality improvement in nephrology: a systematic review. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5121952/ • Effectiveness of Quality Improvement Strategies for the Management of CKD: A Meta-Analysis. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5628709/ • National CKD audit website. https://www.lshtm.ac.uk/research/centres-projects-groups/ckdaudit - welcome • Civil Society and Health. https://www.euro.who.int/__data/assets/pdf_file/0011/349526/Civil-society-web-back-cover-updated.pdf
Outcome measures	• National health administration • National nephrology society • ISN/WHO	• Regular tracking of medical and patient reported outcomes • Publishing registry reports • National and international bench-	• Australia and New Zealand Dialysis and Transplant Registry. https://www.anzdata.org.au/anzdata/ • Canadian Organ Replacement Register. https://www.cihi.ca/en/canadian-organ-replacement-register-corr • Dialysis Outcomes and Practice Patterns Study (DOPPS); (Australia, Belgium, Canada, France, Germany, Japan, Italy, New Zealand, Spain, Sweden, UK, USA). https://www.dopps.org/ • European Renal Association - European Dialysis and Transplant Association (ERA-EDTA), Europe. https://www.era-edta.org/en/ • Finnish Registry for Kidney Diseases Finland. https://www.muma.fi/liitto/suomen_munuaistautirekisteri/finnish_registry_for_kidney_diseases • Scottish Renal Registry. https://www.srr.scot.nhs.uk/ • United Kingdom Renal Registry. https://renal.org/about-us/who-we-are/uk-renal-registry • United States Renal Data System (USRDS) USA. https://www.usrds.org/

Table modified from Tonelli M et al. (2020)[40]

Abbreviations: CKD = chronic kidney disease; CHERISH = CKD Health Evaluation Risk Information Sharing; ESKD = end-stage kidney disease; KDIGO = Kidney Disease: Improving Global Outcomes; KRT = kidney replacement therapy; HTA = Health Technology Assessment; NCD =non-communicable disease; WHO =World Health Organization; ISN = International Society of Nephrology; NPHW = non-physician health care workers; NICE = National Institute for Health and Care Excellence

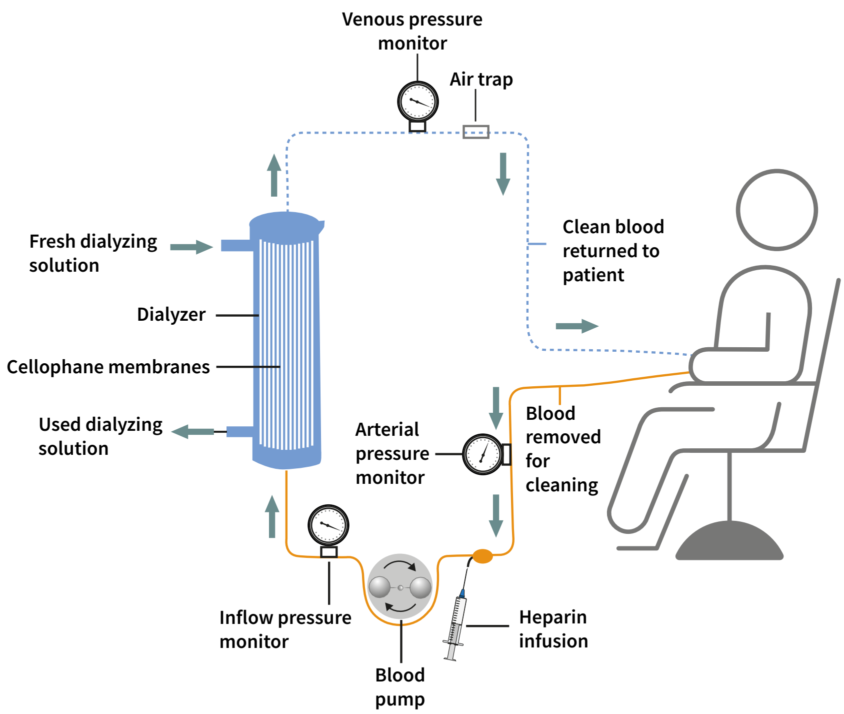
CHAPTER 4

DIALYSIS

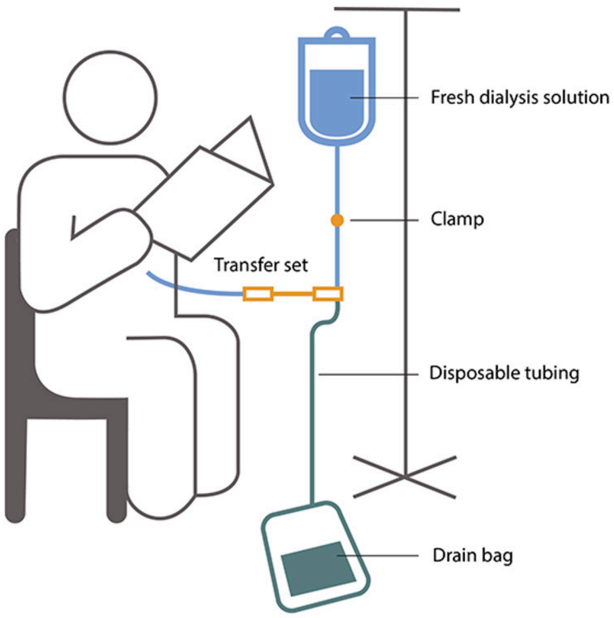
A. DIALYSIS MODALITIES

All patients with kidney failure, and those with severe AKI, are potential candidates for dialysis treatment. Dialysis may be delivered in two forms, HD and PD.

HD (**Figure 8**) requires a specialized machine to 'clean' the blood for 4-5 hours every 2-3 days, and a vascular access (catheter, arteriovenous fistula or graft) to circulate blood from the patient through the machine and back. HD can be delivered in dialysis centers or can be done at home by trained patients or their caregivers.



The hemodialysis blood circuit: A dialysis machine pumps blood from the patient, through disposable tubing, through a dialyser, or artificial kidney, and back into the patient. Waste solute, salt and excess fluid is removed from the blood as it passes through the dialyser.



Reproduced from the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.[55] https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/peritoneal-dialysis

PD (**Figure 9**)[55] is a home therapy which involves the exchange of dialysis fluid through a catheter placed in the abdominal peritoneal cavity 3-4 times a day, performed either manually or by an automated machine during the night. This can be done by patient or a caregiver.

Most patients with kidney failure are suitable for either modality of dialysis (Box 4). Trained personnel, specific supplies, and a sterile environment are required for placement of vascular (for HD) or PD access. HD requires reliably maintained machines, a reliable supply of electricity, a safe water supply, and consumables. PD requires fresh dialysate bags and appropriately sized tubing if doing manually and requires electricity and cycling PD machines if automated. Dialysis staff and patients require education and training for both HD and PD.

Box 4. Medical contraindications to PD and HD[56]

Contraindications to PD:

- *Absolute:* documented ultrafiltration failure, severe inflammatory bowel disease, acute active diverticulitis, abdominal abscess, active ischemic bowel disease, multiple abdominal adhesions, gastroschisis.
- *Relative and/or remediable:* severe malnutrition, obesity, ileostomy or colostomy, multiple hernias, abdominal surgeries, impaired manual dexterity, blindness, unstable or lack of housing, poor personal hygiene, depression, ventriculoperitoneal shunt, severe active psychotic disorder*, marked intellectual disability.*

Contraindications to HD:

- *Absolute:* complete lack of vascular access, severe intolerance to procedure (hemodynamic instability), non-availability of appropriately sized HD circuits (for small children).
- *Relative and/or remediable:* difficulty with transport, coagulopathy.

PD possible if provided by a caregiver

Dialysis does not replace all the functions of normal kidneys, and patients remain at risk for complications including cardiovascular disease, mineral and bone disease, infections, and problems related to dialysis access. All of these may necessitate hospitalizations and additional procedures, compounding morbidity and costs, and increasing mortality risk.[57]

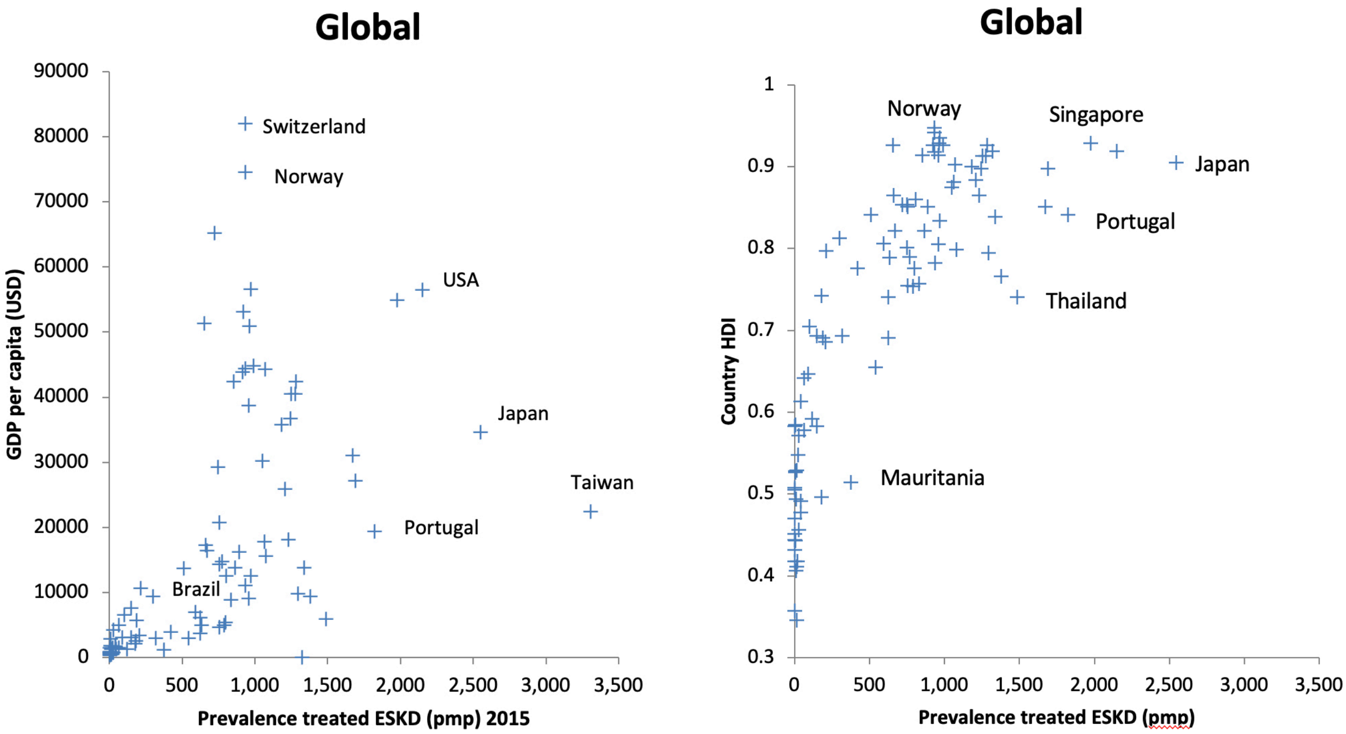
B. AVAILABILITY AND ACCESS TO DIALYSIS

HD has become technically available in almost all countries in recent years.[58] Multiple barriers, however, prevent universal access to this life-saving treatment in LMIC. HD is costly and requires technical expertise and a relatively sophisticated infrastructure for successful, safe, and sustainable implementation. PD, on the other hand, is less resource intensive, with lower capital costs, but implementing PD programs may also be associated with some challenges (discussed later).

In many lower resource settings, dialysis has been predominantly provided by the private sector with limited governmental oversight, and access tends to be driven by market forces.[59] In recent years, public funding for dialysis has increased in many countries, with the dialysis centers set up and run by private providers (public-private partnerships (PPP) model, see Chapter 11).

The association between prevalence of dialysis and wealth of a country, as measured by its gross domestic product (GDP) per capita is linear, with a plateau above a certain level (approximately USD 15 – 20,000 GDP per capita)[60,61] (Figure10). Beyond this, the kidney failure prevalence likely reflects the true disease prevalence rather than the ability to access KRT.[60] A similar relationship exists between the prevalence of dialysis and the human development index (HDI). There are notable exceptions, however, as some countries with lower GDPs do provide universal access to KRT.[62]

Figure 10. Prevalence of treated kidney failure (pmp) relative to (a) gross domestic product (GDP) per capita and (b) human development index, 2015*



**Data compiled from USRDS, World Bank: https://www.usrds.org/reference.aspx; https://data.worldbank.org/indicator/ny.gdp.mktp.cd?end=2015&start=1960; http://hdr.undp.org/en/composite/trends and adapted with permission from Luyckx VA, Figures 3 and 4. From Ethical Challenges Relating to Provision of Sustainable Renal Care in Resource Limited Settings – Focus on Sub-Saharan Africa. 2019, University of Zurich, Faculty of Medicine.[63]*

Abbreviations: USD = United States dollars; pmp = per million population; GDP = gross domestic product; ESKD = end-stage kidney disease; HDI = human development index

Given the growing demand, policymakers in many LMIC have either already announced, or are actively considering, provision of dialysis services. Such decisions have implications for the entire health system and require transparent implementation strategies for the delivery of equitable, safe, and sustainable care.[3]

In addition to the treatment of kidney failure, the availability of dialysis may improve outcomes among patients with severe AKI, as kidney function can recover in the majority of such patients if supported with temporary dialysis. In 2013, it was estimated that every year 13 million people develop AKI around the world, of whom 1.7 million die, most in LMIC.[64] If a dialysis program is set up for patients with kidney failure, the existing service should encompass all patients (adults and children) with AKI.[5,65-67]

System-level implications for stakeholders considering provision of dialysis in low-resource settings are shown in Box 5.

Box 5. Considerations that should be addressed before starting dialysis services

- Is there a societal/political consensus that dialysis should be provided to those who can benefit from it?
- How would dialysis be funded sustainably?
- If dialysis cannot be provided for all, how will access be made equitable?
- Have the opportunity costs - for the health system, for other disease programs, for the spectrum of kidney health and disease – been considered if dialysis were to be provided by the state?
- How can dialysis be provided within the context of integrated care for kidney disease?
- What are the most efficient methods of dialysis delivery within the limits of available resources?
- Has an assessment of cost and feasibility been done to determine which form of dialysis is optimal in the local context?
- How to develop and ensure adherence to acceptable quality standards?
- How to monitor and report outcomes of dialysis consistently?
- If dialysis is not provided or chosen, what alternative support (e.g. conservative kidney management) is in place?

Setting up safe, sustainable, and equitably accessible dialysis services requires planning of service distribution, preferred modality, patient eligibility, and considerations of the funding model.[3] Planning must be based on reliable local epidemiologic data. A trained health workforce is necessary to deliver quality care. Consistent access to dialysis equipment and supplies, medications and diagnostics is essential for safe and effective quality dialysis provision. Establishing practice standards that resonate with the local context, ongoing monitoring and evaluation, and transparent reporting are all important to determine health system impact, acceptability, clinical quality/effectiveness, and to determine outcomes and perform global benchmarking.

Support for dialysis services should be provided in the context of a comprehensive approach to prevention, early detection, and early treatment of kidney disease with the long-term goal of reducing the burden of kidney failure.

5

CHAPTER 5

REQUIREMENTS FOR SETTING UP DIALYSIS SERVICES

Dialysis is a complex process requiring medical, technological, and administrative expertise as well as sustainable financing, and adaptability within local contexts (Box 6).

Box 6. Requirements for a sustainable, safe, and high-quality dialysis program

- Clear and transparent eligibility criteria.
- Availability of adequately trained staff (clinicians, nurses, technicians, other health professionals).
- Services to establish and sustain dialysis access (for HD and PD).
- Reliable infrastructure, machines, water (for HD) and supply of other utilities as well as technical support.
- Ability to access service (for HD - transportation, location of dialysis centers).
- Adherence to validated standard operating procedures for all aspects of care.
- Access to reliable diagnostic services.
- Access to affordable quality medications.
- Appropriate monitoring, evaluation, and quality assurance.
- Availability of hospital support to manage other health conditions and kidney supportive care.
- Sustainable funding model.

Dialysis should be integrated within the health system processes to facilitate the continuous tracking of disease burden, quality assurance and outcomes, promote process efficiencies, and identify unintended consequences. Service planning must anticipate growth, with the likelihood of a progressive increase in demand for dialysis over time.[50,68]

Planning dialysis

Early planning and transparent policy decisions are key to the development of sustainable and equitable programs that are able to consistently deliver high quality care to all populations (including children). Once a decision to provide dialysis has been made, the most appropriate local mix of therapies (HD and PD) should be determined by local data on costs and feasibility and supported by a sustainable financing strategy and transparent deliberation on the extent of service coverage and acceptability to the population.

Governments may feel pressured to start dialysis provision due to extraneous factors – for example, pressure from a donor agency or the private sector - without the presence of all factors that would ensure sustainability (see examples in Box 7 and Box 8). In both of these instances, the focus was on HD without any consideration of alternative modalities.

Box 7. Case Study – Kenya

As a result of lobbying by dialysis patient groups and the Kenya Renal Association, the Kenyan government announced the establishment of at least 1 HD unit with 5 machines each in each of the country's 47 counties. This task involved the government creating new structures in regions that did not have the necessary infrastructure. A number of barriers to the delivery of consistent, safe, and effective care were identified after the service was introduced.[69]

- Long distances for patients to travel to a dialysis facility.
- Insufficient capacity –dialysis frequency reduced, patients had to be turned away.
- No referral policies, limiting provision of planned dialysis.
- Patients requiring urgent dialysis through temporary catheters.
- Lack of expertise in vascular access creation and maintenance leading to complications (infection, thrombosis).
- Poor access to essential medications, especially erythropoietin and iron.
- Out-of-pocket expenses for routine laboratory tests (including hepatitis B, C, HIV).
- Lack of support for pediatric dialysis, kidney transplants and peritoneal dialysis.
- Human resource shortage (dialysis engineers, nurses, vascular surgeons).

Box 8. Case Study – Analysis of a HD Center in a Low-income Country

The Ministry of Health (MOH) of country XX* requested an evaluation by the WHO and the ISN of its planned support to initiate a dialysis service, after a donor had contributed around 1 million dollars to building a dialysis unit in the capital city. The funding was committed exclusively to the creation of infrastructure and only covered the costs of building the unit, including a state-of-the-art water treatment facility and 32 dialysis machines. Dialysis supplies were to be supported for 2 years only. No further support (e.g. for staff training, long-term supplies) was committed. A SWOT (strengths, weaknesses, opportunities, threats) analysis was performed after a 3-day country visit.

Strengths

- Meets a clinical need.
- Support from MOH.
- Donor support for start-up phase.
- Support from WHO, professional societies.
- Good infrastructure.
- Easy communication in an international language (English).
- Presence of a national NCD strategy (although not implemented because of resource limitations).

Weaknesses

- Dependence on donor support.
- Sustainability unclear.
- Human resource shortage.
- No link with hospital or other dialysis centers.
- Inequitable distribution of dialysis services across the country.
- NCD care not part of essential health service package.
- No mechanism for pre-dialysis care.
- Weak health information system, no data on kidney disease burden.
- Lack of quality assurance culture.
- Lack of governance.
- No plan for developing an integrated KRT program.
- Patient eligibility criteria not defined.

Opportunities

- Learn locally from existing private or non-governmental organization (NGO)-run centers.
- Explore sustainable integration with NCD strategy, including CKD prevention.
- Could grow deliberately and carefully if initial limitations transparently communicated and careful monitoring and evaluation in place.
- Training, research, and capacity building through ISN programs.
- Use IT for infrastructure strengthening, e.g. inventory management, clinical data, etc.
- Extend to peritoneal dialysis.
- Leverage an existing diaspora network for training.

Threats

- Vertical program.
- Weak health system.
- High costs, sustainability not defined.
- Demand may exceed capacity.
- Supply chain/procurement issues.
- Competition between local providers.
- Multiple suppliers, independent procurement.
- Conflicts of interest, perverse incentives.
- High risks of infections (likely frequent use of temporary dialysis catheters).

*Country not named for confidentiality.

Because of the high cost and long duration of care, the development of sustainable dialysis programs requires government support and funding commitments as well as the coordinated involvement of multiple stakeholder groups and changes in laws/practice. Box 9 provides an example of such a process culminating in the successful development of near-UHC for dialysis services in Malaysia.[69]

Box 9. Case Study – Malaysia: Near-UHC for Dialysis[69]

Nephrology services in Malaysia began in the 1960s. Alongside rapid economic development, the number of dialysis centers rose from 205 in 2000 to 758 in 2014. The 2016 dialysis incidence and prevalence rates of 261 and 1,295 pmp, respectively, were comparable to developed countries in the region.

How did Malaysia achieve near-UHC for dialysis?

Governance

- Strong collaboration was established between government, professional societies, private industry, NGOs, and local manufacturers.
- Health care laws were modified to enable organizations to start HD.
- PPP were a major departure from earlier policies.
- Dialysis outsourced to private providers by the Public Service Department, Social Security Organization (SOCSO), and Zakat (a kind of tax).

Financing and procurement

- Public financing through taxation and/or social health insurance (e.g. Social Security Organization, SOCSO), is the dominant form of financing.
- The MOH provides funding for the development and operation of dialysis centers, especially in rural areas. The funding of dialysis was one of the first mixed public, private, and non-governmental organization financing operations in Malaysia.

Training of the dialysis workforce

- Certified training programs were set up for nephrologists, renal nurses, and allied health staff.

Ensuring Quality Service Delivery

- Practice Guidelines for kidney replacement therapy and Hemodialysis Quality Standards were developed: (https://www.msn.org.my/msn/Doc/PublicDoc_PB/National_Haemodialysis_Quality_Standards_2018.pdf).

Health informatics

- A National Renal Registry was set up as a collaboration between the MOH and the Malaysian Society of Nephrology.

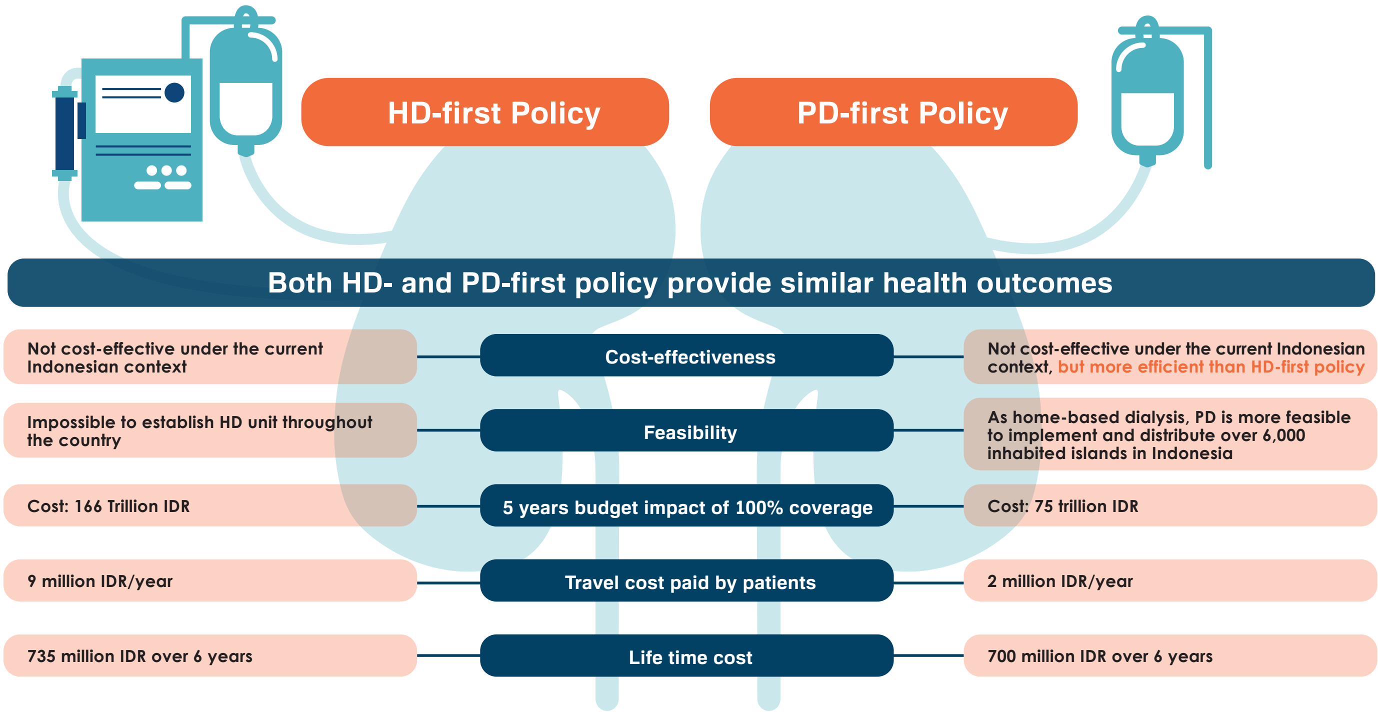
Integrated strategies for CKD

- Given the projected increase in the number of patients, kidney failure prevention initiatives were begun. These include kidney testing in primary care settings, the development of clinical practice guidelines and an operational policy for nephrology service as well as public awareness programs.

A. HEALTH TECHNOLOGY ASSESSMENT (HTA)

HTA is a multidisciplinary process of systematic evaluation of properties, effects, and/or impacts of any technology (such as dialysis), with the goal of evaluating the social, economic, organizational, and ethical issues related to the intervention.[70] This process includes considerations of costs (including out-of-pocket costs), cost-effectiveness, feasibility, and acceptability. An example of an HTA conducted by the Health Intervention and Technology Assessment Program (HITAP) in Thailand, regarding dialysis in Indonesia (Figure 11) can be found at the following link: http://www.hitap.net/en?s=dialysis.[71]

Figure 11. Health Technology Assessment for dialysis for patients with kidney failure in Indonesia



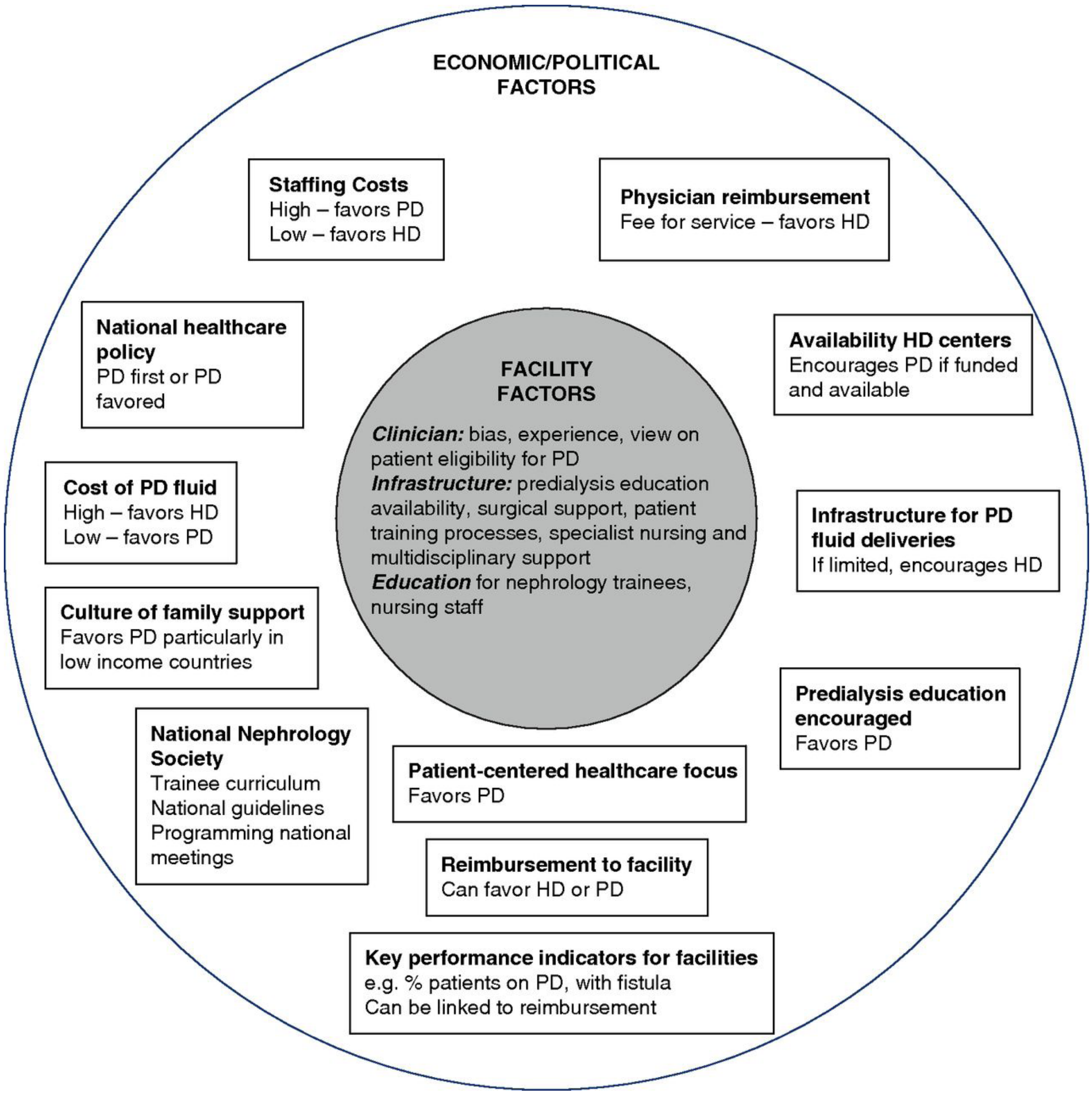
Reproduced from Khoe LC, et al. From Policy Brief. Health Technology Assessment for Renal Dialysis for End-Stage Renal Disease in Indonesia. 2016.[71] Creative Commons CC-BY-NC-NC license.

Abbreviations: HD = hemodialysis; PD = peritoneal dialysis; IDR = Indonesian Rupiah

An example of the range of factors that may influence options, access, and incentives to health services and should be considered for inclusion in HTAs is shown in Figure 12.[72] Because PD is the recommended form of dialysis in most settings, HTA will not be required in all jurisdictions. However, HTA may be useful when barriers to PD are especially pronounced, such as in jurisdictions where PD is costlier than HD.

ECONOMIC/POLITICAL FACTORS

Figure 12. Dialysis modality distribution is determined by factors at individual facility level and factors related to the economic and political environment



Used with permission of the Clinical Journal of American Society of Nephrology, Figure 1 from Brown EA. Influence of Reimbursement Policies on Dialysis Modality Distribution around the World. 2019;14:10–12;[72] permission conveyed through Copyright Clearance Center, Inc.

Abbreviations: PD = peritoneal dialysis; HD = hemodialysis

B. OPERATIONAL PLANNING AND DIALYSIS SERVICE DELIVERY

Service planning

Planning of dialysis should take a health systems approach, using the WHO Building Blocks (Table 2).[73]

Table 2. The relevance of WHO health systems approach to planning of dialysis services

Building Block	Relevance and considerations
Governance	Health technology assessment, transparency, oversight and accountability, integration, robust referral systems, procurement strategies.
Financing	Infrastructure, consumable, human resource, sustainability, reduction of out-of-pocket expenditure.
Health information systems	Surveillance of local kidney disease burden, kidney disease and treatment registries, outcome tracking, inventory management.
Workforce	Training, continuing education, accreditation, fair remuneration, professional development.
Essential diagnostics and technologies	Medication to manage medical problems and complications, appropriate laboratory testing (patient, water), functioning dialysis machines, dialyzer reuse and water treatment systems.
Service delivery	Accessible, equitable, of acceptable quality, and safe dialysis delivery.

Abbreviations: WHO = World Health Organization

Planning should start with an assessment of needs in terms of patient numbers and geographic service location based upon local and/or national epidemiological data, comprehensive and realistic cost estimates for program set-up, and running/maintenance costs. See Annex 1, Tables C and D for lists of basic diagnostics and medicines for kidney care, Annex 1, Tables E and F for PD supply list templates (adult and pediatric) and Annex 1, Tables G and H for HD supply list templates (adult and pediatric). Financial sustainability must be determined up front. Countries should determine a sustainable financing model best suited to local context (see Chapter 11).

Staffing requirements (including physicians, nurses, technicians, and assistive personnel) and other support services (sanitation, security, maintenance, etc.) should be determined to ensure smooth daily operations. Access to other services, e.g. dieticians, social workers, psychologists, vascular access surgeons, radiologists, etc., should be incorporated as per local context and availability.

Tenders, purchasing, and maintenance contract negotiations should involve active stakeholder engagement and consider strategic purchasing, distribution networks, supply chain, inventory management, etc. Attention should be paid to developing systems to track items, monitor stocks, establish efficient distribution networks, improve efficiencies, and minimize risks of corruption.

Pre-dialysis preparation (individual decision-making and support)

Pre-dialysis care by a nephrologist has many advantages with the following standing out: 1) it allows for the slowing down of the progression of kidney disease by delaying the time of admission to dialysis, at a very low cost, 2) it allows the development of a coordinated KRT plan.

Optimal preparation (Box 10) includes timely discussion of treatment choices and preparation such as creation of vascular access for HD, peritoneal catheter insertion for PD, or a pre-emptive transplantation (Box 11). However, this requires the availability of CKD care facilities. In contrast, late presentation limits treatment options, with HD started through a vascular catheter as an urgent life-saving treatment being the most frequent option.

Box 10. Suggested pre-dialysis referral plan for patients with CKD

- All patients with CKD should have access to a CKD service to plan for the initiation of dialysis.
- Referral to a nephrologist with dialysis facilities is recommended once the eGFR falls below 30 ml/min per 1.73m^2 (KDIGO stage G4).*
- It is recommended that dialysis planning (including counselling) starts 1 year prior to expected initiation.[74]
- Dialysis is generally initiated when a patient becomes symptomatic or develops a biochemical indication (e.g. hyperkalemia). Typically, symptoms develop at eGFR < 10 ml/min per 1.73m^2.

**Earlier referral may be considered in specific situations, such as children.*

Abbreviations: G4 = grade 4

Box 11. Considerations in dialysis planning

1. Will the person benefit from dialysis intervention (survival, quality of life)?
2. Is the patient eligible to receive dialysis?
3. Is dialysis capacity available? Is there a waiting list?
4. How will the dialysis be paid for? Will out-of-pocket expenditure be required for any component (medication, investigations, transportation, etc.)?
5. Is kidney transplantation available (locally or elsewhere) and can it be considered?
6. Is a choice of dialysis modalities available? If yes, are they explained and offered to everyone?*
7. Can a dialysis access be created pre-emptively (arteriovenous access for HD or Tenckhoff catheter placement for PD) to avoid use of HD catheters or urgent PD starts?
8. If a decision is taken not to proceed with dialysis, is there adequate conservative kidney management in place?

** Consider using a dialysis decision aid, e.g., https://www.kidneyresearchuk.org/DialysisDecisionAid*

C. PEDIATRIC CONSIDERATIONS

Hemodialysis

In most developing countries, children receiving HD will be in adult units. However, HD in young children is especially challenging and requires skilled nursing care. As such, adult units abstain from providing dialytic support to young children and toddlers. See Table 5 for practice guidelines for pediatric HD.

The choice of vascular access depends on local expertise, patient's size, time available before dialysis, and the presumed waiting time before transplantation. Since expertise for vascular surgery is limited in developing countries, central venous catheters continue to be the most commonly used access in children.[75]

Peritoneal dialysis

In addition to the child's age, the cost of the dialysis bag dictates the prescription of PD, with families in developing countries often electing to use fewer bags than recommended. The non-availability of dialysis bags of pediatric capacity is also a hindrance to the optimal prescription of PD in children.[75] Automated PD is ideally suited for younger children, but is expensive. It allows for night-time PD with dialysis-free period during the day, allowing for schooling and other activities. Furthermore, manual Continuous Ambulatory Peritoneal Dialysis (CAPD) has risks of peritonitis and is associated with parental burn-out in the long run.

Time to initiate dialysis

Although the Kidney Disease Outcomes Quality Initiative (KDOQI) guideline[76] published in 2006 suggested that dialysis should be considered when eGFR falls to < 14 ml/min/1.73m^2 and recommended when eGFR falls further to < 8 ml/min/1.73m^2, three more recent national and international guideline bodies indicate that there is no benefit from starting dialysis early in the absence of symptoms. The United Kingdom's National Institute for Health and Care Excellence (NICE),[77] the Canadian Society of Nephrology,[78] and the 2015 KDOQI guideline for HD adequacy[79] have all suggested that dialysis is initiated at an eGFR of 5 to 7 ml/min/1.73m^2 if there are no uncontrollable uremic symptoms, biochemical abnormalities, or fluid overload. Three studies from the United States Renal Data System (USRDS)[80-82] and the European Society of Pediatric Nephrology (ESPN) registry,[83] also conclude that there is no benefit from starting dialysis early.

Taken together, these registries have examined the association between eGFR at initiation of chronic dialysis and clinical outcomes in over 21,000 children. Of almost 10,000 incident dialysis patients aged 1 to 17 years in the USRDS registry (1995-2016), a higher eGFR at dialysis start was associated with an increased risk of death.[81] Mortality risk increased in those starting dialysis with eGFRs < 5 and ≥ 12 ml/min/1.73m^2, with a greater risk in patients 6 years and older.[80] Studies from the USRDS and the ESPN registry also confirmed these findings. The median eGFR at dialysis start is currently 8.2 and 7.8 mL/min/1.73 m^2 for children in Europe[84] and the United States[82] respectively, with a trend towards an earlier start of dialysis reported in the USRDS registry.

Choice of dialysis

The choice of modality depends on the child's age, size, comorbidities, residual kidney function, available expertise, resources, family structure, and parents'/caregivers' preference.[85,86] PD is the preferred dialysis modality for children when transplantation is delayed or impractical. PD is child friendly, providing less diet restrictions and the continuation of scholastic and physical activities. The choice of dialysis modality also depends on the practices and capacity of the adult nephrology dialysis units in the region.[87]

Impact on family, socialization, education

Where available, a social worker or a child psychologist should screen for psychological concerns.[88]

D. PATIENT SELECTION FOR DIALYSIS

Criteria used to allocate health resources such as dialysis are often intended to promote greater utility of outcomes, interpreted usually as maximizing therapeutic gains (improvements in survival time and quality of life) from a given investment of resources.

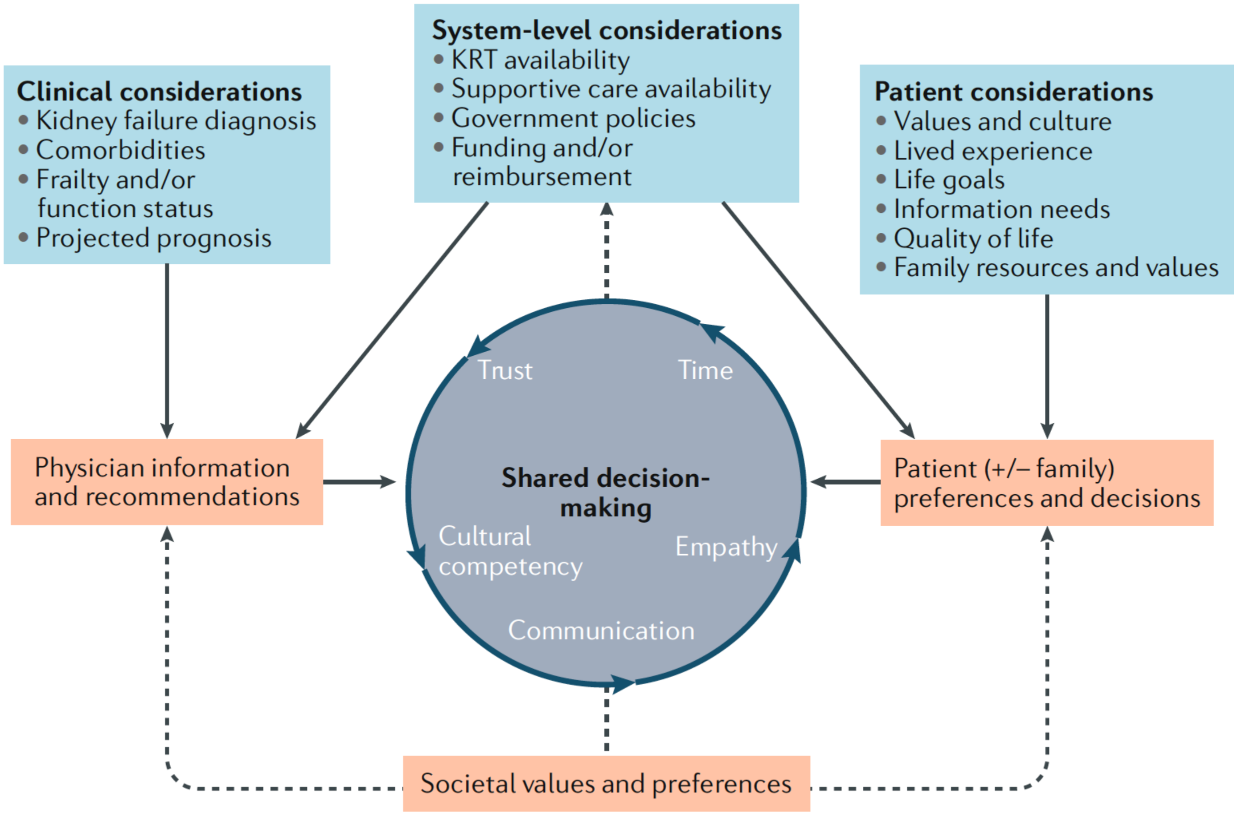
In the wealthy countries, KRT is generally available to those who can benefit from it. In countries where resources are constrained, however, offering universal KRT may not be feasible. In such a situation, decision-making around who gains access to this life saving modality may be contentious. Where inequalities of access are unavoidable, justice and equity require that fair and transparent criteria and procedures governing access are established by legitimate authorities.

In South Africa, for example, only patients who are eligible for a kidney transplantation can be accepted on maintenance dialysis programs in the public sector. Once on dialysis, patients must accept a transplant when offered. This policy has the advantage of providing more patients with the opportunity for dialysis by effectively reducing the number of long-term dialysis patients to match the available capacity. These guidelines were developed after extensive consultation with stakeholders, including patient representatives and ethics experts.[89] Patients who are not eligible for dialysis are offered kidney supportive care. This approach has been supported by the South African Constitutional Court.[90]

Shared decision-making and decision to withdraw or withhold dialysis[91-93]

All patients should be made aware of their choices within the local policy/legal framework and receive support to make an informed decision based on the principles of shared decision-making (Figure 13).[94] This process should be documented for all patients. Decision aids are available to assist patients in informed decision-making.

Figure 13. Shared decision-making in the context of treatment choices for kidney failure



Reprinted by permission from Springer Nature: Martin DE et al. Figure 2. From Ethical challenges in nephrology: a call for action. Nat Rev Nephrol. 2020.[94]

Abbreviations: KRT = kidney replacement therapy

Withdrawal of dialysis (due to medical or non-medical reasons) can be considered at any time during the treatment. In certain situations, a prespecified time-limited trial of dialysis can be offered following which the desire to continue dialysis can be reassessed. In patients without decision-making capacity, if the capacity for informed consent cannot be restored, shared decision-making should be sought from an advance directive or health care proxy. All patients who choose not to start, or withdraw from, dialysis should be offered conservative kidney management (see Chapter 10).

CHAPTER 6

SETTING UP DIALYSIS PROGRAMS

Once a policy decision to set up a dialysis program has been made, detailed planning is required to address those issues related to governance, infrastructure and standards, payment issues, health information systems, human resource needs (including training), capacity for interventions, laboratory facilities and protocols for service delivery. Table 3 summarizes these issues.

Table 3. Requirements for setting up a Dialysis Program

Governance, Legislation and Credentialing

- Determine center location, density, and size to optimize access.
- Establish standards for training and accreditation of all cadres of dialysis workers.
- Establish standards for Quality Assurance, Quality Control and Quality Improvement.
- Determine referral pathways.
- Establish norms for credentialing and oversight of dialysis centers.
- Develop standardized framework purchasing agreements.
- Ensure warehousing and supply chains.
- Ensure technical support for dialysis machines, water treatment and re-use (for HD).
- Establish and monitor safety standards, testing, and reporting.
- Develop consensus guidance on patient eligibility.
- Establish formal grievance redressal process.
- Establish community-based monitoring boards.

Financing

- Determine degree of government financing or support.
- Establish a funding mechanism for all aspects of dialysis, including procurement, staffing, and overheads to ensure equity of access, quality, and sustainability.
- Financing should include ancillary services – e.g. reliable and sustainable access to quality diagnostics and medications, nutritional and psychological support, transport, etc.
- Reliance on external funding, donors, and charities is not sustainable.[95]

Health Information systems

- Establish national or regional registries to report outcomes and audit dialysis units.
- Publish annual reports.
- Link reimbursement to reporting.

Workforce requirements

- Physicians/nephrologists with expertise in all dialysis modalities as well as conservative kidney management.
- Medical professionals skilled in placement of HD vascular access, PD catheter insertion, and management of access-related issues.
- Nursing and support staff.
- Backup services to manage complications.
- Access to social workers, psychologists, dieticians.
- Develop locally appropriate models of task shifting and task sharing between nephrologists and general physicians; surgeons and nephrologists; and physicians and physician extenders.

Training

- Clearly defined curricula and training adapted to local context.
- Competency-based training, with opportunities for professional development.
- Use tertiary care facilities, NGOs, and academic international links (e.g. ISN Sister Renal Center Program, Educational Ambassador Program) to broaden educational opportunities.

Required capacity for interventions and procedures

- Temporary and permanent HD catheter placement.
- PD catheter placement.
- Arteriovenous fistula or graft placement.
- Management of access (vascular and peritoneal) complications.
- For transplantation needs see Chapter 9.

Laboratory services

- Clinical chemistry for assessment of patient health and dialysis quality.
- Microbiology service for blood and peritoneal fluid cultures.
- Dialysate water analysis.

Protocols for service delivery

- Set up and specification of dialysis units, clinics.
- Inventory management, including checklists for HD and PD supplies, basic and essential medications.
- Clinical protocols for all aspects of HD, including complication, and emergency management.
- Clinical protocols for PD - routine, complication, and emergency management.
- Protocols for infection control and management for HD.
- Protocols for transplant preparation and management.
- Protocols for quality assurance.
- Protocols for disaster/crisis preparedness.

Abbreviations: HD = hemodialysis; PD = peritoneal dialysis; ISN = International Society of Nephrology; NGOs = non-governmental organizations.

Detailed considerations for the operation of dialysis services are summarized in Boxes 12, 13, and 14. Table 4 provides the relative advantages and disadvantages of different dialysis delivery mechanisms. As services are being set up, robust attention needs to be given to the maintenance of the equipment and set up. Purchasing the equipment without long-term maintenance planning is a recipe for failure.

Table 5 lists accessible guidelines, tools, and resources for optimal clinical care of patients with kidney failure. Table 6 provides a comprehensive list of requirements for safe and quality dialysis care and can be used to develop preparedness checklists.

The components included in these tables should be prioritized based on local contexts. Some components, however, are essential, whereas others are optional. Omitting any of the essential components will adversely affect service quality. Certain shared competencies (e.g. microbiology, radiology, dieticians, social workers, machine technicians, etc.) have additional value beyond dialysis provision.

Box 12. Essential requirements for HD

Equipment and Supplies

- Personal protective equipment for the care team.
- Resuscitation equipment.
- Patient monitoring equipment for vital signs and other assessments, e.g. glucose.
- Weighing scales that are recalibrated and maintained.
- Dialysis beds/chairs that can be positioned to treat hypotension or arrests.
- Reliable and safe HD machine with volumetric control and ability to do bicarbonate dialysis.
- HD consumables such as dialyzers, tubing, needles and medical surgical supplies.
- Medications and treatments for the provision of dialysis as well as prevention and management of intra-dialytic complications.

Environment

- Water treatment system compliant with local regulations and able to generate water as per Association for the Advancement of Medical Instrumentation (AAMI) or European standards (https://www.aami.org/newsviews/browsetopics.aspx/Dialysis?id=268).
- Waste disposal.
- Isolation area for Hepatitis B /COVID-19 positive patients.
- Adequate storage to safely accommodate medications, dialysis supplies, machines and additives.

People

- Regular visits by a physician/nephrologist.
- Trained dialysis personnel such as nurses, technicians, patients, families and/or assistive staff or volunteers and those in charge of environmental hygiene.

Support Services

- Access to hospital services.
- Water testing services.
- Ability to get vascular access and resolve access related problems.
- Access to basic diagnostic (lab and imaging) investigations to monitor patient health and dialysate quality.
- Reprocessing services including appropriate area and equipment for dialyzer processing for reuse (if applicable).
- Ability to perform regular preventative maintenance of all equipment.

Guidelines and Documents

- Education materials for patients.
- Operational protocols for all aspects of dialysis (including infection prevention).
- Referral protocols.
- Information systems and ability to measure and track outcomes.

Box 13. Essential requirements for PD

Equipment and Supplies

- Personal protective equipment for the care team.
- Resuscitation equipment.
- Patient monitoring equipment for vital signs and other assessments, e.g. glucose.
- Weighing scales that are recalibrated and maintained.
- Dialysis chairs.
- PD Cyclers.
- PD consumables such as transfer sets, mini caps, and medical surgical supplies.
- Medications and treatments for management of common PD problems such as antibiotics, heparin.
- Link with efficient distribution network to ensure regular access to PD supplies.

Environment

- Waste disposal.
- Adequate storage to safely accommodate medications, and supplies.
- Patient's home environment that can be adapted to suit treatment needs.

People

- Trained PD nurses.
- Access to nephrologist.
- Access to nutritionists, psychologists, physical therapists, assistive staff or volunteers and those in charge of environmental hygiene.
- Patients:
    - Motivated, persistent
    - Patient/caregiver ability to identify changes in PD effluent
    - Physical ability to participate in PD either alone, with assistive tools and/or family or caregiver support.

Support Services

- Access to hospital services.
- Access to backup HD services.
- Water testing services.
- Ability to get peritoneal access and resolve access-related problems.
- Access to basic diagnostic (lab and imaging) investigations to monitor patient health and dialysate quality.

Guidelines and Documents

- Education materials for patients.
- Operational protocols for all aspects of PD (including infection prevention).
- Referral protocols.
- Information systems and ability to measure and track outcomes.

Box 14. PD Nurse competency

- Discussion of PD modality selection.
- Care of PD catheter (newly inserted, established, buried, prevention and management of complications).
- Exit site management (dressing, infection prophylaxis, cautery).
- Implementation of prescription including treatment, glucose, selection and composition of solutions, timing, number of hours volume, solution warming and number of exchanges, target weight.
- Equipment management (cycler, assistive devices).
- Prevention, identification and management of complications of PD (fluid volume imbalances, ultrafiltration failure, metabolic imbalances, infection, membrane failure, leaks, hemoperitoneum, hernias, alterations in gastrointestinal function).
- Patient and family education on all aspects of PD.

Table 4. Potential advantages and disadvantages of different dialysis delivery models

Type and location of units	Advantages	Disadvantages
Hospital associated hemodialysis unit	Overheads costs lower Good for complex patients, emergencies, back-up Easy access to medications	Access may be challenging Less individualization of care Possible exposure to multi-resistant germs in hospitals
Free-standing/satellite hemodialysis unit	Accessibility Reduces pressure on hospital service Better individualization of care	Careful planning and investments required to ensure capability to cope with complexity, emergencies Doctors not necessarily always physically present on site Finding trained staff may be challenging, especially in remote locations
Home hemodialysis	Less medicalization of therapy Individualized therapy performed by patient Lower staffing costs Allows greater variety in diet and fluid Similar health outcomes as transplant for some patients Patients more able to participate in pre-dialysis life such as work Frequency can be adjusted Sense of control	Needs appropriate home infrastructure, electricity, running water Stable motivated patient, good health literacy One machine for one patient
Peritoneal Dialysis	Lower costs Less medicalization of therapy Individualized therapy performed by patient Patients mobile and independent (more so with use of cycler) Patients more able to participate in pre-dialysis life such as work Can be done with minimal infrastructure Can be followed up remotely Better quality of life More continuous and physiological	Needs appropriate home conditions (cleanliness, storage of solutions) Stable patient, able to follow instructions, manual dexterity or has a caregiver with these abilities Patients may find self-care challenging, miss communal environment of hemodialysis units Requires back-up hemodialysis if peritoneal dialysis interrupted (catheter issues, abdominal surgery, etc.)
Portable hemodialysis	Patient independence	High tech, high cost Not yet available at scale.

Table 5. Examples of consensus guidelines from various kidney and professional associations to address different aspects of care of patients with CKD

Topic	Organization	Year	Link	Comment
Clinical guidelines for CKD and kidney failure				
CKD evaluation and management	Kidney Disease: Improving Global Outcomes (KDIGO)	2012	https://kdigo.org/guidelines/ckd-evaluation-and-management/	CKD and Dialysis
Blood pressure	KDIGO	2012	https://kdigo.org/guidelines/blood-pressure-in-ckd/	CKD and Dialysis
Diabetes	KDIGO	2020	https://kdigo.org/wp-content/uploads/2020/10/KDIGO-2020-Diabetes-in-CKD-GL.pdf	
CKD-Mineral Bone Density	KDIGO	2017	https://kdigo.org/guidelines/ckd-mbd/	CKD and Dialysis
Anemia	KDIGO	2012	https://kdigo.org/guidelines/anemia-in-ckd/	CKD and Dialysis
Undernutrition in CKD	The Renal Association	2019	https://renal.org/sites/renal.org/files/FINAL-Nutrition-guideline-June-2019-RNG-endorsed.pdf	CKD and Dialysis
Hyperkalemia in Adults	The Renal Association	2020	https://renal.org/sites/renal.org/files/RENAL%20ASSOCIATION%20HYPERKALAEMIA%20GUIDELINE%202020.pdf	CKD and Dialysis
Medication dosing for dialysis	KDIGO St George's Hospital, UK	2011 2009	https://kdigo.org/wp-content/uploads/2017/02/KDIGO-DrugDosingReport-Final.pdf https://www.google.com/search?client=safari&rls=en&q=medication+dosing+for+dialysis+st+george%27s+hospital&ie=UTF-8&oe=UTF-8	CKD and Dialysis
Core medical equipment	World Health Organization (WHO) Indian Society of Nephrology	2011	https://apps.who.int/iris/bitstream/handle/10665/95788/WHO_HSS_EHT_DIM_11.03_eng.pdf?sequence=1 http://isn-india.org/images/Image/Docs/HD_GL.pdf	Includes resuscitation equipment
Cardiovascular and Metabolic Guidelines in Adult Peritoneal Dialysis Patients - Part I – Assessment and Management of Various Cardiovascular Risk Factors	International Society of Pediatric Dialysis (ISPD)	2015	https://journals.sagepub.com/doi/pdf/10.3747/pdi.2014.00279	Cardiovascular disease
Cardiovascular and Metabolic Guidelines in Adult Peritoneal Dialysis Patients - Part II – Management of Various Cardiovascular Complications	ISPD	2015	https://journals.sagepub.com/doi/pdf/10.3747/pdi.2014.00278	Cardiovascular disease
Guidelines for the management of cardiovascular disease in dialysis patients	Indian Society of Nephrology	2017	http://isn-india.org/images/Image/Docs/HD_GL.pdf	Low-resource setting

Topic	Organization	Year	Link	Comment
Shared decision-making regarding care of patients with kidney failure				
A decision aid for the treatment of kidney disease	Kidney Health Australia, Kidney Health New Zealand		https://kidney.org.au/cms_uploads/docs/my-kidneymychoice.pdf	Patient decision aid
Planning, initiation and with-drawal of Renal Replacement Therapy	The Renal Association	2014	https://renal.org/sites/renal.org/files/planning-initiation-final-f506a031181561659443ff000014d4d8.pdf	Dialysis decision-making
Renal replacement therapy and conservative management	UK National Institute of health and care excellence (NICE)	2018	https://www.nice.org.uk/guidance/ng107/chapter/Recommendations	Dialysis decision-making
Dialysis - general				
Renal replacement therapy and conservative management	NICE	2018	https://www.nice.org.uk/guidance/ng107/chapter/Recommendations	Recommen-dations on planning, starting and switching treatments, and coordinating care
Guideline for the optimal care of patients on chronic dialysis in South Africa	South African Renal Society	2015	http://sa-renalsociety.org/wp-content/up-loads/2018/03/SARS-Guideline1_ChronicDi-alysis-Adults_2015d.pdf	Includes timetable for laboratory monitoring
Guidelines for chronic dialysis in children in South Africa	South African Renal Society	2015	http://sa-renalsociety.org/wp-content/up-loads/2018/03/SARS-Guideline2_ChronicDi-alysis-Children_2015.pd	Pediatrics, low-resource setting
Guidelines for Chronic Kidney Dialysis	Department of Health, Republic of South Africa	2010	http://www.kznhealth.gov.za/medicine/dialy-sisguide.pdf	Patient eligibility criteria (not universally accepted)
Antimicrobial stewardship	WHO	web-site	https://openwho.org/courses/AMR-compe-tency	Open learning course
Vaccination	Indian Society of Nephrology	2016	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4928524/	Widely applicable
Vaccination	Centers for Disease Control and Prevention (CDC)	2012	http://www.cdc.gov/dialysis/PDFs/Vacci-nating_Dialysis_Patients_and_patients_dec2012.pdf	Widely applicable
KDOQI clinical practice guide-line for nutrition in CKD: 2020 update	Kidney Disease Outcomes Quality Initiative (KDOQI)		https://www.ajkd.org/article/S0272-6386(20)30726-5/fulltext	Guideline for nutrition in CKD
Hemodialysis				
Hemodialysis Fact Sheet	Kidney Health Australia	2017	https://kidney.org.au/resources/fact-sheets-and-photosheets/haemodialysis-fact-sheet	General information, HD
Hemodialysis	The Renal Association	2019	https://renal.org/sites/renal.org/files/FI-NAL-HD-Guideline.pdf	Clinical practice

Topic	Organization	Year	Link	Comment
Guidelines for Hemodialysis Units	Indian Society of Nephrology	2012	http://isn-india.org/images/Image/Docs/HD_GL.pdf	Comprehensive, Low-resource setting, includes detailed guidance on all aspects of set up of dialysis center
Guidelines for Hemodialysis Units	Mexico's Ministry of Health Mexican Institute for Social Security (IMSS)	2012	https://www.gob.mx/cms/uploads/attachment/file/35874/NOM-003-SSA3-2010.pdf http://www.csg.gob.mx/descargas/pdf/certificacion-establecimientos/modelo_de_seguridad/uhemodialisis/ED2017-2015-EstandaresHemodialisis-v2.pdf http://www.cenetec.salud.gob.mx/descargas/gpc/CatalogoMaestro/IMSS-727-14-DialisisyhemodialisisIRC/727GER.pdf	Includes detailed guidance on all aspects of set up and certification for the practice of hemodialysis in Mexico
KDOQI clinical practice guideline for hemodialysis adequacy: 2015 update	KDIGO	2015	https://www.ajkd.org/article/S0272-6386(15)01019-7/pdf	
Diagnosis, prevention and treatment of haemodialysis catheter-related bloodstream infections (CRBSI): a position statement of European Renal Best Practice (ERBP)	European Renal Best Practice (ERBP)	2010	https://academic.oup.com/ckj/article/3/3/234/2918990	Infection
Management of Blood Borne Viruses in the HD Unit	The Renal Association	2019	https://renal.org/sites/renal.org/files/FINAL-Nutrition-guideline-June-2019-RNG-endorsed.pdf	Infection control
Water treatment systems, dialysis water and dialysis fluid quality for haemodialysis and related therapies	The Renal Association and Association of Renal Technologists	2016	https://www.renaltech.net/uploads/1/3/6/4/136400/guideline_on_water_treatment_systems_dialysis_water_and_related_therapies__jan_2016.pdf	Water systems
The National Haemodialysis Quality Standards 2018	Malaysian Society of Nephrology	2018	https://www.msn.org.my/msn/Doc/PublicDoc_PB/National_Haemodialysis_Quality_Standards_2018.pdf.	Detailed quality metrics, role definitions
Vascular Access: 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)	European Society for Vascular Surgery (ESVS)	2018	https://www.ejves.com/article/S1078-5884(18)30080-7/pdf	Vascular access
Clinical Practice Guideline on Peri- And Postoperative Care of Arteriovenous Fistulas and Grafts for Haemodialysis In Adults	European Dialysis and Transplant Association (EDTA)	2019	https://www.era-edta.org/en/erbp/guidance/dialysis/vascular-access/	Vascular access. Summary Available in multiple languages
KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update	KDOQI	2020	https://www.ajkd.org/article/S0272-6386(19)31137-0/fulltext	Vascular access update
Vascular access types	American Association of Surgical Physician Assistants (AASPA)		https://www.aaspa.com/data/uploads/contentblock/TheInsOutsHemoDialysis.pdf	Table comparing dialysis catheter examples
Needles and cannulas for arteriovenous fistula access	National Kidney Foundation (NKF)	2016	https://www.kidney.org/sites/default/files/Fistula Bulletin_0.pdf	Manual for patient education on HD

Topic	Organization	Year	Link	Comment
Home Hemodialysis Patient Workbook	BC Renal Agency	2017	http://www.bcrenal.ca/resource-gallery/Documents/BCR%20Home%20Hemodialysis%20Patient%20Workbook.pdf	Patient decision aid
Implementing Hemodialysis in the Home: A Practical Manual	International Society of Hemodialysis (ISHD)	2016	http://www.ishd.org/home-hd-toolkit/	Comprehensive resources for LMIC; for developing an HHD program
CDC Dialysis Safety Guidelines	CDC		https://www.cdc.gov/dialysis/index.html	Comprehensive resource of guidelines, checklists, infection prevention tools and education materials
Hemodialysis in children: general practical guidelines	European Pediatric Dialysis Working Group	2005	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1766474/	Guidelines for hemodialysis in children
Peritoneal dialysis				
Prescribing high-quality goal-directed peritoneal dialysis	ISPD	2020	https://journals.sagepub.com/doi/full/10.1177/0896860819895364	Children and Adults
Guidelines for establishing Peritoneal Dialysis Services under the Pradhan Mantri National Dialysis Programme	Ministry of Heath, Government of India	2019	https://nhm.gov.in/New_Updates_2018/Om_and_orders/covid19/Guidelines_for_establishing_Peritoneal_Dialysis_Services_under_PMNDP__1_.pdf	Children and Adults
Guidelines for the practice of peritoneal dialysis and hemodialysis	IMSS		http://www.cenetec.salud.gob.mx/descargas/gpc/CatalogoMaestro/IMSS-727-14-DialisisyhemodialisisIRC/727GER.pdf	Children and Adults
Peritoneal dialysis Fact Sheet	Kidney Health Australia	2017	https://kidney.org.au/uploads/resources/peritoneal-dialysis-fact-sheet-–-kidney-health-australia.pdf	General information, PD
Peritoneal Dialysis – adults and children	The Renal Association	2017	https://renal.org/sites/renal.org/files/final-peritoneal-dialysis-guideline-667ba231181561659443ff000014d4d8.pdf	Pediatrics
Catheter-Related Infection Recommendations: 2017 Update	ISPD	2017	https://journals.sagepub.com/doi/pdf/10.3747/pdi.2016.00120	Infection
Peritonitis Recommendations: 2016 Update on Prevention and Treatment	ISPD	2016	https://journals.sagepub.com/doi/pdf/10.3747/pdi.2016.00078	Infection
Consensus Guidelines for the Prevention and Treatment of Catheter-related Infections and Peritonitis in Pediatric Patients Receiving Peritoneal Dialysis: 2012 Update	ISPD	2016	https://journals.sagepub.com/doi/pdf/10.3747/pdi.2011.00091	Pediatrics
Creating and maintaining optimal peritoneal dialysis access in the adult patient: 2019 update	ISPD	2019	https://journals.sagepub.com/doi/pdf/10.3747/pdi.2018.00232	Pediatrics
A Syllabus for Teaching Peritoneal Dialysis to Patients and Caregivers	ISPD	2016	https://journals.sagepub.com/doi/pdf/10.3747/pdi.2015.00277	Pediatrics

Topic	Organization	Year	Link	Comment
Dialysis in Acute Kidney Injury				
Peritoneal dialysis for acute kidney injury	ISPD	2020	https://journals.sagepub.com/doi/full/10.1177/0896860820970834	Recommendations for Low-resource settings
Recommendations for the Management of Crush Victims in Mass Disasters	Renal Disaster Relief Task Force (RDRTF) of the International Society of Nephrology (ISN)	2012	https://academic.oup.com/ndt/article/27/Suppl_1/i1/1818526	Guidelines for management crush injury after earthquakes and mass disasters
Disaster preparedness				
Disaster planning	End Stage Renal Disease Network of Texas	website	https://www.esrdnetwork.org/disaster-planning	Disaster preparedness
Planning for emergencies	NKF		https://www.kidney.org/sites/default/files/docs/disasterbrochure.pdf	Include emergency checklists, Dietary suggestions
READY Packet	Texas Emergency ESRD coalition	website	https://www.texasteec.org/tools/are-you-ready	READY Checklist Available in Spanish
Emergency preparedness	Renal Support Network	website	https://www.rsnhope.org/rsn-programs/kidney-disease-resources/emergency-preparedness/	Disaster preparedness
Infection control for PD after a disaster	CDC	2005	https://www.cdc.gov/disasters/icfordialysis.html	Infection
Emergency preparedness for dialysis facilities - A Guide for Chronic Dialysis Facilities	Centers for Medicare & Medicaid Services (CMS)	2017	https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/Downloads/EmergencyPreparednessforFacilities2.pdf	Includes checklists for preparation and response
Communicating risk in public health emergencies	WHO	2016	https://apps.who.int/iris/bitstream/handle/10665/259807/9789241550208-eng.pdf?sequence=2	Communication
Ethical issues in infectious disease outbreaks	WHO	2016	https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1	Ethics
National pandemic preparedness:	WHO	2019	https://apps.who.int/iris/bitstream/handle/10665/272253/WHO-WHE-IHM-GIP-2018.1-eng.pdf?ua=1	Disaster preparedness
COVID-19 rapid guideline: dialysis service delivery	NICE	2016	https://www.nice.org.uk/guidance/NG160	Epidemics and Pandemics, Dialysis - provider
Be Prepared: Kidney Patient Prep for Coronavirus	NKF	2020	https://www.kidney.org/contents/be-prepared-kidney-patient-prep-coronavirus	Epidemics and Pandemics, Dialysis - patients
Recommendations for Safely Performing Acute Hemodialysis in Patients with Ebola Virus Disease (EVD) in U.S. Hospitals	CDC	2018	https://www.cdc.gov/vhf/ebola/clinicians/evd/acute-hemodialysis.html	Ebola, acute dialysis
Health emergency and disaster risk management	WHO	website	https://www.who.int/hac/techguidance/preparedness/en/	Disaster preparedness
Multi-sector initial rapid assessment (Mira) guidance	Interagency Standing Committee	2015	https://interagencystandingcommittee.org/system/files/mira_2015_final.pdf	Disaster preparedness

Topic	Organization	Year	Link	Comment
Pediatric considerations				
Clinical practice recommendations for the care of infants with stage 5 chronic kidney disease	European Paediatric Dialysis Working Group	2015	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3722439/	Care of infants
Consensus statement on transition from pediatric to adult renal services	ISN and International Pediatric Nephrology Association (IPNA)	2011	https://www.kidney-international.org/article/S0085-2538(15)55119-3/fulltext	Adolescence
A consensus statement on health-care transition of patients with childhood-onset chronic kidney diseases: providing adequate medical care in adol escence and young adulthood	Japanese Society of Nephrology (JSN)	2018	https://link.springer.com/article/10.1007/s10157-018-1589-8	Adolescence
American Academy of Pediatrics – Section on Nephrology and the American Society of Pediatric Nephrology	American Academy of Pediatrics (AAP)/Choosing Wisely	2018	https://www.choosingwisely.org/clini-cian-lists/aap-aspn-central-lines-or-piccs-in-pediatric-patients-with-advanced-chronic-kidney-disease/	Statement on central line use in pediatric patients
International Pediatric Dialysis Network (IPDN)	IPDN	current	http://www.pedpd.org	Data on pediatric dialysis practices and outcomes, tools and management algorithms
Energy and protein requirements for children with CKD stages 2-5 and on dialysis-clinical practice recommendations from the Pediatric Renal Nutrition Taskforce.		web-site	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6968982/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6969014/	European Society for Paediatric Nephrology (ESPN) clinical practice recommendations for nutrition in pediatric CKD/ESKD

Abbreviations: CKD = chronic kidney disease; HD = hemodialysis; PD = peritoneal dialysis; UK = United Kingdom; ESRD = end-stage renal disease; ESKD = end-stage kidney disease; LMIC = low- middle-income countries; HHD = home hemodialysis

Table 6. General requirements and logistic considerations for dialysis operations (can be used to create a checklist)

Parameter	Yes/No
Infrastructure and security Robust back-up plans must be in place and broadly communicated e.g. for electricity or water failures	
Physical space (see guideline examples, Table 5) Location, accessibility to public transportation Layout (number and spacing of dialysis machines) Space for physical examination, procedures, reprocessing Training facility for peritoneal dialysis (PD) patients Medication preparation area Space for administration of intravenous (IV) medications (e.g. iron) Space for ancillary services, pharmacy Waiting area for patients or family members	
Travel policy Transportation costs covered Transportation costs subsidized, tax deductible Transportation costs refunded Availability of transportation from non-governmental organizations (NGOs), churches etc.	
Safe and appropriate dialyzer reuse space	
Safe and appropriate disposal facilities Infectious waste Non-infectious waste Recycling possibilities: e.g. dialysate canisters, safe reuse of dialysis run-off water	
Accessibility Ramp Lifts (elevators) Dialysis beds/chairs	
Electricity, power Reliable power/water supply Backup power supply/generator	
Water Consistent water quality Water testing facilities Back-up water source Adequate water purification system with maintenance plan	
Telephone, internet Reliable continuous phone service and internet connectivity Plans for back-up if electricity failure, blackouts Listing of numbers: Staff, Emergency services, Emergency contacts, Technical support, Back-up hospital support, Patients, Transplant coordinator, Public health officials, Pharmacy, Laboratory, Radiology	
Health information system Staffing schedules Laboratory and diagnostic test results Patient records: schedules, appointments, medical history, problem list, medications with doses, allergies, emergency contacts Dialysis prescription; outcome tracking Tracking of quality metrics Clinical decision support Inventory management, tracking of equipment, stocks, and supplies Links to clinical guidelines, decision-making tools, literature, online education tools	

Parameter	Yes/No
Fridge: for medication, immunization, specimen and blood product storage	
Kitchen area: for food, beverage preparation and storage	
Disaster plans: See Tables 8 and 9	
Staffing	
Nephrologist (Can be on site or remote) Identified as having overall responsibility for the hemodialysis (HD) and/or PD program Role definition: scope of practice, additional skills (HD and PD catheter placement, removal, arteriovenous fistula (AVF) creation) As per local accreditation standards	
General physicians, internists May be on site in hospital-based units if nephrologists available remotely Role definition - scope of practice; e.g. nurse practitioners may be able to write prescriptions, nephrologists may place vascular access, etc. Required skills – resuscitation, quality assurance	
Surgeons (General, Vascular): Required competencies Some of the surgical competencies may be fulfilled by nephrologists/physicians with additional training Placement of AVFs or grafts for HD Placement of tunneled dialysis catheters (if not done by nephrologists, or in complex cases) Management of fistula stenosis, thrombosis, complications (surgery may be required for complex cases even where interventional nephrology or radiology may be in place) Management of complex PD catheter insertions along with associated procedures such as omentopexy, hernia repair, etc. (even where the majority of PD catheters are inserted by the nephrologist)	
Nurses* Role definition, accreditation standards Scope of practice: Senior nurse has overall responsibility for the program, supported by staff trained with competencies defined in Box 14 There is no clear guidance on optimal nurse: patient ratios as local division of tasks between health care professionals varies (see Table 5 for examples in various guidelines) Nurses play a major role in the running of a PD service and represent the single most important human resource	
Other health workers (Nurse aides)* Role definition, accreditation standards	
Technologists* Role definition – scope of practice; accreditation standards	
Housekeeping staff Appropriate training regarding infection control Insert a section about learners	
Infection control specialists (nephrologists are generally able to make decisions regarding antimicrobial therapy, telephone access to an infectious disease specialist may be helpful) Adequate knowledge of specific risks and requirements for HD and PD	
Machine maintenance support (HD and automated PD) Maintenance support for dialysis machines, water systems is usually provided by the manufacturer Manufacturers also provide training, re-training and back-up for local technicians Ongoing maintenance contracts should be negotiated up front	

Parameter	Yes/No
Shared services	
Laboratory, diagnostic imaging and re-processing technicians Role definition, accreditation standards Scope of practice: Awareness of critical values relevant to dialysis, Microbiology laboratory technicians require specific training for the handling of dialysate samples for microscopy (white cell count, differential and Gram-stain) and culture (sample spinning, blood culture media)	
Radiologist (nephrologists are often able to interpret basic radiological findings or may perform certain procedures with additional training) Scope of practice (varies according to local requirements): Interpretation of X-rays for catheter location, complications; tunneled dialysis catheter insertion, PD catheter insertion; Fistulograms, fistula ultrasound; management of fistula stenosis, thrombosis, catheter malfunction	
Microbiologist/Infectious disease specialist To develop local treatment and culture protocols	
Blood bank technologists For safe transfusion	
Dietician Accreditation standards Knowledge adapted to local dietary habits, socioeconomic constraints	
Social workers, Psychologists, Community Health Workers, peer mentors for HD and PD Patient support, education Teaching support for children Appropriate knowledge of local context, support structures	
Staff Training	
Curricula for each staff category To achieve accreditation per local standards and requirements	
Staff training, education and Continuing Medical Education Dialysis; basic life support (BLS); advanced cardiac life support (ACLS); use of essential equipment; infection control, conduct in outbreaks, epidemics, pandemics; correct use of personal protective equipment; communication with patients; emergency procedures and protocols; avoidance/management of moral distress and burnout	
Staff safety Vaccination for Hepatitis B (document and monitor adequacy of antibody response) and Influenza <and COVID-19 once available> Patient immunization should also be included somewhere	
Hardware, equipment	
Resuscitation equipment (see WHO Core medical Equipment List, Essential Medication List, Essential Diagnostics Lists: https://www.who.int/medical_devices/publications/med_dev_core_equipt/en/ https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?sequence=1&isAllowed=y https://www.who.int/medical_devices/publications/Second_WHO_Model_List_of_Essential_In_Vitro_Diagnostics/en/) Basic requirements: Oxygen, pulse oximeter, electrocardiogram (ECG) machine, emergency medication, intubation equipment, defibrillator, point-of-care blood gas analysis as appropriate for context	
Scale: Reliable and calibrated	
Biohazards and sharps disposal: Adherence to local infection control standards	
Linen: Washable, disposable, in some settings patients bring their own linen. Hygiene concerns must be addressed **Cramp blocks**	
Blood pressure equipment: Including appropriate cuff size for children, obese people	
Glucometers: Specific considerations if Icodextrin in use (details available at www.glucosesafety.com)	

**Tasks can be shared between roles.*
Abbreviations: WHO = World Health Organization

Some general planning principles for consideration are as follows:

- HD units should be designed so patients will be visible to nurses at all times, and vice versa, allow free movement around chairs/beds to facilitate placement of the machine on the side of the patient's vascular access and to allow for assistive devices to transfer patients. There should be separate areas to dialyze patients requiring isolation, a dialyzer reprocessing area, a medication preparation area, waiting and changing areas, toilets for staff and patients, a sluice room, sufficient storage space as well as space for consultation and meetings with patient and family.
- Patients who are dependent on dialysis, regardless of modality, frequently require hospitalization. This requires locally identified hospital facilities that are able to undertake in-patient dialysis treatment (e.g. expertise, machines, plumbing).
- A continuous treated water supply should be ensured. There should be regular communication with local authorities about incoming water quality, for example, added chlorine and contamination. Back-up water supply sources should be identified in case of interruptions. The water treatment plant should include sampling ports and protocols for the monitoring of dialysis water quality should be in place.
- Ensure heat resistant water pipe-lines to allow heat disinfection of water lines, instead of using chemical disinfectants like formalin (in order to reduce the risk of complications).
- Where feasible, there should be a dedicated area for procedures such as HD central venous catheter and PD catheter insertion, as well as such interventions as fluid resuscitation - as required post-dialysis, or interventions for blocked catheters.
- When choosing dialysis machines, it is important to consider local context and opt for simple, reliable machines whilst also considering the exchangeability of supplies between machines, whether there is a reliable supply of consumables, and the availability of technical support. Multiple machines makes/models in one unit should be avoided.
- A comprehensive maintenance contract must be negotiated at the time of purchase of dialysis machines. Donated machines should not be accepted without long-term contractual commitment for maintenance or replacement.
- The choice between dialysis chairs and beds (cribs for infants/toddlers) should be per local practice. Chairs, do though, save space and should be able to recline.
- Resuscitation equipment should be available and checked regularly for functionality.
- Handwashing stations should be set up at regular intervals including at both entrances and exits.
- An oxygen, medical air, and suction outlet should be within reach of each dialysis station. Mobile oxygen tanks should be available in case of emergencies.
- Waste disposal practices should be aligned with local regulations.
- Units should be connected to appropriate facilities for investigations and management of complications.
- Units that service PD patients should have dedicated trained nurses and 24/7 telecommunication options. A separate area should be earmarked for the training of PD patients and the troubleshooting of clinical problems.

Protocols should be readily available for:

- Infection control.
- Vaccination and revaccination.
- Dialyzer reuse.
- Water quality assessment - standards, frequency of testing.
- Assessment of dialysis adequacy - frequency and standards.
- Quality and outcome reporting, including patient-reported outcomes.
- Blood pressure management.
- Fluid and electrolyte management.
- Psychosocial care.
- Pre-transplant work.
- Anemia management.
- CKD-Mineral Bone Density (MBD) management.
- Nutritional assessment and management.
- Vascular access management.
- Management of acute complications to dialysis.
- HD initiation.
- Machine disinfection.

7

CHAPTER 7

CONSIDERATIONS FOR ENSURING QUALITY OF DIALYSIS

Barriers to the provision of dialysis services at a consistent quality level can be encountered at all levels of the health system. Unless addressed specifically, these barriers place the poor and marginalized populations at a particular disadvantage.

The relatively well-off patients who can afford to pay/seek care in the private sector, which is able to provide an acceptable level of service for a cost, are covered either through private insurance or by out-of-pocket payment. The not so well off, however, who get HD in the private sector are at risk of catastrophic health expenditure and poor outcomes. Table 7 provides a list of possible barriers to quality dialysis care and suggests some solutions.

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Table 7. Major challenges and solutions for dialysis care

Challenges	Potential solutions
Sustainability	
• Inadequate Infrastructure • Shortage of trained personnel • Lack of regulatory frameworks for quality assurance • Poor governance • Limited ability to meet current/future demand	• Collaborative training programs (e.g. ISN) • Establish quality standards and QI culture • Establish governance, stewardship and transparency • Defining transparent and broadly acceptable patient eligibility criteria developed according to local values and preferences • Commit to progressive expansion of service over time
Data	
• Dearth of epidemiological data on CKD • Few dialysis registries	• Surveillance to establish disease burden • Establish CKD, AKI, kidney failure registries • Incentivize reporting to registries
Funding	
• No consistent policy to fund KRT • Unplanned development of dialysis services, especially in private sector • High out-of-pocket spending leading to poor outcomes • High cost of PD supplies • Neglect of funding for transplant	• Priority setting and HTA to inform service planning • Sustainable uniform financing under UHC principles • Cover cost of all elements of care of patients with kidney failure • Local production of PD supplies when possible or regional co-operation • Incentivize cost-effective KRT options • Remove perverse incentives
Inadequate infrastructure/logistics	
• Overcrowding • Old refurbished HD machines • Inability to service patients in remote locations • Inconsistent availability of essential services, e.g. electricity, water • Inadequate housing, support system (PD)	• Realistic estimation of needs • Reliable machines with regular service contracts • Set up community HD units • Expand PD program • Train CHWs to monitor PD patients • Use remote monitoring technologies • Use of PD cabins
Shortage of personnel	
• Shortage of health care professionals • Few formal training programs • Migration of trained workforce to 'greener pastures' • Moral distress among nephrology workforce	• Practice task shifting/sharing, clinical decision support • Local/regional/international collaboration for training • Limit 'brain drain' – fair remuneration, good working conditions • Provide professional support and career development opportunities • Telemedicine
Governance challenges	
• Lack of regulatory framework for quality assurance: - for profit private dialysis units on the rise - poor regulatory oversight - non-standardization of dialysis care • Complex procurement procedures • Frequent stock-outs	• Set up a Governance/monitoring Committee • Mandate and incentivize QA and reporting • Mandate adherence to SOPs/quality standards • Transparent central procurement • Efficient distribution • Use technology for monitoring stocks
Perverse incentives/biases	
• Higher reimbursement for hemodialysis • Conflicts of interest, e.g. ownership of dialysis units • Shifting the PD/HD balance favoring HD by for-profit dialysis providers	• Adequate education and training • Shared, data-driven decision-making • Remove disincentive to PD by making reimbursements equal • Declare conflicts of interest

Adapted from Davids MR, et al. (2016),[96] Etheredge H, et al. (2017),[97] Wearne N, et al. (2017),[52] Nunez F, et al. (2016),[98] Mendez-Duran A, et al. (2016),[99] and unpublished data from Ashuntantang G, et al.

Abbreviations: ISN = International Society of Nephrology; QI = quality improvement; CKD = chronic kidney disease; AKI = acute kidney injury; HTA = health technology assessment; UHC = universal health coverage; KRT = kidney replacement therapy; PD = peritoneal dialysis; HD = hemodialysis; CHWs = Community Health Workers; QA = quality assurance; SOPs = standard operating procedures

A. DEFINING SAFE AND MINIMUM STANDARDS FOR SUSTAINABLE DIALYSIS TREATMENT

Several national and international bodies have developed guidelines to standardize dialysis care delivery and ensure quality (Table 5). Guidelines from India, Malaysia, Mexico, and South Africa provide examples of local practical adaptations which may be more generalizable to other lower resource settings (Table 5). The use of validated tools such as ADAPTE[100] can facilitate adaptation to local circumstances.

Vetting, and the eventual acceptance, of these approaches in individual countries or regions should involve a multi-stakeholder approach, including the local nephrology and allied health care community, patients, industry, government, and global health care organizations. Standards may be different from those in developed countries, but should be consistent with local values and preferences, broadly acceptable to all stakeholders and based on local data that suggest such changes are compatible with acceptable outcomes. Examples include reducing HD frequency to twice a week or PD frequency to three exchanges/day - which may be justifiable as a means to improve access to dialysis for more individuals. After their development and acceptance, these standards should be widely disseminated and monitored for impact on outcomes. Timely reporting on quality indicators should be linked to a part of the reimbursement.

Guidelines should be reviewed and undergo periodic reiterative refinement, especially if the outcomes are inferior to accepted global standards. This should be done by regular reviews of quality metrics (Box 15). In addition to the quality of dialysis and patient related outcomes, programs should also be monitored for equity of access and service delivery.

Box 15. Suggested quality criteria for dialysis safety and efficacy

- Shared decision-making.
- Mortality, hospitalization, and drop-out rates.
- Patient centered outcomes – e.g. wait times.
- Transplant (number of patients transplanted or active in transplant list; deceased donor programs, care of living donors).
- Dialysis adequacy (small solute clearance, fluid balance, and patient-reported outcomes).
- Biochemical targets.
- Anemia (hemoglobin, iron, ferritin).
- Nutrition (subjective global assessment, serum albumin.)
- Control of mineral bone abnormalities (parathyroid hormone, phosphorus).
- Appropriate vascular access [proportion of patients using different access types, e.g. arteriovenous (AV) fistula, catheter].
- Number of missed or incomplete treatments.
- Vaccination rates.
- Infection rates: bacteremia (HD), peritonitis and exit-site infection (PD).
- Technique failure, peritonitis rates (peritoneal dialysis).
- Switches between hemodialysis, peritoneal dialysis, transplant.

Disaster Preparedness

Natural or man-made disasters or conflicts can disrupt the delivery of dialysis (Table 8). Box 16 describes the impact of pandemics, disasters or conflicts on dialysis units. Health administrators must have plans in place to address these challenges, which should be conveyed to relevant unit managers and staff. Dialysis units that will absorb a surge in demand (e.g. of AKI or displaced patients) should be identified. Structures for oversight and coordination (including periodic rehearsals) should be in place. Reserves should be in place to respond to sudden surges. Responses should be coordinated with the broader national or subnational efforts.

Table 8. Humanitarian crises and risks for patients on dialysis

Disaster	Risks
Natural: earthquake, floods, tsunami, hurricanes	Threat to buildings, water system, electricity, road closures, infections, displacement, supply shortages, surge in acute kidney injury (AKI) cases
Fires	Threat to buildings, displacement, road closures
Pandemic/epidemic	Surge in AKI cases, staff shortages, restricted access due to lockdowns, personal protective equipment shortages, dialysis unit preparedness, isolation, supply shortages
Man-made: War/conflict/large scale disasters (e.g. explosions, hazardous material leakage)	Patients and staff safety, destruction of facilities, shortage of supplies, displacement, dialysis quality affected
Migrants, refugees, internally displaced persons	Non-eligibility to health care, language/cultural barriers, administrative barriers/hurdles, economic considerations, burden of health expenditure

Box 16. Specific considerations for dialysis units during disasters or conflicts

- Additional dialysis capacity may be required.
- Dialysis units may be physically damaged.
- Power and/or water supply may be threatened.
- Addition of chlorine to city water may require additional water filtering and testing.
- Procurement of dialysis consumable supplies may be threatened.
- Medications may not be available.
- Health care workers may be intentionally targeted, or may flee for safety.
- Patients may be unable to access dialysis units, or may be forced to flee or migrate, sometimes to other countries.
- Infectious disease outbreaks may require the institution of special precautions, including isolation measures to protect staff and patients.
- Local authorities may issue new guidelines.
- Care may be taken over by organizations not familiar with the management of dialysis patients.

National kidney organizations should prepare locally relevant crisis preparedness plans. These organizations should engage and collaborate with other international organizations (e.g. WHO, United Nations Office for the Coordination of Humanitarian Affairs, United Nations High Commissioner for Refugees) and NGOs (e.g. Médecins sans Frontieres/Doctors without Borders, International Committee of the Red Cross) and advocate ahead of time to ensure adequate awareness, enhance preparedness, and provide knowledge back-up.

Table 9 summarizes important considerations required for patients on different types of KRT (links to websites, guidance, and resources on preparedness are provided are provided in Table 5). Annex 1, Table I, outlines potential options that can be considered to increase surge capacity in disasters and outbreaks.[65,101] These issues relate to long-term crises and require different and broader medical and psychosocial support systems. Annex 1, Figure A, is a quick reference guide designed to manage dialysis in low-resource settings during infectious outbreaks. Annex 1, Figure B outlines responsibilities relating to care for refugees and migrants with kidney failure at different societal levels and organizations.[102]

Table 9. Approach to patients on kidney replacement therapy during crises (see Table 5 for links to sources of information)

General

- Peritoneal dialysis: ensure continued dialysis, adequate supplies, sterile technique; vigilance with fluid and dietary intake; medication supplies; protection from infection.
- Hemodialysis: ensure ongoing dialysis, medication; restricted diet; electricity; water; alternative locations with adequate surge capacity to accommodate transient evacuees; transportation to and from dialysis, protection from infection.
- Transplant recipients: ensure ongoing medication supplies, laboratory tests, protection from infection.

Patients

- Assure personal preparedness, adequate medication and supplies.
- Knowledge of how to protect oneself from infectious disease outbreaks.
- Document with medical history, allergies, medications.
- Access to transport – e.g. fuel in car.
- Extra cell phone batteries.
- Non-perishable food including snacks for intra-dialytic hypoglycemia.
- Awareness of how to obtain additional supplies, medications and lab tests.
- Vigilance with diet and fluid intake.

Nephrology/dialysis unit

- Mandatory disaster planning and testing, including patient and resource contact lists, channels of communication, etc.
- Provide patients with disaster medical record with patient information, medication and problem list.
- Prepare patients for locally available alternatives – e.g. for exit site care.
- Provision of contact lists for dialysis supplies and dialysis units.
- Provision of psychosocial support as needed during and after disaste.
- Communication with other stakeholders – e.g. pharmacies for medication supplies.
- Use telemedicine to augment service provision.
- Surge capacity if required to support other affected units; plan for extra patients – unknown Hepatitis B/COVID-19 status precautions.
- If predictable, do extra dialysis before the disaster to “buy time” after the disaster.
- Communication with pharmacies to release medication – reimbursement plans should be in place.
- Curfew letters for patients and staff to travel to and from hemodialysis units.
- Take care of staff needs.

Emergency Providers (local, state, federal)

- Multi-stakeholder participation in planning.
- Evacuation plans, access to medications/services outside of local area.
- Plans for care of minors and other dependent individuals within patient homes, animal care.
- Arrange translators, patient navigators.
- Increase awareness of kidney patients’ needs among emergency personnel through lectures/orientation to frontline staff and include transplant/dialysis patients in the criteria of rapid assessments (e.g. Multi-cluster/sector Initial Rapid Needs Assessment (MIRA) tool, https://emergency.unhcr.org/entry/50179/multicluster-sector-initial-rapid-needs-assessment-mira).
- Consider special requirements in cases of infectious diseases outbreaks.
- Communication with other stakeholders – e.g. military to clear roads; access to fuel for cars.
- Evacuation plans, access to medications/services outside of local area, possible special needs shelters, dietary considerations (may need to include caregivers).
- Plans for care of minors and other dependent individuals within patient homes, animal care.
- In areas where disasters may be frequent, predictable or chronic, consider the development of mobile dialysis services.
- Planning for reimbursement for out-of-region services.
- Lists and mechanisms of transfer to alternative dialysis units.
- Back-ups for water system - tanks.

8

CHAPTER 8

STRENGTHENING DIALYSIS SERVICES – REGISTRIES AND RESEARCH

A. REGISTRIES

Registries systematically collect observational data about specific groups of patients managed in routine clinical practice for a predetermined objective. Registry reports describe the epidemiology and natural history of a disease; capture regional or national variations in treatment and outcomes; evaluate safety and quality of care; track treatment costs; assess patient, economic, and provider-driven demands and help in budgetary allocations. By impacting health care procedures, registries influence policy and thus population health (Box 17).

There are few reliable statistics on KRT from most LMIC. As a result, governments are unaware about how many of their citizens are developing and dying of kidney failure. Also not known is the impact of dialysis (where services are available) on outcomes and cost of care.[96]

Recent work sponsored by the Australian Commission of Safety and Quality in Health Care highlighted that each $1 of expenditure on the Australia and New Zealand Dialysis and Transplant Registry yielded $7 of benefits.[103] These economic benefits, along with the clinical impact on patient outcomes make the case for investment in systematic CKD measurement and reporting compelling. An example of registry improving care is the Registro Colombiano de la Enfermedad Crónica. Cuenta de Alto Costo. https://cuentadealtocosto.org/site/erc/" (Colombian chronic diseases register, including CKD, a high-cost account), which has improved the CKD support in Columbia.

Setting up registries in LMIC has proved challenging – there are no regulations for data submission, the dialysis staff perceives entering data in a registry to be an additional burden, with no immediate reward or impact on service. This highlights the need to incentivize data collection (for example, by making part of the reimbursement contingent to entering data) and embedding registries in the dialysis system from the beginning.

Purpose and scope of registries - To generate information on the prevalence, incidence, and causes of kidney failure in patients on KRT and information on treatments and outcomes by collecting well-defined epidemiological data over many years. Registries might also help track those who choose conservative kidney management, those not eligible for dialysis, or unable to afford dialysis.

Box 17. Ways in which registries can improve the delivery and tracking of KRT*

Preparedness:

- Timely access.
- Workforce density.
- Tracking inventory.
- Forecasting.

Delivery of care:

- Volume, flow.
- Incidence, prevalence of KRT.
- Revealing disparities (geographical, gender) in health care.
- Service utilization.
- Quality indicators.

Effect of care:

- Clinical outcomes.
- Patient-reported outcomes.
- Documenting out-of-pocket health care expenditure.

*not all registries collect data on all points, especially preparedness. The ISN Sharing Expertise to support the set-up of Renal Registries (SharE-RR) is developing a minimum dataset for LMIC registries.

Defining patients to be included - All patients who receive KRT for kidney failure.

Determining what data should be recorded - Core items should be collected for the lifetime of the registry, with provision for collection of additional items of time-limited interest. The ISN Sharing Expertise to support the set-up of Renal Registries (SharE-RR) network of the ISN is developing a set of core data that should be included in registries in LMIC.[104] This lowers the costs and time requirements, and improves compliance.

Documentation and Policies - Clear documentation on the management structure, a description of inclusion or exclusion criteria, a data dictionary, documentation guiding the data collection, processing and cleaning, data access policy, confidentiality, and ethics.

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

Management and Funding - Registries should be independently funded and managed by an experienced group to ensure objectivity.

B. RESEARCH

Clinicians in LMIC with high clinical loads may feel conflicted and vulnerable if not able to appropriately implement guidelines, developed for high-resource settings, for the management of patients with kidney failure in their practice. This can be as a result of several factors, including differences in patient or disease characteristics, health systems, and resource availability, making it difficult to generalize research findings from one region of the world to another. Locally appropriate research is important to contextualize global dialysis guidelines through an understanding of both the burden and drivers of kidney failure, testing of appropriate intervention strategies, and process and economic evaluation.

Health systems should allocate funding for research and development in all aspects of kidney care; in particular, to aid the understanding of the prevalence, distribution, and risk factors of CKD, and the best methods to deliver high-quality, guideline-based care consistent with local health systems. Special attention is needed for implementation research to develop low-cost, culturally appropriate interventions to improve patient outcomes, issues of particular relevance to the management of kidney failure, for example by evaluating the impact of timing of starting patients on dialysis, different dialysis frequencies, implementing locally appropriate infection control protocols or nutritional interventions.

Research should be done around the repurposing of existing therapies to treat new conditions and reverse innovation of existing technologies. In addition to being locally appropriate, research should be locally owned, contribute to local capacity building, and be of high quality. Investment should also be made in capacity building for research, with the support of national and international networks, such as the capacity building programs of the ISN and other professional societies. A suggested research agenda to improve the care of patients with kidney failure is shown in Box 18.

Box 18. Research agenda to improve care of patients with kidney failure in LMIC

- Mapping burden of all stages of CKD (including risk factors) and treated kidney failure.
- Determinants and barriers to appropriate guideline-based care.
- Health system interventions to improve the uptake of guideline-based care to prevent and treat CKD.
- Process innovations to reduce cost of care.
- Health policy research to understand the impact of interventions and interactions between policy and implementation process.
- Evaluating the impact of later start times or different dialysis frequency/dose on outcomes.
- Evaluating the impact of a bundle of interventions on vascular access infection rates.
- Information management.
- Low-cost innovations for dialysis delivery.

9

CHAPTER 9

KIDNEY TRANSPLANTATION AND ITS INTEGRATION WITH DIALYSIS SERVICES

Because kidney transplantation provides the best quality of life and is most cost-effective, it should be available to all suitable patients with kidney failure. Transplant services should be developed incrementally, according to the status of the country's health system. To start with, kidney transplantation might depend on organ procurement from living (related biologically or emotionally) donors, followed by the development of a deceased donor program and the establishment of a network.[105] The promotion of deceased donation requires both engagement with and the education of policymakers, legislators, the community, and the wider medical profession.

Setting up a transplant service requires several components – legislative, administrative, human resource, technologies and findings - to be in place. Since economies of scale require that a certain number of transplants be done, small countries with low requirements may not need to develop their own programs but might consider providing access to their citizens under a regional agreement with neighboring countries, or through more distant international co-operation such as that promoted by the ISN-TTS Sister Transplant Center Programs, a joint partnership of the ISN and The Transplantation Society (TTS). Patients who have a living donor could go abroad for the transplant procedure, with postoperative and chronic follow-up done locally. Box 19 provides an example of a pediatric transplant program in Myanmar as part of such a collaboration.

Box 19. Example of the successful development of a pediatric transplant program

Following the establishment of an ISN-TTS-supported collaboration between Children's Hospitals in Singapore and Myanmar (in Mandalay and Yangon), pediatric transplantation has commenced in Myanmar. This program is part of a comprehensive collaboration involving all aspects of kidney care. Nurses from Myanmar received training in dialysis and transplantation in Singapore and subsequently a multidisciplinary inter-professional transplant team from Singapore has visited several times to perform Myanmar's first pediatric kidney transplants and to train local staff. The visit attracted the attention of Myanmar's Ministry of Health, which is now funding the necessary resources, including equipment, surgical instruments, and a new intensive care unit. It also captured the imagination of the general public and a local charity is supporting the program. The local multidisciplinary inter-professional pediatric transplant team in Myanmar is moving towards full independence with the support of their partners in Singapore.

The success of this program illustrates several important principles about starting kidney transplantation, namely that it:

- should be embedded as one component of integrated kidney care.
- is best started with living-related transplants.
- should receive ongoing support and supervision from external experts in all aspects of transplantation.
- requires government and community engagement to ensure safe, voluntary, and ethical donation, adhering to WHO guiding principles and the Declaration of Istanbul.

The definition of minimum requirements for a kidney transplant program can inform a simple assessment of the readiness of a country/unit to start and incrementally expand a transplant program (Table 10).

Table 10: Requirements for a Transplant Program

Legislation, Credentialing and Regulatory Oversight

- A legal framework to prohibit and criminalize organ trafficking and commercialization.
- Ethical standards, including consent for living and deceased organ donation, and identification, care, and follow-up with the living donor. These should be consistent with the WHO Guiding Principles and Declaration of Istanbul.
- A legislative framework to protect the rights and well-being of organ donors, their families, recipients, and transplant personnel.
- Regulatory oversight to ensure equity and evidence-based schema of organ allocation, safety, and adherence to legislation.
- Credentialing of centers to ensure appropriate standards.
- Regular outcome reporting and audits of transplant units.

Financing

- A national funding mechanism covering all aspects of transplantation, from donation to long-term care of donors and recipients, including affordable medication that is consistently accessible.
- Reliance on external funding, donors and charities is not sustainable.

Workforce

- Physician/nephrologist with expertise in transplantation.
- Surgeon skilled in kidney procurement, implantation, and management of surgical complications.
- Histopathologist skilled in the interpretation of transplant pathology.
- Access to ancillary services for management of medical problems.
- Specialized nursing and support staff.

Interventions and procedures

- Access to dialysis.
- Transplant biopsy and histopathological examination.
- Urinary tract imaging and interventional radiology.

Laboratory

- Standard laboratory assessment of blood and urine for biochemistry, blood count.
- Access to microbiology and virology services, including the ability to screen for diseases that may be transmitted by the donor to the recipient.
- Laboratory assessment of drug levels of immunosuppressants.
- Access to histopathology for assessment of transplant biopsies.
- Access to a laboratory for immunological work up, including human leucocyte antigen (HLA) typing, crossmatch and detection of donor specific antibodies.

Medication

- Standard immunosuppressive agents for induction and maintenance.
- Infection prophylaxis.
- Other basic medications (see Annex 1, Table D).

Protocols

- Living donor selection and evaluation including adequate donor protections and ethical oversight.
- Suitability/eligibility of potential recipients including waiting-list management and criteria for placing active patients on and off hold for medical and other reasons.
- Immunosuppression regimens depending on patient risk of rejection.
- Harvesting, perfusion, and storage of kidneys.
- Immediate post-operative management, fluid management.
- Treatment of rejection and other complications.
- Long-term follow-up with the donor.
- Deceased donor organ consent and procurement.

Abbreviations: WHO = World Health Organization

Special considerations for transplantation in children

Pre-emptive transplantation is the ideal modality of KRT for all transplant candidates but especially for children, in whom dialysis should be considered as a bridge to transplantation. When possible, pediatric kidney transplant services should be set up and performed in specialized centers under the supervision of pediatric transplant specialists. In some countries, pediatric transplants are managed by adult specialists.[106] Certain unique barriers exist around transplants for children – such as lack of local expertise in managing pediatric transplant recipients, negative parental attitudes (including prioritizing investment of limited resources on healthier children, unwillingness to be a donor), and medical barriers, such as abnormalities of urinary tract.[107] All potential pediatric transplant recipients should have a urological assessment given the high frequency of congenital abnormalities. All recommended vaccinations should be completed ahead of transplant since the likelihood of successful response goes down in those on immunosuppressive drugs. Since children have many years ahead of them, the need for a second or third transplant should be explained to parents. Adolescents are considered particularly vulnerable to their lack of persistence with follow up regimens, which can precipitate graft rejection.[108]

10

CHAPTER 10

CONSERVATIVE KIDNEY MANAGEMENT AND ITS INTEGRATION WITH DIALYSIS SERVICES

WHAT ARE KIDNEY SUPPORTIVE CARE AND CONSERVATIVE KIDNEY MANAGEMENT?

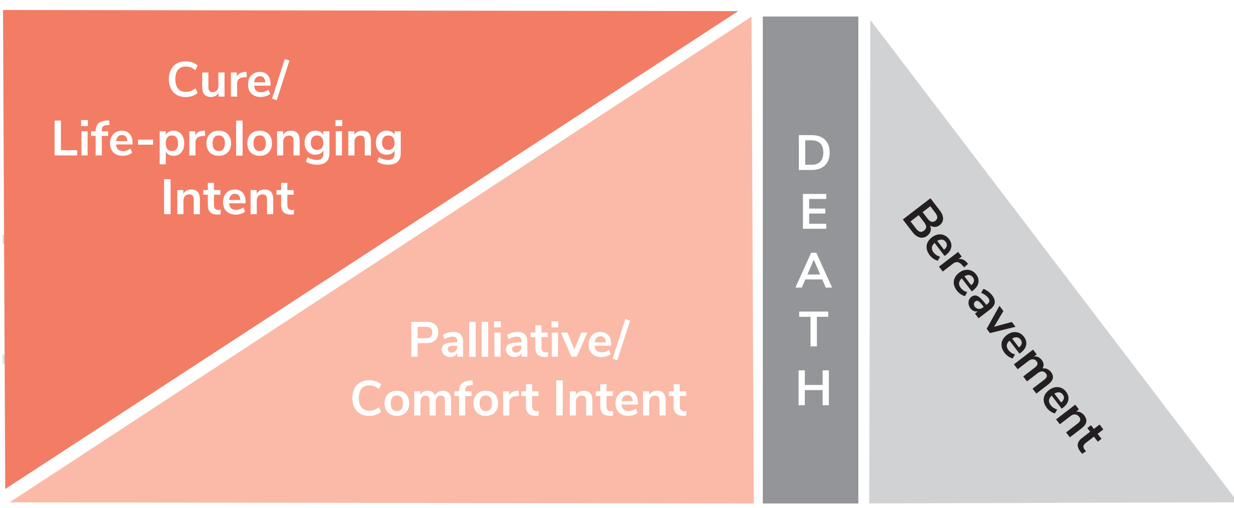
Patients with advanced CKD and kidney failure experience high symptom burden and have complex health and social care needs. Kidney supportive care (KSC) is designed to improve the quality of life of the patients and reduce caregiver burden.

The definition of KSC has been aligned with the WHO definition of palliative care as "*...an approach that improves the quality of life of [people with kidney disease] and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.*"[109]

Patients may decline dialysis; they should then receive KSC along with interventions to slow the progression of disease and manage the complications of CKD (conservative kidney management, CKM). KSC and CKM are better considered and delivered as part of a coordinated therapeutic strategy.

CKM (Figure 14) facilitates a sustainable approach to improving the health of kidney patients as an active process intended to benefit all people (adults and children) with advanced kidney disease, not just those receiving KRT or those who decline KRT in favor of CKM. Therefore, KSC and CKM should be considered as components of an integrated care approach for all patients with kidney failure, and not as cost-saving or as inferior alternatives to dialysis and transplantation. Integration with CKD, transplant, and dialysis services also ensures that access to KSC does not result in restriction of KRT or other aspects of kidney disease prevention and treatment (Box 20).

Figure 14. Supportive care in patients with advanced kidney disease



Box 20. Why KSC should be an integral part of all KRT services

- Dialysis does not mitigate all the symptoms or complications of kidney failure.
- Supportive care is likely to be needed at some stage for most, if not all, individuals with advanced kidney disease because of high symptom burden and their poor quality of life.
- KSC is required for patients who cannot start or want to withdraw from dialysis, or have insufficient resources.
- Setting up dialysis services without considering KSC will likely lead to inferior health outcomes for patients with kidney failure.
- The health professionals providing KSC are likely to be the same as, or colleagues of, those providing dialysis.
- The integration and alignment of KSC with existing kidney disease supply chains and infrastructure can reduce logistical demands and costs of KSC.
- Synergies should be explored with local charities and non-governmental organizations* to maximize reach and efficiency through the sharing of knowledge and resources.

*Some examples: Hospice Africa (https://www.hospice-africa.org), the International Association for Hospice and Palliative Care (https://hospicecare.com/home/), the African Palliative Care Association, (www.african palliativecare.org) and Partners in Health (https://www.pih.org/) Pallium India (https://palliumindia.org/)

In wealthy countries, CKM can be either chosen by the patient or medically advised as part of shared decision-making. CKM may be the only option in some resource-constrained settings where KRT is not available. In both situations, CKM includes a number of components (Box 21).[110]

Box 21. Components of CKM

- Detailed communication about supportive care, crisis management, advance care planning, end-of-life and bereavement care.
- Medical or non-medical interventions to minimize complications and symptoms, including locally accepted traditional therapies.
- Active management of symptoms.
- Dietary advice.
- Psychological support.
- Social and family support.
- Home visits by KSC staff where possible.
- Addressing the cultural and spiritual domains of care.

For the sake of efficiency and integration of care, CKM programs should capitalize on existing workforce capacity and established infrastructure, supply chains, communication channels, and education by interfacing with primary care, community services, and existing streams of medical care (i.e. traditional systems of medicine) and palliative care services. General physicians, geriatricians, nurses, physicians' assistants, other allied health professionals, and community workers may also contribute.

Delivery of CKM should be monitored with context-specific metrics that evaluate all aspects of clinical care, including patient-reported outcomes and experiences, quality of care and costs to ensure quality care, and facilitate program improvement.

Technical requirements of CKM

Management guidelines for CKM have been published by several groups. Delivering CKM requires a package of essential resources and interventions (Box 21), and a suitably trained workforce.[111]

The prescribed standards of care and delivery of interventions should be culturally suitable and sensitive, adapted to socio-economic circumstance and available resources, and tailored for less-well represented populations, including children.

CKM includes a stepwise approach to proactive symptom assessment and management, aimed to improve health related quality of life. Examples of currently available resources describing management of symptoms are included in Table 11.[110,112-114] Table 12 provides a summary of pharmacological, behavioral, and nutritional approaches for symptom management. More elaborate descriptions with more detailed guidance about specific agents and/or dosing can be found elsewhere.[115-117]

Given that CKM is in its infancy throughout the developing world, ongoing research is needed to inform development of locally appropriate patient-centered CKM package and monitoring tools that permit iterative refinement of care delivery (Box 22).

Table 11. Resources for conservative kidney care guiding symptom management

Source	Link
Alberta's Provincial Conservative Kidney Management Pathway	https://www.ckmcare.com/
Kidney Health Australia and St George Hospital, Sydney, Australia	https://stgrenal.org.au/guidelines-and-policies/guidelines/renal-supportive-care/
Canadian Society of Nephrology	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2582781/
North America Mid-Atlantic Renal Coalition	https://www.esrdnetwork.org/sites/default/files/content/pdf/patients/end_of_life/PT-EOL-Flyer_11-12-09.pdf
The Renal Association	https://renal.org/sites/renal.org/files/planning-initiation-final-f506a031181561659443ff000014d4d8.pdf
ANZSN Renal Supportive Care Guidelines	https://onlinelibrary.wiley.com/doi/full/10.1111/nep.12065112
Renal Physician Association and American Society of Nephrology	https://jasn.asnjournals.org/content/11/7/1340.long
WHO palliative care	https://www.who.int/news-room/fact-sheets/detail/palliative-care
KDIGO guidelines (2018)	https://www.kidney-international.org/article/S2157-1716(15)32202-4/fulltext110
NIH Guidance on conservative management for kidney failure	https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/conservative-management
Symptom management: pain, pruritus	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5622905/113 https://www.ajkd.org/action/showPdf?pii=S0272-6386%2817%2930781-3114
Coalition for Supportive Care	http://www.kidneysupportivecare.org
Supportive Care Kidney Research Group	https://sites.ualberta.ca/~kscrg/
Renal Palliative and Supportive Care in South Africa – A Consensus Statement	https://www.journals.ac.za/index.php/ajn/article/view/4009/2331

Abbreviations: ANZSN = Australia and New Zealand Society of Nephrology; WHO = World Health Organization; KDIGO = Kidney Disease: Improving Global Outcomes; NIH = National Institutes of Health

Table 12. Guidance for symptom management as part of kidney supportive care

Address possible contributing factors	Interventions: Non-pharmacologic	Interventions: Pharmacologic
Restless legs syndrome		
• Anemia, iron deficiency • CKD-MBD • Medications	• Avoid stimulants (coffee, alcohol, tobacco) • Exercise, Sleep hygiene	• Gabapentin, pregabalin • Dopamine agonists
Pruritus		
• Anemia, iron deficiency • Dry skin, allergies, infections, inflammation	• Skin care – moisturize, keep cool, avoid scratching • UVB light	• Topical capsaicin, menthol, camphor • Gabapentin, pregabalin • Tricyclic antidepressants
Anorexia, nausea and vomiting		
• Metabolic factors • Gastroparesis	• Stop unnecessary dietary restrictions • Proper oral hygiene • Small frequent meals • Avoid greasy or sweet foods, minimize aromas • Complimentary therapies – relaxation techniques, acupressure	• Psyllium husk • Ondansetron, metoclopramide • Olanzapine or haloperidol
Dry mouth, dysgeusia		
• Gingivitis	• Proper oral hygiene • Rinse mouth regularly, spread over the day • Artificial saliva, lip balm • Add lime, lemon juice to water, suck on hard mints • Rinse mouth with baking soda	
Breathlessness		
• Anxiety • Anemia • Infection • Pulmonary edema	• Sit upright, elevate head end of bed • Position near a window • Pursed lip breathing • Relaxation technique • Reduce fluid (spread over the day) and salt in diet • Oxygen therapy	• Loop diuretics if volume overload • Low dose opioids (e.g. fentanyl, hydromorphone)
Fatigue, sleep disturbances		
• Anemia • Metabolic acidosis • Drug toxicity • Mood disorders	• Exercise • Nutrition and anemia management • Cognitive therapy • Optimize sleep hygiene • Complimentary therapies – relaxation techniques, acupressure • Avoid stimulants (e.g., coffee)	• Gabapentin, doxepin, mirtazapine*
Pain: determine nociceptive or neuropathic		
• Multiple causes, will need work-up	• Physical therapy, massage, acupressure • Behavioral therapies • Intervention: ablative therapies, blocks	• Stepwise increase of analgesics, start from acetaminophen or other NSAID (nociceptive) or gabapentin, pregabalin orTricyclic antidepressants (neuropathic), stepping up to weak and eventually strong opioids

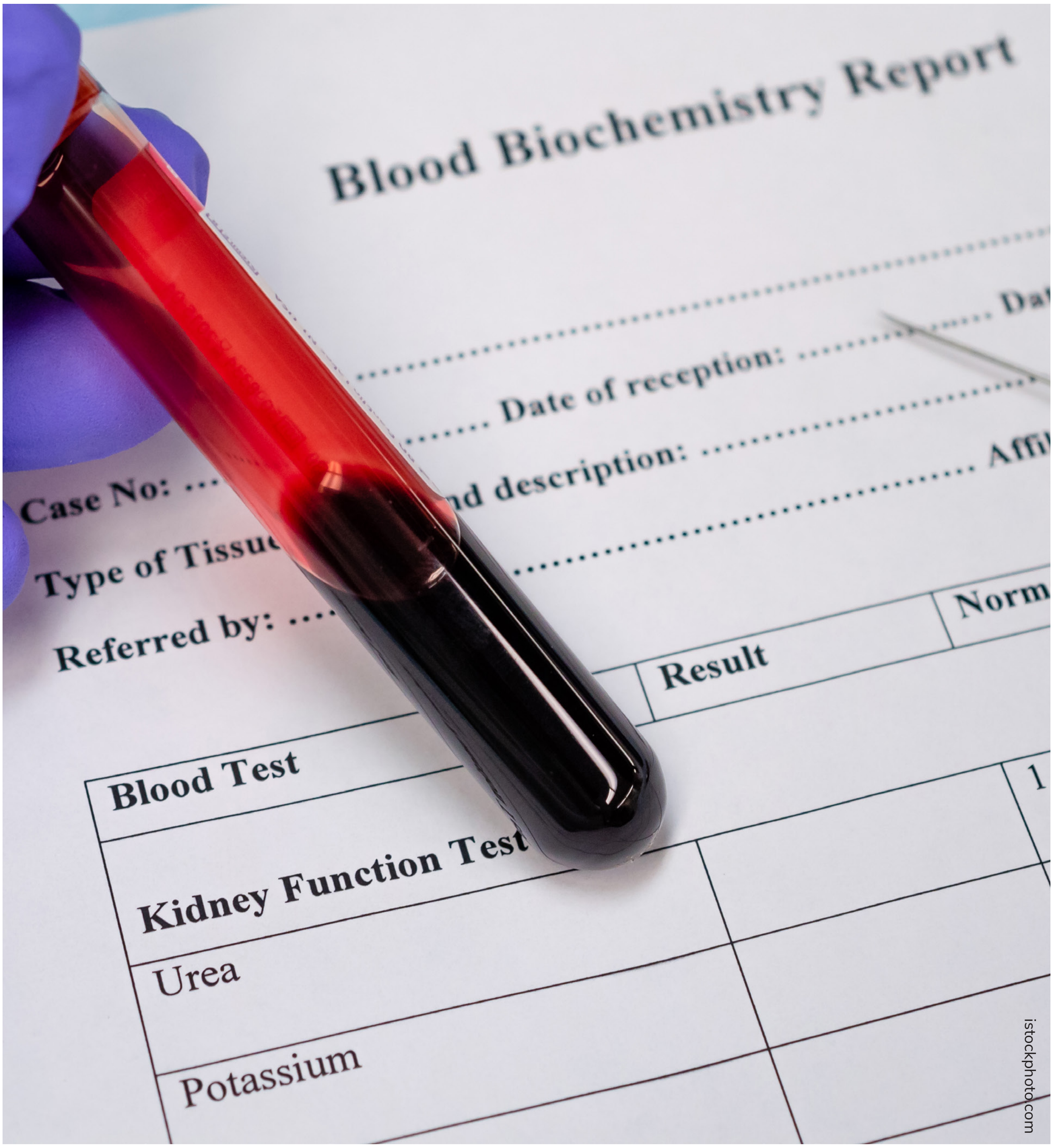
*"*Interventions may also include those aimed at possible contributing factors, such as iron supplements and erythropoietin for anemia*

Adapted from Davison SN et al. (2019)[116]

Abbreviations: CKD = chronic kidney disease; MBD = mineral bone density = UVB = ultraviolet B; NSAID = nonsteroidal anti-inflammatory drug

Box 22. Key research and monitoring areas for KSC

- Feasibility and acceptability of the kidney supportive care packages in local settings.
- Improvements in patient satisfaction: pre- and post-implementation questionnaires.
- Improvement in outcomes as a result of kidney supportive care using routinely collected data and from registries.
- Consult with experts in the field of pediatric palliative care when choosing this pathway for children.



11

CHAPTER 11

APPROACH TO FINANCING OF DIALYSIS SERVICES

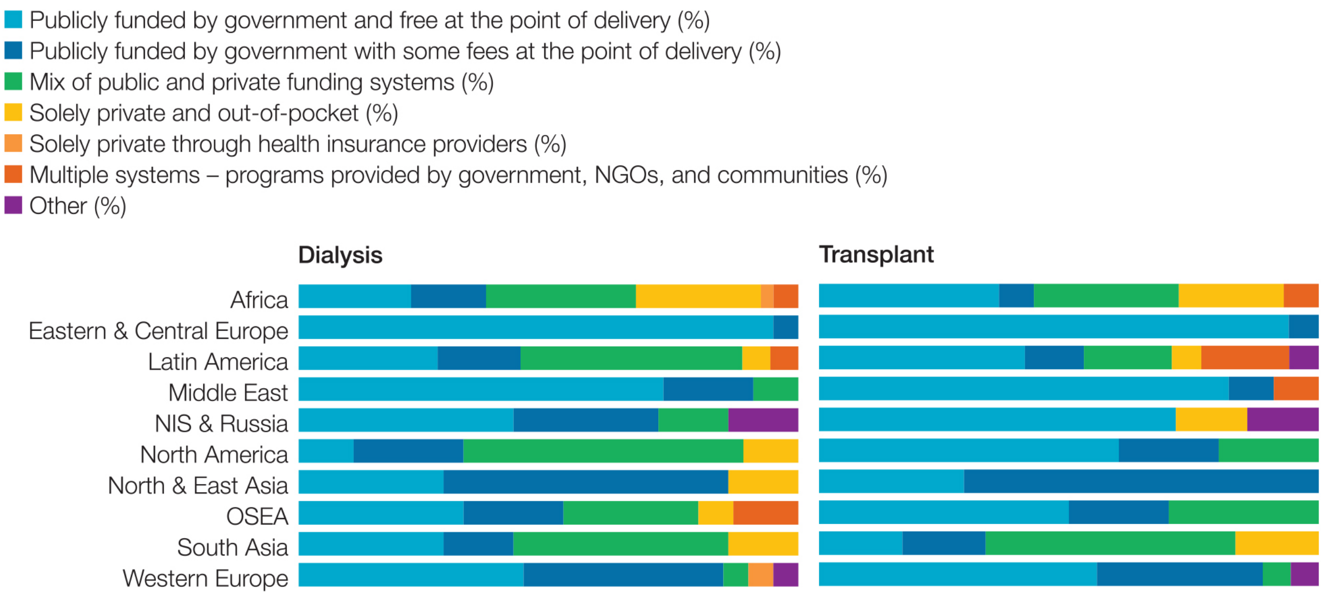
Despite being available in almost all countries, dialysis remains unaffordable when not covered through UHC or health insurance. Global dialysis expenditure (excluding out-of-pocket payments) is around 57 billion USD.[60]

In most higher income countries, dialysis is available through government programs and consumes a disproportionately high proportion of health care budgets (around 2-4% of the budget for 0.15% of the population).[57] Even when provided free, the costs of associated medication, transportation, etc.[118,119] are prohibitive for individuals and families in LIC and LMIC, often forcing them to abandon care. Indeed, CKD is the leading cause of catastrophic health expenditure in LIC and LMIC worldwide.[20]

About 188 million people experience catastrophic health expenditure annually as a result of kidney diseases across LIC and LMIC, *the greatest of any disease group.*

Dialysis is unique amongst medical procedures in that the treatment costs are covered by public funds. This puts pressure on public funding, and governments must figure out ways to cover costs. A range of funding approaches are used to cover the cost of dialysis treatment in different parts of the world. The distribution of current financing models across different ISN regions are illustrated in Figure 15.[37]

Figure 15. Funding models for KRT, by ISN region



Reproduced with permission from The International Society of Nephrology from Bello AK et al. Figure 6.19. From Global Kidney Health Atlas: A report by the International Society of Nephrology on the Global Burden of End-stage Kidney Disease and Capacity for Kidney Replacement Therapy and Conservative Care across World Countries and Regions. Brussels, Belgium, 2019.[37]

Abbreviations: ISN = International Society of Nephrology; NGOs = non-governmental organizations; NIS = Newly Independent States; OSEA = Oceania and South East Asia

Ensuring the sustainable financing of all the components required for service provision must precede any initiation of KRT services, since exclusion of any component can potentially lead to catastrophic health care expenditure[118] and compromise outcomes.[27,120] Policy-making must center on affordability, sustainability, and acceptable quality.

Funding models must factor in growth in the dialysis population as a result of a year-on-year increase in uptake as a result of the increased availability and continued survival of patients leading to an increase in the number of prevalent patients. This would be partly offset by patients getting a transplant, dying, or discontinuing dialysis.

Modern dialysis modalities come with a number of features – both in HD and PD – the addition of which have the potential to increase the cost of treatment. Many of these are not essential but may be pushed by industry. Examples include online hemodiafiltration or profiling options in HD and Icodextrin or use of cyclers in PD. Unless strongly indicated, funding under UHC should cover technologies that meet with the minimum essential criteria to provide reliable service rather than the more expensive alternatives. Reuse of dialyzers reduces HD costs but imposes challenges related to ensuring the safety and efficacy of reused dialyzers. Jurisdictions, therefore, need to make a pragmatic decision about whether the potential savings are worth the extra effort and risk.

Health care financing models to build sustainable dialysis services

The general principles applied to financing of health care to maximize financial risk protection as a component of UHC are ***efficiency*** (optimal use of resources to minimize avoidable losses) and ***progressivity*** (making the service available in an equitable manner to the rich and the poor, such that those with unequal ability to pay do pay differentially).[121,122] Financing choices affect both efficiency and progressivity.

Mechanisms to optimize the use of resources and increase efficiency of dialysis provision are outlined in Box 23.

Box 23. Increasing financial efficiencies in dialysis

- Improved and transparent tracking of finance flows.
- Central negotiated strategic purchasing.
- Disaggregated accounting.
- Efficient intersector reallocation.
- Implementing a partial pay-for-performance model.
- Change of professional behavior (task sharing/shifting).
- Achieving operational efficiencies.
- Product and process re-engineering.
- Local production of equipment and consumables.
- Introducing new/affordable technologies.

Defining the levels and extent of reimbursement coverage is a key part of financing decisions, with the overall goal of promoting sustainability and equity of access to dialysis. Currently, eligibility for reimbursement determines access to dialysis in most LMIC where dialysis is not included under UHC.[123,124] For example, only salaried workers in the private and government sectors, or those with individual wealth can afford dialysis while others cannot. Some countries have more than one reimbursement scheme to fund KRT with different levels/extent of coverage. Unless addressed specifically, these differences may perpetuate inequities in access to and outcomes of KRT. Countries should make every effort to ensure coverage for those who do not have access to an existing insurance scheme. Moreover, funding should include all components of care of patients on dialysis, such as costs incurred on or the management of complications.

Some governments, such as India's, are adopting the principle of progressivity, in that dialysis is provided free to those below a certain income level, whereas those who can, need to pay a (subsidized) cost. A number of other funding approaches have also been used (Box 24). The decision about the right funding model must be made up-front based on local resources since subsidies are difficult to reverse, once implemented. Depending on subsidies or donor funding is not sustainable for the long-term provision of UHC.

Box 24. Health care financing models for dialysis

- **Domestic revenue generation by government:**
  - -General taxation
  - -Specific taxes (tobacco, sugar, alcohol)
  - -Efficiency gains (e.g. reduce fuel subsidies).
- **Insurance contributions:**
  - -Social
  - -Private
  - -Public-private partnership.
- **Alternative sources of financing:**
  - -User fees/out-of-pocket payments
  - -Community participation
  - -Development assistance/charitable/donor funding (not sustainable).

Other countries have adopted variations of these principles, within the overall framework of national health budgets. In addition to funding dialysis, other strategies have been adopted to reduce out-of-pocket expenses, such as direct cash transfers to cover indirect treatment costs.[125]

Disparate financing models also create ***perverse incentives***. For example, nephrologists may be paid per HD session or have financial stakes in HD centers, leading to the disincentivizing of other KRT modalities. In particular, this discourages PD services, which are most cost-effective from the health system perspective. Developed countries that fund all forms of dialysis through tax revenues have rectified this anomaly by making nephrologist reimbursement uniform for both forms of dialysis.

Once broad-based dialysis programs are started, a progressive increase in demand is inevitable as the financial barriers come down. This will require the expansion of services through new revenue sources (taxes), or disinvestment in other services. These investments need to be monitored along with efficiency in governance to optimize the equitable use of limited resources.[126] In addition to investments, financing can be supported through increasing efficiencies (Box 23), which should include both financial and business process innovations, such as change in professional behavior and investments in innovations.

Though sustainable long-term funding usually means from the public sector, there are examples of not-for profit sector providing long-term support for sustainable dialysis. One such example is the Hong Kong Kidney Foundation (HKKF), which has played a major role in promoting automated PD by supporting the cost of machines (partnering with industry and the Hospital Authority). Since 1997, HKKF has raised HK$40,000,000, and acquired 475 PD cyclers, which are loaned free to patients. A total of 1,172 patients had been supported till 2016.

Public-private partnerships

Public-private partnerships (PPP) have become popular for dialysis delivery in countries where the public sector does not have the capacity (manpower, infrastructure) to deliver services. Typically, governments contract private entities to finance, build, operate, and sometimes transfer dialysis units against an agreed-upon rate. Potential advantages include the ability to achieve economies of scale through strategic purchasing and process efficiencies, the scalable training of workforces as well as opportunities to implement standardized operating procedures (SOPs) and improve outcomes.

PPPs transfer the responsibilities and risks of infrastructure and service delivery to the private sector but at taxpayer's expense, and therefore require strong oversight and governance. The scope, governance, gatekeeping, and oversight of PPP models vary. Most projects are limited to HD, while others cover both HD and PD. In Colombia, the dialysis PPP is tied to the promotion of kidney health and prevention of CKD.

Table 13 lists the advantages, innovation opportunities, and challenges connected with the implementation of PPP dialysis programs. Few studies have evaluated the ability of PPP dialysis models to deliver efficiency gains in LMIC with existing problems of access and equity. For example, PPP can result in a decrease in PD utilization or in the increased utilization of expensive medications, which raises the overall cost of dialysis delivery.[124,99,127]

Table 13. Advantages and disadvantages of PPP in dialysis

Advantages and innovation opportunities

- Capable of rapid scale-up (number of units and patients receiving dialysis)
- Implementation of uniform protocols across a large number of units reduces the variability of care whilst improving its quality
- Opportunity to efficiently train large numbers of staff
- Reduced costs through strategic purchasing
- Scalable provision of ancillary services, for example: dietary advice and psychological counselling
- Outcomes and service quality tracking through common information technology platforms
- Value for money by tying service delivery to requirements for workforce capacity-building and ancillary programs

Disadvantages and barriers

- Strong governance and monitoring mechanisms required
- Tendency to see private capital as free goods and overinvest in PPP without rigorous economic analysis
- Lack of regulatory, institutional, and operational competencies
- Contestability between bidders
    - o Low: high private finance costs can inflate contract prices
    - o High: aggressive bidding and misbehavior of market forces lead to unrealistic expectations in the absence of health technology assessment
- Contract disputes and a lack of dispute resolution mechanisms
- Scope for corruption
- Exploitation of workforce (low pay, poor working conditions)

Abbreviation: PPP = public-private partnerships

Financing of essential drugs

Financing strategies for KRT often ignore the consideration of ancillary medical needs[28] such as pre-dialysis preparation, access creation and care, medical management (antihypertensive medicines, drugs for anemia and mineral bone disease, vaccinations, and immunosuppressive drugs for transplant), and management of complications. These limitations result in poor outcomes, in some instances forcing patients to stop dialysis as a result of high out-of-pocket spending, wiping out the expected return on investment made for dialysis. Economic modelling for these expenses will allow for realistic budgeting.

Economic and societal return on investment

While dialysis is expensive, proper planning can provide economic and societal return on investment in terms of monies saved when the most appropriate KRT model is implemented. Patients return to the labor market and contribute to the nation's economy, new jobs are created by the dialysis industry, and skills, trade, and knowledge are generated then leveraged to increase equitable access to health care. Development of tools that allow the measurement and accounting of any return on investment permits the offsetting of some of the expenses made in setting up the services.

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CHAPTER 12

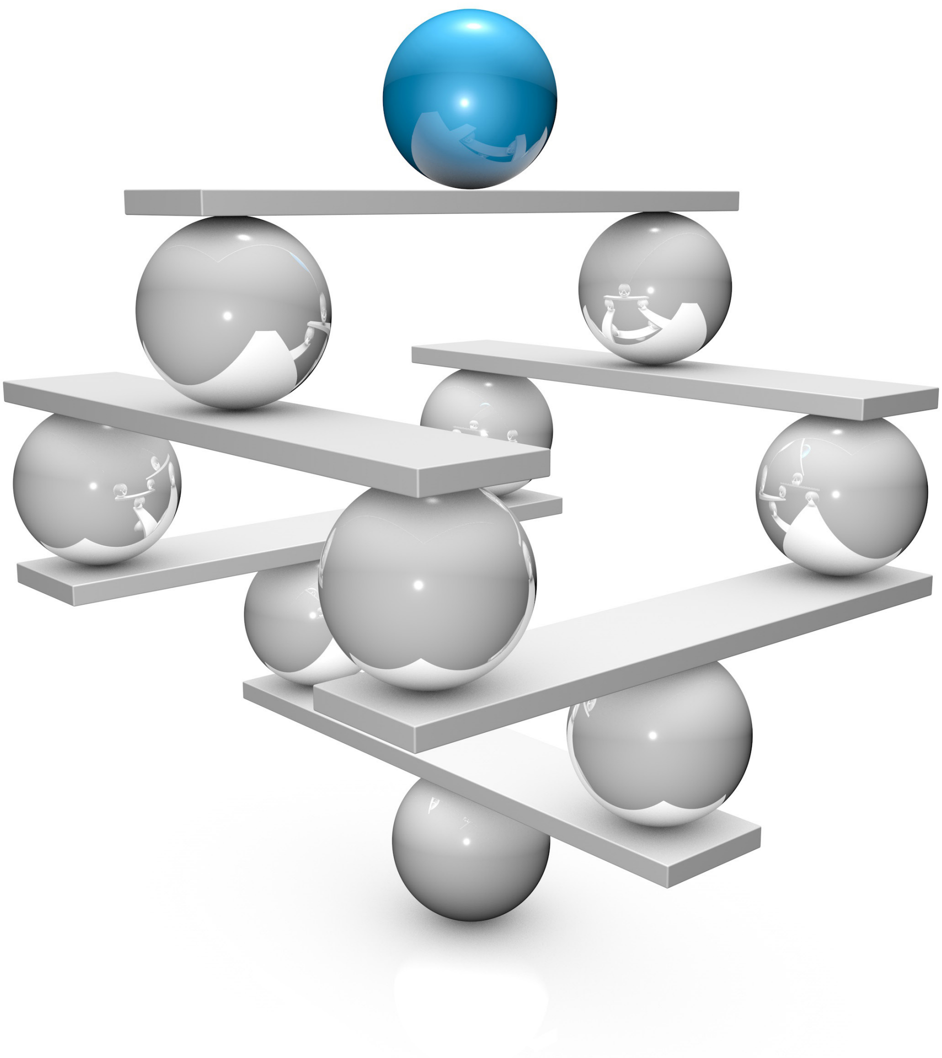
ETHICAL CONSIDERATIONS AROUND THE CARE OF PATIENTS WITH KIDNEY FAILURE

> The rising global demand for KRT poses a number of ethical challenges, which should be addressed in a manner consistent with the principles of equity as well as local priorities and value systems.[126]

There is an inherent tension between respecting the individual's right to life-saving treatment like dialysis, financial risk protection, and achieving justice on a broader scale across the population, with the need to share limited resources with other priorities. This has been discussed in detail elsewhere.[126,128-130] Provision of dialysis has been justified by the social value of not abandoning patients (who can return to improved health and productivity) to almost certain death when KRT is not provided.[48,49,69]

Awareness of ethical challenges is important to informing local and national policy development and decision-making, as these ethical and moral dilemmas can be mitigated pre-emptively where possible, and strategies can be developed to support families and clinicians where resource limitations preclude universal access to dialysis. Examples of ethical challenges encountered during the clinical care of patients with kidney failure are illustrated in Annex 1, Table J.[128]

Other ethical dilemmas related to care of patients on dialysis are discussed elsewhere.[38,126,129,131,132]



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CHAPTER 13

FUTURE DIRECTIONS

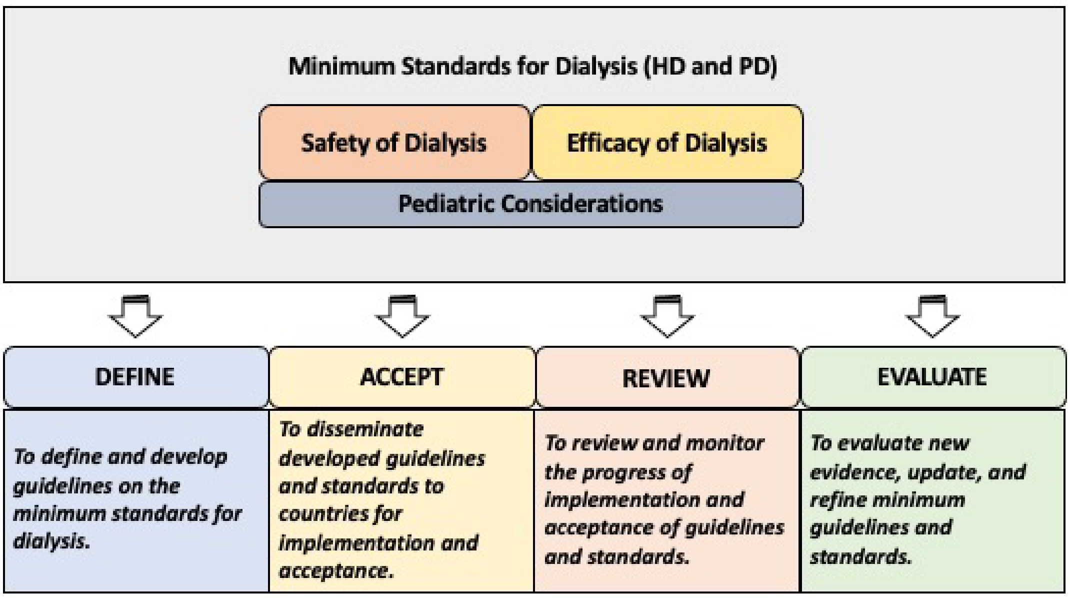
General

- Complete 18 projects of ISN's Strategic Plan for Integrated Care of Patients with Kidney Failure[133] over the next 5-10 years.
- Develop links with Disease Burden Studies/Observatories.
- Develop a framework to generate cost-effectiveness data in the context of local health care system for priority-setting for KRT options.
- Develop a toolkit for assessment of health systems readiness for development of an integrated KRT program.
- Support HTA tools for priority setting and transparent communication of decision-making regarding provision of, and access to, KRT within local contexts.
- Define expectations of donors and various stakeholders (including industry) in terms of fair pricing, fair profits and promotion of global equity.
- Define the essential workforce and their respective competencies to deliver kidney failure care.
- Develop a bank of training resources for different categories of health care workers and integrate with ISN Academy.
- Develop kidney failure registries:
  - Define governance processes and structures
  - Data dictionary and platforms
  - Minimum and progressive registry datasets
  - Incentivize registry data entry
  - Establish linkages with existing datasets.
- Framework for publication of Registry Reports:
  - Develop a Global Observatory of KRT
  - Minimum comparison datasets for access and quality of dialysis to develop a 'global scorecard.'

Dialysis

Implement ISN strategy of developing, implementing, and iterating a sustainable quality-driven dialysis program (Figure 16).

Figure 16. ISN strategy of developing, implementing, and iterating a sustainable quality-driven dialysis program



Reproduced with permission from The International Society of Nephrology from Harris DCH et al. Figure 3. From Strategic plan for integrated care of patients with kidney failure. Kidney Int. 2020;98(5):S117-S134.[133]

Abbreviations: HD = hemodialysis; PD = peritoneal dialysis

- Define minimum safe standards for sustainable dialysis treatment.
- Define the amount of dialysis to be provided and appropriate timing for the initiation of dialysis.
- Develop a monitoring framework for minimum and optimal safety and quality standards for HD and PD that can be accepted in different resource settings.
- Specific guidance on:
    - Dialyzer reuse
    - Achieving international water standards
    - Infection control.
- Set up a mechanism to evaluate new evidence, update and refine minimum standards, guidelines, and recommendations for the delivery of dialysis.
- Establish guidance for quality assurance, monitoring, and evaluation.
- Develop collaborative approaches to promote innovations in dialysis therapy. Some examples:
    - Innovative and efficient water treatment
    - More cost-effective dialysis machinery
    - Inexpensive manufacture of PD solutions
    - Reduction in plastic waste.
- Define care delivery models to build sustainable dialysis services integrated within the health system and within disease prevention programs.

Transplantation

- Define minimum requirements for a kidney transplant program and develop a simple assessment tool to test the readiness of a unit to start a transplant program.
- Define the unique requirements of a pediatric kidney transplant program.
- Undertake an environmental scan of existing transplant programs in LIC and LMIC.
- Define in greater detail recipient evaluation, and how a living donor should be identified, worked up, and followed up.
- Assess and revisit the current training programs supported by ISN and TTS.

Conservative Kidney Management

- Define supportive care, develop internationally accepted terminology, promote acceptance of KSC amongst kidney health workers, and promote nephrology training in this field.
- Develop agreed management guidelines and resources for CKM, that can be adapted locally.
- Undertake an environmental scan of existing CKM programs.
- Provide prognostic tools and information for patients.
- Support development of conservative care programs in places where they do not currently exist, particularly for LIC and LMIC.
- Integrate CKM into country palliative care programs and cross-disciplinary platforms.

CONCLUSIONS

Kidney disease is a growing public health problem worldwide, especially in LIC and LMIC. In response to emerging evidence on the increasing number of premature deaths and DALYs, health care systems around the world are considering providing care to patients with kidney failure. This framework, developed by the ISN in consultation with WHO and a diverse range of experts and stakeholders, provides comprehensive guidance to jurisdictions setting up or expanding KRT to guide delivery of safe and effective dialysis therapy. In particular, dialysis services should be developed as part of an integrated KRT system, with kidney transplantation for suitable subjects and CKM for those who choose it or are unable to receive dialysis or transplantation. Public provision of dialysis should prioritize PD over HD.

The standards proposed here have been defined by several professional organizations and are available in the public domain. A comprehensive listing of such documents has been provided. Optimal medical care of patients with kidney failure extends beyond the technical delivery of dialysis and includes care of associated medical issues that is important for maintaining an optimal health status.

Dialysis is a complex health system intervention, rather than just service to be delivered. In that regard, it requires considerations of other health system building blocks – such as financing, human resource, information systems, access to basic and essential medicines, and governance.

Progress on the provision of equitable kidney care will require global co-operation. The ISN has developed a long-term strategy to improve global access to safe, sustainable, and equitable integrated care for patients with kidney failure. Proposed activities in the action plan include developing evidence-based guidance around data capture, policy creation, definition of quality standards, capacity building, research, as well as a performance measurement framework to assess progress. Output from the projects envisaged in this strategic plan will inform future developments that will lead to development of patient-centered, high quality KRT programs that are integrated into local health care systems.

The ISN will work with WHO to develop such a monitoring mechanism and a Global CKD Observatory to enable the global kidney health community to track progress towards the SDG 3.4 due in 2030 – to reduce excess mortality due to NCDs by one third.

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ANNEX 1

Table A. Interdependent links between kidney disease and the 17 Sustainable Development Goals

	Sustainable Development Goal	Examples of potential impact of achieving the SDG on kidney health
1	End poverty in all its forms everywhere	Improved nutrition, safe water, and access to health care will improve overall health and promote healthy behaviors that will enhance prevention of kidney disease.
2	End hunger, achieve food security and improved nutrition and promote sustainable agriculture	Healthy eating will reduce under- and over-nutrition, both of which are risk factors for kidney disease. Improved access to healthful foods helps management of all stages of kidney disease.
3	Ensure healthy lives and promote well-being for all at all ages	Improved prevention, diagnosis and treatment of kidney disease and its risk factors is part of the goal to reduce mortality due to NCDs. Sustainable financing will allow management of CKD and kidney failure to be included in UHC through integration with national health programs.
4	Ensure inclusive and equitable quality education and promote life-long learning opportunities	Improved health literacy and knowledge will allow right choices around all aspects of kidney care including shared decision-making for care of patients with kidney failure.
5	Achieve gender equality and empower women and girls	Ensures equity of access to diagnosis and treatment of CKD and kidney failure.
6	Ensure availability and sustainable management of water and sanitation for all	Access to safe drinking water will reduce the risk of AKI due to water borne diseases, and CKD in agricultural workers. Safe and reliable water supplies will improve dialysis quality
7	Ensure access to affordable, reliable, sustainable modern energy for all	Stable and sustainable energy supply is essential for dialysis delivery.
8	Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all	Economic prosperity will improve access to health care at all levels including high quality dialysis. In turn, expansion of dialysis sector will create local employment opportunities at multiple levels.
9	Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation	Dialysis infrastructure and location of centers should be sensitive to local needs. An innovation culture will promote exploration of new models of KRT including improved, patient friendly and more affordable dialysis as well as research in artificial organs.
10	Reduce inequity within and among countries	Exchange of knowledge will promote development of sustainable and equitable KRT programs
11	Make cities and human settlements inclusive, safe, resilient and sustainable	Ensures dialysis centers are physically accessible to all, and are structurally sound. Improved built environment will promote physical activity thus positively influencing all aspects of kidney health including for those on dialysis.
12	Ensure sustainable consumption and production patterns	Minimizes and promotes innovative uses for dialysis waste e.g. dialysis water used for toilets; rejected high quality dialysis water put to alternative uses within hospitals or communities
13	Take urgent action to combat climate change and its impacts	Concrete action on climate change will reduce risk of kidney disease through reduced risk of extreme weather, pollution and infections.
14	Conserve and sustainably use the oceans, seas, marine resources for sustainable development	These policies will help make dialysis more sustainable by optimizing use of water and disposable waste generated during dialysis.
15	Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity	
16	Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels	Will improve access to KRT among marginalized populations including migrants, displaced and refugees.
17	Strengthen the means of implementation and revitalize the global partnership for sustainable development	Collaboration between international organizations and professional societies to promote education, advocacy and innovation will lead to better kidney health globally.

Adapted from Luyckx et al.(2018)[21]
Abbreviations: SDG = Sustainable Development Goal; NCDs = non-communicable diseases; CKD = chronic kidney disease; KRT = kidney replacement therapy

Table B. Recommendations for addressing the global challenge of kidney diseases, leveraging the momentum behind the SDGs and the 2030 Development Agenda

1. Work within frameworks promoted by the World Health Organization and the United Nations, such as the Sustainable Development Goals of Agenda 2030 and Life Course approach in the context of Health 2020 to develop and implement policies to integrate strategies for kidney disease prevention and treatment within existing initiatives.
2. Develop and implement public health policies to prevent and reduce kidney disease risk factors in adults and children, including strategies to promote maternal and child health and nutrition, to reduce the burdens of diabetes, hypertension, obesity and tobacco consumption, to promote safe work environments and prevent infectious diseases.
3. Implement and support ongoing surveillance mechanisms to quantitate the burdens of acute and chronic kidney disease within and outside the context of non-communicable diseases, specifically by developing robust national and regional registries for AKI, CKD and kidney failure.
4. Educate the public and people at risk about kidney disease through education campaigns.
5. Improve awareness of kidney disease among all health care workers, ensure access to essential tools and medications required for diagnosis and treatment.
6. Work towards universal health coverage to permit sustainable access to effective and affordable medications (for hypertension, diabetes, cardiovascular disease) to treat risk factors for kidney disease and delay kidney disease progression.
7. Support education for a skilled nephrology workforce to implement prevention and treatment of kidney disease at all stages.
8. Implement early detection, preventive and treatment strategies for AKI.
9. Integrate early evidence-based treatment for CKD acknowledging the important synergies with diabetes, hypertension and cardiovascular disease.
10. Develop and implement transparent policies governing just and equitable access to kidney disease care including dialysis and transplantation, according to international standards, and to support, safe, ethical, affordable and sustainable programs.
11. Promote and expand kidney transplantation programs within countries and across the region.
12. Support local, regional and transnational research on kidney disease to further understanding of prevention and treatment strategies.

International Society of Nephrology.(2020).[22]

Abbreviations: SDGs = Sustainable Development Goals; AKI = acute kidney injury; CKD = chronic kidney disease

Table C. Basic diagnostics for dialysis*

Essential diagnostics	Diagnostic test	Example	Purpose	Importance	Overlap with other conditions
Laboratory tests	Serum electrolytes	Sodium, potassium bicarbonate	Monitor levels	High	CVD, DM
	Creatinine	Serum, urine, PD fluid	To estimate glomerular filtration rate (eGFR) and urine albumin: creatinine ratio (ACR) and urine protein: creatinine ratio, peritoneal equilibration test	High	
	Complete blood count	Hemoglobin, white blood cell count, platelets	Multiple purposes	High	General, infection, hematology
	INR, PTT		Bleeding risk when placing catheters or doing biopsies	High (if biopsies, catheter placement)	General, CVD
	Albumin		Nutrition status, and urine albumin: creatinine ratio (ACR)	High	Liver disease, malnutrition
	Calcium, phosphate, iPTH*		Complications of CKD, metabolic bone disease	Medium	Cancer, hyperparathyroidism
	Glucose	Serum, PD fluid	Diagnosis and monitoring of diabetes, peritoneal equilibration test	High	Diabetes
	Iron studies	Ferritin, total iron binding capacity	Monitor iron stores	Medium	Anemia
	Lipid profile	Total Cholesterol, LDL	Hypercholesterolemia	Medium	CVD, DM, Nephrotic syndrome
	Liver function tests	AST, ALP, ALT	Complications from medication, infections	Medium (high in Hepatitis risk areas)	Hepatitis
	Hepatitis B and C serology		Diagnosis, case-finding	High	Infectious diseases
	HIV serology			High	
	Drug level monitoring*	Cyclosporine, Tacrolimus	Therapeutic range to prevent rejection, toxicity	High if transplantation	Glomerulonephritis
	Urinalysis test strips		Detection of abnormalities in urinary composition	High	Diabetes, infection
	Urine albumin, protein		Detection of kidney disease	High	Diabetes, CVD
	Culture	Urine, blood, PD fluid	For detection and identification of bacterial and fungal species for selection of appropriate antibiotic regimens	High	Infectious diseases
Procedure	Kidney biopsy*	Ultrasound Biopsy needle Preservation solution Histology requirements	Diagnosis of kidney disease, cause of allograft dysfunction	High	Other pathology services
Radiology	X ray	Chest, abdomen	Check dialysis catheter placement	High	General
	Voiding cystourethrogram	Look for structural abnormalities of urinary tract	High (in secondary or tertiary center)	General, pediatrics	
	Ultrasound	Renal ultrasound	Kidney structure, exclude obstruction, for kidney biopsy, vascular access placement	High (in secondary or tertiary center)	General, obstetrics

**Tests not listed in the Second World Health Organization Model List of Essential In Vitro Diagnostics, 2019*

Abbreviations: CVD = cardiovascular disease; DM = diabetes mellitus; PD = peritoneal dialysis; INR = international normalized ratio; PTT = partial thromboplastin time; iPTH = intact parathyroid hormone; HIV =human immunodeficiency virus; LDL = low-density lipoproteins; AST = Aspartate aminotransferase; ALP = Alkaline phosphatase; ALT = Alanine aminotransferase

Table D. Basic medicines for patients with kidney disease*

Clinical entity	Medication/ technology	Example	Purpose	Importance	Overlap with other conditions
Blood pressure (BP)	ACE inhibitor (ACEI)	Enalapril, Lisinopril	Delays progression, benefit cardiovascular disease (CVD), stroke	High	HT, CVD, DM
	Angiotensin receptor blocker (ARB)	Losartan, Telmisartan	Delays progression, cardiovascular disease, stroke	(High if no ACEI)	
	Calcium channel blocker (CCB)	Amlodipine, Verapamil	Strong effect	High	
	Loop diuretics	Furosemide, Torsemide*	Good when GFR is low, good for heart failure	High	
	Thiazide diuretics	Hydrochlorothiazide	Nutrition status, and urine albumin: creatinine ratio (ACR)	High	
Cardiovascular disease (CVD) protection	ACEI, ARB	See above	Prevention and treatment of ischemic heart disease and heart failure with reduced ejection fraction	High	HT, CVD, DM
	Beta Blocker	Bisoprolol	Prevention and treatment of ischemic heart disease	High	
	Diuretics	Furosemide, Torsemide*, Indapamide*	Management of heart failure	High	
	Spironolactone		Management of heart failure – CAUTION risk of hyperkalemia in patients with kidney disease	Medium	
	Statins	Simvastatin	Prevention of CAD in patients with CKD, transplant	High	
	Aspirin		Secondary prevention of MI in patients with CKD, transplant	High	
Diabetes management	Oral hypoglycemic medication	Gliclazide, Metformin, SGLT2 inhibitors*, GLP1 receptor antagonists*	DM management Caution with dosing and glomerular filtration rate	High	DM
	Insulin	Long and short acting	DM management	High	
Management of complications of kidney disease	Phosphate binders*	Calcium carbonate*, Calcium acetate*, Sevelamer carbonate*	Reduces vascular and bone disease	High	Electrolyte abnormalities
	Phosphate, magnesium and potassium supplements*	Potassium chloride, Schohl's solution*, Magnesium sulfate, Sodium phosphate*	For children with tubular disorders	Medium	
	Potassium ex-change resins*	Kayexalate (sodium polystyrene sulphonate)*	Reduces serum potassium	High	
	Sodium bicarbonate	(could use cooking powder)	Treat acidosis of CKD	Medium	
	Erythropoietin*		Treats anemia	High especially if dialysis provided	Anemia, oncology
	Iron	Oral iron Intravenous iron*	Treats anemia	High	
	Antibiotics	Multiple	Infections	High	Infectious diseases
	Allopurinol		Gout	Medium	General
	Vitamin D (25)	Colecalciferol, Calcitriol*, other analogues*	Hyperparathyroidism	Medium	General

Table D. Basic medicines for patients with kidney disease* (CONTINUED)

Clinical entity	Medication/ technology	Example	Purpose	Importance	Overlap with other conditions
Intravenous fluids	Normal saline or other fluid (ideally without potassium)	0.9%	Volume resuscitation Dialysis machine priming, etc.	High	All emergencies, surgery, infections, hyperkalemia, etc.
	Ringer's lactate*		Volume resuscitation, self-made PD fluid	Medium	
	High concentration dextrose *	10/25/50%	Homemade PD solution	Medium	
Transplantation medication	Immunosuppression	Cyclosporine* Tacrolimus*	Prevent allograft rejection	High (if transplantation, tertiary center)	GNs
		Azathioprine Mycophenolate*			
		Prednisone			
	Induction therapies	Anti-thymocyte globulin*	Induction therapy – reduce risk of rejection		
	Antibiotics	Cotrimoxazole*	Prevent pneumocystis pneumonia	High (if transplantation, immunosuppression)	HIV, cancers
	Antivirals	(Val)ganciclovir (oral, iv)	CMV infection		
Management of glomerulo-nephritis (GN)	Cyclophosphamide		Certain types of glomerulonephritis	High (tertiary center)	Transplantation, rheumatology, oncology
	Mycophenolate*		Certain types of glomerulonephritis		
	Corticosteroids**		Most glomerulonephritis	High	
	Rituximab		Certain types of glomerulonephritis	Medium (specialized, expensive)	
	Levamisol		Certain types of glomerulonephritis	Medium	Infections
Dialysis	Erythropoietin*		Treat renal anemia	High	Anemia, cancer
	Iron			High	
	Potassium exchange resins*		(if dialysis infrequent)	High	Pre-dialysis CKD care
	Sodium bicarbonate		(if dialysis infrequent)	High	
	Water soluble vitamins		Replace vitamins lost on dialysis	Medium	
	Calcium gluconate		Temporizing management of hyper-kalemia	Medium	
	Heparin		Prevent clotting	High (if dialysis) – for adults and children	Anticoagulation
	Temporary dialysis catheters*		Dialysis access		Dialysis access
	Permanent dialysis catheters*				
	Tenckoff catheters*				
	Peritoneal dialysate*				
	Hemodialysis dialysate, bicarbonate, etc.*				Dialysis procedure
	Normal saline				General fluids
Vaccinations	Hepatitis B, Pneumococcal, Influenza, COVID-19		Reduce risk of infections	High (especially if HD)	Hepatitis, respiratory infections, COVID-19

**Medicines not listed in the World Health Organization Model List of Essential Medicines (WHO EML), 21st List, 2019*
***Not all subtypes of corticosteroids are included in WHO EML, 21st List, 2019*

NOTE: This list is not exhaustive, locally available medications, in some instances belonging to the same class should be used.
In case of antibiotics, usage should be determined by local sensitivity patterns.

Abbreviations: DM = diabetes mellitus; SGLT2 = sodium-glucose transport protein 2; GLP1 = Glucagon-like peptide-1; GFR = glomerular filtration rate; BP = blood pressure; CAD= coronary artery disease; CKD = chronic kidney disease; MI = myocardial infarction; HT = hypertension; iv = intravenous; CMV = Cytomegalovirus; HIV =human immunodeficiency virus; HD = hemodialysis; PD = peritoneal dialysis

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Table E. Peritoneal Dialysis Supplies: Adult

This table is a template for local use

			Example tracking sheet for budgeting and procurement (will be unit-specific)			
CAPD Catheters	**Specifications**	**Comments**	**Unit Cost**	**Number Required**	**Total Cost**	**Supplier**
	31 cm double cuff straight	* Not available across LMIC				
	37.5 cm double cuff swan neck					
	41 cm double cuff swan neck					
	*27 cm, 30 cm and 32 cm double /single cuff catheter					
	41 cm peel off single cuff catheter					
	31 cm peel off single cuff catheter					
	Peel away sheath introducer kit for Tenckhoff catheter for bedside insertion					
	57-62 cm curled catheter double cuff					
	Locking titanium adapter for PD catheters					
CAPD Disposables	**Types**	**Comments**				
CAPD /APD dialysis fluids	1.5%, 2.5%, 4.25% Dextrose (1 liter / 2 liter / 5 liter) 7.5% Icodextrin 2 liters * 500 ml/1 liter,* Low glucose degradation product (GDP) solutions and amino acid solutions	* Not available in LMIC				
Transfer set						
Mini caps						
PD solution heater or heating pad or any source of dry heat	*Hot water placed in a 2 liter soft drink bottle wrapped in a towel	*May be used in low-resource settings				
Connection Shields impregnated with povidone to cover PD connection		Not essential				
Blue clamps						
Heparin vial	5000 IU in 5 ml					
Face mask		No evidence of reduced infection				
Micropore						
Surgical spirit						
Sterile gauze						
Sterillium						
Povidone, sodium hypochlorite						
Dressing tray set		Not essential				
Hand wash soap						

Table E. (Continued)

CAPD Disposables	Types	Comments	Unit Cost	Number Required	Total Cost	Supplier
			Example tracking sheet for budgeting and procurement (will be unit-specific)			
Clean cotton						
Weighing scale	Or measuring jug used for cooking					
Mupirocin ointment	*50% vinegar / 50% boiled water solution effective against gram negative organisms	*May be used in low-resource settings				
IV stand	*Nail or hook on the wall	*May be used in low-resource settings				
Tissue paper						
PD catheter belt (optional)						
Bucket / water container with tap	Water collected from elsewhere can be treated with bleach and used for hand washing					
Plastic or stainless steel tray	Wiped clean and used as a sterile surface for PD bag in overcrowded housing					
APD Cycler		**Comments**				
	Cassette					
	15 liter Ultra drain bag with tubing (a white bucket with writing on the base in permanent ink is a suitable alternative as it allows identification of cloudy effluent)					
	12 liter drain bag with tubing					
Acute Peritoneal Dialysis		**Comments**				
Acute peritoneal dialysis catheters	14 French x 17 cm stiff catheter (5 cm hole length) / chest drain / vascular catheters/ nasogastric tube	If Tenckhoff catheter (above) not available				
Additional equipment for Acute peritoneal dialysis	PD fluid bottles 1.7% 1 liter,*1.5%, 2.5%, 4.25% fluid bottles; alternatively, locally prepared solutions made using Ringers lactate/plasmalyte B and Dextrose 50%. *See footnote to Annex 1, Table I.*					
	Y connector (or 3 way tap)					
	Urometer					
	Dressing set with sterile gown, head cap and mask					
	Local anesthetic					
	Sterile gloves, needles and syringes					
	Hole towel					
	Dyno plaster					
	Large curved artery forceps					
	1 liter normal saline for artificial ascites					
	Buretrols (or similar in-line volume measurement receptacle) for measuring fluid in pediatrics	Essential				

Abbreviations: LMIC = low- and middle-income countries; CAPD = Continuous Ambulatory Peritoneal Dialysis; APD = Automated Peritoneal Dialysis; PD = peritoneal dialysis; IU = international unit; IV = intravenous

Table F. Peritoneal Dialysis Supplies: Pediatric

This table is a template for local use

			Example tracking sheet for budgeting and procurement (will be unit-specific)			
CAPD Catheters	**Specifications**	**Comments**	**Unit Cost**	**Number Required**	**Total Cost**	**Supplier**
	31 cm double cuff straight	* Not available across LMIC				
	37.5 cm double cuff swan neck					
	41 cm double cuff swan neck					
	*27 cm, 30 cm and 32 cm double /single cuff catheter					
	41 cm peel off single cuff catheter					
	31 cm peel off single cuff catheter					
	Peel away sheath introducer kit for Tenckhoff catheter for bedside insertion					
	Locking titanium adapter for PD catheters					
CAPD Disposables	**Types**	**Comments**				
CAPD /APD dialysis fluids	1.5%, 2.5%, 4.25% Dextrose (1 liter / 2 liter / 5 liter) 7.5% Icodextrin 2 liters * 500 ml/1 liter,* Low glucose degradation product (GDP) solutions and amino acid solutions	* Not available in LMIC				
Transfer set						
Mini caps						
PD solution heater or heating pad or any source of dry heat	*Hot water placed in a 2 liter soft drink bottle wrapped in a towel					
Connection Shields impregnated with povidone to cover PD connection		Increase expense and may be considered non-essential				
Blue clamps						
Heparin vial	5000 IU in 5 ml					
Face mask		No evidence of reduced infection				
Micropore						
Surgical spirit						
Sterile gauze						
Sterillium						
Povidone						
Dressing tray set		Not essential				
Hand wash soap						

Table F. (Continued)

CAPD Disposables	Types	Comments	Unit Cost	Number Required	Total Cost	Supplier
			Example tracking sheet for budgeting and procurement (will be unit-specific)			
Clean cotton						
Weighing scale	Or measuring jug used for cooking					
Mupirocin ointment	*50% vinegar / 50% boiled water solution effective against gram negative organisms	*May be used in low-resource settings				
IV stand	*Nail or hook on the wall	*May be used in low-resource settings				
Tissue paper						
PD catheter belt (optional)						
Bucket / water container with tap	Water collected from elsewhere can be treated with bleach and used for hand washing					
Plastic or stainless steel tray	Wiped clean and used as a sterile surface for PD bag in overcrowded housing					
APD Cycler		**Comments**				
	Cassette					
	15 liter Ultra drain bag with tubing (a white bucket with writing on the base in permanent ink is a suitable alternative as it allows identification of cloudy effluent)					
	12 liter drain bag with tubing					
Acute Peritoneal Dialysis		**Comments**				
	14 French x 17 cm stiff catheter (5 cm hole length) / chest drain/ vascular catheters/ nasogastric tubes / Cook multipurpose drainage catheter / Arrow multipurpose drainage catheters	If Tenckhoff catheter (above) not available				
	PD fluid bottles 1.7% 1 liter,*1.5%, 2.5%, 4.25% fluid bottles; alternatively, locally prepared solutions made using Ringers lactate/plasmalyte B and Dextrose 50%. *See footnote to Annex 1, Table I.*					
	Y connector (or 3 way tap)					
	Urometer					
	Dressing set with sterile gown, head cap and mask					
	Local anesthetic					
	Sterile gloves, needles and syringes					
	Hole towel					
	Dyno plaster					
	Large curved artery forceps					
	1 liter normal saline for artificial ascites					
	Buretrols (or similar in-line volume measurement receptacle) for measuring fluid in pediatrics	Essential				

Abbreviations: LMIC = low- and middle-income countries; CAPD = Continuous Ambulatory Peritoneal Dialysis; APD = Automated Peritoneal Dialysis; PD = peritoneal dialysis; IU = international unit; IV = intravenous

Table G. Hemodialysis Supplies: Adult

This table is a template for local use

Dialysis Supplies			Comments	Example tracking sheet for budgeting and procurement (will be unit-specific)			
Dialyzers	**Flux**	**Surface area m2**		**Unit Cost**	**Number Required**	**Total Cost**	**Supplier**
	Low	1.3, 1,6, 2,0	It is recommended to have 2 different membranes to respond allergic reactions e.g.: polysulfon and polyethersulfone, or polysulfon and triacetate or AN69 avoid Ethylene Oxide sterilized membranes				
	Medium*	1.3, 1,6, 2,0	As above.* Erratic availability in LMIC				
	High*	1.3, 1,6, 2,0	As above.* Erratic availability in LMIC				
CRRT Machine/ Filters	**Types**						
	High flux filters + tubing sets*	0.6, 1.0	*Not available uniformly across LMIC				
	Hemofiltration machines*		*Not available uniformly across LMIC				
	HCO^{3} containing substitution fluids*	5 liter-bags	25 liters/patient/day treatment				
Plasmapheresis Filter							
		0.3, 0.6					
HD Machines							
	Basic technology	Blood pump, Ultrafiltration control, heat disinfection					
	Advanced technology*	Endotoxin filter water inlet, blood pressure monitor*	* Erratic availability in LMIC				
	High technology*	blood volume control, on-line priming, sodium and ultrafiltration profiling, single needle hardware*	* Erratic availability in LMIC				
Catheters	**Types**	**diameter x length**					
	Double lumen (temporary)	11.5 French, length 15 cm for right jugular, 20 cm for left jugular and 25 cm for femoral*	Blood flow =<250 ml/min				
		14 French, length 15 cm for right jugular, 20 cm for left jugular and 25 cm for femoral*	Blood flow = >250 ml/min * Erratic availability in LMIC				
	Permcath (tun-neled, permanent, double lumen)	14-16 French x 19 cm tip to cuff*	Right jugular position				
		14-16 French x 24 cm tip to cuff	Right - Left jugular position * Erratic availability in LMIC				
		14-16 French x 28 cm tip to cuff	Left jugular position * Erratic availability in LMIC				
		14-16 French x 55 cm tip to cuff*	Femoral position * Erratic availability in LMIC				

Table G. (Continued)

Dialysis Supplies			Comments	Example tracking sheet for budgeting and procurement (will be unit-specific)			
HD Tubing	**Volume**			**Unit Cost**	**Number Required**	**Total Cost**	**Supplier**
	Adult 150-200 ml	Double needle					
	Adult 180-230 ml	Single needle*	* Erratic availability in LMIC				
Others	**Supplies**	**Details**	**Need to be compatible with specific dialysis machine**				
	Portable reverse osmosis (RO) system		* Erratic availability in LMIC				
	Sodium bicarbonate PART-B		Only if $NaHCO^3$ not available in powder concentrate				
	Acid concentration PART-A	Canister 5L/treatment	Glucose containing				
	Sodium bicarbonate concentrate 650 g		4 Hour treatment				
	Sodium bicarbonate concentrate 900 g		6 -8 Hour treatment				
	15 gauge AV fistula needle						
	16 gauge AV fistula needle						
	Machine disinfectant	Citric acid 50 % in combination with heat disinfection peracetic acid for cold disinfection	Citric acid = disinfection and decalcification (daily) peracetic acid = cleaning of organic deposits, fat and proteins (1/wk)				
	Dialysis fluid filters	Endotoxin filter on water inlet, produce ultrapure dialysate	* Erratic availability in LMIC				
	Y connector	Single needle dialysis	* Erratic availability in LMIC				
	Gloves, syringes, Micropore plasters, Tegaderm, gauze, safety goggles, surgical mask						
	IV set						
	Transducer protector						
	Heparin vial	5000 IU in 5ml	Anticoagulation + priming permanent catheter				
	Sterile dressing tray set						
	Hand wash solution						
	Machine surface cleaning solution	1% hypochloride or ethanol 70%					
	Normal saline bottle	1 liter bag (priming + rinse back/treatment)					
	Seats or beds + linen						
	Waste segregation bin						
	Uninterrupted power supply backup						
	Cardiac monitor						

Table G. (Continued)

Dialysis Supplies			Comments	Example tracking sheet for budgeting and procurement (will be unit-specific)			
Water treatment system		**Function**	**Need = 180 L/treatment**	**Unit Cost**	**Number Required**	**Total Cost**	**Supplier**
	Raw water storage tank	If the supply of water is not continuous (e.g. tank of 1000 liters)					
	Booster pump	Pressure in system > 2 bar					
	Sieving system for large suspended particles	50μ filter with rinse back system in small units with low consumption. Sand filter with rinse back system for high consumption					
	Ion-exchanger (=Softener)	Exchange of CA and Mg-ions to Na-ions. dwell time = minimum 8 minutes	Protection of RO-membrane				
	Carbon filter	Adsorption of Chlorine and Chloramine	Protection of RO-membrane				
	5μ filter	Sieving of small Carbon particles	Protection of RO-membrane				
	Booster pump	If not built-in RO-system					
	Reverse osmosis system	Rejection of ions of metals, salts, chemicals and organic materials (bacteria, viruses and endotoxins)	A properly functioning membrane will reject 95-99% of the ions				
	Storage tank purified water	When the loop is an open system					
	UV radiation(1) or endotoxin filter(2)	(1) sterilization system or (2) adsorption system for endotoxins	Location = between RO and Loop inlet				
	Distribution loop	Steel or hard plastic (PEX). Lead or aluminum tubing are absolutely forbidden	Avoid dead ends and curves				
	Heat disinfection system for the loop*	Disinfection	* Erratic availability in LMIC				
	Air conditioning or other cooling system	The temperature of the incoming water must be <30°C (850F)					
	Monthly testing = endotoxin level < 100 IU/ml 2/year = chemical analysis on ions, salt and metals	Water safety, Quality control	See text * Erratic availability in LMIC				
	Streptokinase/ urokinase Tissue plasminogen activator (TPA)	Can be used in very diluted concentrations and very small volumes or fill catheters when thrombosed	Use for permanent catheters only, caution if bleeding risk If temporary catheters are blocked they need to be changed				

Abbreviations: LMIC = low- and middle-income countries; CRRT = continuous renal replacement therapy; HD = hemodialysis; IU = international units; RO =reverse osmosis; AV = arteriovenous

Table H. Hemodialysis Supplies: Pediatric

This table is a template for local use

Dialysis Supplies			Comments	Example tracking sheet for budgeting and procurement (will be unit-specific)			
Dialyzers	**Flux**	**Surface area m2**		**Unit Cost**	**Number Required**	**Total Cost**	**Supplier**
	Low	0.4, 0.8, 1.0, 1.3	*Erratic availability or non-availability in LMIC				
	Medium	0.5, 0.7, 0.9, 1.1					
	High	0.2, 0.6, 0.7, 1.0, 1.3, 1.4,1.6					
CRRT Machine/ Filters	**Types**						
	*Filters	0.6, 1.0	*Not available uniformly across LMIC				
	*Hemofiltration machines	With pediatric software					
	HCO^{3} containing substitution fluids*	5 liter-bags (e.g. child 10 kg = total fluid 7,2 liters)					
Plasmapheresis Filter							
	Sizes	0.3, 0.6					
HD Machines							
	* For infants/ neonates		*Not available in most LMIC				
	For children	*Same machines as for adults but with special "pediatric software"					
Catheters	**Types**	**diameter x length**					
	Double lumen (temporary)	*6.5-7.0 French x 7.5 -10 cm	* Erratic availability in LMIC				
		8 French x 12cm	Blood flow = >250 ml/min * Erratic availability in LMIC				
		*9 French x 12cm	Right jugular position				
		10 French x 12cm	Right - Left jugular position * Erratic availability in LMIC				
		11.5 French x 13.5cm	Left jugular position * Erratic availability in LMIC				
	Permcath (tunneled, permanent)	*10 French X 18cm and 28cm	Femoral position * Erratic availability in LMIC				
		*12 French x 18 cm					
		14.5 French x 28cm					
		* 8 French x 18 cm (tip to cuff 15 cm)					
HD Tubing	**Volume**						
	Pediatric	108 ml priming volume					
	Pediatric	*96 ml *85 ml	*Often unavailable in LMIC				
	Adult	150 ml					
	Adult	132 ml					

Table H. (Continued)

Dialysis Supplies			**Comments**	**Example tracking sheet for budgeting and procurement (will be unit-specific)**			
Others	**Supplies**	**Details**	**Need to be compatible with specific dialysis machine**				
	Portable reverse osmosis (RO) system						
	Sodium bicarbonate PART-B		Only if $NaHCO^{3}$ not available in powder concentrate				
	Acid concentration PART-A	Canister 5L/treatment	Glucose containing				
	Sodium bicarbonate concentrate 650 g		4 Hour treatment				
	Sodium bicarbonate concentrate 900 g		6 -8 Hour treatment				
	15 gauge AV fistula needle						
	16 gauge AV fistula needle						
	Machine disinfectant	Citric acid 50 % in combination with heat disinfection peracetic acid for cold disinfection	Citric acid = disinfection and decalcification (daily) peracetic acid = cleaning of organic deposits, fat and proteins (1/wk)				
	Dialysis fluid filters	Endotoxin filter on water inlet, produce ultrapure dialysate	* Erratic availability in LMIC				
	Gloves, syringes, Micropore plasters, Tegaderm, gauze, safety goggles, surgical mask						
	IV set						
	Transducer protector						
	Heparin vial	5000 IU in 5ml					
	Sterile dressing tray set						
	Hand wash solution						
	Machine surface cleaning solution	1% hypochloride or ethanol 70%					
	Normal saline bottle	1 liter bag (priming + rinse back/treatment)					
	Seats or beds + linen						
	Waste segregation bin						
	Uninterrupted power supply backup						
	Cardiac monitor						

Table H. (Continued)

Dialysis Supplies			Comments	Example tracking sheet for budgeting and procurement (will be unit-specific)			
Water treatment system		**Function**	**Need = 180 L/treatment**	**Unit Cost**	**Number Required**	**Total Cost**	**Supplier**
	Raw water storage tank	If the supply of water is not continuous (e.g. tank of 1000 liters)					
	Booster pump	Pressure in system > 2 bar					
	Sieving system for large suspended particles	50μ filter with rinse back system in small units with low consumption. Sand filter with rinse back system for high consumption					
	Ion-exchanger (=Softener)	Exchange of CA and Mg-ions to Na-ions. dwell time = minimum 8 minutes					
	Carbon filter	Adsorption of Chlorine and Chloramine	Protection of RO-membrane				
	5μ filter	Sieving of small Carbon particles	Protection of RO-membrane				
	Booster pump	If not built-in RO-system					
	Reverse osmosis system	Rejection of ions of metals, salts, chemicals and organic materials (bacteria, viruses and endotoxins)	A properly functioning membrane will reject 95-99% of the ions				
	Storage tank purified water	When the loop is an open system					
	UV radiation(1) or endotoxin filter(2)	(1) sterilization system or (2) adsorption system for endotoxins	Location = between RO and Loop inlet				
	Distribution loop	Steel or hard plastic (PEX). Lead or aluminum tubing are absolutely forbidden	Avoid dead ends and curves				
	Heat disinfection system for the loop*	Disinfection	*Not available uniformly across LMIC				
	Air conditioning or other cooling system	The temperature of the incoming water must be <30°C (850F)					
	Monthly testing = endotoxin level < 100 IU/ml 2/year = chemical analysis on ions, salt and metals	Water safety, Quality control,	Monthly see text				
	Streptokinase/ urokinase Tissue plasminogen activator (TPA)	Can be used in very diluted concentrations and very small volumes or fill catheters when thrombosed	Use for permanent catheters only, caution if bleeding risk If temporary catheters are blocked they need to be changed				

This list is not exhaustive. Full range of supplies (membranes, bloodlines, catheters, machines) should be available for different groups according to size/weight of children (bodyweight<10 kg, < 15kg, < 25 kg)

Abbreviations: LMIC = low- and middle-income countries; CRRT = continuous renal replacement therapy; HD = hemodialysis; IU = international units; RO =reverse osmosis; AV = arteriovenous; IV = intravenous

Table I. Principles of optimizing dialysis surge capacity

Note that this table is linked to Annex 1, Table E and Table F

- Fluid restriction.
- Dietary salt restriction.
- Use oral sodium bicarbonate (baking soda, 29 mEq HCO_3 per 1/2 teaspoon), potassium binding resins (Sodium polystyrene sulfonate 15 g 3-4 times a day).
- Add loop diuretics/increase dosage, combine other classes.
- Modify hemodialysis prescription – reduce frequency/duration.
- If using Continuous Renal Replacement Therapy (CRRT) – use homemade replacement fluid* recipes.
- Consider acute peritoneal dialysis – stiff catheters may be used, fluid may be prepared locally# if commercial solutions not available.

Data from Cullis B, et al. (2020)[65] and Burgner A, et al. (2020)[101]

**1 L 0.9% NaCl with KCl as needed + 1 L D5W with 150 mEq $NaHCO_3$ + 1 L 0.9% NaCl with 1 g $MgCl_2$ + 1 L 0.9% NaCl with 1 g $CaCl_2$ = 4 L (153 mEq/L Na, 37.5 mEq/L HCO_3, 2.6 mmol/L Mg, and 2.25 mmol/L Ca, 1250 mg/dL dextrose)*

#1 L Plasmalyte B + 30 mL 50% Dextrose (15 g) = Glucose 1.45%, Na 126 mmol/L, Bicarbonate 27 mmol/L, K 3.8 mmol/L, Mg 1.45 mmol/L, Osmolality 342.

1 L Ringer's lactate + 30 mL 50% Dextrose (15 g) = Glucose 1.45%, Na 127 mmol/L,

Lactate 27 mmol/L, K 3.8 mmol/L, Ca 1.36 mmol/L, Mg 1.45 mmol/L, Osmolality 346.

Figure A. Quick COVID-19 Reference Guide for Dialysis in Low Resource Settings

COVID-19

Quick COVID-19 Reference Guide for Dialysis in Low Resource Settings

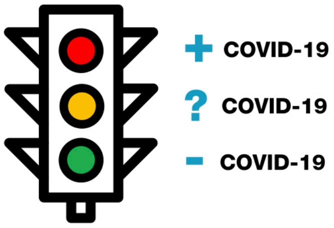
All guidance should be in accordance with local/national health authorities and reviewed with multidisciplinary team in local settings

Adapt the Existing Environment Checklist

- Modify waiting area to allow social distancing.
- Restrict unnecessary traffic.
- Staff complete self-assessment prior to coming to work.
- Triage team to screen patients on entry.
- Staff should proceed to designated zones, not mix.
- Dialysis start times should be staggered if possible.

Adapt the Existing Environment

Locating groups of patients by risk in zones to minimise exposure and cross-contamination.



Red and Amber patients: isolated room. If not possible, consider splitting the unit into zones with distance between and separate entrance/exits if possible (see Example Dialysis COVID-19 Floor).

Hygiene All Staff and Patients

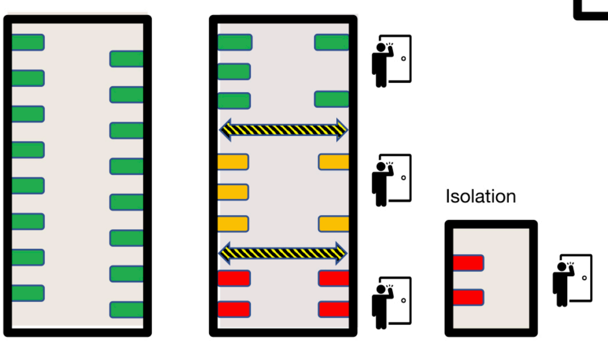
- Wash hands frequently.
- Do not reuse linen.
- Each zone should have enough disposable equipment to reduce the need for traffic to other areas.
- Staff should not take any personal equipment into the clinical area.
- If PPE is limited, prioritize staff and patients in Red and Amber Zones.
- If masks are in limited in number, prioritize use in Red and Amber Zones for staff. Patients advised to use homemade face mask.

Patient and staff allocation as per category of COVID-19

Staff should be allocated to a specific patient group and not care for patients from another category.

All patients should be continuously monitored for change in signs and symptoms of COVID-19.

Example Dialysis COVID-19 Floor:



- Green: COVID-19 negative patients.
- Yellow: COVID-19 suspected patients.
- Red: COVID-19 positive patients.
- Physical barrier to keep categories separate where possible.
- Own access.

**2 isolation beds used at maximum capacity of 3 shifts can dialyse 18 patients a week on twice-weekly dialysis.

Reproduced with permission from The International Society of Nephrology.

Available at: https://www.theisn.org/initiatives/covid-19/knowledge-sharing-tools-infographics-quizzes/

Infographic is also available in Dutch, French, Spanish, Portuguese, and Russian.

Abbreviations: PPE = personal protective equipment

Figure B. Responsibilities relating to care for refugees and migrants with kidney failure at different societal levels and organizations

Reproduced with permission from Elsevier from Van Biesen W et al. Figure 2. From Caring for Migrants and Refugees with End-Stage Kidney Disease in Europe. Am J Kidney Dis. 2018;71(5):701-709 © 2017 by the National Kidney Foundation, Inc.[102]

Table J. Specific examples of ethical challenges arising in treatment of kidney failure for clinicians and patients/families

Category	Clinical challenges which frequently raise ethical questions	Relevant ethical principles
Diagnosis	• Late referral and diagnosis • Lack of strict criteria for withholding and withdrawing dialysis • Variability in referral criteria for transplantation	Justice Benefit – Harm Autonomy
Prognosis	• Challenges in medical assessment • Disputed concept of "futility" - Are some patients harmed by dialysis? - Will dialysis bring meaningful improvement? - Late emergency presentation	Benefit Harm
Decision-making	• Shared decision-making • Limited options • Moral distress[a] - Patients and families - Health care workers • Limited patient capacity to make decisions	Autonomy Justice
Dialysis	• Patient eligibility • Limited access • Clinical compromises - Dialysis dose (reduced frequency of hemodialysis sessions or peritoneal dialysis exchanges) - Inappropriate use of temporary vascular access - Lack of medication (affordability, availability) - Infrastructure failures or insufficient capacity - Staff shortages • Insufficiently trained health care workforce • Availability of supportive/palliative care • Catastrophic health expenditure • Conflicts of interest - Physician, center, decision makers - Financial, non-financial	Autonomy Justice Benefit – Harm
Social context	• Priority setting • Resource allocation • Resource availability • Potential social/emotional harm - Catastrophic health expenditure and consequences of worsening poverty - Loss of breadwinner - Lack of socialization, education (especially children on hemodailysis) - Pressure on relative to donate where transplantation is possible • Late presentations limit possibility of shared decision-making and advance care planning • Patient vs. relatives' desires/decisions • Vulnerable populations (women, children, ethnicities, gender, elderly, etc.)	Justice Autonomy Benefit – Harm

Adapted from Kahrass H, et al. (2016).[128]

[a]*Moral distress refers to the state where an individual is aware of the correct course of action but due to external circumstances (generally resource limitations) cannot carry this out.*

ANNEX 2

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Abbreviation: ISN = International Society of Nephrology

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