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Strategic Plan for Integrated Care of Patients with Kidney Failure

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The views expressed in this commentary are solely the responsibility of the authors and they do not necessarily reflect the views, decisions, or policies of the institutions with which they are affiliated.

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ABSTRACT

There is a huge gap between the number of patients worldwide requiring versus those actually receiving safe, sustainable, and equitable care for kidney failure. To address this, the International Society of Nephrology coordinated the development of a Strategic Plan for Integrated Care of Patients with Kidney Failure. Implementation of the plan will require engagement of the whole kidney community over the next 5-10 years.

INTRODUCTION

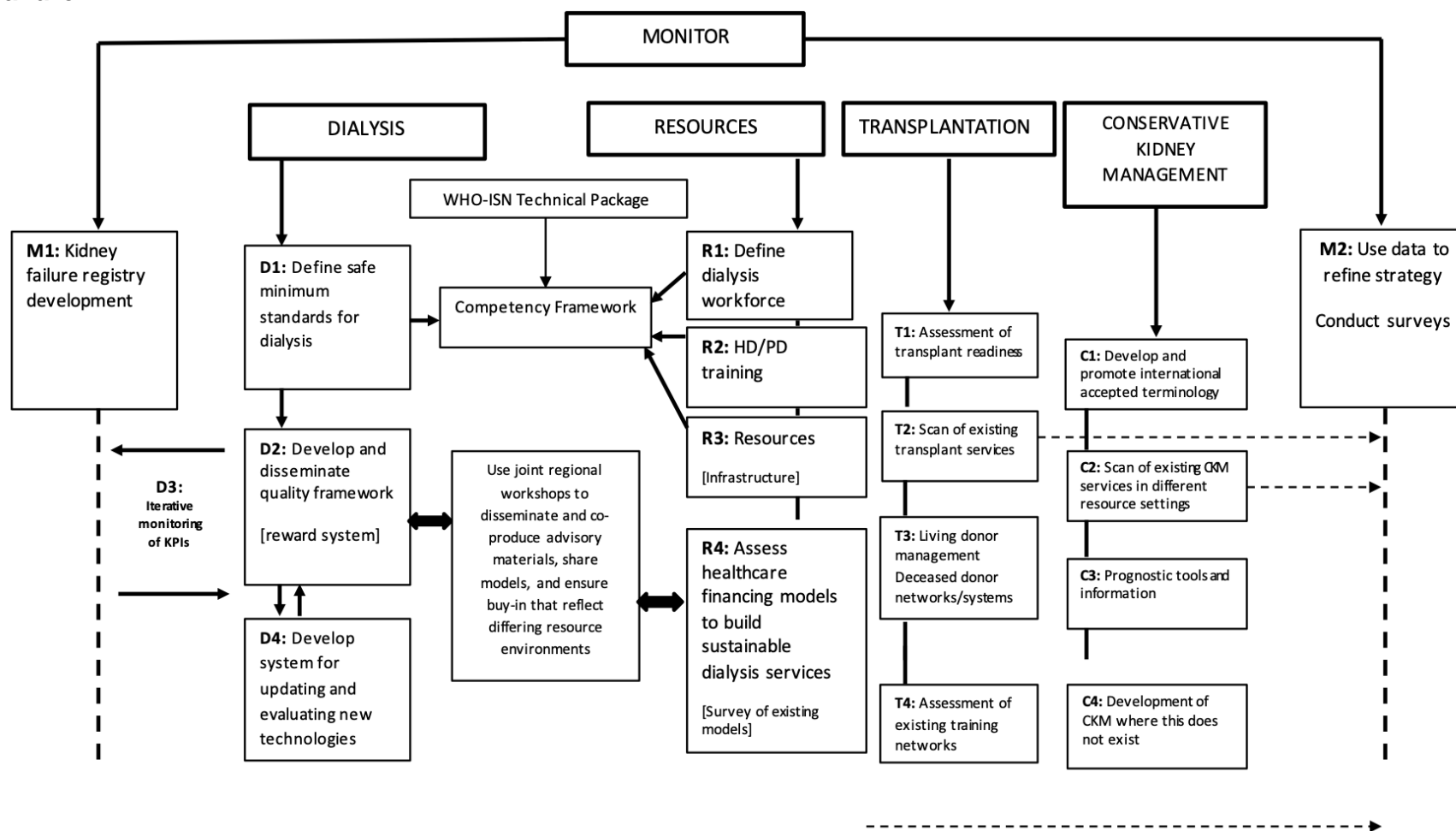
A major complication of chronic kidney disease (CKD) is kidney failure, which requires kidney replacement therapy (KRT; dialysis or kidney transplant) or conservative kidney management (non-dialytic care). Particularly in low-income countries (LIC) and lower-middle income countries (LMIC), many patients with kidney failure are unable to receive safe, sustainable, and equitable care for kidney failure. Nevertheless, an increasing number of people with kidney failure is able to access KRT worldwide, and the fastest growth is expected in LIC and LMIC.¹

As part of its focus on integrated care of patients with kidney failure, the International Society of Nephrology (ISN) held a summit in Sharjah, United Arab Emirates, in March 2018, bringing together kidney patients, healthcare professionals, researchers, and policy makers.² Working groups focused on eight themes: estimates of kidney failure burden and treatment coverage, advocacy, education and training/ workforce, financing and funding models, ethics, dialysis, transplantation, and supportive care.² Action plans were developed to assist with the formulation of a 5-10 year strategy to improve global access to safe, sustainable, and equitable

integrated care for patients with kidney failure. Proposed activities included data capture, policy creation, definition of quality standards, evidence-based guidance, capacity-building, implementation, and research, as well as a performance measurement framework to assess progress.³⁻¹³ In parallel, the ISN is working with the World Health Organization (WHO) to develop a technical package for those wishing to start or expand dialysis services.

To develop the 5 -10 year strategy, the activities and deliverables from the above-mentioned action plans were categorized into five themes: *Monitor, Dialysis, Resources, Transplantation, and Conservative Kidney Management*. The current framework used for development of the Strategic Plan for Integrated Care of Patients with Kidney Failure is presented in Figure 1 with project plans detailed in each theme. Partners in these endeavors will include patients, governmental agencies, policy makers, academic institutions, healthcare institutions, industry partners, research funding agencies, clinicians, and researchers.

Figure 1. The current framework used for development of the Strategic Plan for Integrated Care of Patients with Kidney Failure



Arrows indicate flow of work in a specific order, which in some situations is bidirectional (thick arrows); lines without arrow heads are meant to imply simultaneous work packages
 KPIs = key performance indicators; WHO = World Health Organization; ISN = International Society of Nephrology; HD = hemodialysis; PD = peritoneal dialysis; CKM = Conservative Kidney Management

Barriers to setting up and implementation of KRT services can be encountered at all levels of the health system, most arising from fundamental issues of governance and planning. While these barriers are widespread, they place the socially disadvantaged, minorities, indigenous populations, the poor, women, and children at a particular disadvantage. The relatively well-off city-dwelling patients who can afford to pay seek care in the private sector, which is usually able to provide an acceptable level of service for a cost. Urban people are more likely to have insurance coverage either through private insurance or as employment benefit. Table 1 provides a list of barriers to quality KRT service in LMIC.

Table 1. Barriers to implementation of KRT services in LMIC

<p>Governance</p> <ul style="list-style-type: none"> • Poor planning leading to limited ability to meet current/future demand • Lack of formal health technology assessment and priority setting in KRT • Overemphasis and unplanned development of HD • Lack of regulatory framework for quality assurance • Poor regulatory oversight • Complex procurement procedures • Strategic purchasing not followed • Frequent stock-outs
<p>Funding</p> <ul style="list-style-type: none"> • No consistent policy to fund KRT • High out-of-pocket spending • High cost of PD supplies • Neglect of funding for transplant and conservative kidney management
<p>Inadequate infrastructure/logistics</p> <ul style="list-style-type: none"> • Overcrowding • Old refurbished HD machines without long-term maintenance plan • Inability to service patients in remote locations • Inconsistent availability of essential services, e.g. electricity, water • Inconsistent water quality for HD • Home environment not conducive for PD (inadequate housing, support system) • Poor distribution network for PD supplies • Lack of pediatric KRT/dialysis programs
<p>Human resource shortage</p>

-
- Shortage of all cadres of healthcare professionals
 - Few formal training programs
 - Migration of trained workforce to ‘greener pastures’ (brain drain)
 - Physician-centered care delivery, lack of multidisciplinary care
 - Moral distress among nephrology workforce
-

Perverse incentives/biases

- Unregulated expansion of private sector
 - KRT facilities concentrated in urban areas
 - Higher reimbursement for HD
 - Conflicts of interest, e.g. ownership of dialysis units
-

Data and research

- Dearth of epidemiological data on CKD
 - Few dialysis or transplant registries
 - Lack of locally appropriate implementation research
-

Clinical

- Late detection of CKD – missed opportunities for prevention and management
 - Late nephrology referral leading to missed opportunities for KRT planning
 - Lack of shared decision making
 - No consistent access to standard diagnostics and medicines
 - Lack of support services – e.g., radiology, histopathology, microbiology, and immunology
-

KRT = kidney replacement therapy; LMIC = lower-middle-income countries; HD = hemodialysis; PD = peritoneal dialysis; CKD = chronic kidney disease

The development of the Strategic Plan has been interrupted by the COVID-19 crisis, which has highlighted the likelihood that future practice of kidney failure care will need to change, especially in LIC and LMIC.^{14,15,16} Shifting healthcare priorities, interruption of supply chains and transportation, enforced isolation of at-risk or infected patients and staff, cancellation of elective procedures, cessation of kidney transplantation, and increased need of acute dialysis during the COVID-19 crisis have exposed deficiencies in health systems and the special vulnerability of patients with kidney failure, and the need to anticipate and address their unique needs. Once the COVID-19 crisis has passed, future iterations of this Strategic Plan will include preparedness for man-made, natural, and infectious disasters.

THEME 1: MONITOR

Theme Leads: Frederic Finkelstein, Fergus Caskey, Aminu Bello

The core values of an integrated kidney failure program include equity, sustainability, and transparency. At each stage of a program's development and evolution, upholding these values requires measures that allow advocates and policy makers to assess the health needs of a population, plan the healthcare service provision required, and provide quality assurance for the care.

In the action plans arising from the summit, the need for metrics to inform/guide decision-making/policy and practice was a recurring theme. As a result, the cross-cutting *Monitor* theme was established with the intention to improve the ability of the global kidney community to generate data that can be used for monitoring, audit and quality assurance, and to inform ethical decision-making and practice.

AIM

- To consider all settings, but prioritize efforts to improve monitoring in LIC, LMIC, and vulnerable populations in all countries.
- To support the development of a sustainable measurement infrastructure that will evaluate quality of care and enable the delivery of context-specific optimum care to people with kidney disease while adhering to ethical principles regarding data/sample collection, privacy, and confidentiality.
- To capitalize on existing resources and opportunities for monitoring, such as the ISN's Global Kidney Health Atlas (ISN-GKHA) and the Sharing Expertise in establishing Renal Registries (SharE-RR) project.

- To develop a training and support infrastructure for renal epidemiology, registry methods, information governance and ethics, and survey development.
- To develop a dissemination plan for impact on population health.
- To work with topic experts in other working groups/committees to agree on measurable standards of care based on existing and new evidence-based guidelines. These will need to be appropriate for countries at different stages of economic development in terms of (a) the healthcare resources and (b) the registry infrastructure.
- To work with experts in other working groups/committees to develop ways to monitor compliance with ethical principles that they have established. These will need to be appropriate for countries at different stages of economic development in terms of (a) the healthcare resources and (b) the registry infrastructure.
- To partner with other organizations to build capacity and implement change, including government institutions, nephrology societies, non-governmental organizations (NGOs), for profit and not for profit healthcare providers, and academic institutions.

The *Monitor* Working Group will provide oversight and coordination of delivery of the activities, with specific tasks being delivered by two sub-groups based on (a) SharE-RR and (b) the ISN-GKHA (Tables 2, 3, and Figure 2).

Table 2. Monitor Project 1 (M1): Establish, enable, and develop kidney failure registries that are underpinned by robust and ethical governance processes and structures

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> Fergus Caskey will lead through the SharE-RR (a) steering committee for oversight and (b) network of registry expert volunteers for delivery Capacity building opportunities will be explored with leads of ISN Programs, ISN Academy Plans will be developed in collaboration with ISN-GKHA to optimize synergies Opportunities for registry data and resources to have impact will be explored with WHO, UN, GBD, WB, ADB 	<ul style="list-style-type: none"> SharE-RR 	<ul style="list-style-type: none"> 12-36 months

Challenges

- Supporting the many countries that may wish to establish a renal registry

Resources required

- Support for (a) monthly core group telephone-/video-conferences, (b) opportunistic meetings at international conferences, (c) hosting of webpage
- Support (in kind) from existing registries and academic centers including courses

Equity considerations

- There are potentially many countries who would like to join SharE-RR

Deliverables

- A survey of existing data collection activities including definitions, stakeholders, barriers, policies, platforms, and data linkage with look-up tables for survey results
- Agreement on (1) a minimum dataset and (2) a progressive dataset
- Scoping review of ethical issues for renal registries
- Development of ISN ‘registry standards’ document and ‘registry checklist’ for publications
- Applications for ISN fellowships, educational ambassadors, and Sister Renal Centers (SRCs)
- Local champions – recognition and network

Assessment of Performance

Metrics for evaluating progress

- Meetings held and membership of SharE-RR network
- Numbers of workshops, fellowships, ambassadors, SRCs

Metrics for evaluating output/outcomes

- Production of guidance/toolkits
- Numbers of new registries developed or implementing the ISN ‘standards’

SharE-RR = Sharing Expertise in establishing Renal Registries; ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas; WHO = World Health Organization; UN = United Nations; GBD = Global Burden of Disease; WB = World Bank; ADB = Asian Development Bank

Explanatory Notes for Table 2, *Monitor Project M1*

SharE-RR was established by the ISN as a pilot project in 2017. The aim was to create a resource available to kidney health advocates in countries wishing to establish or develop a renal registry to support advocacy, quality assurance, and research.¹⁷ The core group included members from five registries in high-, middle- and low-income countries – European Renal Association-European Dialysis and Transplant Association (ERA-EDTA), Australian and New Zealand Dialysis and Transplant (ANZDATA), United States Renal Data System (USRDS), African Association of Nephrology (AFRAN), and Latin American Society of Nephrology and Hypertension (SLANH). Following a successful pilot, it was agreed to make SharE-RR a formal advisory group of the ISN. The core group of SharE-RR – the steering committee – was extended to balance global coverage by including a second registry from the Asia/ Pacific region, the Japanese Society for Dialysis Therapy Renal Data Registry (JRDR). This steering committee continues to meet monthly by telephone-/video-conference. In addition, there will be a SharE-RR network of interested partners that will be open to interested parties from established registries, new registries, and organizations interested in supporting this work. This network will keep in touch electronically and meet opportunistically at international meetings. Task-specific, time-limited mini projects will be established to deliver mini projects aligned with the goals of the *Monitor Working Group*, such as running workshops, developing toolkits, writing guidance documents, and producing reports. Resources for these activities will be provided pro bono by the SharE-RR network organizations where possible, but if additional support is required, then funding will be sought from external or existing ISN funding programs.

Table 3. Monitor Project 2 (M2): Establish the capacity to refer to existing data and, where such data don't exist, conduct surveys

<u>Who:</u> ISN	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> Aminu Bello will lead through the ISN-GKHA (a) steering committee for oversight and (b) various ISN regional boards for implementation <p>Who: We will work with the following stakeholders to ensure success:</p> <ul style="list-style-type: none"> Local kidney societies/ communities Potential partners (SharE-RR, kidney failure strategy working groups (<i>Transplant, Dialysis</i>), sister professional organizations (IDF, WHF) and multilateral bodies such as the WHO, UN, WB, and ADB 	<ul style="list-style-type: none"> Literature WHO, GBD, etc. ISN-GKHA 	<ul style="list-style-type: none"> 36 months
<p>Challenges</p> <ul style="list-style-type: none"> Providing a timely responsive service to other work groups 		
<p>Resources required</p> <ul style="list-style-type: none"> Curation of resource hub Support for administering global surveys 		
<p>Deliverables</p> <ul style="list-style-type: none"> Process for administering global surveys (working with ISN-GKHA to incorporate questions into ISN-GKHA every four years) Resource hub that brings together and makes accessible the existing data on kidney health and services (e.g., from ISN-GKHA, WHO, GBD, WB, ADB) Templates/ surveys/ spreadsheets/ existing tools to assess workforce/ costs 		
<p>Assessment of Performance</p> <p>Metrics for evaluating progress</p> <ul style="list-style-type: none"> Launching of resource hub Numbers of requests for assistance dealt with through (a) resource hub and (b) administering a global survey <p>Metrics for evaluating output/ outcomes</p> <ul style="list-style-type: none"> Complex evaluation of impact and dissemination 		
<p>ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas; SharE-RR = Sharing Expertise in establishing Renal Registries; IDF = International Diabetes Federation, WHF = World Heart Federation; WHO = World Health Organization; UN = United Nations; WB = World Bank; ADB = Asian Development Bank; GBD = Global Burden of Disease</p>		

Explanatory Notes for Table 3, Monitor Project M2

The ISN-GKHA is an ISN-led initiative to gather data to determine the world status of existing resources, structures, and organizations available to people with kidney disease. The first iteration (2016)^{18,19} served as a baseline to define the current state

and identify key gaps in specific areas and regions. This information informed local and international bodies regarding key activities that are needed to improve outcomes, including implications for health care policy within the global health agenda. As the ISN-GKHA will be regularly updated, it will give an ongoing ‘scorecard’ allowing countries to track progress in each region and country. The ISN-GKHA team will work with the Strategic Plan’s working groups to convert their data requirements into questions/items that can be included in an ISN-GKHA survey. This approach limits global surveys to every four years, but importantly minimizes burden on respondents. There are also plans for a searchable data repository that would bring together data from the ISN-GKHA and existing sources, such as the WHO, World Bank, Asian Development Bank, and Global Burden of Diseases. This would make existing data more readily available and should reduce the need for additional data collection to a minimum. This resource hub could be hosted on the ISN website.

Figure 2. Gantt chart

	2020				2021				2022	2023	2024	2025-2029			
1. SharE-RR															
Confirm new structure															
Core group calls ¹															
Workshop ²															
Core group F2F meeting ³															
Call for Network members ³															
Network F2F meeting															
Mini projects															
i. Publish registry survey															
ii. Survey resource on-line ⁴															
iii. Registry ethics review															
iv. Minimum dataset guide															
v. Registry standards guide															
2. ISN-GKHA															
Development of Resource hub															
i. Templates and tools															
ii. ISN-GKHA Interactive online tool															
Assessment of Performance															

i. Finalize evaluation strategy																			
ii. Interview ISN-GKHA target users																			
iii. Incorporate feedback into plan																			
Conducting ISN-GKHA survey																			
i. Agree questions for next survey																			
ii. Translate/ pilot/ revise survey																			
iii. Launch survey																			
iv. Data cleaning/ analysis/ write																			
v. Release survey results																			
Monitor Working Group																			
Progress reports and review																			

¹Monthly by telephone-/video-conference

²Annually at the World Congress of Nephrology (WCN), if they prove effective and the International Society of Nephrology support continues. Format/content will need to evolve.

³Bi-annually at the WCN and American Society of Nephrology Kidney Week meetings (opportunistic).

⁴Data from the global survey of renal registries carried out in 2018, some of which will be published in a peer-reviewed journal but the rest will be useful for sign-posting to registries with expertise in particular registry methods.

SharE-RR = Sharing Expertise to support the set-up of Renal Registries; F2F = face to face; ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas

THEME 2: DIALYSIS

Theme Leads: Simon Davies, Adrian Liew, Saraladevi Naicker

The quality of dialysis delivered to patients varies between different regions, different countries, and different facilities across the world.^{19,20} Safe and effective delivery of dialysis is especially challenging in LIC and LMIC. Limited organized oversight further hampers standardized application of evidence-based guidelines in these settings. Variation in outcome is also dependent upon appropriate patient guidance for dialysis or conservative kidney management (CKM). While guidelines for hemodialysis (HD) and peritoneal dialysis (PD) have been produced for more than 20 years in HIC, they are often not practical, adaptable, or sustainable in different resource-limited healthcare settings in LIC and LMIC.

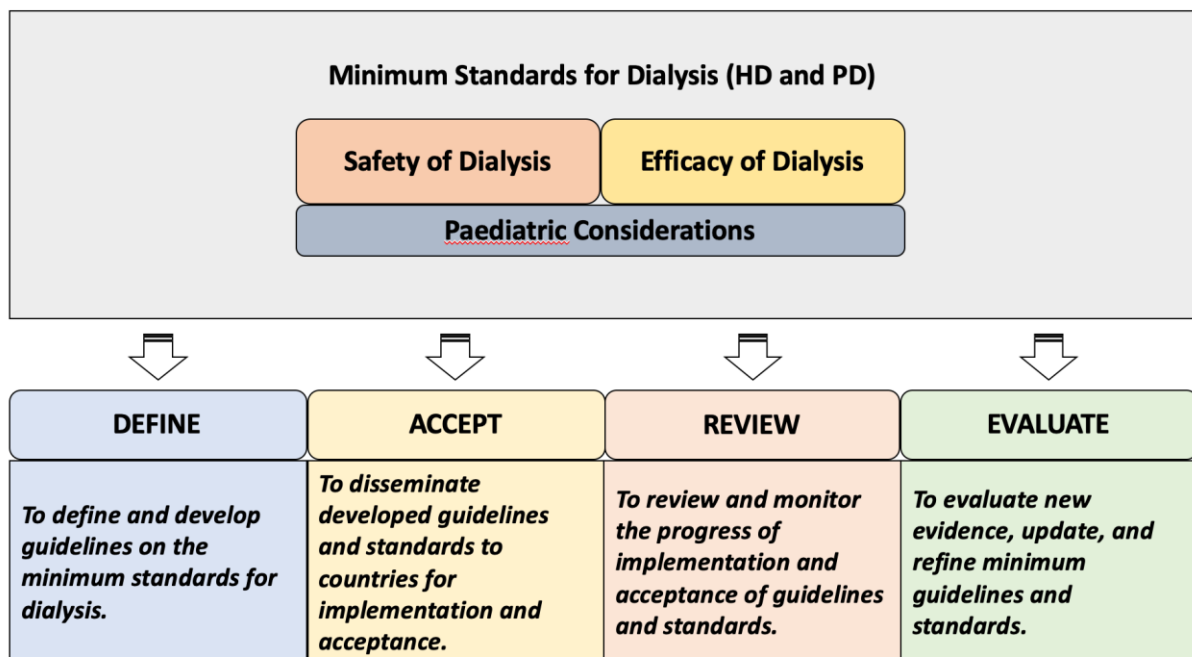
AIM

The aim of the *Dialysis Working Group* is to define, recommend, apply, and develop a monitoring framework for minimum and optimal safety and quality standards for sustainable PD and HD. In addition, there is a need to define the safety standards for pediatric dialysis facilities.

SUMMARY OF ACTIVITIES

Figure 3 summarizes the four major activities (**Define**, **Accept**, **Review**, **Evaluate**) that the *Dialysis Working Group* will undertake to achieve its aims. Details of each activity are outlined in Tables 4-7. The ISN Dialysis Committee will provide the continual oversight, review the developed guidelines, and monitor the progress of the *Dialysis Working Group*. The *Dialysis Working Group* will be the executive arm of the ISN Dialysis Committee and ensure that the aims of the group are achieved in a timely manner.

Figure 2. Summary of the aims and activities of the *Dialysis Working Group*



HD = hemodialysis; PD = peritoneal dialysis

Table 4. *Dialysis Project 1 (D1): DEFINE - To define minimum safe standards for sustainable dialysis treatment*

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • WHO-ISN Collaboration members and <i>Dialysis Working Group</i> • Key Partners: WHO, ISPD • Future dissemination partners: Patient organizations, industry, NGOs, PPP, ISHD, KDIGO, KDOQI, KHA-CARI, ERBP, local MOH, national nephrology organizations, university-based global health programs 	<ul style="list-style-type: none"> • Published guidelines • AAMI water standards • National societies • Governments • ISN Collection⁵ 	<ul style="list-style-type: none"> • 12-24 months
<u>Challenges</u>		
<ul style="list-style-type: none"> • Integration of existing guidelines and identification of the existing gaps which mean that minimum safe standards, applicable in lower resource settings, are not identified 		
<u>Resources required</u>		
<ul style="list-style-type: none"> • Support for (a) regular core group telephone-/video-conferences, (b) opportunistic meetings at international conferences, working closely with the <i>Resources Working Group</i> • Secretarial/organization support 		
<u>Equity considerations</u>		
<ul style="list-style-type: none"> • Minimum standards must not be used to reduce quality, safety, or efficacy of dialysis treatment 		
<u>Deliverables</u>		
Set of recommendations adapted to local settings utilizing the ADAPTE ²¹ framework for:		
<ul style="list-style-type: none"> • Pre-dialysis care, dialysis initiation, dialysis frequency, and dose (both HD and PD) • Recommendations for HD to include vascular access, water treatment, dialyzer reuse, machine sterilization, monitoring and reporting safety and outcomes, infection control • Recommendations for PD to include catheter placement, connection systems, infection control, and possible development of local source of dialysate and equipment • Recommendations for infection control to include prevention of access infection, infection control standards, patient isolation, vaccination of patients and staff, and careful monitoring of adverse events • Competency framework for the dialysis workforce (in collaboration with the <i>Resources Working Group</i>) • Comprehensive catalog of resource requirements, e.g., infrastructure, protocols (in collaboration with the <i>Resources Working Group</i>) 		

WHO = World Health Organization; ISN = International Society of Nephrology; ISPD = International Society for Peritoneal Dialysis; NGOs = Non-governmental Organizations; PPP = public-private partnerships; ISHD = International Society for Hemodialysis; KDIGO = Kidney Disease Improving Global Outcomes; KDOQI = Kidney Disease Outcomes Quality Initiative; KHA-CARI = Kidney Health Australia Caring for Australasians with Renal Impairment; ERBP = European Renal Best Practice; MOH = Ministry of Health; AAMI = Association for the Advancement of Medical Instrumentation; HD = hemodialysis; PD = peritoneal dialysis

Explanatory Notes for Table 4, *Dialysis Project D1*

This project will build on the existing WHO-ISN Collaboration, part of which is creating a technical package for setting up dialysis treatment in low-resource settings. This technical package, combined with the definitions for safe minimum standards for dialysis, will inform both the resource requirements and the competency framework which will underpin the work of the *Resources Working Group* and the subsequent development of the quality framework by the *Dialysis Working Group* (Figure 1). This will ensure that the quality framework can include agreed competencies and infrastructure requirements. Existing guidance on dialysis will be reviewed and a gap-analysis undertaken to establish areas in which information is lacking and where this is the case, consensus guidance will be developed. To ensure relevance, this gap-analysis will be both literature-based and informed by focus group meetings held opportunistically at international/national conferences, especially those in low resource settings and collaboratively with the *Resources Working Group*. This process will take a number of specific issues into account, including, but not exclusively:

1. Define the amount of dialysis to be provided and appropriate timing for the initiation of dialysis
2. Consider incremental dialysis for both HD and PD as ways of reducing costs and optimizing care and quality of life for patients
3. The role of 'PD-first' programs
4. Barriers to achieving international water standards
5. Dialyzer re-use
6. Determine the feasibility of telemedicine utilization for staff training, monitoring patients, etc.

7. Explore innovative approaches to dialysis therapy, including creative use of solar energy, innovative and efficient water treatment, more cost-effective dialysis machinery, inexpensive manufacture of PD solutions, and reduction in plastic waste.

Table 5. *Dialysis Project 2 (D2): ACCEPT- To develop an incremental monitoring framework for minimum and optimal safety and quality standards for hemodialysis and peritoneal dialysis that can be accepted in different resource settings*

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • <i>Dialysis, Resources, and Monitor Working Groups</i> • Key Partners: WHO, ISPD, ISN Dialysis Committee • Future dissemination partners: Patient organizations, industry, NGOs, PPP, ISHD, KDIGO, KDOQI, KHA-CARI, ERBP, local MOH, national nephrology organizations, university-based global health programs 	<ul style="list-style-type: none"> • Outputs from Project D1, including the competency frameworks and resource requirements 	<ul style="list-style-type: none"> • 24-60 months
<u>Challenges</u>		
<ul style="list-style-type: none"> • To agree on an incremental set of key performance indicators (KPIs) that can form the basis of a progressive monitoring framework that is feasible for countries/jurisdictions to implement at their own pace • To determine how these performance indicators will be captured 		
<u>Resources required</u>		
<ul style="list-style-type: none"> • Systems and mechanisms developed by the <i>Monitor Working Group</i> • Support for regional meetings and workshops to disseminate and receive feedback on the acceptability and feasibility of implementing the monitoring framework 		
<u>Equity considerations</u>		
<ul style="list-style-type: none"> • It is likely that the adoption of the monitoring framework will proceed at a different pace in different resource settings 		
<u>Deliverables</u>		
<ul style="list-style-type: none"> • An agreed set of KPIs and standards that can be used to monitor the safety and quality of dialysis that has international buy-in and is suitable for phased introduction using the resources developed by the <i>Monitor Working Group</i> (e.g., national registries with agreed definitions) as well as oversight mechanisms within local jurisdictions 		

WHO = World Health Organization; ISPD = International Society for Peritoneal Dialysis; ISN = International Society of Nephrology; NGOs = Non-governmental Organizations; PPP = public-private partnerships; ISHD = International Society for Hemodialysis; KDIGO = Kidney Disease Improving Global Outcomes; KDOQI = Kidney Disease Outcomes Quality Initiative; KHA-CARI =

Explanatory Notes for Table 5, *Dialysis Project D2*

Using the minimum safe standards for sustainable dialysis treatment developed for Project D1, combined with the competency framework (developed for the dialysis workforce) and resource requirements (infrastructure protocols) co-developed with the *Resources Working Group*, a framework of key performance indicators (KPIs) will be developed. These measures will include specific metrics (e.g., outcome reporting, staffing [numbers, competencies], implementation of safety protocols), and how they should be reported, with both minimum and aspirational standards. To ensure that this framework has international buy-in, especially in low-resource settings, it will need to be developed in collaboration with healthcare providers, commissioners, and policy makers. Given the overlap with the work of the *Resources Working Group* on healthcare models to build sustainable dialysis services, it is proposed that these working groups use joint regional workshops to develop the framework. It is likely that the introduction of KPIs will need to be incremental, and thus prioritized over time, to give opportunity for appropriate mechanisms to be developed in low-resource settings.

Table 6. *Dialysis Project 3 (D3): REVIEW - Iterative review and monitoring progress of implementation of the quality framework*

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • <i>Dialysis, Resources, and Monitor Working Groups</i> • ISN Dialysis Committee 	<ul style="list-style-type: none"> • Quality framework • Key performance indicators (KPIs) 	<ul style="list-style-type: none"> • 24-60 months

Challenges

- To develop and implement a progressive reporting system for the incremental KPIs defined in Project D2 that is feasible for countries/jurisdictions to engage with at their own pace

Resources required

- Systems and mechanisms developed by the *Monitor Working Group*
- Support for regional meetings and workshops to disseminate and receive feedback on the feasibility of implementing the monitoring framework

Equity considerations

- It is likely that the implementation and reporting of the monitoring framework will proceed at a different pace in different resource settings

Deliverables

- Implementation of the agreed mechanism and format for iterative monitoring and reporting of the progressive KPIs and standards developed in Project D2, that is sensitive to local requirements
- Publication of regular reports, for example, in line with the reports of the ISN-GKHA

ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas

Explanatory Notes for Table 6, *Dialysis Project D3*

This project will require close working with the *Monitor Working Group* and will depend heavily on the local development of reporting mechanisms, e.g., registry development. It is likely that the adoption of KPIs will be very modest at first and experience even from well-developed reporting systems has shown that a focus on small numbers of KPIs at any one time is more productive than taking too broad an approach from the start.

Table 7. *Dialysis Project 4 (D4): EVALUATE* - To evaluate new evidence, update and refine minimum standards, guidelines, and recommendations for the delivery of dialysis

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • <i>Dialysis, Resources, and Monitor Working Groups</i> • ISN Dialysis Committee 	<ul style="list-style-type: none"> • Literature review • Guideline review 	<ul style="list-style-type: none"> • Annually review

Challenges

- To identify new evidence that is of sufficient importance to inform a change in the dialysis quality framework and to develop an appropriate performance indicator

Resources required

- Literature and guideline review
- If new evidence of sufficient importance is identified, then in collaboration with the *Resources Working Group*, its implementation in resource challenged settings will need review at joint regional workshops and appropriate health economic evaluation

Equity considerations

- It is likely that some new technologies will be challenging to implement in low-resource settings

Deliverables

- An annual summary of new evidence in dialysis treatment
- The development of new key performance indicators to support monitoring of new dialysis practice where this is appropriate

Explanatory Notes for Table 7, *Dialysis Project D4*

The main purpose of this project, which should be undertaken annually, is to ensure that the quality framework remains relevant and informed by the best evidence available. New technologies may be either resource neutral, beneficial, or challenging, so health economic evaluation is critical, and the focus will be on developments suitable for low-resource settings. One of the key functions of this project group may be to support or lobby for independent evaluation before incorporation into the dialysis quality framework. It should be recognized that this will not be confined to technological developments as changes in practice may be of equal relevance and thus changes to the competency framework may be required in collaboration with the *Resources Working Group*.

THEME 3: RESOURCES

Theme Leads: Vivek Jha, Tushar Vachharajani, Roberto Pecoits-Filho

A range of resources (human, material, and financial) are required to ensure effective delivery of care to patients with kidney failure. Resource availability is directly linked to the wealth of countries. According to the ISN-GKHA, dialysis is available in almost all countries. However, availability is not synonymous with uniform accessibility and/or uniform adherence to quality standards along with advocacy.²⁰

Lack of skilled workforce (nephrologists, nurses, and dialysis technicians) is a major barrier in providing optimal care of patients with kidney failure in resource-limited settings. In the absence of standards or regulatory oversight, the quality of training and the competencies of personnel engaged in dialysis delivery remains highly variable. Also, very little is known about the incentives and reimbursements required to improve the human capital shortfall in care of patients with kidney failure. This impacts the quality of care delivered to patients with kidney failure and their outcomes.

AIM

The aim of the *Resources Working Group* is to make recommendations on

1. the required competencies of the care providers involved in care delivery to patients with kidney failure,
2. the requirements, needed resources, and delivery mechanisms for workforce training,

3. the incentives required to attract and retain a skilled dialysis workforce
4. the non-human resources required for dialysis, and
5. the dialysis delivery models to build sustainable dialysis services and a framework to measure implementation.

SCOPE AND LIMITATIONS

The group will limit the scope of activities to HD and PD since transplantation is covered in Theme 4, *Transplantation*, and conservative care in Theme 5, *Conservative Kidney Management*. The group will interact closely with the *Dialysis Working Group* that is developing the quality and monitoring standards (since they have direct impact on resource requirements), the *Monitor Working Group* (to ascertain baseline and measure changes over time), and the team working on the WHO-ISN Collaboration towards development of a technical package for dialysis care delivery. Together, the groups will develop an implementation and monitoring plan to measure the impact of the projects outlined in this document.

Availability of resources depends on local healthcare priorities and policies and current state of development of health services. Still, several opportunities exist to make efficient use of resources already available in the existing healthcare systems to support effective delivery of care to patients with kidney failure. As the group develops training frameworks, ongoing consultations will be needed with policy makers and educators to ensure these can be embedded in local systems. This will be facilitated by the ISN Regional Boards and regional, national nephrology societies and individuals (local champions) through data-driven advocacy.

Understanding the factors (i.e., incentives, working conditions, remuneration, and other factors) required to attract and retain a skilled workforce can be achieved through the use of discrete choice surveys.²² The surveys determine the relative importance of different components of employment including monetary and non-monetary benefits such as pay, provision of housing, training opportunities, health insurance, typical workload, and location of work. The results from these surveys will provide employers and policy makers with good evidence about the incentives required to build and maintain a sustainable dialysis workforce. Similar surveys have been conducted for public sector nurses in Malawi²³ and community health workers in India.²⁴

The group also recognizes that emerging countries around the world are quite heterogeneous, are at different stages of development in terms of delivery of care to patients with kidney failure, and will have different resource needs and ability to meet them. This will change over time. The purpose of this group is not to be prescriptive in terms of defining resource requirements. Rather, countries/regions should be able to choose from a menu of most appropriate 'incremental' KPIs and standards (developed by the *Dialysis Working Group*) mapped against the local policies and use that information to identify current resource requirements. This will require periodic 'horizon scanning' – to be undertaken in collaboration with the *Monitor Working Group*.

The *Resources Working Group* will carry out its activities in four projects, detailed in Tables 8-11.

Table 8. Resources Project 1 (R1): Definition of the essential workforce and their respective competencies to deliver kidney failure care

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • Project leads • <i>Monitor</i> Working Group, ISN-GKHA, SharE-RR, consultation with Regional and National Societies 	<ul style="list-style-type: none"> • ISN-GKHA 	<ul style="list-style-type: none"> • 12-18 months
<u>Challenges</u>		
<ul style="list-style-type: none"> • Definition of essential workforce and their minimal/ideal competencies that applies to different regions and socio-economic realities. Stakeholders likely to differ across regions. 		
<u>Resources required</u>		
<ul style="list-style-type: none"> • Support for (a) regular core group telephone-/video-conferences, (b) meetings at international conferences, working closely with the <i>Monitor</i> Working Group • Additional collection of data and data extraction from the ISN-GKHA • Secretarial/organization support 		
<u>Equity considerations</u>		
<ul style="list-style-type: none"> • It is likely that there will need to be different role definitions for the essential workforce, since a single definition will not apply across different regions 		
<u>Deliverables</u>		
<ul style="list-style-type: none"> • A list of competencies and capabilities mapped to healthcare provider, service settings and locally acceptable quality standards • Recommendations about transferability of responsibilities between care providers (cross training) 		
<u>Assessment of Performance</u>		
Metrics for evaluating progress		
<ul style="list-style-type: none"> • Meetings held and contacts with other Societies • Launch of the resource document with the definition of the essential workforce 		
Metrics for evaluating output/ outcomes		
<ul style="list-style-type: none"> • Production of guidance/ toolkits • Numbers of initiatives based on the <u>guidance provided by the output of this project</u> 		
<small>ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas; SharE-RR = Sharing Expertise in establishing Renal Registries</small>		

Explanatory Notes for Table 8, Resources Project R1

The group recognizes that an increase in the number of specialized care providers is not possible in the short-term, requires change in policies, and is beyond the scope of this group’s activities. However, understanding the factors that will attract or retain a skilled dialysis workforce is achievable. Other disease specific care models (such as HIV) have taught us that if the skills needed to provide care to patients with

kidney failure are matched against a specific, discrete set of tasks, the available healthcare providers in a given region could be re-trained to support the overall treatment goal with short-term skills development courses to meet this goal in the short-term. Examples from existing dialysis programs suggest that *task-shifting* and *task-sharing*, if done appropriately and in a regulated manner, can improve the efficiency and quality of care delivered.²⁵ An important goal is understanding labor force dynamics that will attract or retain key personnel in the range of services required in the care of patients with kidney failure.

Addressing the shortage and training needs of the healthcare workforce falls under various designations in different regions. Guidance will be taken from other examples of addressing similar needs – for example, through task-shifting and task-sharing.²² Besides the nephrologists and nurses who are specifically trained in providing kidney replacement therapy, other partners should be identified as potential team members. A system of certification guaranteeing the level of competency should be developed in consultation with appropriate agencies in different jurisdictions

To provide background information needed to define the needs and demands, data regarding kidney failure care for different regions of the world must be compiled. Since most of the LIC and LMIC lack a CKD registry,²⁶ data compiling and needs assessment can be achieved by tapping into existing resources such as the ISN-GKHA. This data collection phase will be the most challenging aspect and will have to be integrated with the *Monitor* Working Group's plans to avoid duplication of efforts. Additional survey studies, including the discrete choice surveys, will be

required to determine both the financial and non-financial incentives and reimbursement needed to attract key personnel, as well as the current level of skill/competency of the partners. In order to define specific roles of health workers and competencies needed to perform these tasks the plan would be to develop a single document for the categories identified in Table 12.

Table 9. Resources Project 2 (R2): Training resources

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • Project leads • ISN Education Working Group, graduated ISN Fellows 	<ul style="list-style-type: none"> • ISN-GKHA • ISN Regional Board input 	<ul style="list-style-type: none"> • 12-18 months

Challenges

- Language and cultural diversity
- Funding stream to support both initial and ongoing training programs

Resources required

- Support for (a) regular core group telephone-/video-conferences, (b) meetings at international conferences, working closely with the *Dialysis Working Group*
- Secretarial/organization support
- Subjects experts, Research Fellows
- ISN Academy, dialysis industry-sponsored courses, university online courses, ISN Fellows who have returned to their home country after completing their training, patient groups

Equity considerations

- It is likely that there will be a need to identify, develop and integrate different training formats (online, didactics, workshops) across different regions

Deliverables

- A repository of training centers and online courses
- Mapping of training resources to competency levels
- A pilot program to deliver minimum skills standards for various health care providers and study its effectiveness
- Development of an ISN suggested minimum skills requirement checklist to help regional agencies/universities to establish a Skills Competency Certification Program (which can be implemented at ISN Regional Training Centers/partner universities)

Assessment of Performance

Metrics for evaluating progress

- Number of sites per ISN Region equipped to offer competency training

Metrics for evaluating output/ outcomes

- Number of trainees/ISN Region/year completing the skills training

ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas

Explanatory Notes for Table 9, *Resources Project R2*

All healthcare providers need training to achieve skills and become competent, both in their core areas as well as to acquire transferable skills required for task-shifting or task-sharing as needed. The main purpose of this project is to make sure that all stakeholders have access to culturally appropriate training resources in order to develop the required competency. Region-specific assessment of available training centers and curricula will be required to implement any capacity building strategy. These centers will require ongoing monitoring and improvement to impart the most current education and training relevant to providing optimal care to patients with kidney failure. This project will have the following parts: a) assessment of currently available resources, and b) development of new resources.

The ISN has been successful in developing global nephrology partnerships with various organizations to improve workforce skills. The ISN Programs support emerging centers by establishing Sister Renal Center partnerships, develop and deliver continuing medical education courses, provide online training tools through ISN Academy, and have identified a dedicated group of Educational Ambassadors who deliver focused clinical training. Currently, 10 Regional Training Centers (RTC) have been assigned for workforce capacity building and knowledge transfer. The existing RTC can be further developed to build a Skills Competency Certification Program for various services needed to provide comprehensive care of patients with kidney failure in partnership with regional universities/certifying organizations.

Table 10. Resources Project 3 (R3): Assessment of resources beyond workforce

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> Project leads <i>Dialysis Working Group, ISPD, Industry</i> 	<ul style="list-style-type: none"> ISN-GKHA, ISN Collection 	<ul style="list-style-type: none"> 12-18 months
<u>Challenges</u>		
<ul style="list-style-type: none"> To agree on a set of resources to support the delivery of kidney failure therapy with minimum standards and compatible to local reality To map the resources against the quality and standards framework (<i>Dialysis Working Group</i>) 		
<u>Resources required</u>		
<ul style="list-style-type: none"> Support for (a) regular core group telephone-/video-conferences, (b) opportunistic meetings at international conferences, working closely with the <i>Dialysis Working Group</i> Secretarial/organization support 		
<u>Equity considerations</u>		
<ul style="list-style-type: none"> It is likely that there will need to be different definitions for the essential resources beyond workforce, since a single definition will not apply across different regions 		
<u>Deliverables</u>		
<ul style="list-style-type: none"> Create a comprehensive description of the resources as described in Table 13 and map them against the quality and standards framework (<i>Dialysis Working Group</i>) Create a list of essential medicines and technology Updated versions of above as new information emerge 		
<u>Assessment of Performance</u>		
Metrics for evaluating progress		
<ul style="list-style-type: none"> Launch of the resource document with the definition of the essential resources beyond workforce 		
Metrics for evaluating output/ outcomes		
<ul style="list-style-type: none"> Production of guidance/ toolkits Numbers of initiatives based on the guidance provided by the output of this project 		
<small>ISPD = International Society for Peritoneal Dialysis; ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas</small>		

Explanatory Notes for Table 10, Resources Project R3

The availability and quality of care delivered to patients with kidney failure is interconnected to the existing resources and funding to support such a program. Besides the skilled workforce, identifying the minimum infrastructure and other supporting resources is key to defining funding needs. Table 13 lists the resources beyond workforce to be considered while building a care program. As with human

resource, material resource requirements will also change with time as health systems move up the scale of quality of care delivery.

Table 11. Resources Project 4 (R4): Care delivery models to build sustainable dialysis services

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> Project leads <i>Dialysis</i> Working Group, HTA Specialists, Health Economists (identify from Summit participants) 	<ul style="list-style-type: none"> WHO Global Healthcare database World Bank database 	<ul style="list-style-type: none"> Start 2020, end 2021

Challenges

- Allocating funds to build a sustainable treatment program raises ethical dilemmas, e.g., how can the allocation process be effective and non-discriminatory (equitable)?
- Limited resources to be used that would benefit the most can bring the challenge of creating principles of “rationing of care.” How does one decide who gets dialyzed and who gets comfort care? How does one prevent misuse of “rationing of care” strategy?

Resources required

- Support for (a) regular core group telephone-/video-conferences, (b) opportunistic meetings at international conferences, working closely with the *Dialysis* Working Group
- Secretarial/organization support
- Inputs from sociologists, health economists, ethicists and HTA experts

Equity considerations

- Inputs from health economists and health technology experts will be required:
 - Are the allocated funds used equally between adult and pediatric population?
 - How does one accommodate special populations such as refugees, illegal immigrants, victims of natural disasters?
- How does a government justify allocating funds from the national health budget towards improving management goals of one specific disease?
- What role will be played by WHO, World Bank and Regional Developmental Banks?

Deliverables

- An online resource reference hub for the dialysis care delivery models
- Guidance document for HTA of available treatment options for kidney failure care
- Guidance document to support the implementation of PPP

Assessment of Performance

Metrics for evaluating progress

- Interaction with health economists/HTA specialists
- Launch of the resource document with the definition of the essential workforce

Metrics for evaluating output/ outcomes

- Production of guidance/ toolkits
- Number of initiatives based on the guidance provided by the output of this project

HTA = Health Technology Assessment; WHO = World Health Organization; PPP = public-private partnerships

Explanatory Notes for Table 11, *Resources Project R4*

Access to care for kidney failure is limited due to funding barriers in large parts of the world. Funding is needed for both building skilled workforce and the infrastructure.

The delivery of dialysis services requires innovative models that are efficient and cost effective. Health Technology Assessment should be done in all jurisdictions to prioritize service development, such as choice of dialysis modality and development of socially acceptable, equitable, and transparent eligibility criteria. There is also a role for system-level innovations to reduce cost, such as incremental dialysis, early vascular access creation (incentives), equal nephrologist compensation for HD/PD, link with quality of care/outcome reporting, etc.

In contrast to developed countries with well-established dialysis delivery systems, emerging countries have a wide range of care delivery models, often several in one country. These include delivery through the public sector (government), private industry (public-private partnerships [PPP] or investments [PPI]), charitable NGOs, charitable foundations, etc. However, there are no set guidelines or health policies that are available to guide governments on building such partnerships.

Table 12. Specific tasks and suggested primary provider (with alternatives in low resource areas) needed to develop competencies in LIC and LMIC

Specific tasks	Provider	Alternative / task sharing in LIC	Setting for service	Other groups	ISN capabilities
Kidney failure diagnosis and risk assessment and treatment: HD/PD	Nephrologist / Dialysis doctor	PCP, internist, Advanced Practice Provider (APP)	Hospital, out-patient dialysis clinics, consulting rooms	ISPD, ISHD, ASN, ERA-EDTA, SLANH, AFRAN, APSN, national Societies	Academy, Regional Training Centers, Workshops, CME, WCN

Skilled dialysis service	Nursing personnel including Kidney Supportive/Palliative Care nurses	Dialysis technicians	Hospital, outpatient dialysis clinics	ISPD, ISHD, nursing societies / organizations / local universities	Academy, Regional Training Centers, Workshops
Skilled dialysis service	Dialysis technicians	No alternatives to Dialysis technicians	Hospital, outpatient dialysis clinics	ISPD, ISHD, nursing societies / organizations / local universities	Academy, Regional Training Centers, Workshops, CME, WCN
Kidney chemistry, Urine studies, HLA	Lab personnel	College graduates / dialysis technicians for point of contact screening tests	Lab services – hospital, centralized lab	Laboratory, certification bodies, regulatory agencies	Academy, Regional Training Centers, Workshops
Care coordination *	Social Workers / community health workers	Nurses, volunteers, administrative staff with hands-on training	Hospital, outpatient dialysis clinics, telemedicine	NGO volunteer groups	Academy, Regional Training Centers, Workshops
Nutritional counseling*	Dietitians	PCP, Nurses, technicians with on the job cross training, caregivers, patient groups	Hospital, outpatient dialysis clinics, telemedicine	International Society of Renal Nutrition	Academy, Regional Training Centers, Workshops
Supportive care*	PCP, internist, nephrologists, nurses, community health workers	Traditional healers, spiritual healers. non-allopathic doctors, nurses	Hospital, outpatient dialysis clinics, home	NGO supportive / palliative care groups	Academy, Regional Training Centers, Workshops
Social and moral support*	Consumer / family caregiver, community health workers	Religious and patient groups	Home	Kidney patient associations Kidney foundations	Academy, Regional Training Centers, Workshops

LIC = low-income countries; LMIC = lower-middle-income countries; HD = hemodialysis; PD = peritoneal dialysis; PCP = Primary care physician; ISPD = International Society for Peritoneal Dialysis; ISHD = International Society for Hemodialysis; ASN = American Society of Nephrology; ERA-EDTA = European Renal Association – European Dialysis and Transplant Association; SLANH = Latin American Society of Nephrology and Hypertension; AFRAN = African Association of Nephrology; APSN = Asian Pacific Society of Nephrology; CME = Continuing Medical Education; WCN = World Congress of Nephrology; HLA = human leucocyte antigen; NGO = Non-governmental Organizations

*These tasks can be shared between several groups

Table 13. List of resources beyond workforce

Resources	Description
Capital	Hospitals, equipment (HD machines, water treatment system), electricity, consumables, record keeping (office supplies-computers/printers)
Infrastructure	Transport and infrastructure for home deliveries
Other sectors	Social services, community, ambulance, voluntary services
Natural resources	Water, land
Recycling resources	Sewage, biohazard material
Hemodialysis access, equipment, and consumables	Catheters, water treatment, filters and lines, needles, reprocessing systems, blood pressure monitors, heparin, saline, preventive maintenance of equipment needs
Peritoneal solution consumables and material	Catheters, solutions
Medications	ESA, iron, phosphate binders, antihypertensive/antidiabetic drugs, intra-dialytic symptom drugs
Supporting technology	Electronic medical records, telemedicine, remote monitoring, electronic point-of-care decision support systems
Monitoring	Registry
Protocols	SOPs for different functions/procedures, QC benchmarks, natural disaster plans

HD = hemodialysis; ESA = Erythropoiesis-stimulating agents; SOPs = standard operating procedures; QC = quality control

THEME 4: TRANSPLANTATION

Theme Leads: David Harris, Elmi Muller, Philip O'Connell

Transplantation services for kidney failure are non-existent, poorly developed, and/or poorly integrated with dialysis in many countries, especially LIC and LMIC.² The aim of the *Transplantation* Working Group is to define key considerations for development and expansion of kidney transplantation as a component of integrated kidney failure care. This will involve identification of countries with no or limited

services and training programs, development of materials necessary for implementation of sustainable transplantation programs, and definition of pathways to develop those programs. The *Transplantation* Working Group will carry out its activities within four projects, detailed in Tables 14-17. Progress with these initial projects will define the direction of future activities.

Table 14. *Transplantation* Project 1 (T1): Develop a simple assessment tool to test the readiness of a unit to start a transplant program

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • Project leads • ISN and TTS working group • ISN/TTS Sister Transplant Centers (STC) Program • WHO and DICG 	<ul style="list-style-type: none"> • WHO-ONT Global Observatory on Donation and Transplantation • Data from ISN/TTS STC Program 	<ul style="list-style-type: none"> • Document to be completed and submitted for publication by mid-2021 • To be implemented from 2021, starting in 2-3 countries identified by the Working Group • To be implemented in remaining countries over next 5-10years

Challenges

- Engaging with national health departments, ensuring safety of donor and that donation is voluntary and ethical

Resources required

- Those involved with ISN TTS STC Program to use experience to develop tool

Equity considerations

- Applicability of assessment tool to LIC/LMIC units
- Donation must be ethical and voluntary, adhere to WHO guiding principles, and conform to the Declaration of Istanbul

Deliverables

- Paper submitted for publication by mid-2021

Assessment of Performance

Metrics for evaluating progress

- Submission of a brief paper describing an online assessment tool

Metrics for evaluating output/outcomes

- Availability of online tool
- Tool applied in 2-3 countries in 2021, with a plan for following years

ISN = International Society of Nephrology; TTS = The Transplantation Society; WHO = World Health Organization; DICG = Declaration of Istanbul Custodian Group; ONT = Spanish Transplant Organization; LIC = low-income countries; LMIC = lower-middle-income countries

Explanatory Notes for Table 14, *Transplantation Project T1*

An online assessment tool that can be updated as required, describing how to start a kidney transplant program in countries without current programs or approaches. The tool should have the following characteristics:

- Defines the resources and other ingredients needed to develop a successful transplant program (Box 1).
- Explains the options that can be adopted depending of the state of readiness.
- Outlines principles to protect health and rights of the donor.
- Is adaptable depending on local context, including a focus on resources that could be shared regionally and internationally.
- Defines which courses and other education opportunities are or should be available.
- Cites existing documents, yet incorporates key points into the tool, rather than just as appendices or citations.

Box 1. Minimum resources to start a transplant program

Surgical procedures:

- Open nephrectomy
- Laparoscopic nephrectomy*
- Multi-organ deceased donor procurement*

Radiology and interventional procedures:

- Biopsy
- Nephrostomy
- Embolization of an intrarenal aneurysm

Nuclear medicine:

- Isotope* measurement of glomerular filtration rate

Laboratory:

- Standard laboratory assessments
- Microbiology
- Drug monitoring
- Tissue typing
- Complement-dependent cytotoxicity (CDC) cross matching test
- Flow cytometric lymphocyte cross match

Human resources:

- Physician-nephrologist
- Surgeon
- Radiologist
- Anesthetist
- Pharmacist
- Microbiologist
- Pathologist
- Nursing and support staff

*optimal

Note: an active dialysis program is essential

Table 15. *Transplantation* Project 2 (T2): Undertake an environmental scan of existing transplant programs in low- and middle-income countries

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none">• Project leads• Potential partners will include representatives from TTS, WHO, DICG, ESOT, and ISN	<ul style="list-style-type: none">• ISN-GKHA	<ul style="list-style-type: none">• Construct questionnaire by end 2020• Administer survey in 2021
<u>Challenges</u>		

-
- Developing an ISN-GKHA questionnaire of sufficient detail
 - ISN-GKHA timelines

Resources required

- ISN-GKHA

Equity considerations

- Nil specific
-

Deliverables

- Survey questionnaire
-

Assessment of Performance

Metrics for evaluating progress

- Questionnaire developed and survey administered

Metrics for evaluating output/ outcomes

- Analysis and publication of survey results
-

TTS = The Transplantation Society; WHO = World Health Organization; DICG = Declaration of Istanbul Custodian Group; ESOT = European Society for Organ Transplantation; ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas

Explanatory Notes for Table 15, *Transplantation Project T2*

- The project team will work with ISN-GKHA to develop a survey which will be administered by ISN-GKHA.

Table 16. *Transplantation Project 3 (T3): Define in greater detail recipient evaluation, and how a living donor should be identified, worked up, and followed up*

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • Project leads • ISN and TTS working group • DICG, KDIGO 	<ul style="list-style-type: none"> • Published Literature • DICG data/publications • TTS ethical guidance • WHO guiding principles • KDIGO 	<ul style="list-style-type: none"> • Tools to be developed and available for distribution by mid-2021 • Assistance with adaptation and implementation of tools from late 2021, starting in 2-3 countries identified by the Working Group • Widespread adoption of tools will take 5 or more years

Challenges

- Nil specific

Resources required

- Nil specific

Equity considerations

-
- Applicability of process to LIC/LMIC individual units
 - Protection of living donor and prevention of organ trafficking
-

Deliverables

- Tools ready for distribution by mid-2021, with updating and adaptation as required
-

Assessment of Performance

Metrics for evaluating progress

- Progress with tools

Metrics for evaluating output/outcomes

- Tools completed by mid-2021
 - Applied in 2-3 countries from late 2021, with a plan for following years
-

ISN = International Society of Nephrology; TTS = The Transplantation Society; DICG = Declaration of Istanbul Custodian Group; KDIGO = Kidney Disease Improving Global Outcomes; WHO = World Health Organization; LIC = low-income countries; LMIC = lower-middle-income countries

Explanatory Notes for Table 16, *Transplantation Project T3*

Existing publications (e.g., KDIGO) will be adapted to create tools that can be used for recipient assessment and living donor assessment and management. These should include:

- Details around living donor workup and care, with definitions/minimum criteria which should be comprehensive, and relevant existing resources included, appended, and cited where appropriate
- A comprehensive stepwise clinical approach to working up and caring for recipients drawn from existing guidelines and modified for local needs
- A focus on adherence to ethical guidelines
- A focus on what the minimum resources should be
- What is acceptable in terms of travel for transplant and commercial transplant with reference to ethical standards for living donor recruitment, evaluation, and follow-up
- A focus on areas not covered adequately by existing documents. Key points should be incorporated into the document, rather than just appended or cited

Table 17. *Transplantation Project 4 (T4): Assess and revisit the current training programs supported by ISN and TTS*

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> Project leads Potential partners will include TTS, as well as regional societies, e.g., ESOT, and ISN An assessment of outcomes from previously funded programs by contacting individuals who were involved in TTS/ISN sister program training; and of existing on-line training resources 	<ul style="list-style-type: none"> Awardees from ISN/TTS Sister Transplant Centers (STC) Program 	<ul style="list-style-type: none"> Plan to start survey in 2020
<u>Challenges</u>		
<ul style="list-style-type: none"> Travel and workforce issues with COVID-19 		
<u>Resources required</u>		
<ul style="list-style-type: none"> Survey of past recipients of relevant ISN TTS programs (fellowships, STC), in conjunction with ISN staff 		
<u>Equity considerations</u>		
<ul style="list-style-type: none"> Determination that donor selection is equitable and not a burden carried by one section of society, e.g., gender of donor vs recipient 		
<u>Deliverables</u>		
<ul style="list-style-type: none"> Survey by existing ISN TTS staff Assessment of existing transplantation training resources 		
<u>Assessment of Performance</u>		
Metrics – for evaluating progress		
<ul style="list-style-type: none"> Number of transplants Patient and graft survival Percent of donors that are female vs percent of donors that are male 		
Metrics for evaluating output/ outcomes		
<ul style="list-style-type: none"> Ongoing programs, patient and graft survival, donor follow and complications, transplant numbers 		
<p>TTS = The Transplantation Society, ESOT = European Society for Organ Transplantation; ISN = International Society of Nephrology</p>		

Explanatory Notes for Table 17, *Transplantation Project T4*

- With ISN Programs staff, the aims of the survey are to look at specific outcomes, and identify limitations in the previous training programs, advise on the expansion/modification of these programs, and identify more partnership and training opportunities, including a possible network of ISN TTS Regional Training Centers.

- To assess whether current programs are achieving their mission of establishing viable and expanding transplant programs, that donors are protected and cared for, and outcomes are acceptable.
- Current online resources will be assessed for their suitability for transplantation training, and with the aim of developing new resources as required.

THEME 5: CONSERVATIVE KIDNEY MANAGEMENT

Theme Leads: David Harris, Mark Brown

Conservative kidney management (CKM) without dialysis services for kidney failure are non-existent, poorly developed, and/or poorly integrated with dialysis in many countries, especially LIC and LMIC.² The aim of the *Conservative Kidney Management Working Group* is to define key considerations for development and expansion of conservative care as a key component of integrated care for patients with kidney failure. This will involve identification of countries with no or limited services and training programs, development of materials necessary for implementation of sustainable conservative care programs, and definition of pathways to develop those programs. Interim definitions of kidney supportive care and conservative kidney management are provided in Table 18. The *Conservative Kidney Management Working Group* will carry out its activities within four projects, detailed in Tables 19-22. Progress with these initial projects will define the direction of future activities.

Table 18. Interim definitions of kidney supportive care and conservative kidney management

Kidney Supportive Care (KSC): Services aimed at improving the health-related quality of life (HRQoL) of patients with established chronic kidney disease. Based on principles of palliative care, defined by the World Health Organization as an approach that improves the HRQoL of patients and their families, through the prevention and relief of suffering by early identification and impeccable assessment and treatment of pain and other physical, psychosocial, and spiritual problems.

Conservative Care can be an alternative to kidney replacement therapy and delivered in one of two settings:

1. As ‘conservative kidney management’ (CKM), where conservative care is either chosen or medically advised. This is planned, holistic, person-centered care that does not include dialysis but includes the following:
 - Interventions to delay progression and minimize risk of adverse events or complications
 - Shared decision making
 - Active symptom management
 - Detailed communication including advance care planning
 - Psychological support
 - Social and family support
 - Cultural and spiritual domains of care

2. As ‘choice-restricted CKM’, where resource constraints have prevented or limited access to kidney replacement therapy and therefore, while conservative care is not chosen, is preferable to no care at all

Table 19. Conservative Kidney Management Project 1 (C1): Define supportive care, develop internationally accepted terminology, promote acceptance of kidney supportive care amongst kidney health workers, and promote nephrology training in this field

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • Project leads • Draft manuscript with input from KDIGO group to ensure alignment 	<ul style="list-style-type: none"> • Existing literature and KDIGO guidelines²⁷ 	<ul style="list-style-type: none"> • Paper to be written by end of June 2021 • Promotion of Supportive Care and training from Jan 2022 including the development of a global curriculum for KSC training
<u>Challenges</u>		
<ul style="list-style-type: none"> • Obtaining agreement on future terminology 		
<u>Resources required</u>		
<ul style="list-style-type: none"> • Scan of existing literature and guidelines 		

Equity considerations

- Nil specific

Deliverables

- Submission of the paper by September 2021

Assessment of Performance

Metrics for evaluating progress

- Submission of paper

Metrics for evaluating output/ outcomes

- Publication of paper
- Change in extent of KSC training over the next 5 years
- Development of an ISN KSC training curriculum

KDIGO = Kidney Disease Improving Global Outcomes; KSC = Kidney Supportive Care

Explanatory Notes for Table 19, *Conservative Kidney Management Project C1*

A manuscript that:

- Discusses terminology used in the literature and major guidelines from Canada,²⁸ Australia,^{29,30} KDIGO,²⁷ and possibly elsewhere
- Defines an internationally acceptable terminology
- Promotes ways to get the message about kidney supportive care (KSC) and CKM to all kidney health workers
- Promotes training for all nephrology trainees in this field with the same insistence as exists for dialysis and transplant training

Table 20. *Conservative Kidney Management Project 2 (C2): Undertake an environmental scan of existing CKM programs*

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none">• Project leads• Other experts in CKM will be consulted about the appropriateness of the survey questions	<ul style="list-style-type: none">• ISN-GKHA	<ul style="list-style-type: none">• Develop questionnaire by end 2020• Administer survey in 2021

Challenges

- Developing an ISN-GKHA questionnaire of sufficient detail
- ISN-GKHA timelines

Resources required

-
- ISN-GKHA

Equity considerations

- Nil specific

Deliverables

- Survey questionnaire

Assessment of Performance

Metrics for evaluating progress

- Questionnaire developed and survey administered

Metrics for evaluating output/ outcomes

- Analysis and publication of survey results

CKM = Conservative Kidney Management; ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas

Explanatory Notes for Table 20, *Conservative Kidney Management Project C2*

- The project team will work with ISN-GKHA to develop a survey which will be administered by ISN-GKHA.

Table 21. *Conservative Kidney Management Project 3 (C3): Provide prognostic tools and information for patients*

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> • Project leads • Once the document is finalized, consult other relevant groups for their views on prognostic tools, including French REIN registry, USRDS, ANZDATA • Once the document is finalized, consult other groups for their views on patient information tools, including Coalition for Supportive Care of Kidney Patients (USA), Supportive Care Kidney Research Group (Canada), Kidney Health Australia, The Renal Association / Kidney Care UK, Sociedad Española de Nefrología 	<ul style="list-style-type: none"> • Literature scan 	<ul style="list-style-type: none"> • Draft resources to be sent for comment by June 2021 • Resources to be available for dissemination by end of 2021 • Distribution of information via ISN Academy and broadcasts from 2022 onwards
<u>Challenges</u>		
<ul style="list-style-type: none"> • Development of a prognostic tool that addresses HRQoL as well as survival and other relevant outcomes 		
<u>Resources required</u>		
<ul style="list-style-type: none"> • Nil additional 		

Equity considerations

- Applicability of tools and patient information to low resource settings

Deliverables

- Completion of these two separate resources by end of 2021, then
- Distribution of this information for clinicians and patients via ISN Academy and broadcasts from 2022 onwards

Assessment of Performance

Metrics for evaluating progress

- Completion of resources

Metrics for evaluating output/outcomes

- Distribution of resources
- Uptake of tools and patient information (possibly via ISN-GKHA survey)

REIN = Renal Epidemiology and Information Network; USRDS = United States Renal Data System; ANZDATA = Australian and New Zealand Dialysis and Transplant; USA = United States of America; UK = United Kingdom; ISN = International Society of Nephrology; HRQoL = health related quality of life; GKHA = Global Kidney Health Atlas

Explanatory Notes for Table 21, *Conservative Kidney Management Project C3*

Two sets of resources and accompanying papers: one describing likely survival and available tools to predict mortality and health related quality of life at the start of dialysis or if receiving CKM, the other describing available online resources about KSC and CKM for patients and their families.

- Note: drafts of these papers are already available from Gregorio Obrador
- These papers will describe applicability of tools in different regional settings
- Survival data will be gathered from registry reports (mainly for KRT) as well as published manuscripts
- Whilst the first paper will describe tools predicting survival, as well as patient information, it is important that there be an emphasis on providing information beyond survival e.g., quality of life, etc.
- Should include a critical literature review of published data on prognostic tools for survival of dialysis and conservative pathway patients

- Useful resources include papers by Couchoud et al.,³¹ McArthur et al.,³² and Tan et al.³³

Table 22. Conservative Kidney Management Project 4 (C4): Support development of conservative care programs in places where they do not currently exist, particularly for LIC and LMIC

<u>Who</u>	<u>Where/Data Source</u>	<u>Timeline</u>
<ul style="list-style-type: none"> Project leads Support will include experts in conservative care and representatives from organizations including Renal Physicians of USA, European Association of Palliative Care, Coalition for Supportive Care of Kidney Patients Volunteers from the writing group to act as implementation advisors from 2022 	<ul style="list-style-type: none"> ISN-GKHA 	<ul style="list-style-type: none"> Materials assembled by end 2021 Contacts identified and support provided from 2022, starting in 2-3 countries identified by ISN-GKHA Full implementation in all LIC and LMIC will likely take 10 or more years (aim for 50% completion in 5 years, 100% in 10 years)

Challenges

- Misuse of conservative kidney management (CKM) as a strategy to avoid funding kidney replacement therapy

Resources required

- Nil specific for assembling materials
- Government funding for implementation

Equity considerations

- Competing health care priorities in LIC and LMIC

Deliverables

- Materials identified and collated by end 2021
- Support provided to new kidney supportive care (KSC) and CKM programs from 2022: 2-3 by end 2022; 50% of countries by end 2026; 100% of countries by end 2031

Assessment of Performance

Metrics for evaluating progress

- Completion of assembly of documents
- Contacts with LIC/LMIC facilitated

Metrics for evaluating output/ outcomes

- Collated and distributed materials
- Support provided to 2-3 new KSC and CKM programs by end 2022

LIC = low-income countries; LMIC = lower-middle-income countries; USA = United States of America; ISN = International Society of Nephrology; GKHA = Global Kidney Health Atlas

Explanatory Notes for Table 22, *Conservative Kidney Management Project C4*

A set of materials will be identified, collated and assembled, including those identified in Project C3. These should be suitable for updating as required. The documents should have the following characteristics:

- a. Define CKM principles and describe models that illustrate comprehensive step-by-step approaches to implementation of KSC and of CKM
- b. Importantly, they must be applicable in units with very few resources and limited workforce, for example only one non-medical healthcare worker (HCW)
- c. They must also be adaptable depending on local context, including number and expertise of HCW and resources
- d. For KSC, applicable and adaptable to pre-kidney failure, dialysis, transplant, chosen (CKM) and choice-restricted CKM, with palliative care contexts
- e. Comprehensive, with relevant existing resources included, appended or (if freely available) cited, including those identified in Projects C1-C3
- f. To include how and what to train HCW about KSC and CKM. Define which courses and other education opportunities are available (ISN to be asked to develop on-line webinars and curriculum)
- g. Not to include patient education about KSC or CKM, which will be covered in Project S3
- h. For KSC, to include stepwise clinical management of key symptoms and signs (e.g., pain, pruritus, depression, etc.) This document must define which, and provide or append or refer to a care plan for each. These can be drawn from existing guidelines with modification for local needs. A symptom management algorithm/decision support tool could be translated into several common languages. Initial guidelines are available from Canada²⁸ and Australia²⁹

- i. To include how to assess performance of KSC and CKM programs (at individual patient, caregiver, and unit level)
- j. Key points to be included amongst the materials, rather than just appended or cited
- k. Existing resources: Kidney Supportive Care Research Group's website,³⁴ Australian guidelines (2013),³⁰ WHO palliative care,³⁵ KDIGO (2015),²⁷ Moss and the Renal Physicians Association of USA (2010),³⁶ Lam et al. CJASN paper³⁷
- l. *Conservative Kidney Management* Working Group to suggest other documents, including existing tools and calculators, palliative or supportive care courses
- m. Initially, the group will need to define which areas are not covered adequately by existing documents, and will need to be written and by whom.

AUTHOR CONTRIBUTIONS

DCHH, SJD, FOF, and VJ were responsible for conception, organization, writing, editing, and reviewing the manuscript. AKB, MB, FJC, AL, EM, SN, POJ, RPF, and TV were responsible for initial drafts and revision of specific sections of the manuscript. JD was responsible for editing, revision, and logistic organization, including reference management. All other authors were responsible for initial drafts of specific sections of the manuscript, review, and validation after each review.

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The views expressed in this commentary are solely the responsibility of the authors and they do not necessarily reflect the views, decisions, or policies of the institutions with which they are affiliated.

WORKING GROUP MEMBERS DISCLOSURE

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