# Dialysis initiation, modality choice, access, and prescription: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference



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Globally, the number of patients undergoing maintenance dialysis is increasing, yet throughout the world there is significant variability in the practice of initiating dialysis. Factors such as availability of resources, reasons for starting dialysis, timing of dialysis initiation, patient education and preparedness, dialysis modality and access, as well as varied "country-specific" factors significantly affect patient experiences and outcomes. As the burden of end-stage kidney disease (ESKD) has increased globally, there has also been a growing recognition of the importance of patient involvement in determining the goals of care and decisions regarding treatment. In January 2018, KDIGO (Kidney Disease: Improving Global Outcomes) convened a Controversies Conference focused on dialysis initiation, including modality choice, access, and prescription. Here we present a summary of the conference discussions, including identified knowledge gaps, areas of controversy, and priorities for research. A major novel theme represented during the conference was the need to move away from a "one-size-fits-all" approach to dialysis and provide more individualized care that incorporates patient goals and preferences while still maintaining best practices for quality and safety. Identifying and including patient-centered goals that can be validated as quality indicators in the context of diverse health care systems to

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achieve equity of outcomes will require alignment of goals and incentives between patients, providers, regulators, and payers that will vary across health care jurisdictions.

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KEYWORDS: goal-directed dialysis; hemodialysis; home dialysis; initiation; modality; peritoneal dialysis; prescription; symptom control; vascular and peritoneal dialysis access

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uring the past 3 decades, the number of persons undergoing maintenance dialysis globally has increased dramatically. In 2010 it was estimated that the number of patients on dialysis was more than 2 million worldwide, and modeling data suggest this number will more than double by 2030. Several factors have contributed to the increase: improved survival of the general population, reduction in mortality of dialysis patients, an increase in the incidence of chronic kidney disease (CKD), broadening of kidney replacement therapy acceptance criteria, and greater access to maintenance dialysis in low- and middle-income countries. 1,3–5

The circumstances of dialysis initiation and the choices regarding initial modality and access can significantly affect patient experiences and outcomes. Lack of patient preparedness and an urgent start to dialysis are associated with lower survival and higher morbidity. Home modalities such as home hemodialysis and peritoneal dialysis can improve patients perception of autonomy. Lower mortality, fewer medical complications, and lower costs are associated with hemodialysis vascular access via an arteriovenous fistula (AVF) versus

<sup>&</sup>lt;sup>12</sup>See Appendix for list of other conference participants.

arteriovenous graft (AVG) or central venous catheter (CVC). 4 Yet in some circumstances—such as in older patients or those with poor arteriovenous access—an AVG or CVC may be preferred.

Historically, the evaluation of "dialysis adequacy" has been based on small solute clearance. This limited focus excludes the multidimensional parameters involved in achieving optimal dialysis and overlooks necessary evaluations that reflect the many comorbidities present in the dialysis population and how well or how satisfied the patients feel about their treatment. Patients and clinicians can have divergent and sometimes conflicting goals for hemodialysis treatment, with clinicians focused on outcomes such as mortality and biochemical markers and patients prioritizing their well-being and lifestyle.9 For example, some patients on home hemodialysis have reported a willingness to trade months of survival for ability to travel. 10 With the increasing recognition of the importance of patient preferences and satisfaction for shared decision-making and assessing outcomes, 8,9,11-17 it has become clear that a more multifaceted approach is needed for evaluating dialysis as a treatment modality.

In January 2018, KDIGO (Kidney Disease: Improving Global Outcomes) convened a Controversies Conference titled "Dialysis Initiation, Modality Choice, Access, and Prescription." Here we present a summary of the discussion, including knowledge gaps, areas of controversy, and priorities for research. The conference agenda, discussion questions, and plenary session presentations are available on the KDIGO website: http://kdigo.org/conferences/controversies-conference-on-dialysis-initiation/. It should be noted that patients who have a clear path to preemptive or planned kidney transplantation were not considered by the discussants.

#### **DIALYSIS MODALITIES AND AVAILABILITY**

Dialysis modalities include in-center, satellite or self-care, where dialysis is undertaken with access to support staff to aid in the dialytic procedure, and home hemodialysis, as well as continuous ambulatory and automated peritoneal dialysis. Prescription patterns can be categorized as conventional, incremental, intensive (short daily or nocturnal), trial-based, and palliative. Availability of modalities and prescription patterns is usually more a function of local resources, reimbursement policies, and infrastructure than informed patient preferences. In some parts of the world, in-center hemodialysis is the predominant modality, whereas a "peritoneal dialysis first" approach is taken in a number of jurisdictions with excellent outcomes. In industrialized countries, peritoneal dialysis is often more cost-effective than hemodialysis, yet the opposite may be true for countries with no local manufacturing of peritoneal dialysis fluids or with tariffs on importing peritoneal dialysis supplies. 19-21 Factors that have been independently associated with a lower likelihood of use of peritoneal dialysis are diabetes as the cause of end-stage kidney disease (ESKD), higher health care expenditure as a percent of gross domestic product, a larger number of private, for-profit hemodialysis facilities, and greater cost of peritoneal dialysis consumables relative to staffing.<sup>20</sup>

Early mortality (death within the first 90 days of starting dialysis) disproportionately affects patients receiving in-center hemodialysis. This is likely due, at least in part, to selection bias because patients with acute kidney injury complicating chronic kidney failure or those with poorer health status are more likely to use in-center hemodialysis than peritoneal dialysis.<sup>22</sup> Strategies to reduce early mortality are not well studied.

The only absolute contraindication for maintenance hemodialysis is the absence of possible vascular access or prohibitive cardiovascular instability. Peritoneal dialysis is contraindicated if the peritoneal cavity is obliterated, the membrane is not functional, or catheter access is not possible. Anuria is not a contraindication for peritoneal dialysis. All other health conditions are relative contraindications, and therefore the selection of dialysis modality needs to reflect informed patient choice with decision support appropriate to the health care system. Patients and caregivers need to be informed of the challenges, considerations, and trade-offs of the different dialysis modalities so that modality selection can be tailored to their health and social circumstances.

In multiple countries it has been reported that men more commonly receive dialysis than do women.<sup>2,23,24</sup> Further investigation is needed to clarify whether and where disparities exist, and whether disparities result from biological differences or sociocultural biases.

Of note, conference participants recognized that preserving residual kidney function is important and should be a goal for all clinicians and dialysis patients. Yet residual kidney function should not be the sole consideration in selecting the initial dialysis modality, because the quality of evidence comparing decline in residual kidney function across modalities is based on small, mostly single-center, observational studies from more than 2 decades ago.<sup>25</sup> As such, available data are not robust enough to suggest one modality is favorable over another.

Similarly, although there is evidence that some patients may benefit from incremental versus thrice-weekly hemodialysis in terms of preserving residual kidney function, <sup>26</sup> there is currently not enough evidence for widespread adoption of incremental dialysis as a means to preserve residual kidney function.

### Urgent versus nonurgent and planned versus unplanned starts

Urgent starts are defined as those in which dialysis must be initiated imminently or in less than 48 hours after presentation to correct life-threatening manifestations. Nonurgent starts are those in which dialysis initiation can be more than 48 hours after presentation. A planned approach is one in which the modality has been chosen prior to the need for dialysis and there is an access ready for use at the initiation of dialysis. An unplanned start is dialysis initiation when access is not ready for use or requires hospitalization or when dialysis is initiated with a modality that is not the patient's choice. Hemodialysis or peritoneal dialysis is possible in both planned or unplanned and urgent or nonurgent start

situations. However, patients who require urgent dialysis in the setting of hyperkalemia, volume overload, or marked uremia are not good candidates for urgent-start peritoneal dialysis. The following are 5 key elements to a successful urgent start in patients in whom peritoneal dialysis is considered by the physician and patient as optimal therapy:<sup>27</sup>

- (i) Ability to place a peritoneal catheter within 48 hours
- (ii) Staff education regarding use of catheter immediately after placement
- (iii) Administrative support in inpatient and outpatient settings
- (iv) Identification of appropriate candidates for urgent-start peritoneal dialysis
- (v) Utilization of protocols in every step of the urgent-start process (from patient selection for peritoneal dialysis through appropriate post-discharge follow-up)

The major barriers to an urgent-start peritoneal dialysis program are lack of operators who can place a peritoneal dialysis catheter within the urgent start time frame (i.e., 48 hours) and limited capacity of the health care facility to support peritoneal dialysis treatment for urgent-start patients and train patients on short notice. Where technical expertise in PD catheter placement is lacking, this can generally be addressed by increasing access for training in interventional nephrology by nephrologists and/or radiologists. When critical illness, time, or capacity to offer hemodialysis and peritoneal dialysis limit the initial choice, patients need to subsequently be provided with support to enable transition to their preferred modality when feasible.

## PATIENT EDUCATION AND SUPPORT Preparation for dialysis

Education and decision aids are essential in helping patients to better understand kidney failure, weigh available treatments, maintain a feeling of control, and share information with family members and/or carers. <sup>14</sup> Additionally, early education is associated with lower mortality after dialysis is initiated. <sup>15</sup>

Effective education is usually offered to patients as they approach CKD G4.<sup>28</sup> Education materials may include tours or videos with interviews of patients using the different modalities. In the absence of patient- or system-specific contraindications to a form of dialytic therapy, all options should be equally represented. Comprehensive education may also be available in the inpatient setting and for those who did not have regular follow-up with a nephrologist or access to dialysis education prior to starting dialysis.

The dialysis modality is ideally chosen with timely and shared decision-making among the health care team, patients, and their carers. Discussions about options and implications of various dialysis modalities need to include persons who start dialysis in an unplanned fashion. The approach for choosing modality is ideally person-centered, engaging the patient in choosing the dialysis modality in the context of their goals for care, local resources, out-of-pocket costs, capacities of regional health care facilities, and medical feasibility.

Table 1 | Patient and health care system barriers to homebased or self-care dialysis and potential solutions

Barriers	Potential solutions
Patient/carer-specific	Patient & carer support
Lack of awareness	Education and training: flexible
	group and individualized
	training programs
Physical and cognitive barriers	Carer programs: increased
	support and peer education
	Home visits, assisted home
	dialysis, remote monitoring
	Provision of dialysis in
	nursing homes
Social considerations	Government policy and
	incentive programs
Carer burden	Transparent information
	regarding burden of dialysis
0 . ( )	Respite care for carers
Out-of-pocket costs	Public policies to eliminate
	or minimize out-of-pocket costs  Reimbursement of out of
Physical space at home	pocket costs Independent community homes
Physical space at nome	Development in technology
Perceptions and fears of	Education and counseling:
dialyzing at home (e.g.,	psychosocial therapy
needle phobia, body image)	psychosocial therapy
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Health care system-specific	Public advocacy
Accessibility	
By patient location	Independent community houses
Distance between patient's	Home training programs
home and training center Extended care facilities	
Lack of infrastructure	Flexible and individualized programs
Delivery models	Innovations: hub & spoke,
Delivery models	supportive networks, centers
	of excellence
Economic	Incentive payments
Within-health care variability	meentive payments
Health care team bias	Health care team training

Patients do perceive that home dialysis (peritoneal dialysis or hemodialysis) offers the opportunity to thrive; improves freedom, flexibility and well-being; and strengthens relationships.  $^{8,13}$  With appropriate adequate predialysis support and training, it is estimated that up to 50% of patients with ESKD will attain self-care dialysis.<sup>29</sup> However, some voice anxiety and fear about performing dialysis treatments at home because of lack of confidence in their ability to master the technical aspects of dialysis, including self-cannulation for home hemodialysis, and because of isolation from medical and social support.<sup>8,13</sup> Because many more patients around the world could be dialyzing at home or undertaking self-care than are doing so presently, the conference attendees recommended a goal of encouraging and supporting patients to select a home-based therapy (peritoneal dialysis or home hemodialysis) or self-care dialysis and to identify ways of overcoming barriers to this goal (Table 1). At the same time, it was recognized that many patients in many parts of the world will need or prefer in-center hemodialysis and that available dialysis modalities in some countries may depend upon local circumstances.

#### Supporting patients during dialysis

After a patient starts dialysis, the health care team needs to provide ongoing support to optimize the health benefits of the selected modality. Support may be needed most in the period immediately after initiation and may decrease over time. Early attrition from peritoneal dialysis or home hemodialysis may result from catheter or mechanical problems, infection, management in a small center, or delayed referral to nephrologists or for CKD care. Anticipating and preventing these modifiable factors or quickly addressing such issues is important. Patient confidence in handling home dialysis procedures needs to be assessed prior to the start of dialysis and subsequent to initiation.

Frailty can impact dialysis complications and overall patient experience as well as prognosis. Because frailty can occur at any age, it is ideally assessed on a regular basis so that any reversible issues are identified and used to inform decision-making about treatment and support for the patient.

#### TIMING AND PREPARATION FOR DIALYSIS INITIATION

A specific estimated glomerular filtration rate (eGFR) value for initiating dialysis in the absence of symptomatic kidney failure has not been established. Indeed, the IDEAL study did not demonstrate any clinical benefit in commencing dialysis at higher levels of eGFR, and the variability in measurement of eGFR in CKD G5 is such that it should not be considered to reliably reflect kidney function.<sup>31</sup> Registry data indicate mean predialysis eGFR varies among countries (approximately 5 ml/min per 1.73 m<sup>2</sup> in Taiwan; average 8.5 in the UK, 7.3 in Australia, 6.4 in New Zealand, 9-10 in Canada and France, and 11 in the US). 32-35 Generally, current guidelines do not support preemptive dialysis initiation, 36-38 although an exception is the 2011 European guideline.<sup>39</sup> While the optimal timing for starting dialysis is unclear, and in clinical practice the reasons for initiating dialysis are varied, 40 risk equations can be helpful in predicting a time frame for when kidney replacement therapy may be necessary (Table 2).

Initiation of dialysis is usually considered when one or more of the following are present: symptoms or signs attributable to kidney failure (e.g., neurological signs and symptoms attributable to uremia, pericarditis, anorexia, medically resistant acid-base or electrolyte abnormalities, reduced energy level, weight loss with no other potential explanation, intractable pruritus, or bleeding); inability to control volume status or blood pressure; and a progressive deterioration in nutritional status refractory to interventions. Depending on the patient's preferences and circumstances, an aggressive trial of medical nondialytic management of advanced CKD symptoms may be warranted before initiating maintenance dialysis.

In adults older than 60 years, in the absence of acute kidney injury and where low levels of albuminuria exist, declines in eGFR may be relatively slow,<sup>34</sup> and therefore the risk of dying before the need to initiate dialysis is higher than in other populations. Indeed, 20% to 35% of older CKD G4–G5 patients die per year before reaching dialysis.<sup>41</sup> Additionally,

Table 2 | Risk equations for predicting time frame to needing kidney replacement therapy

Patient group	Risk predicted	Reference
CKD G3 or G4	5-year kidney replacement therapy predicted by age, sex, eGFR, hemoglobin, proteinuria/albuminuria, systolic BP, antihypertensive medication use, and diabetes and its complications	Schroeder et al. <sup>77</sup>
CKD in older adults	5-year mortality predicted by age, sex, race, eGFR, urine albumin-to-creatinine ratio, smoking, diabetes mellitus, and history of heart failure and stroke	Bansal et al. <sup>44</sup>
> 75 years old, within 3 months of dialysis	Mortality predicted by age, gender, specific comorbidities, albumin levels, and mobility	Couchoud et al. <sup>43</sup>
> 15 years old, initiating dialysis	6-month mortality predicted by older age, underweight, chronic lung disease, coronary artery disease, peripheral vascular disease, cerebrovascular disease (particularly for patients < 60 years of age), late referral to nephrologist care, and underlying cause of kidney disease.	lvory et al. <sup>45</sup>

BP, blood pressure; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate.

older patients have a lower likelihood of survival in the 90 days after initiating dialysis. 42 If patients have no other indications for starting dialysis, the decision may be made to delay initiation of dialysis in older patients until eGFR falls to <6 ml/min per 1.73 m<sup>2</sup>. In patients with late-stage CKD, it is important to discuss options for both medical and dialytic management in the event that acute kidney injury or additional significant illness occurs. Decision-making, including advanced care planning, can be aided using predictive models such as those developed by Couchoud et al., 43 Bansal et al., 44 and Ivory et al. 45 This planning often includes individualized discussions regarding clinical course, goals of therapy, and patient preferences. Patients need to be made aware of the options of medical management without dialysis, such as supportive care and/or comfort measures and hospice care, when appropriate. 46-48

#### **Predialysis assessments**

For patient-reported outcome measures, available assessments pertain to symptoms, objective markers of nutrition, functional capacity, and markers of kidney function. Available clinical reported outcomes include muscle strength, gait speed, body mass index, and biomarkers such as eGFR, serum albumin, etc. There is considerable variation in physician reliance on biochemical and hematologic variables such as creatinine, eGFR, urea, bicarbonate, potassium and phosphate levels, and hemoglobin levels among patients at the start of dialysis. Indices that measure frailty in CKD may be useful for informing patient decision-making, but further

Table 3 | Dialysis modality and initiation timing: research needs and proposals

#### Key questions and approaches for investigation

#### Dialysis initiation

Whether to initiate

When to initiate

- Can a CKD Frailty Index be used to inform patient decision-making? What would constitute the index—could it be based on the IPOS-Renal index?
- Could a CKD Frailty Index be combined with traditional and novel biomarkers and clinical scoring systems (serial assessments of fluid status, nutritional status and/or body composition) to guide initiation of dialysis?
- To what extent do uremic symptoms change after initiation of dialysis?
- Could a CKD Frailty Index be used to identify clinically important changes over time in individuals before dialysis and after initiation of dialysis? Are the changes different with HD versus PD?
- Is it possible to predict which patients improve and which get worse?
- With aggressive medical management, can the initiation of dialysis be delayed safely?
- Can an integrated care model improve quality and decrease costs for patients with kidney disease as they transition from CKD G5 to G5D (https://innovation.cms.gov/initiatives/comprehensive-esrd-care/)?

Timing of referrals and unplanned starts

- How can the number of unplanned starts be reduced?
- How can referral and optimal management of patients with advanced CKD be improved?
- How can CKD patients at highest risk of acute kidney injury or heart failure exacerbations be identified?
- Do tablet holidays from drugs such as diuretics, ACE inhibitors, metformin, and NSAIDs prevent exacerbations?
- How can outcomes for post-acute kidney injury patients be improved?
- What measures can promote kidney recovery among acute kidney injury patients (in inpatient and outpatient settings)?
- Should dialysis be different for CKD G5 to G5D versus CKD with superimposed acute kidney injury?
- What is the real-world effectiveness and cost effectiveness of universal screening for CKD in high-risk populations?
- How effective are public health surveillance systems (public health lab and provider prompts) for CKD screening and risk prediction?
- Can multidisciplinary care during transition periods improve patient outcomes such as survival, hospitalization, cost-effectiveness, and guality of life?
- For patients choosing PD with a late referral, how do the outcomes compare for those who start with PD versus those who start with a short period of HD?
- What are the outcomes of urgent start PD versus short-term and long-term HD as evaluated in large-scale studies?

#### Choice of modality

- What is the preferred timing for educating patients regarding dialysis modalities? Does the optimal time vary based on patient characteristics?
- What is the optimal content and format for educating patients regarding the advantages and disadvantages of each modality? How do we check their understanding?
- What are the outcomes of various dialysis modalities in subgroups of patients (e.g., pediatric, pregnant)?
- What are the characteristics and commonalities of "unexpected" deaths within the first 90 days of initiating dialysis, particularly in those with low burden of coexisting illnesses?
- What are the barriers to equal gender access to therapies, and how do these vary by country?
- Is respite care effective in retaining patients on home dialysis?
- What is the effectiveness of telemedicine and/or remote monitoring compared with conventional care in patients undergoing home dialysis to increase time on therapy and reduce complications?

#### **Dialysis prescription**

- What is the threshold of kidney function or related symptoms at which to consider incremental dialysis?
- As evaluated by randomized controlled trials, how do outcomes such as residual kidney function and
  patient-reported outcomes compare with incremental dialysis versus conventional, full-dose initiation (HD or PD)?

#### Monitoring

 How does telemedicine and/or remote monitoring compare with conventional care in patients undergoing home dialysis?

ACE, angiotensin-converting enzyme; CKD, chronic kidney disease; HD, hemodialysis; IPOS, Integrated Palliative care Outcome Score; NSAID, nonsteroidal anti-inflammatory drug; PD, peritoneal dialysis; RCT, randomized controlled trial.

research is needed regarding the effectiveness of this approach (Table 3).

The timing of predialysis assessments depends on the absolute level and rate of decline in kidney function, symptom load, and associated metabolic, hematologic, and clinical comorbidities but will generally fall within the range of monthly to every 3 months. There was general consensus that symptoms such as anorexia, nausea, and fatigue should be improved or resolved within 3 months after starting dialysis therapy, although it was recognized that there is a lack of data to inform interpretation of symptom changes after initiation of kidney replacement therapy.

#### Predialysis care and referrals

Timely predialysis care has been associated with improvement in measurable outcomes such as delayed initiation of dialysis, cardiovascular complications, and mortality. Optimal multidisciplinary predialysis care includes not only timely referral but also frequent visits where patients can access different members of the care team. Registry data report wide variation in the transition period from CKD G5 to CKD G5D. A minimum 90-day transition period aligns with acute kidney injury recovery, registries, and early mortality on dialysis; however, the effects of interventions on lifestyle and risk factor modification may require years to take effect. The

Table 4 | Strategies to avoid late referral for specialized nephrology care

Provider	Strategy
Primary care	Education     o Recognizing at-risk groups     o Screening (eGFR, uACR, risk prediction)     o Preventive treatment
	o Timely referrals
Laboratory	<ul> <li>Improved availability of eGFR reporting and uACR testing</li> </ul>
•	<ul><li>Automated risk reporting and prompts for referral</li><li>Decision support integrated into EMR</li></ul>
	<ul> <li>Predefined multi-component CKD screen test</li> </ul>
de De Wh Ea pa EM EN EN EN	<ul> <li>Regional reporting of geographic and demographic trends in CKD screening and diagnosis</li> <li>Designation of CKD as a reportable disease when risk threshold is reached</li> </ul>
	Early notification surveillance systems for patients and primary care providers
	<ul> <li>EMR notification system of need for screening</li> </ul>
	<ul> <li>Evaluation of cost-benefit of mass screening</li> </ul>
	<ul> <li>Public awareness campaign</li> </ul>

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; EMR, electronic medical records; uACR, urine albumin-to-creatinine ratio.

predialysis CKD care time frame is ideally long enough to encompass the 90-day transition period.

Recommendations for "timely referral" to a nephrologist, particularly for access creation, are mostly based on time to dialysis—for example, 6 months before the need to start dialysis. Although the timing to start dialysis can be difficult to accurately predict, evidence-based kidney failure risk equations could be used to create a more standardized approach.<sup>52</sup> However, this must be combined with, rather than replace, clinical judgment. Strategies to avoid delayed referral are listed in Table 4.

## Tailoring timing and support for certain subgroups of patients

Initiation of dialysis in the setting of a failing graft or moving between dialysis modalities. Patients with a failing kidney transplant may not be adequately prepared for approaching ESKD because the focus of care may be to maintain graft function rather than prepare for dialysis. CVCs are used in nearly two-thirds of patients with failed kidney transplant grafts, 53 and the relatively low prevalence of AVFs or AVGs in this group at initiation of dialysis needs to be investigated more thoroughly.<sup>53</sup> Collaboration with CKD programs may be beneficial, especially as eGFR declines below 20 to 30 ml/ min per 1.73m<sup>2</sup>. Education and review of patient preferences and life goals are important, as is the preparation for possible next steps such as hemodialysis, peritoneal dialysis, another kidney transplant, or supportive care, as part of the patients' ESKD life plan.<sup>54</sup> Studies based on global kidney transplant registries will be needed to track specific issues in managing patients with failing kidney grafts.

Data from the United States indicate that peritoneal dialysis patients under nephrologist supervision have a very low rate of arteriovenous access upon transition to hemodialysis.<sup>55</sup> Hence, time-dependent surveillance of effective clearances and ultrafiltration volumes are necessary in patients on PD. Predictive models are needed to identify peritoneal dialysis patients that require transition preparation such as education and vascular access creation, <sup>56,57</sup> particularly to support home hemodialysis when appropriate.

Pediatric initiation of dialysis. Pediatric models of care were not a focus of this conference. In children, the unique aspects of growth, nutrition, and cognitive as well as emotional maturation increase the complexity of diagnosis, treatment, and decision-making, and therefore having a multidisciplinary team to address these issues is especially important. Children will have different needs as they age, and it is important to recognize that young adulthood and the transition to independent living can be a time when patients need a lot of support. In the pediatric population, CKD is more likely to lead to ESKD versus death, and therefore, validated prediction models for referral to preemptive transplant or dialysis are especially important. In a retrospective cohort study of 603 children with eGFR < 60 ml/min per 1.73m<sup>2</sup>, kidney failure risk equations provided excellent discrimination of the risk of developing ESKD in 1 or 2 years in those with a kidney failure risk equation (KFRE) score of at least 13.2% compared with those with a score less than 13.2%.<sup>58</sup> A pediatric global initiative to determine the impact of early versus late initiation of preemptive transplant or dialysis could be conducted as a pragmatic randomized controlled trial, with a similar approach to that of the IDEAL study in adults<sup>59</sup> but with outcomes concentrated on growth, cognitive development, and nutritional status.

**Pregnancy and initiation of dialysis.** The definitive method for determining pregnancy in the setting of kidney failure is ultrasound, because levels of β-hCG can be increased during kidney failure, leading to false-positive pregnancy test results. 60 Conception pre-dialysis results in higher infant survival and lower likelihood of prematurity than conception after starting dialysis. 61 Cohort data have indicated that dialysis intensity affects outcomes, with longer durations resulting in a higher live birth rate, longer gestational age, and greater infant birth weight.<sup>62</sup> In pregnant women undergoing dialysis, an intensive prescription should be considered. During pregnancy, women on dialysis need to be monitored for low potassium, phosphate, and folate, as well as high glucose, especially for patients undergoing tidal peritoneal dialysis. It is also important to evaluate for anemia and assess nutrition and magnesium levels. Previously the timing of initiation of dialysis in pregnancy was based on high urea levels (blood urea nitrogen [BUN] > 36 mmol/l, goal to decrease < 18 mmol/l). The goal currently is to initiate at BUN < 18 mmol/l, 63 also recognizing anecdotally the importance of fluid, electrolyte, and acid-base disturbances. A possible strategy for research is evaluating registry data to determine the impact of early versus late initiation of dialysis in pregnancy, along the lines of the IDEAL study in adults<sup>59</sup> but with outcomes concentrated on live birth rate, pregnancy survival, gestational age, and birth weight.

## Table 5 | The integrated ESKD life plan approach for dialysis access implementation<sup>a</sup>

#### Options for dialysis access according to ESKD life plan

- Conservative treatment (no dialysis, no access)
- Pre-emptive transplant (no dialysis access; consider in future as needed)
- Peritoneal dialysis (PD catheter, no AV access; consider in future as needed)
- Hemodialysis (AVF, AVG, CVC: access planning)

#### Hemodialysis access planning

- Consider likelihood of long-term survival (> 1 year)
- Poor: Maintain conservative care and periodically reassess for changes. These patients are more likely candidates for AVG or CVC
- o Good: Assess quality of vessels for AV access
  - $\blacksquare$  AV access not feasible  $\rightarrow$  CVC
  - AV access feasible → consider AVF likelihood of usability success; decision on the preferred access is to achieve complication-free access while preserving vessels for future sites per individualized ESKD life plan: e.g., in an <u>optimal</u> scenario where all vessels available: forearm AVF, upper arm AVF, AVG
- Once HD access is established, consider improvements of care
   Timely shift to kidney transplant or PD, whenever feasible and appropriate
  - Shift from CVC to AVF or AVG, as soon as possible when feasible and appropriate
  - Secondary shift from AVG to AVF, when AVG is failing; when feasible and appropriate
- o When planning a dialysis access procedure, always keep in mind next possible access(es) for the individual patient to attain the longest and most feasible access life plan for the individual patient based on their ESKD life plan and goals of care

AV, arteriovenous; AVF, arteriovenous fistula; AVG, arteriovenous graft; CVC, central venous catheter; ESKD, end-stage kidney disease; PD, peritoneal dialysis. 

aModified in accordance to the KDOQI Vascular Access Guidelines 2018, presented at NKF SCM 2018, Austin, TX (April 2018).

#### **DIALYSIS ACCESS AND PREPARATION**

It is widely accepted that preemptively establishing dialysis access leads to better patient outcomes; however, there are significant challenges and barriers within health care systems and among payers and patients to establish dialysis access that is matured and functional for dialysis initiation (Supplementary Table S1). 64-70 According to most guidelines, peritoneal dialysis access should be prepared whenever possible at least 2 weeks before starting kidney replacement therapy. 71,72 For patients referred late, this recommendation might determine a temporary or definitive shift of patients to hemodialysis. However, recent evidence has demonstrated that urgent-start peritoneal dialysis is possible and safe, if properly conducted.<sup>73</sup> Although meeting participants acknowledged the benefits of fistulas,<sup>74</sup> they recognized the "fistula-first" approach is not appropriate for all patients. There is a need to reconsider established paradigms for dialysis access within the framework of the patient's ESKD life plan,<sup>54</sup> taking into account individual patient and vessel characteristics and patient life goals and preferences. Age, comorbidities, likelihood of long-term survival, treatment goals, and timing of dialysis initiation are all factors that could affect the choice for access and require individualization for each patient. 54,75 It is also important to keep in mind the subsequent best treatment modality and access for the individual patient (Table 5). Many patients are able to undertake home HD with permacaths, and the lack of surgically created vascular access is not an absolute contraindication to self-managed home HD.

## Selection and management of access as related to funding policies

Selection and management of access that is tightly linked to funding policies may have serious implications for patient health. In resource-limited environments, if surgery is less expensive than endovascular procedures, it can put patients at risk for early exhaustion of vascular access sites. Economic constraints leading to prolonged use of nontunneled CVCs can increase the risk of infection for patients. Conversely, in resource-rich environments, well-reimbursed endovascular procedures can lead to over-intervention, vessel damage, and premature loss of vascular access. Ideally, financial incentives should be aligned with best care practices. Unfortunately, there is no consensus, evidence base, or outcome measure for best practices at the individual patient level that can be measured on a population basis. Additionally, specific outcomes used as a measure of best practice at the population level do not always apply at the patient level. To provide individualized patient care, it may be necessary to adopt "process" versus outcomes measures of best practice, such as percent of patients referred to and evaluated for vascular access before dialysis initiation. Targeting process best practices (e.g., referral for vascular access) may lead to better best practice outcomes (e.g., more functional AV accesses). Priorities for research and education are described in Supplementary Table S2.

#### Access "exit strategies"

Important in the decision-making process for choosing initial dialysis access is the consideration of what options are available if the initial access fails. Currently there is no published evidence to inform back-up, and therefore research is needed to evaluate the optimal order of exit strategies in access for hemodialysis. Given the various modalities and access needs of each patient, such access contingency and succession plans must be individualized. At best, the consequences of lack of planning—as discussed above for failing transplants and PD patients—highlights the need for access contingency and succession planning.

#### PROVIDING "ADEQUATE" DIALYSIS AND SYMPTOM CONTROL

For decades, dialysis adequacy has been defined by small solute clearance (Kt/V and urea reduction ratio in hemodialysis; Kt/V and creatinine clearance in peritoneal dialysis). Measuring small solute clearance has been emphasized in clinical practice guidelines, used as the basis for clinical performance measures and/or payment, and treated by many clinicians as dogma. However, evidence for relationships between small solute clearance, plasma levels of these solutes, and clinical outcomes and/or symptomatology is weak. It is increasingly recognized that small solute clearance reflects only one of many aspects of dialysis care that are likely to

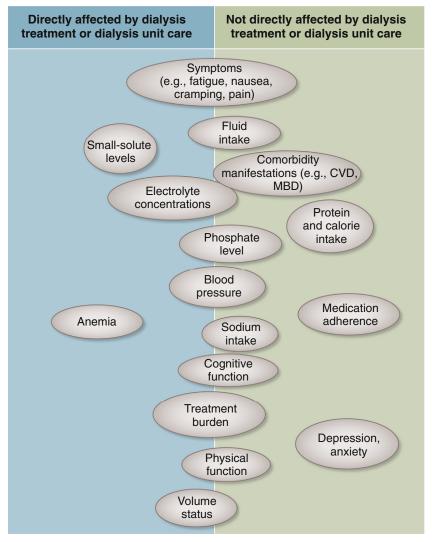


Figure 1 | Potential targets for goal-directed dialysis care. This schematic illustration serves to identify targets or outcomes that might be considered in developing goal-directed dialysis care. Some targets or outcomes, such as anemia, are principally affected by dialysis care providers through an erythropoiesis-stimulating agent and iron dosing, while others, such as protein and calorie intake, are less directly affected. Many targets or outcomes are affected by both dialysis treatment or care and by nondialysis factors. CVD, cardiovascular disease; MBD, mineral and bone disease.

affect outcomes. 16,18,76 Therefore, solute kinetic goals should be interpreted and implemented in the context of the patient's overall goals and clinical status.

Meeting participants favored a comprehensive view of ESKD care with a more multifaceted paradigm replacing what is currently referred to as "dialysis adequacy." Multiple measures and goals should be considered when assessing adequacy of dialysis, including small solute clearance, residual kidney function, volume status, biochemical measures, nutritional status, cardiovascular function, symptoms, and the patient's experiences and goals. While many meeting participants felt that a rigid emphasis on solute clearance does not serve the interests of all patients, there was general agreement that clinicians should continue to recognize accepted minimums for small solute removal during dialysis. It was also recognized that research is needed to investigate the importance of other solutes including middle and large solutes, protein-bound and

carbamylated molecules, and metabolic products of intestinal bacteria as potential contributors to poor functional status, symptoms, comorbidities, and mortality among patients being treated with maintenance dialysis.

It should be recognized that patients may interpret "adequacy" differently than clinicians, and therefore goals for treatment should be individualized and reassessed over time. To this end, many—but not all—meeting participants propose that the term "adequate dialysis" be changed to "goal-directed dialysis," which specifically refers to using shared decision-making between the patient and care team to establish realistic care goals to allow the patient to meet his or her own life goals and allow the clinician to provide individualized, high-quality dialytic care.

The components of goal-directed dialysis can be thought of as those directly affected by the dialysis procedure, such as small solute clearance, electrolyte concentrations, volume

#### Table 6 | Implementation needs for goal-directed dialysis

- Education for clinical care teams
- Tools for eliciting and documenting patient goals
- Incorporation of symptom assessment and other patient-centered outcomes into routine clinical practice
- Increased flexibility for dialysis schedules
- Establishment of metrics for success
- Quality assessment approaches that accommodate individualized targets
- Buy-in from multiple stakeholders
- Aligned incentives across stakeholders

status, and intra-dialytic symptoms, as well as those that are indirectly affected by the dialysis procedure, such as symptom burden, nutritional status, activity level, work capacity, and social engagement (Figure 1). Priorities should be individualized and consistent with achievable goals for the patient. A patient's priorities will likely change between the initial months of dialysis and thereafter; therefore, prioritization requires ongoing discussions between patients and clinicians about realistic expectations and prognosis. Discussion may need to be tailored depending on the patient's cognitive function, health literacy, numeracy, socioeconomic status, and initial dialysis experiences.

#### Implementing goal-directed dialysis

Implementing goal-based care would require a significant shift from current international practice as well as buy-in from multiple stakeholders including patients, providers, regulators, and payers, who may have conflicting expectations and motivations (Table 6). Tools are needed for facilitating communication between patients and clinicians because they may have limited experience expressing or eliciting, respectively, care objectives and priorities. In health care systems, incentives for providers and payers need to be aligned, and methods for assessing patient-centered outcomes such as symptoms will need to be validated and then incorporated into routine care, possibly through technology. As was discussed previously for vascular access, assessing the quality of highly individualized care will likely require the development of process measures.

#### **CONCLUSION**

A major theme identified during the conference was the need to move away from a "one-size-fits-all" approach to dialysis and provide more individualized or personalized care. Identifying and achieving patient-centered goals is now recognized as an important component of dialysis care, and these will require provider tools, patient tools, and alignment of goals and incentives among patients, caregivers, health care providers, regulators, and payers. Meeting participants acknowledge that any suggestion for moving toward patient-centered, goal-directed dialysis assumes that whatever systems are in place for delivering dialysis are modifiable. Admittedly, in some regions around the world, ability to change existing structures may be limited. Thus, the approaches outlined here

are meant to serve as strategies that may be implemented via a variety of tactics depending on the local environment.

This conference is first of a series of dialysis controversies meetings to help provide a blueprint for delivery of optimal contemporary kidney replacement therapy. Subsequent topics in this conference series will address management of dialysis complications, innovations in kidney replacement therapy, and blood pressure and volume management in ESKD.

#### **APPENDIX**

#### Other conference participants

Ali K. Abu-Alfa, Lebanon; Joanne M. Bargman, Canada; Anthony J. Bleyer, USA; Edwina A. Brown, UK; Andrew Davenport, UK; Simon J. Davies, UK; Frederic O. Finkelstein, USA; Jennifer E. Flythe, USA; Eric Goffin, Belgium; Thomas A. Golper, USA; Rafael Gómez, Colombia; Takayuki Hamano, Japan; Manfred Hecking, Austria; Olof Heimbürger, Sweden; Barnaby Hole, UK; Daljit K. Hothi, UK; T. Alp Ikizler, USA; Yoshitaka Isaka, Japan; Kunitoshi Iseki, Japan; Vivekanand Jha, India; Hideki Kawanishi, Japan; Peter G. Kerr, Australia; Paul Komenda, Canada; Csaba P. Kovesdy, USA; Ed Lacson, Jr, USA; Maurice Laville, France; Jung Pyo Lee, Korea; Edgar V. Lerma, USA; Nathan W. Levin, USA; Monika Lichodziejewska-Niemierko, Poland; Adrian Liew, Singapore; Elizabeth Lindley, UK; Robert S. Lockridge, USA; Magdalena Madero, Mexico; Ziad A. Massy, France; Linda McCann, USA; Klemens B. Meyer, USA; Rachael L. Morton, Australia; Annie-Claire Nadeau-Fredette, Canada; Hirokazu Okada, Japan; Jose J. Perez, USA; Jeff Perl, Canada; Kevan R. Polkinghorne, Australia; Miguel C. Riella, Brazil; Bruce M. Robinson, USA; Michael V. Rocco, USA; Steven J. Rosansky, USA; Joris I. Rotmans, the Netherlands; María Fernanda Slon Roblero, Spain; Navdeep Tangri, Canada; Marcello Tonelli, Canada; Allison Tong, Australia; Yusuke Tsukamoto, Japan; Kriang Tungsanga, Thailand; Tushar J. Vachharajani, USA; Ismay N. van Loon, the Netherlands; Suzanne Watnick, USA; Daniel E. Weiner, USA; Martin Wilkie, UK; Elena Zakharova, Russian Federation

#### DISCLOSURE

CTC declared having received consultancy fees from Medtronic and NxStage; speaker honoraria from Fresenius; and research support from Medtronic, MG declared having received consultancy fees from B. Braun Medical and speaker honoraria from Medtronic. DCHH declared having received speaker honoraria from Otsuka Japan and research support from National Health and Medical Research Council. AY-MW declared having received speaker honoraria from Sanofi Renal; and research support from Otsuka and Sanofi Renal. DCW declared having received consultancy fees from Akebia Therapeutics, Amgen, AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Janssen, and Vifor Fresenius; speaker honoraria from Amgen and Vifor Fresenius; and research support from AstraZeneca. WCW declared having received consultancy fees from Akebia Therapeutics, AMAG, Amgen, AstraZeneca, Bayer, Daichii-Sankyo, Relypsa, and ZS Pharma; speaker honoraria from FibroGen; and research support from National Institutes of Health. CAP declared having served on advisory boards of AstraZeneca, Janssen Cilag, and Vifor; and received speaker honoraria from AstraZeneca, Novartis, Sanofi, and Vifor. All the other authors declared no competing interests.

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#### **SUPPLEMENTARY MATERIAL**

Table S1. Barriers to choosing dialysis access.

**Table S2.** Research questions and priorities for education in dialysis access.

Supplementary material is linked to the online version of the paper at www.kidney-international.org.

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