



## Ethical issues in dialysis therapy

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Treatment for end-stage kidney disease is a major economic challenge and a public health concern worldwide. Renal-replacement therapy poses several practical and ethical dilemmas of global relevance for patients, clinicians, and policy makers. These include how to: promote patients' best interests; increase access to dialysis while maintaining procedural and distributive justice; minimise the influence of financial incentives and competing interests; ensure quality of care in service delivery and access to non-dialytic supportive care when needed; minimise the financial burden on patients and health-care system; and protect the interests of vulnerable groups during crisis situations. These issues have received comparatively little attention, and there is scant ethical analysis and guidance available to decision makers. In this Health Policy, we provide an overview of the major ethical issues related to dialysis provision worldwide, identify priorities for further investigation and management, and present preliminary recommendations to guide practice and policy.

### Introduction

Renal-replacement therapy, the life-saving treatment for end-stage kidney disease, is provided by long-term dialysis or kidney transplantation. Transplantation extends patients' lives, provides better quality of life, and is more cost-effective than dialysis.<sup>1,2</sup> However, many patients are not suitable candidates for transplantation, and the availability of transplants is limited by the persisting global shortage of donor kidneys—and in some countries, by insufficient infrastructure. Dialysis is often more readily available. The number of patients receiving dialysis has risen steadily since the early 1990s.<sup>3</sup> According to US Renal Data System, the prevalence of dialysis rose from 1095 per million population in 1996, to 2067 per million population in 2014. However, a large proportion of patients with end-stage kidney disease in low-income and lower-middle-income countries have no access to dialysis. An estimated 2.28 million patients died in 2010 because of non-availability or unaffordability of dialysis, almost all in low-income and lower-middle-income countries.<sup>3</sup>

In addressing the economically and socially costly burdens of advanced kidney disease, health policy makers and professionals confront many ethical issues. These are particularly challenging in the context of end-stage kidney disease and renal-replacement therapy, within which clinical and policy decisions can be a matter of life and death. The International Society of Nephrology convened an Ethical Dialysis Task Force to examine this subject. In this Health Policy, we, as members of this task force, explore several aspects of dialysis provision that raise ethical concerns of global relevance. Although ethical issues require elaboration in the context of specific health-care systems and patient populations, we provide some general recommendations for practice wherever dialysis services are available.

### Financing of dialysis

#### The range of costs worldwide

The global market for dialysis was valued at more than US\$75 billion in 2011.<sup>4</sup> The costs of providing dialysis, and the costs incurred by patients needing dialysis, vary

between and within countries.<sup>5,6</sup> In the USA, 468 000 people received dialysis in 2013, with a total Medicare spend of \$30.9 billion, representing 7.1% of total health-care expenditure.<sup>7</sup> In Thailand in 2008, an estimated 12 000 people received dialysis at a cost of \$76 million, or 2% of national health-care expenditure.<sup>8</sup> The average annual cost of providing dialysis to a patient under bundling was \$31 000 in the USA in 2011,<sup>9</sup> compared with approximately \$3200 in India in 2014.<sup>10</sup> These costs usually cover only the dialysis treatment itself, and not ancillary expenses such as medications or transportation. Factors that affect the absolute costs include the local economy for health-care products and services, the funding model for dialysis, and the health-care system. These factors determine if, and how much, patients are required to pay upfront for dialysis.<sup>11</sup> For example, the cost of a haemodialysis session to patients in different facilities in India can vary from \$10 to \$50.<sup>10</sup>

#### Financial interests and service delivery

The costs of dialysis provision are affected by system-level factors that incentivise policies or practices that can financially benefit industry, institutions, and health professionals. In a pay-for-performance system, prioritisation of less complex patients likely to require fewer interventions (so-called cherry-picking) will positively affect performance metrics and result in financial benefits to clinicians or facilities.<sup>12</sup> Nephrologists might also have financial interests in referring patients for dialysis at particular centres, recommending specific renal-replacement therapy modalities (for example, hospital haemodialysis instead of home-based treatment),<sup>13</sup> or avoiding referral for transplantation for fear of loss of revenue—or, conversely, in premature referral for financial gain.

Such competing interests might result in higher costs for patients or health-care systems, or in compromised clinical care. Lowering costs is important because financial barriers are often the main obstacle to access to dialysis, and because many patients suffer serious financial harm as a result of dialysis treatment. Out-of-pocket payment for dialysis often constitutes catastrophic

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For the US Renal Data System see <https://www.usrds.org/adr.aspx>

health expenditure for patients and their families.<sup>14</sup> Physicians and dialysis centres might also compromise patient care to reduce costs, increase profits, or provide care to more patients. In some regions, for example, dialysis units show wide variations in the quality of workforce, adherence to standard operating protocols, dialyser reuse practices, and standards for water treatment, vascular access, and infection control.<sup>10,15</sup> Dialysis session duration and frequency might be reduced to accommodate extra patients, and documentation of patient care is often suboptimal.<sup>15</sup>

In addition to the costs of dialysis itself, the management of comorbidities and complications of dialysis requires substantial investment. From the perspective of policy makers, the costs of providing dialysis could easily be reduced by investment in prevention and management of chronic kidney disease<sup>5</sup> and improving access to transplantation.<sup>1</sup> However, financial considerations and pressure from interest groups can encourage policy makers and physicians to prioritise investment in dialysis at the expense of other services, or discourage investment in development of cheaper dialysis machines and consumables. Although dialysis is justified as a so-called life-support service, the lack of investment in adequate prevention and methods to delay progression of chronic kidney disease results in ongoing growth of the dialysis population and costs attributable to end-stage kidney disease.<sup>16</sup>

### Clinical care and decision making Dilemmas for dialysis

Decision making in dialysis can create ethical dilemmas around autonomy, beneficence, and non-maleficence. For example, how can we enable patients or their surrogate decision makers to make informed and voluntary decisions in the treatment of end-stage kidney disease? Or, when is dialysis in the best interests of the patient?

Consistent with the principles of beneficence and non-maleficence, dialysis should only be provided when it is clinically appropriate. Provision of futile interventions imposes costs and undermines efforts to provide necessary health care to all patients. However, when the financial costs are not an immediate concern for patients or physicians, initiation or continuation of dialysis might be considered the default option or clinical norm for patients with end-stage kidney disease. A review of qualitative research reported that some patients have insufficient choice about dialysis treatment.<sup>17</sup> Factors that can undermine the quality of patients' decision making include inadequate information about options, timing and expected benefits of dialysis, insufficient time for decision making, resource constraints, influence of peers and family, and reluctance to deviate from the status quo.<sup>17</sup> Very young and elderly patients, people with multiple comorbidities, patients who present with an acute diagnosis of end-stage kidney disease, individuals with poor education, and people from socioculturally

marginalised groups might experience additional barriers to effective decision making. Other barriers include cognitive impairment or immaturity, language difficulties, and inadequacy of data about the outcomes of treatment for particular groups.<sup>18</sup>

### Clinical decision making

Physicians have a responsibility to provide competent patients or their surrogate decision makers with sufficient information about treatment options, which they can evaluate in the light of their own values and preferences. In a patient with end-stage kidney disease, this means explanation of all available renal-replacement therapy options: the benefits, burdens, and consequences of dialysis; differences between various forms of dialysis (haemodialysis or peritoneal dialysis, home or in-centre dialysis) and alternatives such as kidney transplantation and non-dialytic conservative care.<sup>19</sup> Discussion of benefits and burdens should be evidence-based as much as possible, with data interpreted in the context of the individual patient's qualitative treatment goals.

Discussions should include the potential physical, psychological, and socioeconomic consequences of specific choices, and patients and their families should be given time to reflect on their options and to ask questions, especially before making critical decisions such as initiation or withdrawal of dialysis. The decision to commence or decline dialysis should be open to review at a later date.<sup>20</sup>

Professionals involved in decision making around dialysis should be wary of their own potential biases and factors that could undermine or compromise their clinical objectivity, such as lack of familiarity with dialysis in a specific patient population, or personal financial interests in particular treatment modalities. Training in communication and ethical decision making related to provision of end-of-life care can assist physicians to support effective decision making and to manage issues that arise—for example, when dealing with surrogate decision-makers, and conflicts with advance care directives. Guidelines to support shared decision making and advanced care planning might be useful, particularly in the context of end-stage kidney disease.<sup>21</sup> Education programmes for patients and surrogate decision-makers are also valuable to improve health literacy and empower autonomous decisions about renal-replacement therapy.

### Care when renal-replacement therapy is not appropriate or available

Many individuals with end-stage kidney disease will receive conservative care rather than renal-replacement therapy, either because insufficiency of resources makes dialysis unavailable, or because dialysis is either not started or is withdrawn in the patient's best interests. Irrespective of the reasons, these patients should receive the best available care. Patients receiving dialysis might also benefit from access to supportive care or hospice

services.<sup>22</sup> As patients approach the end of life, provision of palliative care becomes essential.

Conservative and palliative care programmes are emerging as key strategies for management of end-stage kidney disease when access to renal-replacement therapy is insufficient. However, many countries with inadequate dialysis services do not have adequate palliative care services. Where such care is unavailable, patients dying from end-stage kidney disease experience significant suffering, which places enormous psychosocial burdens on caregivers, families, and communities.<sup>22</sup> Where palliative care services are available, patients might not receive a timely referral if nephrologists are unfamiliar with those services or do not see provision of palliative care as part of their professional responsibilities. Emerging evidence suggests that nephrologists and health systems are becoming increasingly aware of the importance of being able to provide end-of-life care to these patients.<sup>23</sup>

### Distributing dialysis resources

Even when dialysis is in the best interests of patients with end-stage kidney disease, resource constraints can limit the ability of health service providers to treat them. When making decisions about funding, governmental authorities must consider the broader health needs and resources available within the population. If access to dialysis is determined only by the ability of patients to fund their own treatment, authorities should—at the very least—help to reduce the cost of dialysis so that financial access inequities are reduced. When governments are able to fund dialysis for at least some patients, respect for justice requires that efforts are made to promote equity in access to the available resources.

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

Procedural justice requires that decisions about access policies be made by legitimate authorities who are accountable to those affected by the decisions. Such decision making should be transparent, informed by relevant evidence and ethical principles, and consistent in the application of principles or rules. Procedures should be established to engage stakeholders and experts in decision making and to provide opportunities for appeal and revision of individual decisions. Patients with end-stage kidney disease and clinicians working in nephrology are both key stakeholders and experts, and inclusion of their perspectives would help to ensure validity and feasibility of policies.

Distributive justice requires the development of frameworks to guide allocation of limited resources—for example, guidelines to determine eligibility for access to

dialysis or access to funding for dialysis. Decision makers determining eligibility criteria can face several potentially conflicting goals, such as the maximisation of utility (commonly interpreted as maximising the number of quality-adjusted life-years [QALYs] gained by providing treatment to particular individuals or groups) versus maximisation of equality of opportunity—for example by providing everyone with a period of free dialysis to give them time to pursue a potential kidney transplantation or to find their own funding for dialysis. Another goal might be promotion of equality in lifespan, which would usually lead to prioritisation of young people for dialysis to compensate for the greater reduction in their life expectancy compared with that of older patients in the absence of treatment.

Criteria can be applied to promote particular goals of allocation policy. Some criteria that are commonly associated with unfair discrimination, such as age and economic status, might be justifiably included in policies where they objectively influence legitimate considerations such as risks and benefits of treatment. But care should be taken to ensure these are not simply used as proxies for evidence-based evaluation of the likely outcomes of treatment in particular populations. Further, modifiable factors that could affect utility calculations (eg, economic status when capacity to fund treatment of comorbidities might influence the value of dialysis) should be used with caution and only as a temporary measure while efforts are made to address underlying socioeconomic inequities.

Access criteria and policy must be informed by an understanding of broader access issues relating to prevention and management of chronic kidney disease, supportive care, management of comorbidities and complications, and general health-care services. For example, access to dialysis in South Africa is conditional on a commitment by patients that they will accept transplantation.<sup>24</sup> This policy has, in theory at least, the advantage of providing more patients with the opportunity for dialysis by effectively reducing the number of patients on long-term dialysis (depending on the availability of renal transplants). However, patients who face barriers to transplantation, such as adolescents considered at high risk of non-compliance with immunosuppression or people unable to afford immunosuppression, might be denied the opportunity for dialysis (Muller E, personal communication). This represents a case of double jeopardy, in which the access policy could further disadvantage people who already had disadvantage.<sup>25</sup>

Even in countries where access to dialysis is unrestricted, systemic factors might undermine equity, particularly in minority and socioeconomically disadvantaged groups.<sup>26,27</sup> Even when individuals in these groups receive dialysis, it might be in lower-quality facilities. For example, despite living closer to higher-quality dialysis units than their white counterparts, African-Americans are less likely to obtain care in such units.<sup>26</sup> This factor might be due to more segregated

## Panel 1: Ethical principles and goals for health authorities and dialysis care providers

- Individuals with end-stage kidney disease should have access to the best available care in renal-replacement therapy and supportive and end-of-life care when required<sup>21</sup>
- Health professionals and policy makers should strive to reduce the costs of dialysis, using simple, safe, and affordable modalities without compromising the quality of care provided to patients
- Commercial competing interests on the part of policy makers and health service providers, including nephrologists, should be routinely disclosed to the public and patients
- Where rationing of dialysis resources is necessary and unavoidable, access to dialysis should be equitable
- Physicians have an obligation to provide information about risks and benefits of dialysis and to support patients or their surrogate decision makers in qualitative evaluation of treatment options
- Decisions about initiation or withdrawal of dialysis should not be considered irrevocable; however, decision makers should be informed of the potential limitation of future options that could be the consequence of initial decisions
- Policies and guidelines governing access to dialysis should strive to:
  - Avoid futile treatment
  - Assure a minimum expected benefit threshold, below which the burdens of initiating or continuing dialysis are considered disproportionate and hence unacceptable (within the sociocultural context)
  - Promote equality of opportunity
  - Maximise utility gains from the available resources
  - Exclude criteria that are not morally justifiable with respect to allocation decisions, such as race, sex, religion, or social status
  - Ensure transparency of policies and processes

## Panel 2: Practical recommendations regarding dialysis for health authorities\*

- Efforts to reduce the costs of providing dialysis to those with end-stage kidney disease should occur in conjunction with more cost-effective efforts to prevent development of and to manage end-stage kidney disease within a population—eg, health systems should establish programmes of kidney disease prevention and health promotion, in conjunction with renal-replacement therapy programmes
- Minimum standards of quality and safety should be established for all dialysis units and regulations introduced where necessary to ensure standards are maintained
- Audit systems should be designed to facilitate and encourage documentation of patient care and transparent reporting of costs and outcomes of care to provide an evidence base for decision making and objective evaluation of performance
- Regulatory safeguards should be implemented where necessary to prevent undue commercial influences on clinical decision making
- Locally appropriate policies or guidelines governing access to dialysis should be developed and transparently implemented in accordance with principles of procedural and distributive justice

\*National or regional issues might influence specifics of these recommendations, but we recommend transparency in clinical practice.

For more information on new modalities for dialysis see <http://www.dialysisprize.org/>

social networks with little information about options for care, preferential referral to lower-quality facilities, or non-acceptance of these patients in centres that engage in cherry-picking. In low-income or middle-income countries, patients might be unable to pay the high out-of-pocket payment charged by better-quality facilities.

All access policies that involve rationing should be regularly reviewed for evidence concerning their outcomes since guidelines sometimes produce outcomes that conflict with their intended goals. For example, the policy for dialysis funding in Texas, USA, aimed to minimise governmental costs of care provision to undocumented migrants while prioritising the saving of lives by offering only emergency dialysis. Instead, this policy resulted in more costly care and worse patient outcomes.<sup>28</sup>

Health systems sometimes confront specific crises that place unexpected pressures on delivery of dialysis services and might necessitate revisions to policies for resource allocation, at least temporarily. Environmental disasters, such as earthquakes, might not only reduce the availability of existing resources by destroying dialysis units or preventing transport of essential products such as dialysis fluid, but also produce a surge in demand, as a result of acute kidney injury. In addition, public health disasters, such as the 2015 Ebola virus epidemic, can increase demand while complicating the delivery of dialysis services by exposing dialysis personnel to risk of infection.<sup>29</sup> Finally, economic or social crises such as the surge of refugees reaching western Europe in 2015, can also result in demand for dialysis services beyond a country's capacity to provide them. Societies that might have well established policies of providing care to all, including refugees, could be unable to do so as a result of reduced service availability or due to overwhelming financial burdens.

Existing policies must be evaluated in the light of resource constraints and demand for services during crises; existing values and principles must be reapplied, not necessarily re-evaluated. The outcomes might fall short of the desired goal, but the resultant inequalities should be just. In responding to crises, or in planning for potential crisis management, policy makers can draw on pre-existing crisis management plans such as those developed in anticipation of influenza pandemics.<sup>30</sup>

## Conclusion

Despite substantial international differences among health-care systems and public health priorities, the core ethical values and principles of health service provision are common to all societies. Grounded in the human right to health, they include the promotion of equity, provision of best possible care, the prevention of harm, and the engagement of patients and their families when making important decisions about their own care. Application of these values and principles in practice will have different results in different health-care systems, depending on the practical realities, cultural preferences, and relative value accorded to particular health-related outcomes. Nevertheless, international collaboration is needed to investigate areas of ethical concern in dialysis provision and to establish common ethical frameworks, clinical guidelines, and educational resources that could be adapted to the local context. Collaboration improves

### Panel 3: Practice recommendations for health professionals involved in dialysis care

- Nephrologists and renal care nurses should collaborate with other health professionals, social scientists, and ethicists, in the investigation of specific ethical issues at the local, regional, or international level
- Priorities for research might include assessment of the impact of costs on clinical decision making in different countries and investigation of burdens of care in special populations such as infants and those with complex comorbidities; such research might inform development of evidence-based communication tools and allocation policies respectively
- Professional societies and medical councils should ensure that health-care professionals working with patients with end-stage kidney disease are familiar with their responsibilities for patient care, including their obligations to provide care to those who might be perceived to pose risks to care providers (eg, from infectious disease) and to provide or refer patients to palliative care services
- Supportive care should be made part of end-stage kidney disease management plans, and appropriate facilities should be developed
- Guidelines for clinical decision making, specifically with regard to withdrawal of dialysis, “do not resuscitate” orders, and time-limited trials of dialysis should be developed; where guidelines exist and have been implemented, sharing of best practices and outcomes across jurisdictions is essential
- Nephrologists should refer patients to available services when they are unable to provide such care
- Nephrologists should receive education about shared decision making, advance care planning, and end-of-life counselling, and communication about end-of-life care
- Dialysis providers should be trained in clinical decision making conversations, and develop multidisciplinary teams in collaboration with providers of other treatment options such as transplantation or supportive care
- Dialysis units should institute a process of second conversation, which will prepare the patient for future decline and serve as an optimal time for advance care planning if the conservative care pathway is chosen

efficiency and ensures more robust examination of ethical issues from diverse perspectives.

Panels 1, 2, and 3 highlight preliminary recommendations for ethical governance, policy, and practice, which must be further explored in dedicated projects. The International Society of Nephrology will elaborate a context-specific plan of action for research, policy development, resource growth, and programme implementation in ethical dialysis and integrated end-stage kidney disease care.

Providing care for patients with end-stage kidney disease is practically and ethically complicated for

physicians and policy makers worldwide. Together with patient organisations, nephrologists have a responsibility to advocate on behalf of patients with end-stage kidney disease in the promotion of care and ethical practice and policy, and to engage with policy makers. Collaboration with other health professionals and researchers addressing similar ethical and practical concerns in other fields of health care will facilitate advances in development of resources for clinicians—for example, guidelines for shared decision making and management of conflicts of interest—and for policy makers, such as analysis of resource-allocation issues.

The aim of equitable access to renal-replacement therapy and best practice care for all patients with end-stage kidney disease presents major ethical, practical, and economic challenges for health-care systems. Challenges, some of which might be more pressing in emerging economies, include increasing access to dialysis; helping patients and families to make the best decisions about management of end-stage kidney disease; ensuring that patients receive high-quality chronic dialysis that is based on standards accepted worldwide, and have access to high quality end-of-life care when required; ensuring that the cost of dialysis does not unduly burden the health-care system or patients; and minimising the impact of financial competing interests on decision making in policy and practice. Another challenge that the global community faces is the provision of dialysis to specific populations during periods of crisis. The global nephrology community must work to address these issues in collaboration with other health professionals, health authorities, patients, and their families.

#### Contributors

VJ and DEM prepared the first draft. JF, DH, and AL provided overall guidance. All other authors provided data, reviewed, and contributed to the report.

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VJ reports grants from Baxter Healthcare and GlaxoSmithKline and personal fees from NephroPlus; NephroPlus is a dialysis provider. DEM reports personal fees from WHO, outside the submitted work. SD reports grants and personal fees from Baxter Healthcare and Fresenius Medical Care; both are dialysis providers. JMB reports institutional support from Baxter Healthcare for education in home dialysis. DH reports personal fees from Roche Myanmar, outside the submitted work. JF, FF, MM, GR, and AL declare no competing interests.

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