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Evidence-based guidelines

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Guidelines for the use of economic evaluation to inform policies around access to treatment for kidney failure

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Abstract

Kidney failure is the most advanced stage of chronic kidney disease, at which point patients require kidney replacement therapy (KRT) in the form of kidney transplant or lifelong dialysis to survive. Although many governments seek to provide KRT for patients with kidney failure under publicly funded health schemes, KRT requires considerable financial and human resources, which may need to be diverted from other health programmes. In deciding which KRT services to provide, to whom, and under which conditions, economic evaluation can show the trade-off between the cost and benefit of different policy options. This Guideline has been written for nephrologists, clinicians and policymakers, to build confidence in requesting, contributing towards, and using the results from economic evaluation studies. It is aimed at outlining the cases in which economic evaluation may support KRT policymaking and to lay out good practice for economic evaluation of KRT services. Recommendations cover the process of developing the policy and research questions, conducting the economic evaluation and interpreting results for policy.

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Introduction

Kidney failure is the most advanced stage of chronic kidney disease. Patients who reach this stage require kidney replacement therapy (KRT) — specifically, dialysis or kidney transplantation — to sustain life. Although long-term dialysis is associated with lower patient survival and quality of life than kidney transplantation[1,2], dialysis accounts for about 80% of all KRT[3], due mainly to organ shortages and a lack of infrastructure for kidney transplantation. For people with contraindications or who choose not to receive KRT, conservative kidney management (CKM) provides holistic, person-centred end-of-life care[4].

An estimated 4 million people receive KRT worldwide; however, millions of individuals with kidney failure remain unable to access it[5]. Despite similar incidences of kidney disease across regions, the prevalence of treated kidney failure largely correlates with country income levels, with the unmet need for KRT in low-income countries estimated at around 98%, compared with 30% in high-income countries[6]. This gap will likely widen with expected increases in the prevalence of kidney failure in low-income regions as a consequence of population aging and an increase in the prevalence of risk factors such as diabetes, hypertension and metabolic diseases. Although CKM should in principle be widely available to patients who are not on KRT, the quality and accessibility of CKM are inadequate in many low- and middle-income countries (LMICs)[7].

The high-cost of KRT prevents many patients from accessing care, with studies suggesting that kidney disease is the biggest cause of catastrophic health expenditures worldwide[6,8–11]. Governments can improve equity in health care access, enhance patients' quality and length of life, and reduce financial risk to households by providing KRT under Universal Health Coverage (UHC) schemes[12]. However, government resources are finite and the allocation of budget and health care resources to KRT services diverts resources from other areas.

KRT is a lifelong treatment that continues until the patient dies. Provision of KRT therefore has a high cost, is resource intensive and requires long-term government investment to build health-system capacity[5]. Although KRT recipients comprise less than 0.05% of the world population, national spending for financing KRT can be up to 4% of national health budgets[3]. In resource-constrained settings, questions are often raised around the financial sustainability of covering the costs of KRT given available resources, whether the health care infrastructure is sufficiently developed to meet demand and whether investment in KRT is justified given other, often pressing, health needs in the country[13–16]. For governments that aim to incrementally expand access to KRT services, questions arise around who to prioritize, with what services and under what co-payment system[13].

Within the context of UHC, policymakers must justify the use of public resources to fund KRT. In practice, the prioritization of KRT provision involves a complex decision-making process. One of the many inputs into this decision-making process, alongside equity and feasibility considerations, is the value for money of the proposed policies — or in other words, how much health and societal benefit can be realized from resources invested. An economic evaluation can provide insights into the cost-effectiveness of different KRT modalities to inform decisions on how to best allocate limited resources, by outlining the trade-off between the costs and benefits of two or more policy options[17]. However, the capacity to conduct economic evaluation also varies across regions; low-income countries typically have the lowest capacity to conduct such evaluations[18], despite facing the greatest constraints in terms of budget and resources.

The purpose of this evidence-based guideline is to equip policymakers and medical personnel with insight into the principles of economic evaluation within the context of policies for kidney-failure services, and to increase confidence in requesting and using economic evidence. We provide guidance on the type of decision questions that can be informed by economic evaluation, provide an overview of the main steps involved and describe principles that underlie the conduct of a good-quality economic evaluation that provides useful information for policymaking. This guideline is primarily targeted at nephrologists, clinicians and policymakers who are interested in using economic evaluation as a tool to inform policies around KRT service provision. We have prioritized KRT for this guideline, as its very high costs risk the diversion of funds away from other health programmes and at times require a separate budget line to provide funding. However, we believe that the guideline may also be beneficial to government officials or researchers who generate evidence to inform policy, as well as national peer review bodies and funding agencies as a general reference for applying economic evaluation to health policy decisions. Although the primary focus is services for kidney failure, the principles and methods for conducting economic evaluations presented in this guideline are intended to be adaptable to other health policy areas. We emphasize the importance of tailoring the approach to fit local contexts, and believe that the guidance may also support policymakers and stakeholders who work in other areas of health policy in which economic evaluation is an essential tool for decision-making. A template model has been included to illustrate the recommendations laid out in this article (Supplementary Data 1). Our main focus is resource-constrained settings, and we have therefore sought to provide an overview of different approaches that may be used based on the question, available resources and capacity of the local team.

Methods

Discussions during the International Society of Nephrology World Congress of Nephrology 2023 in Bangkok, Thailand, identified the need to strengthen capacity in resource-constrained settings to understand when and how to use economic evaluation to inform policies on the technologies and services provided for kidney failure. This task force was formed to provide such guidance. Members of the task force comprise three health economists (I.E., M.I.M. and Y.T.), a nephrologist (V.L.), a public health specialist (P.F.H.), a physician with expertise in providing peritoneal dialysis (PD) (K.C.) and a research team from the Health Intervention and Technology Assessment Program Foundation in Thailand (S.B., K.K.C., A.N.M., B.W.B.C., C.S. and P.S.). All members of the task force have experience in conducting research to inform national policy decisions, with collective experience in the economic evaluation of KRT across six countries.

The first step taken by the task force was to define the scope of the guideline, in terms of the type of policy questions that would be addressed, target audience for the guidance and principles for setting recommendations. The task force then reviewed the literature for existing economic evaluations within the guideline scope. Findings from the literature review, alongside established practices for economic evaluation, were used to inform preliminary recommendations, which were validated by a Delphi panel.

The full task force was responsible for defining the project scope, agreeing on key questions, and composing the recommendations. I.E., V.L. and M.I.M. had a predominantly advisory role, whereas other task force members synthesized evidence for the recommendations. Separate to the task force, a voting panel of 14 specialists in health economics and 13 nephrologists, clinicians and policymakers in LMICs validated recommendations through a Delphi panel (see details below).

Selection of evidence

An umbrella review was conducted to synthesize methodological approaches for economic evaluations aimed at informing policies regarding treatments for kidney failure (Supplementary Methods, Umbrella review protocol and search results). Briefly, we conducted a search for economic evaluation studies to assess the cost-effectiveness of policies to treat kidney failure. MEDLINE and Embase (via Ovid) and Web of Science were searched for systematic reviews of economic evaluations for policies or treatments for kidney failure. Searches of the included systematic reviews were updated to identify the most recent economic evaluation studies. We included all primary studies that conducted ex ante economic evaluations of interventions to treat kidney failure or policies to provide care for patients with kidney failure. For included studies, we extracted data on study methodology and assessed the quality of the study using the Criteria for Health Economic Quality Evaluation (CHEQUE) Tool[19]. The analytical framework for the umbrella review was based around the CHEQUE tool and the ISPOR-SMDM Modelling Good Research Practices Task Force reports[20], as standards of best practice for economic evaluations to inform policy.

Formulation and grading of recommendations

Based on results from the umbrella review, members of the task force proposed an initial set of recommendations, which were reviewed and revised by the full task force through moderated group discussion. Recommendations were graded with reference to standard applied public health economics texts[17,20–22], using the following criteria:

1. **Strong recommendation:** adheres to recognized good practice for conducting economic evaluations. The method is both methodologically sound and practical to implement in LMIC settings. Strong recommendations are supported by evidence and align with accepted international standards for health economic evaluations (comprising good-practice guidelines, textbooks and checklists required by journals for publication). They are feasible to implement in LMICs with minimal adjustment and are expected to provide reliable, policy-relevant results.
2. **Moderate recommendation:** recognized good practice for economic evaluation but does not fully account for the specific challenges encountered by LMICs. Moderate recommendations are methodologically rigorous and have good consensus among task-force members, but some challenges may exist for their practical implementation in LMICs. Adjustments might be needed, but the core methodology remains valid and applicable.
3. **Conditional recommendation:** good practice for economic evaluation does not fully address LMIC challenges, but the recommendation is the best available given current knowledge. Although the recommendation has methodological limitations, it represents the best option given the current constraints in LMICs. The approach is considered useful, but additional work may be required to refine and adapt it to the local context.

Delphi panel to validate recommendations

Two Delphi panels validated the recommendations. The first Delphi panel comprised 14 health economics experts who were affiliated with an agency that produces evidence for government policy in LMICs. These experts were asked whether the recommendations adhered to good economic evaluation practice whilst accounting for challenges that may be faced in LMICs (including limited data availability, technical expertise and resources to conduct economic evaluation). The second Delphi panel comprised 13 nephrologists, clinicians and policymakers in LMICs. This second group of experts was asked whether each recommendation was clear, relevant and practical to implement in their setting. Further details on expert selection are provided in Supplementary Methods (Methods and results for the Delphi panel). The full list of Delphi panel members can be found in the Acknowledgements.

A draft version of the manuscript was circulated to voting panel members, who rated their agreement with each recommendation on a five-point scale via an e-questionnaire. Voting panel members were asked to justify their ratings for all recommendations and to provide suggestions for statement revision if they did not select "agree" or "strongly agree". Questions posed to the panel are detailed in Supplementary Methods (Methods and results for the Delphi panel). Any item without consensus was modified by the task force based on comments received and reviewed again by the voting panel. The consensus criterion (80% agreement) was met after two rounds of voting. Definitions of terms used in this manuscript are provided in Box 1.

Summary of recommendations

The recommendations cover the process of using economic evaluation to inform policy, from defining the policy question and identifying whether an economic evaluation study is needed, through model development, data collection, results generation and use of results in policy design.

Fig. 1 presents a schematic of the economic evaluation process and results generated, which is elaborated upon in later sections. We recommend that relevant experts and affected parties are engaged throughout the process to ensure that the decision question addresses the relevant policy issue, inform design of the model and data inputs and provide face validity checks of the final results. The timeline to conduct an economic evaluation can stretch from a few weeks to over a year, depending on the depth of analysis required and available resources. A summary of the recommendations from each section is provided in Table 1. The rationale for the strength of each recommendation is provided in Supplementary Methods (Grading the strength of recommendations).

1. Define the decision problem

1.1 Agree on the decision question

Recommendations. 1.1.1 Review the decision question with policymakers and subject-matter experts to ensure that the analysis is policy relevant and practical to implement (*Strong recommendation*).

Engaging with decision makers and subject-matter experts to clearly formulate the policy question at the start of the process can help to ensure that an economic evaluation is both policy relevant and practical to implement[23]. Although the appropriate subject-matter experts to involve will depend on the local context and decision problem, they may include frontline health care workers (for example, nephrologists, dialysis nurses, primary-care doctors and/or transplant surgeons); representatives from professional associations for kidney disease, internal medicine or transplantation; researchers (particularly those who administer renal registries); representatives from national health insurance agencies; representatives from government departments that are responsible for the planning or provision of kidney-failure services; or representatives from patient groups, service providers, manufacturers, civil society and the public.

At this stage, it can be helpful to explore a range of policies that may be appropriate: KRT is rarely cost-effective relative to other health services[13], but certain policies may offer a more favourable balance

Box 1 | Definition of terms

Comprehensive kidney management
Planned, holistic, person-centred care that includes the following:
- Interventions to delay progression of kidney disease 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

Of note, comprehensive conservative care does not include dialysis[4].

Disability-adjusted life year
A measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death. A disability-adjusted life year represents 1 year of healthy life, and is usually expressed as disability-adjusted life years lost compared with theoretical maximum, this being a life with maximum achievable life expectancy and without disability or disease[146].

Discounting
The process of converting costs or benefits to be incurred or received at different points in the future to a present value so that they can be compared in commensurate units as if they all occurred at the same point in time. Discounting is used in economic evaluations to adjust for the social or individual preference for the timing of costs and outcomes[147].

Haemodialysis
Haemodialysis (HD) requires a specialized machine to 'clean' the blood for 4–5 h every 2–3 days, and a vascular access (catheter, arteriovenous fistula or graft) to circulate blood from the patient through the machine and back. HD can be delivered in dialysis centres or can be done at home by trained patients or their caregivers[148].

Health technology assessment
The systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences. The approach is used to inform policy- and decision-making in health care, especially on how best to allocate limited funds to health interventions and technologies. The assessment is conducted by interdisciplinary groups using explicit analytical frameworks, drawing on clinical, epidemiological, health economic and other information and methodologies[149].

Incremental cost-effectiveness ratio
A summary measure representing the economic value of an intervention, compared with an alternative (comparator). It is usually the main output or result of an economic evaluation. An incremental cost-effectiveness ratio is calculated by dividing the difference between the intervention and comparator in total costs (incremental cost) by the difference between the intervention and comparator in the chosen measure of health outcome or effect (incremental effect) to provide a ratio of 'extra cost per extra unit of health effect' for the more expensive therapy versus the alternative[146].

Kidney replacement therapy
Dialysis or kidney transplantation (required for ongoing life support in patients with kidney failure).

Modality
Form of kidney replacement therapy (HD, PD or transplantation).

Opportunity cost
The opportunity cost of an intervention is the benefit foregone as a consequence of adopting a new intervention. In a fixed budget health care system where increased costs will displace other health care services already provided, the opportunity cost is measured as the health lost as a result of the displacement of activities to fund the selected intervention[146].

Peritoneal dialysis
Peritoneal dialysis is a home therapy that involves the exchange of dialysis fluid through a catheter placed in the abdominal peritoneal cavity 3–4 times a day, performed either manually or by an automated machine during the night. This can be done by patient or a caregiver[148].

Quality-adjusted life year
The quality-adjusted life year is a summary outcome measure used to quantify the effectiveness of a particular intervention. As the benefits of different interventions are multi-dimensional, quality-adjusted life years have been designed to combine the impact of gains in quality of life and in quantity of life (i.e. life expectancy) associated with an intervention[146].

between cost and health outcomes than others. For example, if the initial policy question is whether to provide haemodialysis (HD) free of charge for all patients, other policies to consider may include a PD-first policy (in which all patients with kidney failure receive PD unless contra-indicated), explicit prioritization criteria for which patients receive dialysis (for example, those likely to survive the longest, achieve the highest quality of life, or who are eligible for transplantation[24]), increased investment in high-quality CKM strategies or reimbursement of a maximum number of HD sessions per patient per year. This process can shortlist policy options that may be feasible to implement according to existing resources for further evaluation, with the understanding that these may not be optimal and would require ongoing policy review for progressive expansion of KRT access over time.

Table 2 outlines potential policy questions related to the provision of KRT services that can be addressed by economic evaluation studies. The first group of questions are exploratory and either directly compare different KRT modalities or compare targets for the proportion of patients on each modality. These questions indicate which modalities, or split of modalities, are most cost-effective, but they may be difficult to translate into policy without further analysis of

policies to achieve defined targets. For evaluations that compare KRT modalities, it is important to highlight to policymakers that a reliance on one sole modality is rarely sustainable, as patients may need to start on or switch to a different modality for health or social reasons. The second group of questions considers policies that define the services that are provided, eligibility criteria that defines who may access these services, principles to prioritize who receives the services and/or strategies to increase the supply or demand for particular services. These questions are aimed at providing practical recommendations for policymaking.

1.2 Define the research question

Recommendations. 1.2.1 Clearly describe the population, intervention and comparator, in agreement with subject-matter experts and the decision maker. Include any details that may influence health outcomes and cost (*Strong recommendation*).

1.2.2 Clearly state the perspective(s) of the analysis. We recommend that the payer perspective is always included. It may also be relevant to consider societal perspectives if there are notable outcomes or costs for patients, caregivers, or other members of society. Adhere to existing national guidelines if available (*Moderate recommendation*).

1.2.3 Identify costs that are relevant to the chosen perspective(s) (*Strong recommendation*).

1.2.4 If equity is important for decision-making, clearly specify whether equity will be incorporated in the cost-effectiveness analysis, as well as how it will be defined and measured (*Moderate recommendation*).

A research question clearly sets expectations between the modeller, policymaker and other experts around what is being modelled, to ensure alignment with the policy under consideration. Of note, a policy question may require evidence from different types of study. We only cover research questions for cost-effectiveness evidence in this guideline.

Population. The population considered in the analysis should encompass all individuals affected by the intervention[19]. Although this approach may encompass all patients with kidney failure, the population considered depends on the decision question and context. For example, in an evaluation of the cost-effectiveness of reimbursing automated peritoneal dialysis (APD) within the context of a PD-first policy[25], the study population encompasses only those patients initiating dialysis on PD. If a similar study were conducted in a setting without restrictions on who can access HD or PD, the study may consider all dialysis patients, particularly if it was thought that the introduction of APD may decrease the proportion of patients on HD.

When defining the population, it may be important to discuss, agree on and document the following points:

- Whether the intervention would apply to all people with kidney failure (prevalent) or only new (incident) cases.
- Whether all patients with kidney failure are covered or only those enrolled under a particular health insurance or social security scheme. In countries that are still in the process of expanding national health insurance coverage, it may be beneficial to explicitly state assumptions around the percentage and profile of the patients who will be enrolled over the time frame of the study.
- Whether there is important heterogeneity in the population that is relevant to the decision question. For kidney failure, age and comorbidities (for example, diabetes and cardiovascular disease) often have important implications for health outcomes and cost.

Intervention. The intervention being evaluated need not be a specific KRT modality (for example, HD or kidney transplantation). Depending on the decision question, the relevant intervention(s) could be an allocation algorithm, conditions to access care, changes in laws or clinical-practice guidelines, a specific technology or scenarios of different targets (Table 3). In all cases, it is important to provide details about the intervention that may influence the health outcomes or cost. For technologies, these details may include the setting (for example, hospital, satellite centre or home-based), frequency and length of

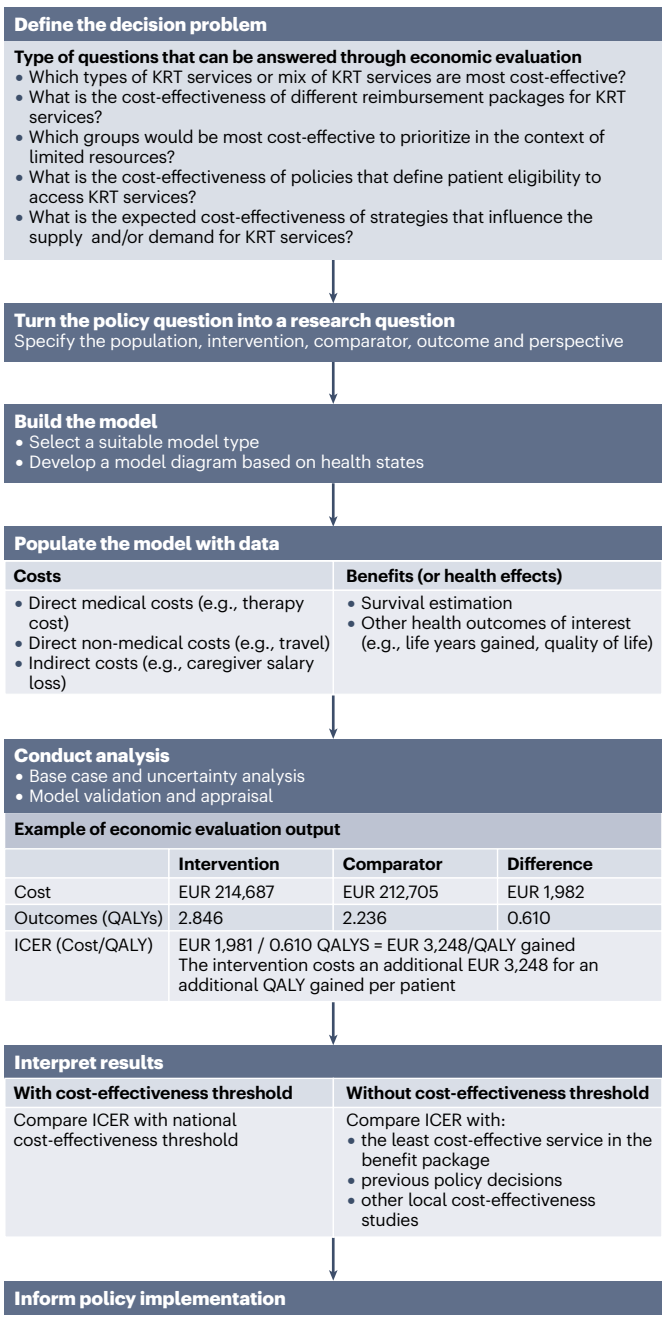


Fig. 1 | Main steps involved in conducting an economic evaluation for kidney replacement therapy policies. ICER, incremental cost-effectiveness threshold; KRT, kidney replacement therapy; QALY, quality-adjusted life year.

Table 1 | Summary of recommendations

Section	Recommendation(s)	Strength
1. Define the decision problem		
1.1 Agree on the decision question	1.1.1 Review the decision question with policymakers and subject-matter experts to ensure that the analysis is policy relevant and practical to implement	Strong
1.2 Define the research question	1.2.1 Clearly describe the population, intervention and comparator, in agreement with subject-matter experts and the decision maker; include any details that may influence health outcomes and cost	Strong
	1.2.2 Clearly state the perspective(s) of the analysis. We recommend that the payer perspective is always included; it may also be relevant to consider societal perspectives if there are notable outcomes or costs for patients, caregivers or other members of society; adhere to existing national guidelines if available	Moderate
	1.2.3 Identify costs that are relevant to the chosen perspective(s)	Strong
	1.2.4 If equity is important for decision making, clearly specify whether equity will be incorporated in the cost-effectiveness analysis, as well as how it will be defined and measured	Moderate
1.3 Identify the need for economic evaluation	1.3.1 Review what is already known about health outcomes and costs of proposed policy interventions; decide whether conducting an economic evaluation is warranted	Strong
1.4 Evaluate the transferability of other studies	1.4.1 Evaluate whether the policy question and data from existing studies are relevant to your research question and setting; in most cases it is more informative to develop a model specific to the policy question and context than to adapt results from another setting	Conditional
2. Conducting the economic evaluation		
2.1 Scope of an economic evaluation	2.1.1 Document and justify the chosen discount rate and time horizon; adhere to existing national guidelines if available	Strong
	2.1.2 A lifetime horizon is normally most appropriate to capture relevant health outcomes and costs, given that most kidney-failure interventions attempt to extend lifespan	Strong
2.2 Model type and structure	2.2.1 Decide which type of model to use (for example, decision tree, cohort Markov model, discrete event simulation or another model type) based on the decision question and available modelling resources; modelling resources to consider include the size of the modelling team, their experience and available time	Conditional
	2.2.2 The model structure should reflect any aspect of the natural course of disease, clinical pathways and feasible health care delivery in the country that markedly impacts the costs and clinical outcomes of the interventions being assessed	Strong
	2.2.3 Keep the model as simple as possible to address the policy question; a simple model will facilitate clear communication of model outputs, limitations and policy implications to the policymaker	Strong
2.3 Populate the model with data	2.3.1 Cost data (units of resources and cost per unit) should be as country specific as possible; wide variation in health care-associated costs between countries complicates the ability to use or adjust cost data from other settings	Strong
	2.3.2 Use, wherever possible, country-specific survival and quality-of-life data. Where they exist, renal registries or local studies may be a source of relevant data, provided that they are sufficiently representative and of sufficient quality	Moderate
	2.3.3 All data sources (including expert opinions) should be clearly documented, with limitations in terms of representativeness or quality noted	Strong
2.4 Analysis	2.4.1 Results should be presented as an ICER or average cost per outcome of each intervention; ICERs should be calculated pairwise as the difference in cost and health outcomes between an intervention and the next best alternative; disaggregated costs and outcomes should also be shown	Strong
	2.4.2 Budget impact analysis should be calculated. Depending on the policy question and context, estimations of resource requirements (in terms of required health care personnel and health care centre capacity) may also be an important input for decision-making	Strong
	2.4.3 Uncertainty analysis is essential; highlight any sources of uncertainty that may affect which option is most cost-effective	Strong
3. Using economic evaluation results for policymaking		
3.1 Interpreting results	3.1.1 Results should be presented in easy-to-read format, using graphs and tables that allow the policymaker to quickly understand the health impacts and cost trade-offs between policy interventions	Strong
	3.1.2 If cost-effectiveness thresholds are standard policy-related practice, then analysts can consider showing the calculated ICERs in relation to the thresholds; if no cost-effectiveness threshold exists, comparison can be made with the ICERs of other health interventions in the benefits package	Strong
3.2 Appraising the quality of an economic evaluation	3.2.1 Where available, the quality of an economic evaluation study can be appraised following local methodological guidelines; in the absence of country-specific guidelines, guidelines from neighbouring countries or international frameworks and checklists can be used	Strong
	3.2.2 Appraisals of economic evaluations should review the appropriateness of the analysis for the decision question, the methodological rigour, the feasibility of implementing the proposed policies and the inclusion of appropriate stakeholders throughout the evaluation process	Strong
3.3 Informing policy	3.3.1 Use results from economic evaluation and budget impact analysis, alongside other criteria and consultations with key stakeholders, to inform decision making and policy implementation relevant to the local context	Strong

For all recommendations, the strength applies to the full recommendation (that is, all statements in a given recommendation). ICER, incremental cost-effectiveness threshold.

delivery (for example, 4-h sessions delivered 3 times per week), specific technology (for example, continuous ambulatory peritoneal dialysis (CAPD) or APD), and whether consumables and adjunct therapies (for example, erythropoietin) are reimbursed. Example descriptions of reimbursement policies and allocation algorithms have been published elsewhere[26,27].

One important consideration for KRT at this stage is the package of care to be provided and the minimum quality of care. For HD this may include vascular-access operations, erythropoietin, consumables and transportation; for transplantation, it may include pre-transplantation evaluation and long-term immunosuppressive therapy. Ancillary services and medications can improve patient survival, quality of life and equity (for example, if pre-transplantation tests are not covered, patients from lower socio-economic backgrounds may be less likely than those with higher socio-economic backgrounds to receive transplants). Certain interventions may also be cost saving for the government if they reduce inpatient costs for complication-related hospitalizations[28]. Their inclusion or exclusion should be agreed upon and clearly defined in the description of the intervention. If the policy under discussion will apply across different health insurance schemes, consideration of inequalities in terms of the package of care between schemes may help to define what is (and is not) covered. The economic evaluation can either explicitly define improvements in the package of care as a policy intervention or incorporate scenarios with different minimum packages of care to compare the cost and benefit implications.

Comparator. The comparator should appropriately measure the opportunity cost of the intervention[19]. Opportunity cost refers to the use of resources (for example, budget, hospital beds, or health care staff) that could have been allocated to other areas of the health system, although the scope of this definition depends on the perspective of the analysis (see Sect. 2.1, below). The comparator for an economic evaluation may be the current policy, actual practice, or a 'do-nothing' scenario[17]. In the context of kidney failure, CKM may be an appropriate comparison, even if it is not well-established within the country, if it is considered by stakeholders to be the minimum acceptable level of care[4]. If national guidelines exist for conducting health-economic evaluation, they may provide guidance on the appropriate comparator to use to ensure standardization with other studies used for policymaking.

Table 2 | Examples of policy questions related to the provision of services for kidney failure that can be addressed by economic evaluation

Type of decision question	Primary purpose	Examples from published economic evaluation studies
Exploratory		
Modality of KRT	To advocate for changes to the current policy or mix of services *Example*: is kidney transplant more cost-effective than dialysis for the national health insurance scheme?	Kidney transplantation compared with dialysis[76,107–110] Comparison of types of dialysis[111–116]
Goal setting	To identify the target mix of KRT modalities *Example*: would a 20% higher uptake of CAPD be more cost-effective than the current programme?	Increased uptake of home HD[30] Increased proportion of patients on PD and/or with a transplant[117–123]
Policy design		
Reimbursement	To decide which technologies and services to provide free-of-charge or with some level of co-payment; to determine the level of co-payment required for KRT services *Example*: What is the budget impact and cost-effectiveness associated with adding erythropoietin to the benefit package so that it is free of charge for all dialysis patients? *Example*: What are the expected costs and health outcomes of reimbursing transport to HD centres for HD patients below the poverty line, compared with no reimbursement? *Example*: What is the expected cost-effectiveness of changing from a co-payment of $10 per HD session to a co-payment of $100 per year to cover 2 HD sessions per week?	Number of HD sessions reimbursed per patient[26]; whether to reimburse new dialysis technologies[25,124–127]
Allocation/prioritization	To prioritize who receives services in the context of resource constraints *Example*: Which patients should be prioritized for reimbursement of 3 HD sessions per week over 2 HD sessions per week?	Criteria to prioritize patients for dialysis or CKM[128]; algorithms to allocate kidney transplant recipients[27,129–131]
Access conditions	To define eligibility criteria to access services *Example*: What is the cost-effectiveness of restricting access to HD services to patients with a life expectancy longer than 6 months and providing CKM for others?	PD-first policy (access to HD is restricted to people who cannot use PD for health or social reasons)[26,29,72,132]
Strategies to increase demand	To evaluate strategies to influence demand for KRT modalities in a free choice system *Example*: What is the cost-effectiveness of reimbursing electricity bills for patients on APD to increase the proportion of KRT patients on PD? *Example*: What is the cost-effectiveness of multidisciplinary patient education for those with stage 4 CKD to increase the uptake of PD?	No economic evaluation studies identified
Strategies to increase supply	To evaluate strategies to address constraints in the supply of services *Example*: What is the cost-effectiveness of transplanting organs from high-risk donors?	Transplanting low-quality kidneys to overcome organ shortages[83,90,133–139]; laws or procedures aimed at increasing organ donation (for example, opt-out laws)[82,96,140–142]

This list is intended to be illustrative and is not exhaustive. APD, automated peritoneal dialysis; CAPD, continuous ambulatory peritoneal dialysis; CKD, chronic kidney disease; CKM, conservative kidney management; HD, haemodialysis; KRT, kidney replacement therapy; PD, peritoneal dialysis.

Table 3 | Interventions that could be considered for different types of decision questions

Type of decision question	Intervention	Examples of interventions
Modality of KRT	KRT modality	CAPD; APD; hospital-based HD; living donor organ transplantation
Goal setting	Scenarios that define targets (for example, the proportion of patients on each modality or percentage increase in KRT patients on a specific modality)	Increasing the proportion of patients initiating dialysis on PD from 10% to 30%; increasing the number of transplants from 100 to 500 per year
Allocation/prioritization	Algorithm or principles for prioritization	Prioritizing kidney-transplant recipients according to time on the waiting list or according to life expectancy; prioritizing patients for dialysis according to eligibility for transplantation
Access conditions	Set of conditions that defines who is eligible for each service	PD-first policy (patients eligible for PD will only be reimbursed for PD and not for HD); HD is only provided to patients with life expectancy over 6 months
Strategies to increase supply or demand	The specific strategy/strategies proposed	Soft opt-in laws for organ donation; patient education programmes to improve PD uptake
Reimbursement	New technology/services to be reimbursed, or proposed changes to the minimum package of care	Remote monitoring of patients for APD; three sessions of HD per patient per week; erythropoietin included in the package of care

This list is illustrative and not exhaustive. APD, automated peritoneal dialysis; CAPD, continuous automated peritoneal dialysis; HD, haemodialysis, KRT, kidney replacement therapy; PD, peritoneal dialysis.

Particularly in resource-constrained settings, current policies may deviate from what actually happens in practice. An evaluation of the PD-first policy compared with HD-first in India accounted for this mismatch by defining two baseline scenarios: one assumed current patterns of dialysis use whereas the other assumed adherence to the national guidelines[29].

Perspective. Perspective refers to the viewpoint of the analysis, which defines the costs and health outcomes considered. Most studies aimed at informing policy will take the perspective of the government payer, which may be the national health service, health insurance agency or another funder. The research team may also wish to consider a societal perspective if the interventions under consideration are expected to have considerable societal impact. In the context of policies for kidney failure, societal impacts may include the level of risk for patients from changes to organ-donation procedures, implications for equitable access to care, burden on caregivers, or out-of-pocket costs for patients. One cost-effective analysis adopted a national health service perspective for their base case comparison of home versus in-centre HD for patients who experienced PD failure, in line with national guidelines, but also reported the societal perspective to capture productivity loss of the patient and caregiver[30]. The researchers determined that home HD compared with in-centre HD was less cost-effective from a societal perspective (GBP 30,497 per life year gained compared with GBP 24,220 per life year gained from the health-system perspective) owing to the need for the caregiver to spend more time at home caring for the patient[30]. The role of perspective in economic-evaluation studies has been explored in detail elsewhere[31,32].

Outcomes. Cost-effectiveness analyses produce an estimate of the additional cost per unit health (for example, per quality-adjusted life year or per life year gained). These analyses require that the costs and health (and potentially social) outcomes of interest are defined. As policymakers are often most interested in the outcomes achieved by investing in KRT services compared with investment in other areas of the health system, it is often most informative to use generic health outcome measures instead of kidney-disease-specific outcomes.

Health outcomes: Common health outcome measures for health are life years, quality-adjusted life-years (QALYs) and disability-adjusted life years (DALYs). Life years may be sufficient if the interventions are only expected to differ in terms of survival, whereas QALYs and DALYs may be applied if there is an interest in accounting for quality of life in addition to life years gained. QALYs reflect preferences specific to the population of interest, whereas DALYs use a universal set of disability weights that are applicable across countries[33,34]. Although widely accepted measures in health economics, both QALYs[35–37] and DALYs[38–40] have been criticized. Policymaker acceptance and understanding of QALYs and DALYs may influence whether they are an appropriate health outcome measure to use.

Discussions with the policymaker or other involved parties may highlight additional outcomes of interest, such as average survival, social participation, days with complications, average time on the transplant waiting list, or days off work. In particular, patient experience may help to identify important outcomes to consider. As policymakers may have different interests or levels of understanding of health outcomes, it may be beneficial to include more than one metric (for example, life years and QALYs).

Cost outcomes: The selection of costs to be considered depends on the perspective chosen for the analysis (for example, whether the analysis is from the perspective of the government payer or society). A general overview of costs included under each perspective has been provided elsewhere[22,41]. Where they exist, country-specific methodological guidelines for economic evaluation or health-technology assessment (HTA) often detail which costs should be considered[42,43].

Equity outcomes: Equity may be an important criterion for policymaking. It can be considered from the perspective of horizontal equity, in which people with similar needs receive the same treatment (for example, defining a standard package of care for all patients with kidney failure). By contrast, vertical equity prioritizes those with greater need (for example, lower co-payment for low-income groups)[16]. Techniques are available that enable assessment of equity as a cost-effectiveness analysis outcome; however, these techniques require more comprehensive data collection than is needed for standard cost-effectiveness analysis. The extended cost-effectiveness analysis method, for example, accounts for distributional effects (that is, the extent to which the costs and/or benefits are distributed evenly across subgroups) and financial-risk protection afforded by each intervention. A tutorial on extended cost-effectiveness analysis can be found

elsewhere[44]. Subgroup analysis can examine the relative costs and health outcomes for specific groups, for example, informal-sector workers, to determine if these individuals are equally likely to benefit from a policy. Although outside the scope of this article, equity may also be considered as a separate criterion to cost-effectiveness during the policymaking process[45]. As different people may have different perspectives on equity and the inequities that are important for the decision-making process, it is beneficial to come to a common understanding of how equity is defined and measured if it will be considered for decision-making. It is possible that multiple dimensions of equity (for example, geographic or socio-economic) may be considered.

1.3 Identify the need for economic evaluation

Recommendations. 1.3.1 Review what is already known about health outcomes and costs of proposed policy interventions. Decide whether conducting an economic evaluation is warranted (*Strong recommendation*).

Economic evaluation considers the cost and health outcomes of two or more competing alternatives from the perspective of a particular audience (for example, the national health insurance agency, ministry of health or society)[17]. Prior to conducting a full economic evaluation, it can be useful to review what is already known about the costs and benefits of the intervention(s) relative to the comparator, to identify what information is available and whether the analysis will provide additional information for the policymaker. Benefit can be measured in terms of health outcomes (for example, survival, quality of life, years on dialysis) or in terms of health and social outcomes (for example, caregiver quality of life).

- If either the intervention or comparator is cheaper and has better health outcomes, economic evaluation is unlikely to provide any additional information for policy beyond what is already known (Fig. 2).
- If the intervention is more expensive with better health outcomes or cheaper with worse health outcomes, economic evaluation is recommended (unless a reduction in health outcomes is considered unacceptable by the decision-maker). For example, dialysis is more expensive than conservative care, but leads to better health outcomes for the majority of patients.

For certain decision questions, the expected health outcomes and/or costs of the intervention may be very similar to the comparator. For example, systematic reviews suggest comparable survival rates and quality of life between HD and PD, when controlling for patient characteristics[46–50]. In such situations, the decision on whether or not to conduct an economic evaluation might depend on the decision context and level of uncertainty. If local experts consider uncertainty to be high, there may be interest in conducting an economic evaluation[17]. However, if the budget impact is expected to be low or if local experts have a high level of confidence in the existing evidence, the local team may decide not to conduct an economic evaluation and to instead proceed with existing evidence or only focus efforts on analyses of costs (if health outcomes are thought to be comparable) or health outcomes (if costs are believed to be similar).

1.4 Evaluate the transferability of other studies

Recommendations. 1.4.1 Evaluate whether the policy question and data from existing studies are relevant to your research question and setting. In most cases it is more informative to develop a model specific to the policy question and context than to adapt results from another setting (*Conditional recommendation*).

Time and resource constraints may prompt interest in the use or adaptation of economic-evaluation studies or models from other settings. Adaptive health technology assessment (aHTA) methods are growing in popularity as a structured way of transferring cost-effectiveness estimates from one setting to another. However, there are important limitations to this approach. Costs are seldom generalizable between countries, even when applying aHTA methods[51]. In the context of KRT, the cost of transplantation is highly dependent on economies of scale, whereas the relative costs of HD and PD may depend on import regulations for dialysate and nurse salaries[4,52,53]. There may also be important context-specific differences that limit generalizability, for example, in terms of the specific package of care provided, accessibility of health services and profile of patients. Published studies often lack specific details of the health-system context, reimbursement schemes, patient profiles, interventions and comparators, all of which are required to judge the generalizability of findings across contexts. An alternative approach if time constraints are a factor is to develop a simple de novo cost-effectiveness model that incorporates an uncertainty analysis to understand the impact of model assumptions and low-quality data. For example, a rapid cost-effectiveness analysis was used to inform policies for acute kidney injury in Rwanda[54].

2. Conducting the economic evaluation

Below, we outline the main steps involved in conducting an economic evaluation. We anticipate that most readers of this article are users, rather than producers, of economic evaluation; therefore, this section describes the main concepts and highlights the key principles of a rigorous economic-evaluation study, to enable the user to contribute to discussions throughout the modelling process. It is worth highlighting that simple models that are context-specific, fully address the policy issue and are well understood by the modeller and decision-maker alike are often the most informative models for policymaking.

2.1 Scope of an economic evaluation

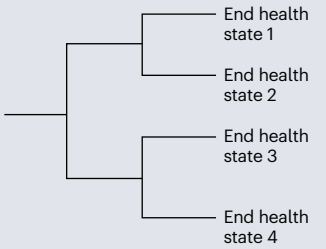
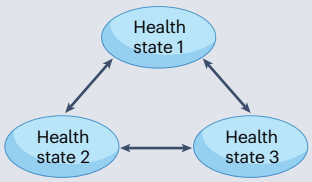
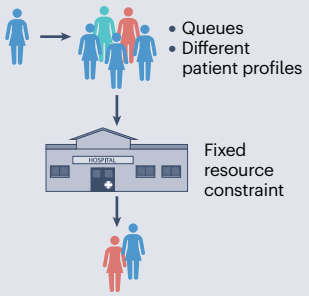
Recommendations. 2.1.1 Document and justify the chosen discount rate and time horizon. Adhere to existing national guidelines if available (*Strong recommendation*).

2.1.2 A lifetime horizon is normally most appropriate to capture relevant health outcomes and costs, given that most kidney-failure interventions attempt to extend lifespan (*Strong recommendation*).

		Intervention benefit (relative to comparator)			
		Higher	**Same**	**Lower**	**Unknown**
Intervention cost (relative to comparator)	**Higher**	Conduct EE	Choose comparator	Choose comparator	Conduct EE
	Same	Choose intervention	EE not relevant for decision	Choose comparator	Conduct EE
	Lower	Choose intervention	Choose intervention	Conduct EE	Conduct EE
	Unknown	Conduct EE	Conduct EE	Conduct EE	Conduct EE

Fig. 2 | Decision matrix to determine the need for an economic evaluation for policymaking. In all cases that state "Choose intervention", the comparator is dominated and the intervention dominates; conversely in all cases that state "Choose comparator", the intervention is dominated and the comparator dominates (see Section 2.4 for further details). EE, economic evaluation. Adapted with permission from Manns et al.[145], National Kidney Foundation.

Table 4 | Comparison of model types for the economic evaluation of policies related to kidney replacement therapy service provision

Model type	Decision tree[a]	Cohort Markov model[b]	Discrete event simulation[c]
Summary	Appropriate for short time horizons and simple calculations of outcomes[23]	Enables the inclusion of repeated events and probabilities that vary over time[23]	Able to track individual profiles and account for resource constraints[143]
Diagram (illustrative)			
Example question	What is the cost-effectiveness of reimbursing vascular access for patients requiring HD in the benefit package?	What is the cost-effectiveness of a policy to limit HD reimbursement to people with more than 6 months' life expectancy?	Is low-quality organ transplantation more cost-effective than staying on the waiting list for a higher-quality organ?
Potential degree of analytic difficulty	Low: simple decision trees can often be produced in spreadsheet format, increasing both ease of sharing the model and understanding; an add-in to create decision trees is freely available[144]	Medium: may be constructed in spreadsheet format, but the inclusion of multiple probabilities increases the complexity of model calculations	Complex: tracking individuals requires use of specialized software or advanced programming skills

[a]Decision tree: disease progression and/or treatment pathways are modelled as sequential steps, with a probability assigned to each branch of the model. [b]Cohort Markov model: patients are modelled as progressing between health states, with probabilities determining the likelihood of individuals moving from one health state to another within a fixed length of time (e.g., the likelihood of transition from peritoneal dialysis to HD within a 1-year period). [c]Discrete event simulation: queuing rules model access to a fixed resource (e.g., hospital bed, doctor's appointment, donor organ). HD, haemodialysis.

This section covers two considerations that account for time in the model: the discount rate and time horizon. The discount rate and time horizon both affect the extent to which future costs and outcomes affect the cost-effectiveness result. For example, a higher discount rate and a shorter time horizon would favour short-term improvements in health impact and cost reduction. We recommend that country-specific guidelines are followed where they exist, for consistency and comparability with other health-economic evaluations. We refer the reader to existing literature for an overview of these concepts[22,55] and for further details on discounting[56,57] and time horizon[58].

Discount rate. The discount rate determines how future costs and health outcomes are valued relative to current costs and health outcomes. In many countries, the required discount rate for costs and outcomes can be defined through a reference case or HTA guidelines[55,59]. The treasury or ministry of finance might also provide general recommended discount rates[57]. In settings in which a defined discount rate is not available, a value may be used from neighbouring countries, the WHO Choosing Interventions that are Cost-Effective programme[60] or the literature, with a deterministic sensitivity analysis to assess whether the choice of discount rate influences the most cost-effective option. Although 3% is often used as a discount rate, higher discount rates may be more appropriate in lower-middle income and low-income settings to reflect economic growth[57]. Conversely, in settings that prioritize health promotion and prevention as a health-sector-wide strategic objective, a lower discount rate may be considered[61].

Time horizon. Time horizon is the time period over which an economic evaluation assesses the costs and health outcomes of an intervention. The choice of the appropriate time horizon depends on the period of time required to capture differences in costs and health outcomes between the interventions and comparator. In most cases, a lifetime horizon is appropriate, which means that the analysis includes all costs and outcomes of the patient until death[19].

2.2 Model type and structure

Recommendations. 2.2.1 Decide which type of model to use (for example, decision tree, cohort Markov model, discrete event simulation or another model type) based on the decision question and available modelling resources. Modelling resources to consider include the size of the modelling team, their experience and available time (*Conditional recommendation*).

2.2.2 The model structure should reflect any aspect of the natural course of disease, clinical pathways and feasible health care delivery in the country that markedly impacts the costs and clinical outcomes of the interventions being assessed (*Strong recommendation*).

2.2.3 Keep the model as simple as possible to address the policy question. A simple model will facilitate clear communication of model outputs, limitations and policy implications for the policymaker (*Strong recommendation*).

Model type. Economic-evaluation studies use different types of models to calculate costs and health outcomes (Table 4). All model types can include considerations such as equity and complications. For most policy questions related to kidney failure, a cohort Markov model will be appropriate. For policy questions that relate to the allocation or prioritization of constrained resources (for example, algorithms to prioritize recipients of donated kidneys), discrete event simulation can

incorporate constraints and/or provide insights into efficiency–equity trade-offs. Similarly, microsimulation models might be suitable if the decision problem requires an analysis of multiple patient (or donor) characteristics.

Ultimately, the most appropriate model is one that will be used to inform policy. Three-way trust between the policymaker(s), modelling team and the model is important to ensure that model results are used to inform policy[62]. If, for example, there is limited capacity to develop and communicate results from a cohort Markov model with confidence to policymakers, a simpler approach with extensive uncertainty analysis (see Sect. 2.4, below) may be sufficient. Discussion between researchers, subject-matter experts and policymakers prior to model development might be needed to identify a model type that balances the required complexity to answer the question with timelines for decision-making, expertise of the research team and comfort of the policymaker when using the outputs from the model.

Model structure. Although model structure is dependent to a certain extent on model type, in the context of kidney-failure models, it generally defines the different health states of patients. In a decision tree, this may be shown as progression along a clinical pathway (the course of treatment or care according to disease progression), whereas for cohort Markov models it shows the transition between different states (such as hospital-based HD and death). There can be a temptation to make the model structure as close as possible to clinical pathway and patient experience. However, as a general principle, a model should only be as complicated as it needs to be to capture the main differences in health outcomes and costs between interventions and the comparator that are relevant for decision-making[63]. This approach can reduce propagation of uncertainty through the model, decrease data requirements and simplify model verification (that is, the ability to check for errors).

Published economic evaluations can help to define a model structure. However, the context and decision question of any published model must be considered to determine whether it can be transferred to another setting and policy question.

2.3 Populate the model with data

Recommendations. 2.3.1 Cost data (units of resources and cost per unit) should be as country specific as possible. Wide variation in health care-associated costs between countries complicates the ability to use or adjust cost data from other settings (*Strong recommendation*).

2.3.2 Use, wherever possible, country-specific survival and quality-of-life data. Where they exist, renal registries or local studies may be a source of relevant data, provided that they are sufficiently representative and of sufficient quality (*Moderate recommendation*).

2.3.3 All data sources (including expert opinions) should be clearly documented, with limitations in terms of representativeness or quality noted (*Strong recommendation*).

Economic-evaluation models require three main types of data: data on costs, data on the probability of an individual changing between clinical states (for example, survival on APD or annual probability of switching between KRT modalities), and health outcomes data for each health state. The model structure should never be modified to fit the data[64]. As a general principle, when data are missing (that is, they cannot be identified or accessed), a best-guess value (one that experts consider to be likely) and plausible range can be identified through expert opinion with uncertainty analysis conducted to identify the implications of the missing or poor-quality data. A report exists on good practices for structured elicitation of expert opinion[65]. All data sources should be clearly documented, with limitations or potential sources of bias reported.

Cost data. The cost data required will depend on the perspective taken. A general description of costs under each perspective is provided elsewhere[22]; where they exist, country-specific reference cases or HTA guidelines may define which costs should be included under the payer and societal perspectives. For government-funded health services or national health insurance schemes, all aspects of the service that are free to the patient would normally be included under the payer perspective, whereas any medical costs that the patient needs to pay (for example, if adjunct therapies such as anaemia treatment or immunosuppressive therapy are not covered) and non-medical costs incurred by the patient and caregiver (such as transportation to the hospital or wage foregone due to time off work) would only be included under the societal perspective.

Cost data are often not transferrable across settings and therefore use of local data is recommended[66]. If a costing study already exists for a country, we recommend that the methodology is checked to determine whether the population and context of the costing study is the same as the population and context for the economic evaluation, as well as whether all costs required for the chosen perspective of the economic evaluation were included in the costing study. In the absence of a national costing database or costing study, reimbursement rates for existing services can be requested from the national health insurance agency or government payer. With sufficient time and resources, missing costs can be collected through costing studies in hospitals or health care centres. Otherwise, surveys can be sent to health care providers, patients and caregivers to request cost information.

For new technologies, formal written requests to the manufacturer can provide information on the cost and potential discounts with economies of scale. This approach can be effective as the manufacturer is aware that the policy decision may be contingent on the price offered[67].

For all costs, it is good practice to separately report unit costs and volume[19]. Prior to analysis, costs should be adjusted to the same currency and calendar year. A practical guide to adjust for currency and inflation is provided elsewhere[68]. A general guide to costing health programmes can be downloaded from the Global Health Cost Consortium[69].

Survival and probabilities of switching. Depending on the quality of local data, different approaches are available for calculating patient survival on each KRT therapy, the probabilities of complications, and the probability of switching between KRT modalities. If patient-level data are available, time-to-event data can be used to estimate survival curves that are adjusted for patient characteristics such as age and comorbidities. Otherwise, average probability can be calculated from renal registry data or other databases. For datasets that report disease-specific (as opposed to all-cause) mortality, the analyst will need to adjust mortality estimates using life tables or other population-based mortality estimates. The Canadian Agency for Drugs and Technologies in Health (CADTH) and the UK's National Institute for Health and Care Excellence (NICE) have both developed guidance for the selection and use of survival data in economic evaluations[70,71].

If data from local registries or national studies are not available (or considered to be of low quality), data from systematic reviews, neighbouring countries and/or structured expert opinion may be used. The most appropriate data to use will depend on the data quality

and representativeness of the available data for the local population[66]. For example, survival data for dialysis patients registered under a private health insurance fund may be less representative of patient survival under a universal health coverage policy (which may enrol patients of lower socio-economic status) whereas systematic reviews from countries with high HD service quality may be less representative of survival in countries with constraints on health care personnel, prohibitive out-of-pocket payments for adjunct services (such as anaemia management) and/or old HD machines.

Health outcomes for different health states: quality-adjusted life years and disability-adjusted life years. As described earlier, many health or social outcomes may be of interest to the decision-maker. In the context of an economic evaluation, health outcomes are most often reported in terms of life years or in terms of QALYs or DALYs, which account for quality of life in addition to years of life[19]. If the only health outcome of interest is life years, no additional data collection is required.

For studies that calculate QALYs, utility scores for each health state are required, representing quality of life compared with that of full health. The best-quality utility data are derived from studies conducted in the same jurisdiction as the economic analysis that use a representative population and an instrument validated for the specific population. If no validated tools are available for the specific context of interest, a study in the population of interest can be conducted using tools borrowed from a nearby jurisdiction that is judged to be representative. For example, one survey of dialysis patients in Indonesia was conducted using the EQ-5D value set from Thailand[72]. Alternatively, utility scores can be taken from meta-analyses in the literature[73–75], or from a neighbouring country if it is judged to be representative. For example, one study in Demark used utility data from Sweden, matched for covariates such as age[76].

If DALYs are used instead of QALYs, a universal set of standard disability weights is applied instead of utility scores. Disability weights measure life lost because of premature mortality and time lived in a state with a worse quality of life[34]. Data are also required on life expectancy at age of death, which can be taken from life tables. Disability weights and life tables are available from the Institute for Health Metrics and Evaluation[77]. Local life tables may also be used, where they exist.

2.4 Analysis

Recommendations. 2.4.1 Results should be presented as an incremental cost-effectiveness ratio (ICER) or average cost per outcome of each intervention. ICERs should be calculated pairwise as the difference in cost and health outcomes between an intervention and the next best alternative. Disaggregated costs and outcomes should also be shown (*Strong recommendation*).

2.4.2 Budget impact analysis should be calculated. Depending on the policy question and context, estimations of resource requirements (in terms of required health care personnel and health care centre capacity) may also be an important input for decision-making (*Strong recommendation*).

2.4.3 Uncertainty analysis is essential. Highlight any sources of uncertainty that may affect which option is most cost-effective (*Strong recommendation*).

Incremental cost-effectiveness ratios. Results from a cost-effectiveness analysis are normally calculated as an ICER. An ICER is a pairwise comparison between two options that presents the difference in cost (incremental cost) against the difference in health outcomes (incremental outcomes). The most common units for an ICER are cost per life year, cost per QALY, and cost per DALY, which represent the additional cost per life year gained, cost per QALY gained, or cost per DALY averted, respectively. For example, if the ICER of a PD-first policy compared with a CKM programme is $20 per QALY, it means that the PD-first policy has better health outcomes, but an extra $20 must be paid for each additional QALY gained. ICERs are calculated using the following equation:

$$\text{ICER} = \frac{\text{Cost(policy1)} - \text{Cost(policy2)}}{\text{Outcomes(policy1)} - \text{Outcomes(policy2)}}$$

If one policy intervention is compared with the comparator, policy 1 in the above equation will represent the intervention and policy 2 the comparator. If there are two or more policy interventions in addition to the comparator, each ICER will be calculated relative to the next most cost-effective option (that is, if more than one intervention has been identified, only the least cost-effective intervention will be directly compared with the comparator in the results table; the ICER of more cost-effective interventions will be calculated relative to the next most cost-effective option)[19,78]. A tutorial for ICER calculation can be found elsewhere[78].

The results of these analyses are sometimes presented as "dominant" or "dominated" rather than as an ICER, as per the concepts highlighted in Fig. 2.

- A **dominated** option is less effective and more costly than the comparator (that is, worse health at a higher cost)[78].
- A **dominant** option is more effective and less costly than the comparator (that is, better health at a lower cost)[78].

Another unit that is sometimes used to measure cost-effectiveness is net monetary benefit (NMB), which re-scales health benefit in monetary terms[78]. The higher the NMB, the more cost-effective the option. The NMB can be useful for comparing multiple interventions, as it is always calculated relative to the comparator (thereby avoiding multiple pairwise comparisons), and is required for analyses such as value of information and cost-effectiveness acceptability curves. However, the NMB may be less intuitive to understand than an ICER. NMBs are calculated using the following equation:

$$\text{NMB} = [\text{Outcomes(intervention)} - \text{Outcomes(comparator)}] \times \text{threshold} - [\text{Cost(intervention)} - \text{Cost(comparator)}]$$

Budget impact and resource needs. Cost-effectiveness analyses, as discussed above, provide information on the additional health outcomes realized with additional spending. They do not report on additional budget or health care resources required. Analysts can, however, use information from cost-effectiveness models to estimate budget impact, which accounts for the number of patients, uses actual (not discounted) costs and shows budget outlays over time horizons relevant to the budget holder. Further information is available in good-practice reports[79,80].

In resource-constrained settings, estimates of the required health care workforce and infrastructure can be useful for policymaking. Population estimations from the budget impact analysis can be used as the basis to estimate resources required. For HD, this may include the number of HD nurses, technicians, haemodialysis machines and

nephrologists, for example. If existing resources are insufficient, this information can be used to plan for the incremental scale-up of capacity or phased implementation of a new policy. If coverage of UHC is still expanding, policymakers might be interested in a scenario analysis of the budget impact and resource requirements under different forecasted changes in coverage and/or health care utilization. This scenario analysis can be conducted by changing the projected eligible population in the analysis.

Uncertainty analysis. Policies must always be made under some level of uncertainty. Uncertainty analyses show the impact of this uncertainty on results, so that policies can be made with an understanding of the potential risks of each option. The most important consideration for uncertainty analysis is whether there is a change in the most cost-effective option.

The following uncertainties can be explored through uncertainty analysis:

- Uncertainty in the decision problem (decision uncertainty): this considers disagreement around the appropriate research question (population, intervention, comparator, outcomes). Scenario analysis can be conducted using a different comparator, considering different assumptions around the intervention (for example, with and without a minimum package of care), or patient profile.
- Uncertainty in the model boundaries (methodological uncertainty): the discount rate and time horizon can be varied to determine whether they affect the most cost-effective option. Varying the discount rate is normally recommended[55,81]. Analysis of different time horizons may only be applicable if the lifetime horizon is very long[58]. Evaluations of transplantation could incorporate variations in time horizon[82,83].
- Uncertainty in the data (parameter uncertainty): different data sources can be used and parameters varied (either individually or simultaneously) to assess whether data limitations are important. The simplest of these use data from alternative studies to address concerns about data quality or generalizability (for example, to compare cost-effectiveness estimates with survival from the renal registry or from a systematic review) and deterministic sensitivity analysis, in which the value of individual parameters is changed.
- Uncertainty in model structure (structural uncertainty): if there was significant disagreement during determination of model structure, the model structure can be modified to determine whether it makes a difference to the most cost-effective option.

Further information on interpreting the results from uncertainty analysis is presented in Sect. 3.1.

Subgroup analysis. If appropriate to the decision question, subgroup analysis can show whether the balance of costs and health outcomes differs across different subgroups of the population. One reason for subgroup analysis is to consider whether policies would have inequitable impact. For example, one study reported that in the Philippines, dialysis policies disproportionally benefited individuals working in the formal sector (that is, those employed by the government or a company), with other individuals experiencing higher out-of-pocket costs and poorer health outcomes[26]. Subgroup analysis requires different data inputs for each subgroup. Some considerations for subgroup analysis in economic evaluation may be found in the NICE health technology evaluation manual[84].

3. Using economic-evaluation results for policymaking

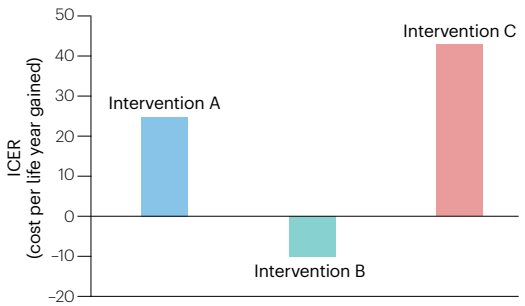
3.1 Interpreting results

Recommendations. 3.1.1 Results should be presented in an easy-to-read format, using graphs and tables that allow the policymaker to quickly understand the health impacts and cost trade-offs between policy interventions (*Strong recommendation*).

3.1.2 If cost-effectiveness thresholds are standard policy-related practice, then analysts can consider showing the calculated ICERs in relation to the thresholds. If no cost-effectiveness threshold exists, comparison can be made with the ICERs of other health interventions in the benefits package (*Strong recommendation*).

Presentation of results. Results should be presented in easy-to-read formats, such as simple bar charts or uncomplicated tables. Readers of these graphs and tables should be able to quickly understand the health impacts and cost trade-offs between policy interventions. An example is shown in Fig. 3. We recommend that disaggregated results are always shown, so that differences in costs and benefits are presented alongside the overall cost-effectiveness results.

If understandable to policymakers, ICER planes can be used to present cost-effectiveness results, where the x-axis represents effectiveness and the y-axis represents costs. An example ICER plane is shown in Fig. 4. The comparator is placed at the centre of the plane, which is divided into four quadrants: the top-right quadrant (more costly and more effective), the top-left quadrant (more costly and less effective), the bottom-left quadrant (less costly and less effective) and the bottom-right quadrant (less costly and more effective). For example, if the comparator is full reimbursement of 2 weekly sessions of HD (current policy), comprehensive CKM for all patients with kidney failure is likely to fall into the bottom-left quadrant (less costly and less effective); CKM for patients with a life expectancy of less than 6 months might fall into the bottom-right quadrant (less costly and more effective, as patients have a better quality of life); and reimbursement of three weekly sessions of HD will most likely fall into the top-right quadrant (more costly and more effective).



	Intervention A	Intervention B	Intervention C
Incremental cost[a]	$125	−$20	$430
Incremental life years gained[a]	5	2	10
ICER (cost per life year gained)[a]	$25/LY	−$10/LY	$43/LY

[a]Relative to next best alternative

Fig. 3 | Example presentations of cost-effectiveness results. In this example, intervention B is the most cost-effective option, as it is cost saving with an incremental health benefit. Intervention C is the least cost-effective option, as it has the highest incremental cost-effectiveness ratio (ICER) in terms of incremental cost per incremental life year (LY) gained.

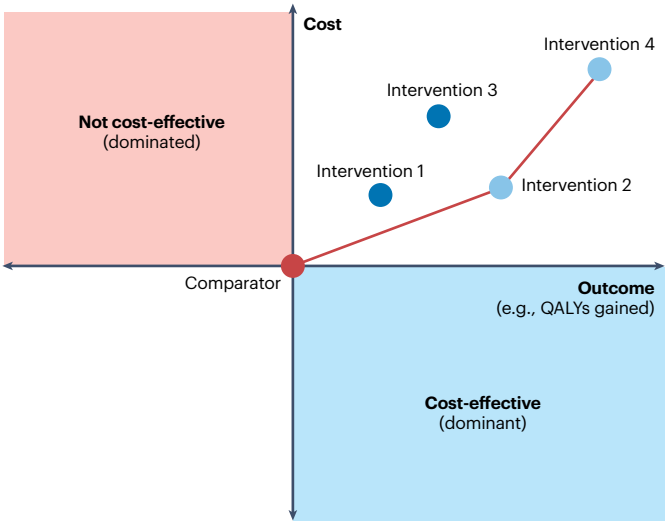


Fig. 4 | Illustrative example of an incremental cost-effectiveness ratio plane. The plane shows the comparator (red circle) and policy interventions (blue circles). The red line connects the most cost-effective interventions (known as the cost-effectiveness frontier). QALY, quality-adjusted life years.

Determining whether a policy is cost-effective. Policies that are more expensive with less benefit (top left of the ICER plane) are not cost-effective relative to the comparator, whereas policies that are less expensive with more benefit (bottom right of the ICER plane) are cost-effective (Fig. 4). However, interventions in the top right and bottom left of the ICER plane are harder to interpret. Whether a policy intervention is considered cost-effective in these two planes is a context-specific value judgement. For example, in an economic evaluation that compares dialysis with CKM, dialysis would be expected to lie in the top-right quadrant, as it is more expensive than CKM but has better health outcomes. This example requires consideration and judgement as to whether the additional resources required for dialysis are justified based on the health gain. To ensure that this judgement is consistent across different policy questions for health, some countries have defined cost-effectiveness thresholds, which represent the value (or range of values) below which an ICER is considered good value for money[85]. In Thailand, for example, interventions that have an ICER less than THB 160,000per QALY are considered to be cost-effective[86]. Cost-effectiveness thresholds are meant to represent the health opportunity cost, which can be thought of as the extent to which the change in policy will overall lead to better health for the same amount of spending. An introduction to cost-effectiveness thresholds is available elsewhere[85,87].

The following rules of thumb can be used to guide discussions around whether or not a policy is cost-effective for a particular setting:

- **If a cost-effectiveness threshold exists.** In certain settings, a cost-effectiveness threshold (CET) may have been officially adopted for policymaking, or researchers may have undertaken an analysis to estimate one. If a threshold is used, *cost-effectiveness results below the threshold are considered cost-effective*, whereas interventions with results above the threshold would realize less health gain for the same amount of spending (Fig. 5).
- **If no cost-effectiveness threshold exists.** Three main approaches are available in the absence of a cost-effectiveness threshold.
  - First, in countries with cost-effectiveness evidence for interventions currently included under the UHC benefit package, the policy intervention can be considered cost-effective if the ICER is lower than the least cost-effective service currently provided under the UHC benefit package. This approach may be feasible for LMICs that have determined the benefit package based on cost-effectiveness estimates[88,89]. It should be noted that this approach assumes that either the existing least cost-effective approach will be taken out of the benefit package, or additional budget will be allocated to the health sector[85].
  - An alternative option is comparison against previous policy decisions. If other cost-effectiveness studies have been undertaken to inform policy in the country (even if on an ad hoc basis), a decision threshold can be inferred based on interventions adopted or not by the health system. For example, one study inferred a threshold from previous health insurance agency decisions regarding dialysis in the USA[90].
  - Finally, cost-effectiveness studies that have been conducted of other health programmes or health services in the country can provide a benchmark. However, if few studies are available, or they are not felt to be applicable, the use of thresholds estimated in multi-country studies might be the most appropriate option[91].

We recommend against two approaches that are sometimes used to judge the cost-effectiveness of interventions. The first is comparison with a cost-effectiveness threshold defined as 1–3 times the gross domestic product of a country. The World Health Organization explicitly advises against this approach[87]. The second is reference to willingness-to-pay (WTP) thresholds that have not been estimated in reference to available budget or system efficiency, as these thresholds can lead to overall loss of health[17,92]. If the WTP-based CET is set too low, it may exclude interventions that could generate important health gains for certain populations. Conversely, if the WTP-based CET is set too high, it may lead to the exclusion of cost-effective interventions that offer health benefits, while allowing the funding of higher-cost interventions with lower health benefits[85]. It is also worth highlighting that all of the recommended approaches are aimed at finding an appropriate country-specific benchmark, which is unlikely to be transferrable across countries.

Policymaking in the presence of uncertainty. Uncertainty can affect recommended policy options and have important considerations for decision-making. Below we consider approaches for addressing uncertainty when considering results from scenario analysis, deterministic sensitivity analysis and probabilistic sensitivity analysis.

In the context of scenario analysis, uncertainty can be addressed by modelling different sets of assumptions. If the most cost-effective policy intervention (or a policy intervention that is cost-effective relative to a threshold) is different in a scenario analysis, it highlights that the results are sensitive to the set of assumptions in the scenario analysis. In this case, it may be appropriate to consult with a broader range of stakeholders to build confidence around which scenario is most likely to reflect reality. Parametric and discrepancy approaches can deal with this uncertainty quantitatively[93,94] but are analytically demanding and still under development[95].

For deterministic sensitivity analysis, the impact of data uncertainty can be estimated by modelling changes to the value of parameters. If the value of one or more parameters is found to influence the

most cost-effective policy or the cost-effectiveness of a policy relative to a threshold, the analyst can conduct a threshold analysis. The threshold analysis will show the value at which the policy intervention is no longer cost-effective relative to the threshold or other policy options. For example, threshold analysis has been used to find the living donation rate at which a soft opt-out law for kidney donation was no longer cost-effective in Australia[96]. Further discussion with experts or consultation of the literature can characterize how likely it is that the parameter could reach the threshold value, and therefore confidence in the cost-effectiveness results. In another study, threshold analysis suggested that maternal pertussis immunization would only be cost-effective if hospitalization rates were more than eight times higher than rates reported by the national hospital database; this finding provided a benchmark for policymakers with which to judge the likelihood of the vaccine being cost-effective[97]. It is important to note that a parameter can have a big impact on the cost-effectiveness of a policy intervention, but unless it changes the policy's cost-effectiveness relative to other policy options or the comparator, it is unlikely to be important for decision-making.

Probabilistic sensitivity analysis shows the probability of each policy being the most cost-effective option, given uncertainty. As a rule of thumb, if the probability of a policy intervention being cost-effective is high, the policymaker can have greater confidence in the cost-effectiveness analysis results. If the probability of each policy being the most cost-effective is relatively similar, the policymaker might wish to prioritize other criteria for decision-making. Plotting of the probabilistic sensitivity analysis results on the ICER plane can visually show the uncertainty. In settings without an established cost-effectiveness threshold, cost-effectiveness acceptability curves can be a useful way of presenting the results of probabilistic analysis, as the probability of each intervention being cost-effective is shown across different thresholds. Methods such as expected value of partial perfect information can identify whether additional data collection would reduce this uncertainty[98,99]. Tutorials are available for developing and interpreting cost-effectiveness acceptability curves[100] and the value of information analysis[95,101].

Ultimately, the policy made in the context of uncertainty is likely to depend on decision-maker risk tolerance. Clear communication of which sources of uncertainty are important to the decision can support this process.

3.2 Appraising the quality of an economic evaluation

Recommendations. 3.2.1 Where available, the quality of an economic evaluation study can be appraised following local methodological guidelines. In the absence of country-specific guidelines, guidelines from neighbouring countries or international frameworks and checklists can be used (*Strong recommendation*).

3.2.2 Appraisals of economic evaluations should review the appropriateness of the analysis for the decision question, the methodological rigour, the feasibility of implementing the proposed policies and the inclusion of appropriate stakeholders throughout the evaluation process (*Strong recommendation*).

Appraisals of economic evaluations should involve experts from different disciplines. The quality of economic evaluations can be assessed across a number of dimensions. First, any appraisal should assess whether the research question is appropriately aligned with the policy problem and context. This assessment can be performed by considering whether the research question matches the policy problem, whether the results are practical and feasible to implement, whether the analysis has addressed concerns of the payer and/or decision-maker, and whether appropriate stakeholders have been engaged throughout the process to ensure that the evaluation accounts for the local context and stakeholder concerns.

A number of guidelines and checklists have been developed to assess the methodological rigour of studies. If local guidelines exist, they should be followed to ensure consistency across studies and to verify that country-specific standards have been followed. The Guide to Economic Analysis and Research website includes links to guidelines from many countries[102]. In the absence of local guidelines, a number of international standards exist to evaluate study quality (for example, CHEQUE[19], the Drummond checklist[17] and the Philips checklist[103]) and reporting (for example, CHEERS[104]).

Finally, we recommend that researchers take steps to improve the transparency and validity of their model. Transparency measures include clear communication of details regarding the model structure, data and assumptions, to enable their critique by technical and non-technical audiences[105]. Model validation should be performed as a way of judging a model's accuracy. Steps for model validation include face validity, in which impartial experts judge how the decision problem has been transformed into a model, the quality of evidence used, and whether the results make sense; examination of formulas in the model (error checking); comparison with other models addressing similar research questions; and comparison between model outputs and real-world data[105].

3.3 Informing policy

Recommendations. 3.3.1 Use results from economic evaluation and budget-impact analysis, alongside other criteria and consultations with key stakeholders, to inform decision-making and policy implementation relevant to the local context (*Strong recommendation*).

Results from economic evaluation and budget-impact analyses should be used to inform policies regarding the provision of KRT under UHC, taking into account the level of uncertainty in the results and other relevant decision-making criteria. One way in which

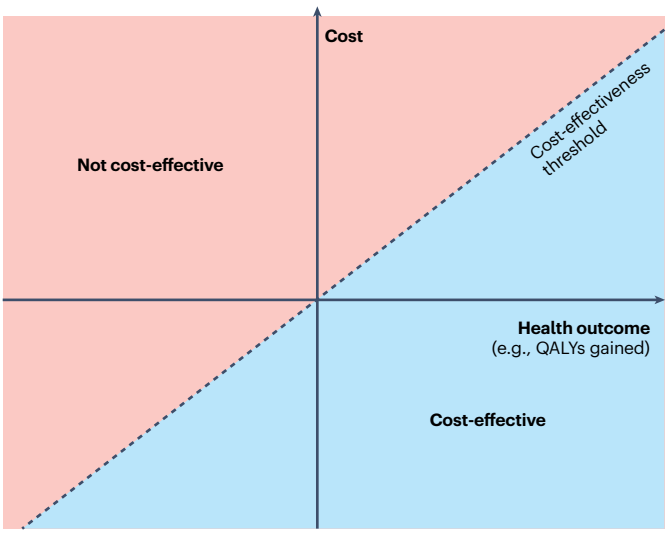


Fig. 5 | An incremental cost-effectiveness threshold plane, showing a sample cost-effectiveness threshold. The gradient depends on the cost-effectiveness threshold that has been set. QALY, quality-adjusted life year.

economic evaluation can inform decision-making is during price negotiation with suppliers (for example, related to the price of PD dialysate, HD machines, medicines for patients on dialysis and/or service fees). Approaches such as value-based pricing can quantitively determine a ceiling price but may be challenging to implement (see the WHO plain language summary on value-based pricing for further information[106]). Alternatively, sensitivity analyses showing 'what-if' scenarios that vary price and coverage (volume) over a relatively wide range can identify acceptable pricing strategies. For medical devices such as HD or APD machines, price negotiations will need to account for maintenance costs in addition to the cost of the machine. If direct medical costs represent a large proportion of the budget, central tendering and bulk procurement may result in more favourable price agreements.

Conclusions and perspectives

Although resource-constrained settings may be limited in their data and technical capacity for economic evaluation, it is preferable that the process of policymaking is informed by the available evidence, whilst acknowledging its limitations, as opposed to policymaking without evidence. The guidance presented here highlights that economic evaluation models do not need to be complex to be useful for policymaking. We advocate for models that are relevant to the policy at hand, context specific and transparently communicated so that decision-makers can understand the underlying model assumptions and policy implications. Our recommendations are aimed at increasing the use of economic evidence for KRT policymaking, so that future policy decisions are made with a better understanding of the health and cost implications of policies to sustainably improve access to KRT.

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