Incorporating Value of Health System Impact in Economic Evaluations of Therapies of Chronic Diseases

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Background

- Economic assessments of healthcare interventions for health technology assessments (HTAs) consider societal impact to a very limited extent, focusing on productivity losses.
- However, societal impact can be broader, as highlighted by the COVID-19 pandemic, which showed a severe impairment in the ability of the healthcare system to provide adequate and timely care to patients in many routine indications due to unprecedented increases in COVID-related hospitalizations.
- The impact of healthcare interventions on healthcare system capacity and security has been identified as a priority value element for consideration by HTAs recently.[1]
- In imperfect markets with permanent excess demand, the accounting costs of resources underestimate their opportunity costs. Hence, reliance on accounting costs in economic evaluations of interventions that can reduce future demand for care leads to undervaluation of these interventions.
- Attempts have been made to evaluate the value of vaccines by accounting for their impact on health system capacity, through valuing bed-days used by patients with vaccine-preventable disease by their opportunity cost.[2-4]

Methods

- Chronic kidney disease (CKD) has high and increasing prevalence. Coupled with supply shortages of dialysis equipment, disposable materials, and adequate workforce, this creates a temporary, or in some settings even permanent, excess demand for renal care services and dialysis specifically. A pragmatic literature review was performed to identify the potential causes of supply shortages for dialysis services, both on the demand and on the supply side.
- Although the theory of health economics acknowledges the need to use opportunity costs for valuing healthcare,[5] for practical reasons, traditional HTA decisions value resources used on their accounting costs. This might potentially lead to an undervaluation of the true costs of delaying dialysis for patients in the case of CKD. Sandmann et al. developed a new method for calculating opportunity costs to avoid potential undervaluation of healthcare services,[3] and the method was applied to infectious diseases.[2,3]
- We investigate the idea of applying the theoretical approach of Sandmann et al.[3] to Stage 3B CKD concentration on hemodialysis costs to identify challenges and next steps towards broader application of the method in chronic diseases. A model on estimated glomerular filtration rate (eGFR) slope is used to demonstrate its potential impact on the results of economic evaluations of CKD therapies and HTA decisions.

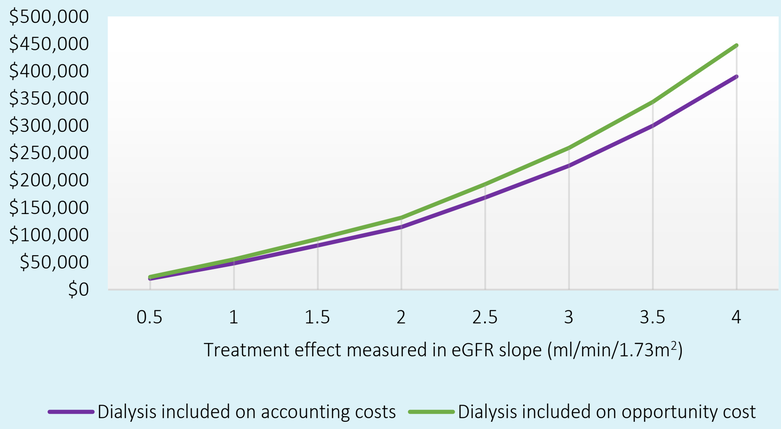
Results

	Theoretical Approach	CKD

Step 1: Identifying resource use (RU) associated with the disease	• In current applications of the opportunity cost method,[2,3] RU is expressed in bed-days on normal ward. While this approach may be directly applicable for certain chronic diseases (e.g., major depressive disorder), other indications will also entail RU items such as intensive care unit (ICU) beds, ambulatory care, or nurse time.	• Hemodialysis treatment uses a variety of resources that can be classified in different ways; one of them is a classification into resources with fixed, variable, and mixed costs.
		  • Fixed costs do not change with the number of treatments (e.g., cost of the dialysis machine and its maintenance).
		  • Variable costs increase when the number of treatments increases (e.g., material cost of consumables [dialysate acid, bicarbonate, catheters, needles], overhead costs [electricity, water]).
		  • Mixed (or semi-variable) costs are composed of fixed and variable components or increase stepwise (e.g., cost of human resources [nephrologists, nurses]).

Step 2: Determine/ assess presence and nature of excess demand for each identified RU item	• The opportunity cost of resources is only different from their accounting cost if there is an excess demand present for them; hence, it is important to understand what components of RU are impacted by excess demand. • The presence and magnitude of excess demand differs greatly across countries and depends on the healthcare system too (e.g., whether it is dominated by private or public care providers). • Excess demand may be permanent or temporary (e.g., related to the disruption in supply chains during the COVID-19 pandemic).	• Permanent and temporary shortages can occur in the service of dialysis both due to supply-side reasons and due to changes in the demand for dialysis. • Permanent demand-side changes are attributable to the 29.3% increase in the global all-age prevalence of CKD between 1990 and 2017,[6] leading to a growing demand for dialysis services globally. • COVID-19, especially in the early stages of the pandemic, exerted a temporary shock[7,8] on the emergency supply of dialysis services, affecting variable and mixed RU as well. Acute kidney injury (AKI) was associated with increased severity of COVID-19, with a high prevalence among hospitalized patients, with even higher probability among patients in the ICU. Supply concerns were documented in the United Kingdom (UK),[9,10] as patients in the ICU with AKI needed continuous hemofiltration, and the increased demand caused shortages in the supply of fluids and disposables needed for the procedure. Similar concerns were raised in the United States (US) regarding supply of equipment, but also with respect to workforce providing dialysis (partly due to illness or quarantine),[11,12] and rationing strategies were proposed as a temporary solution. • Shortage of workforce in nephrology care (including physicians, surgeons, nurses, and technicians) was reported at various levels across countries already before the COVID-19 pandemic.[13] There is a more than thirty-fold difference between high-income and low-income countries in density of nephrologists (30.3 vs. 0.9 per million population). A shortage of nephrologists and nurses was reported by 70% and 57% of countries surveyed, respectively, including in most of the countries with relatively good nephrologist density.[13]
Step 3: Decide aggregation level in quantitative assessment considering findings from Step 2	• In previous studies, bed-day was used as a RU unit, which is a composite resource including physical equipment and staff time, and variable and fixed costs.[2,3] • If components of the resource may be used separately, and excess demand is only present for some of the components, it is more accurate to assess RU at a more granular level. Currently, a disaggregated approach faces serious data limitations. Besides the opportunity cost of bed-days in the UK,[3] we are not aware of published opportunity cost estimates for healthcare resources.	• Treating a hemodialysis session as a composite RU unit in the cost-effectiveness analyses of CKD therapies relying on opportunity costs is adequate if a permanent excess demand is present for dialysis sessions. • In countries where excess demand is only present for certain components of dialysis provision (e.g., for healthcare staff), it is more appropriate to only account for the foregone net monetary benefit associated with the scarce resource.
Step 4: Identify the foregone service provision	• In applications to vaccine-preventable diseases, it was assumed that bed-days used to treat vaccine-preventable outcomes lead to a patient from the waiting list not getting access to that resource and therefore to treatment; thus, the net monetary benefit (NMB) corresponding to this foregone treatment is lost. • For other applications, one needs to identify the patients who are partly or entirely excluded from medical care under excess demand circumstances and their alternative treatment courses with and without full access to the resource, so the foregone benefit of the foregone treatment can be calculated as outlined in the next step.	• The foregone treatment in an excess demand situation for dialysis varies across countries and time. • In low- and middle-income countries, healthcare resources are limited; many people do not receive renal replacement treatment[14] and die prematurely. In this case, the foregone treatment benefit is the loss in quality-adjusted life-years (QALY) associated with premature death. • Excess demand situations in CKD can lead to underdialysis, decreasing flow rate, switching to intermittent therapy, or decreasing number of treatments.[11,15] To identify the foregone treatment benefit associated with these rationing measures, data are needed on their impact on the quality of life and life expectancy compared to full dialysis access. • If excess demand is expected to resolve over time, the foregone treatment benefit should only be assumed for the time period characterized by excess demand.
Step 5: Determine opportunity cost corresponding to RU items at the aggregation level chosen in Step 3 and based on comparator determined in Step 4	• As proposed by Sandmann et al.[3] the opportunity cost of a resource (OC_i) is the sum of the incurred expenditure to treat the preventable outcome (C_i) and the forgone NMB associated with treating another patient instead: $$OC_i = LOS_i * \left(\frac{C_i}{LOS_i} + \frac{B_j * \lambda - C_j}{LOS_j}\right)$$ where LOS_j and LOS_j are the length of stay (or resource units) of provided and foregone treatments, respectively. B_j is the QALY benefit, C_j is the cost associated with the foregone treatment, and λ is the willingness-to-pay threshold.	• As a simple illustration, we estimated the impact of using the opportunity cost of dialysis instead of its accounting cost in the cost-effectiveness analysis of a hypothetical treatment slowing the decrease of the eGFR in CKD patients under the assumption that excess demand is handled by excluding some patients from treatment, leading to their premature death. As the alternative, use of dialysis service provided to one patient is to provide the same treatment to another patient, and the opportunity cost of dialysis is calculated as the gross monetary benefit – i.e., $B_j * \lambda$ – since $C_i = C_j$. ***Modelling Method*** • A Markov microsimulation model was used to compare a hypothetical treatment against standard of care (SoC) in a commercial US perspective on a lifetime horizon. The model is composed of a combination of two sub-models: one describing the progression of CKD, and another modeling cardiovascular (CV) events for patients.[16] ***Key Inputs and Assumptions*** • Transition probabilities between health states and probability of CV events were based on published risk equations estimated on Study of Heart and Renal Protection data.[17] • It was assumed that excess demand for hemodialysis cannot be resolved by increasing the number of transplants or patients on peritoneal dialysis. ***Results*** • The figure shows the economically justifiable price (EJP) at a willingness-to-pay threshold of $150,000 as a function of eGFR slope gain. The results indicate that accounting for the opportunity cost of dialysis could significantly impact the EJP and thereby the incremental cost-effectiveness ratio of an innovative therapy that slows kidney function decline and delays the need for renal replacement therapy.

Input	Value	Source
Mean starting eGFR level (ml/min/1.73m^2)	33	Assumption
Mean annual eGFR slope on SoC (ml/min/1.73m^2)	-6	Assumption
eGFR threshold for initiating dialysis (ml/min/1.73m^2)	10	Assumption based on NKF guidelines
Annual care cost of CKD Stage 3B patients	$5,805	Schlackow et al. 2019[18]
Annual care cost of CKD Stage 4 patients	$7,526	
Annual care cost of CKD Stage 5 patients	$7,526	
Annual care cost of patients on dialysis	$94,617	United States Renal Data System. 2019 Annual Data Report Reference Tables[19]
Annual care cost of transplanted patients	$37,558	



Discussion

- Accounting for the opportunity cost of healthcare resources may make a substantial difference in cost-effectiveness assessments of treatments that delay dialysis.
- A lower difference between valuations is expected if dialysis rationing is associated with lower total QALY loss than exclusion of certain patients from treatment or if excess demand is only present for a limited time period.

Conclusions and future directions

- Although always mentioned in health economics textbooks, opportunity costs are rarely used to value resources used in economic evaluations of interventions. The method proposed by Sandmann et al.[3] for considering the health system impact is applicable beyond vaccines but requires careful consideration of the RU components that make up the care service that is subject to excess demand; and the also the therapy that would be provided to patients who cannot get access.
- Challenges remain to be overcome on the input data side too, specifically for assessing the opportunity cost of RU items. To our knowledge, currently this is only estimated for hospital bed days in a UK setting.
- Establishing a repository of opportunity cost of various healthcare resources, including time of healthcare staff, may support the general application of the method on cost-effectiveness analyses and HTA models.

References