How Should We Use Age to Ration Health Care? Lessons from the Case of Kidney Transplantation

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Competing visions for health reform in the United States and renewed interest in health technology assessment (HTA) have led to fierce national debates about the appropriateness of rationing. Because of a limited supply of organs, kidney transplantation has always required rationing and overt discussion of the ethics that guide it, but the field of transplantation has also contended recently with internal calls for a new rationing system. The aim of the Life Years from Transplantation (LYFT) proposal is to allocate kidneys to patients who obtain the greatest survival benefit from transplantation, which would lengthen the lives of kidney transplant recipients but restrict the ability of older Americans to obtain a transplant. The debate around the LYFT proposal reveals the ethical and policy challenges of identifying which patients should receive a treatment based on the results of cost-effectiveness and other HTA studies. This article argues that attempts to use HTA for healthcare rationing are likely to disadvantage older patients. Guiding principles to help ensure that resources such as kidneys are justly allocated across the life span are proposed. **J Am Geriatr Soc 2010.**

Key words: health policy; kidney transplantation; geriatrics

President Obama, Congressional leadership, and corporations have cited finite resources and an expanding cohort of older adults as evidence of the pressing need to reform health care in the United States.[1–5] Policy debates have often focused on whether reforms will ultimately involve the use of health technology assessment (HTA), such as cost- and comparative-effectiveness studies, to restrict access to expensive and scarce therapies.[6,7] Opponents have denounced such reforms as a covert mechanism for age-based rationing and even "death panels" for older adults.[8] Despite retorts by the White House that rationing is anathema to American health care,[9] this response misses the fact that, in certain areas of medicine, rationing has been explicit for decades.

Since its inception, the field of kidney transplantation has struggled with the problem that there are fewer kidneys than the number of people who need them. Recently, the United Network for Organ Sharing (UNOS), which regulates U.S. organ transplantation, proposed sweeping changes in kidney allocation based on HTA analyses. The Life Years from Transplantation (LYFT) proposal aimed to improve survival for kidney transplant recipients in part by decreasing access to transplantation for older adults.[10,11] The proposal faced sharp criticism because of ethical concerns about age-rationing but also because the LYFT system has limited accuracy in predicting which patients derive the greatest benefit from transplantation.[12] The demise of this attempt to change how kidneys are rationed raises compelling questions about the design and implementation of HTA in health policy. Is it ethically defensible to use age to ration medical resources such as kidney transplants? If age is used, what principles should guide the development of a rationing system that respects the rights of older individuals?

THE NEED TO BETTER ALLOCATE A SCARCE RESOURCE

A number of pressing concerns motivated UNOS to transform the process for rationing kidneys: the ever-increasing waiting time for a kidney, the rapid growth in the number of older individuals eligible for a kidney transplant, and the lesser effectiveness of transplantation in these patients compared to younger patients. In particular, UNOS representatives have argued that the devastating mortality rate with end-stage renal disease (ESRD) creates an imperative to get as much life out of each transplanted organ as possible (Table 1).[10]

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Table 1. Criticisms of the Current System for Kidney Allocation that Motivated the Development of the Life Years from Transplant Proposal[10]

Waiting time for a kidney transplant has increased greatly
The current system does not seek to maximize survival for patients on the kidney transplant waiting list, and mortality and morbidity for wait-listed patients are high
In the current system, mismatches between expected patient survival and kidney allograft survival are common, and many functioning kidney transplants are lost because the recipient dies; this problem is most common in older recipients

Developed decades ago, the existing system to allocate kidney transplants to adults with ESRD has primarily emphasized fairness according to a single principle: the longer a person has waited for a kidney, the more priority he or she has to receive one.[13] The system does not take into account how long someone is projected to live before or after receiving a kidney transplant. As a result, higher priority could be given to transplanting a 65-year-old on dialysis with diabetes mellitus and extensive vascular disease who has accumulated more waiting time than a more recently listed 30-year-old with no comorbidities.

This system arguably was successful when the number of older adults receiving transplants was relatively small, but recent trends have transformed the demographics of renal transplantation and contributed to dissatisfaction with the current method of kidney allocation. The epidemics of diabetes mellitus, hypertension, and obesity have led to tremendous growth in the number of patients with ESRD, especially older adults. This, in turn, has greatly increased the demand for kidney transplantation, such that many patients die before a kidney becomes available. The waiting list for kidney transplantation more than doubled, from 30,010 candidates in 1997 to more than 83,000 candidates in 2009. During the same period, the proportion of kidney transplant recipients aged 65 and older increased from 6.5% to more than 16% (Figure 1).[14] Twenty years ago, transplantation in patients aged 60 and older was rare. Today, centers commonly accept patients in their 70s, and even patients aged 80 and older have received kidney transplants.[15,16]

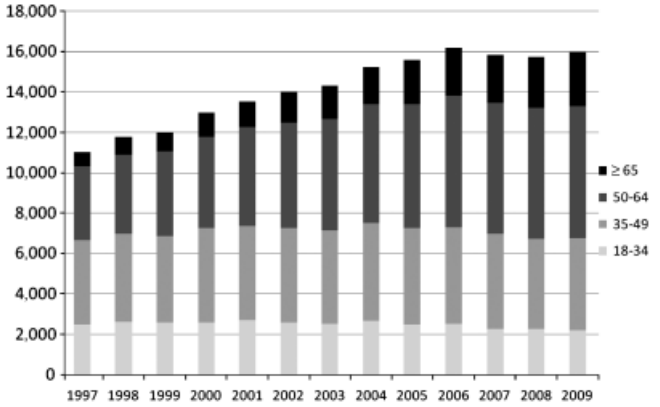

Figure 1. Increasing age of U.S. kidney transplant recipients.[14]

The rising age of kidney transplant recipients also raised the concern that donor kidneys are not effectively allocated or are even wasted. A number of studies have shown that older adults with ESRD live longer with a kidney transplant than they would have lived on dialysis and therefore derive a benefit as individuals,[17] but from a societal perspective, the *comparative* survival benefit derived from a transplant is greater in younger recipients. Specifically, younger patients gain more additional years of life from kidney transplantation than older patients do. Older kidney transplant recipients are more likely to die while their transplanted kidneys still function—an outcome that some view as a waste of valuable organs.[10] Seen from the perspective of HTA, a kidney transplanted into a younger person provides greater returns in terms of survival benefit, quality of life, and cost of therapy per year of life gained than a kidney transplanted into an older person.[18]

The LYFT Proposal: Maximizing the Life Gained from Each Kidney

In 2007, UNOS proposed a solution. Instead of using waiting time to assign priority for a kidney transplant, UNOS would assign priority based on the additional projected years of survival a patient would obtain from a transplant.[11,12] In research simulations used to derive the LYFT system, older age proved to be a powerful predictor of relative survival benefit. As a result, older adults would receive lower scores and lower priority for a kidney.[11] This, in turn, means that the LYFT system would probably increase the net survival of transplant recipients, and thus transplanted kidneys would last longer. The LYFT system could decrease average waiting times for a kidney (as long as 4 years in many regions) because fewer patients with failed transplants would return to the waiting list. Unfortunately, these achievements come at a cost; as patients get older, their access to transplantation decreases.[19]

The basic formula to determine the transplant survival benefit for an individual—his or her "LYFT score"—is straightforward. Projected years of survival on dialysis are subtracted from projected years after a kidney transplant. (There is also an adjustment reflecting lower quality of life on dialysis, omitted here for simplicity.) The consequences of LYFT for different transplant candidates would be profound. For example, suppose the 65-year-old candidate with diabetes mellitus cited earlier would live 1 year on dialysis and 4 years with a transplant. He would have a LYFT score of 3 and lower priority for a transplant than the 30-year-old candidate, who has the same blood type but a LYFT score of 9.[11] In contrast, under the existing system, the 65-year-old would receive the kidney if he had waited longer. Figure 2 shows how the LYFT proposal would shift kidney transplants to younger patients.

The use of age to assign priority for transplantation has obvious benefits. Chronological age is difficult to falsify—physicians, patients, and policy-makers understand what it means—but using age as a criterion to allocate a scarce resource such as donor kidneys presents challenges. Although older age is associated with greater probability of disease, age itself is not a disease.[20] Another limitation of the LYFT model is that it does not adequately distinguish between variations in health between individuals of the

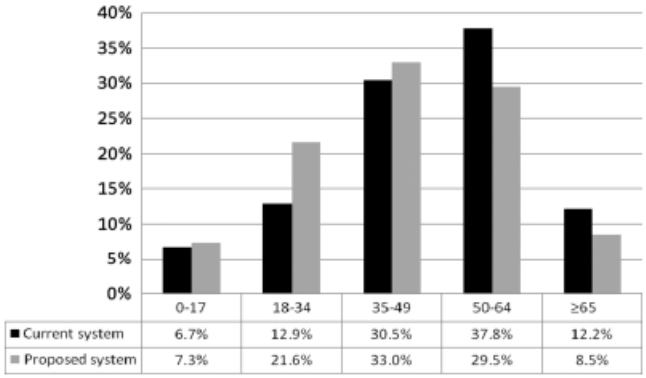

Figure 2. The Life Years from Transplantation proposal would shift kidney allograft allocation toward younger patients.[19]

same age, whether young or old. At a given age, some older adults have marked functional impairment and thus greater risk of death, whereas others have maintained function and vitality. From the perspective of a highly functional older individual, the LYFT system is unfair.

Analytical Frameworks for Rationing Care with Health Technology Assessment Such as LYFT

To show how the LYFT analyses relate to contemporary debates about health reform, it is useful to define HTA and how, given its place in the recently passed healthcare legislation, HTA will be employed as a tool to promote efficiency. HTA encompasses comparative effectiveness, cost-effectiveness, and cost-benefit studies; all provide information about outcomes with different treatment strategies. These studies can also be used to determine access to medical care based on findings that one approach to care is superior.[18,21] HTA typically involves comparing the outcomes (e.g., survival) of different treatments for the same patient. The LYFT analysis instead compares the same treatment (a kidney transplant) for different patients, although the output of the LYFT analysis—a ratio of cost to health outcome—is also what a cost-effectiveness analysis provides. With kidney allocation, the "cost" is the limited resource of a donated organ, whereas cost-effectiveness analysis commonly expresses the cost in dollars.

The focus on HTA by President Obama and others has attracted strident criticism because of fears that administrative panels—within the federal government, quasigovernment agencies, or insurance companies—will ultimately use this research to decide which treatments are acceptable and for whom.[22,23] As U.S. healthcare legislation is implemented, it is unclear what role and powers the new U.S. board tasked with funding and interpreting HTA will have,[24] yet such HTA-driven rationing is already implemented through diverse areas of the medical system, including the Veterans Health Administration and private pharmacy plans.[25–27] It is used in other Western nations (such as the United Kingdom with its National Institute for Health and Clinical Excellence board).[18] Given that medical costs will continue to pose a substantial economic burden, HTA-driven rationing will play a role in the delivery of U.S. health care in some form, and as with LYFT, concerns will persist that administrative panels will not allocate treatments in a way that respects the circumstances of individual patients, especially older adults.

How the LYFT Proposal Informs Future Debates About the Ethics of Using Age to Assess Treatment Benefit

Using age to guide access to care can be acceptable, but the rationing system must respect principles that safeguard the rights of older individuals. Before describing these principles, the standard ethical arguments supporting age as a criterion to allocate treatments are reviewed and their shortcomings in the context of the LYFT proposal and scientific advances in geriatric medicine illustrated.

Despite the high-profile use of the word "rationing" to accuse others of ethical failings in health reform debates,[8] the use of age to ration treatment has gained legitimacy in medical ethics. The LYFT system conforms to utilitarian theory to optimize outcomes for the greatest number of patients with ESRD (in this case, the outcome of mortality).[13] Contemporary ethicists such as Daniel Callahan and Ezekiel Emanuel have also developed ideas about why limiting health care for older people is reasonable and humane.[28–30] Callahan argues that the high price of medical innovations has made it increasingly difficult for nations such as the United States to fund universal medical care. He suggests that biomedical research offers a false promise of longer and better life for everyone and that care for older adults (who benefit less from medical technology) should instead focus on dignity and relief of suffering.[28]

Ezekiel Emanuel, now Special Advisor for Health Policy in the White House, developed the "complete lives" principle of distributing healthcare resources. This principle holds that rationing health care according to age is not utilitarian but egalitarian because it maximizes the possibility that every person could experience the different stages of life. Hence, older adults should have less priority for kidney transplants or other treatments because they have already enjoyed "a complete life." Emanuel has identified areas as diverse as vaccination, intensive care admissions, and transplantation in which withholding therapies from older adults may be considered. Unlike the HTA approach that led to the LYFT formula, Emanuel does not focus primarily on whether older patients derive less relative therapeutic benefit than younger patients do but instead argues that directing healthcare resources to younger people gives them a greater chance of being able to reach all of life's stages.[29]

Arguments based on utility or the life-cycle approach are vulnerable to the criticism that allocating therapies according to age does not respect the rights of older adults as individuals. Although extreme old age is arguably a "complete life," over the course of the last century, the concept of what "old" means has shifted.[16,31] Today, some patients in their 70s thrive after kidney transplantation, and others engage in vital activities such as running for President of the United States. The notion of a "natural" life span is a cultural construct as well as a biological reality.[20]

Transplant leaders have rejected the LYFT proposal because it does not adequately address the fact that, although age adds value in predicting survival, it is too indirect a means to capture the health of older adults.[12] The LYFT formula predicts individual survival using only the

comorbidities of diabetes mellitus, prior transplant, cause of kidney disease, and body mass index. Recipient age contributes nearly 25% to an individual's LYFT score.[11] By lumping together transplant candidates of similar ages, this proposal does not take advantage of a substantial body of literature on healthy aging.

An important insight of geriatric medicine is that a tally of comorbidities and age is not sufficient to represent the health of older adults. Measures of function are essential. Functional status and physical activity may reveal the cumulative impact of comorbidities and capture the effects of age-related syndromes such as frailty. For example, the Vulnerable Elders Survey-13 (VES-13) of adults aged 65 and older measures difficulties performing everyday activities such as walking, shopping, and managing personal finances. The VES-13 has a high degree of accuracy in predicting 2-year mortality or new disability.[32] As shown in Appendix 1, a number of other studies have advanced the methodological sophistication of risk models that predict survival in older individuals.[33–36] These risk models have not been validated in ESRD but provide transplant researchers a template to design and validate methods to predict mortality in kidney transplant patients.

The lack of inclusion of functional status and other measures of health in the LYFT formula stems from problems with the data used. The architects of the LYFT system used the best data set available to them—registry data on patients with ESRD from the Organ Procurement and Transplantation Network (OPTN).[11] Although powerful, these data have serious flaws. OPTN data lack high-quality information on functional status, changes in health over time, and comorbidities. For instance, the three physical function fields are coarse, ranging from no limitations to wheelchair bound.[37] Similarly, the OPTN does not record prior cardiovascular events or results of cardiac tests but instead provides a restricted range of fields related to the presence of angina pectoris. This limited characterization of cardiac status is especially important because cardiovascular events are the leading cause of death in ESRD and because prior studies suggest that inclusion of comorbidities improves the prediction of survival for transplant patients.[38,39] Not surprisingly, the LYFT formula has limited accuracy in modeling survival benefit from transplantation.[11,12]

This accuracy problem is an important lesson to proponents of using HTA to determine when certain treatments—from kidney transplants to intensive care unit beds—should be approved and who should get them.[6] The debate over LYFT reveals how challenging it will be to identify patients who benefit the most from a scarce or expensive treatment. The "devil" is in the data set.

Nevertheless, making use of age *as one factor* along with other informative health data to predict health outcomes and ration treatments is ethically defensible. Below, principles for developing sound policies that use age as a criterion to select patients are summarized.

A Framework for Evaluating Age-Rationing of Treatments and a Proposed Research Agenda

The successful use of HTA in health policy will depend on guiding principles acceptable to physicians, policy-makers, and the public. Kidney allocation provides a useful example of the kind of research agenda that is needed to determine which patients derive the most benefit from an intervention. This agenda matters not only for sharing kidneys, but also to a larger national audience looking to see whether transplantation will lead the way in treating older adults fairly while employing the tools of HTA.

First, as with the development of LYFT, the process of using HTA to identify which patients receive a therapy should be transparent and objective. The data sets and analyses used by policy-makers need to be publicly available. The people who perform these analyses should be free of conflicts of interest.

Second, age rationing of therapies should be considered only in situations in which the costs of not doing so are unacceptably high. Although the determination of an unacceptably high cost may be contentious, important benchmarks would include large differences in survival (measurable in years) or substantial reductions in suffering from receiving a therapy. For instance, in kidney transplantation, the cost of maintaining the current system is a far greater number of deaths of patients with ESRD than if age rationing were implemented through LYFT.

Third, as argued above, proposals such as LYFT that involve age rationing should be judged according to whether they distinguish adequately between individuals of the same age. The analysis of which patients benefit from therapy should be based on a data set with detailed assessment of comorbidities and functional status. The HTA research should report whether the inclusion of these data diminishes the predictive value of age.

The field of renal transplantation needs research into what factors explain differences in mortality between older transplant candidates. In addition to functional status data, the predictive ability of LYFT should be reexamined with the addition of validated data about prior myocardial infarction, stroke, peripheral vascular disease, malignancies, and tobacco use.[40,41] This research will require new, prospective data collection by transplant centers; UNOS is committed to this long-term process. In the interim, this research might take advantage of large data sets generated by dialysis corporations and major healthcare organizations or data from non-U.S. countries that have accurate information on comorbidities and medical testing. For dialysis patients and kidney transplant candidates, there is wide variation in physical function.[42,43] Transplant leaders committed to driving better survival through more-efficient kidney allocation need to study whether this variation affects transplant endpoints.

Last, empirical assessment of how transplant candidates themselves believe that organ rationing should take place would enrich this research agenda. Minimal information exists, for instance, about whether kidney transplant candidates would consider a system that matches projected kidney allograft survival with patient survival to be more acceptable than a system based primarily on waiting time.

Weighing the Burdens of Collecting More Information About Transplant Candidates

The policy implications of this research agenda will depend on the burdens imposed on transplant centers. More-detailed clinical assessments of transplant candidates will consume resources that health insurance should reimburse.

On the other hand, in the current system, costs are higher when patients with comorbidities and poor functional status suffer perioperative complications with prolonged hospital stays. Centers could see a financial upside if changes in organ allocation led to selection of patients who recovered rapidly from transplant surgery.

The UNOS Kidney Committee also cited concerns that clinical variables used to generate the LYFT score should not be easily falsifiable. For instance, if peripheral vascular disease were a component of LYFT, a patient's foot amputation might be withheld from UNOS to improve the patient's priority. To some extent, center audits could address this concern over data reliability.

Last, the barriers to completing the many steps to transplant eligibility are well described.[44] Creating new steps will require justification that the effort and expense do not slow the already cumbersome process of being accepted to the waiting list.

CONCLUSIONS

The LYFT proposal to use age for rationing kidneys has substantial relevance to contemporary debates about the role of HTA in allocating expensive or scarce treatments. Broad criticisms of any healthcare rationing ignore the ethical imperatives that limited resources such as organ transplants create. Were it implemented, the LYFT system could drive important gains in survival from renal transplantation at the cost of disadvantaging older transplant candidates, but the failure of the LYFT proposal to be accepted reveals the challenge of finding high-quality data to predict which patients benefit most from treatment. When rationing care includes an age criterion, the process of selecting candidates for therapies must respect principles that safeguard older patients. The process must be transparent, and the high costs of not rationing care efficiently must be evident. Last, the rationing system must account for clinically significant differences in health between older individuals.

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APPENDIX 1. Risk Scales Developed to Predict Mortality Among Older Adults[33–36]

	Carey	Inouye	Lee	Walter
Population	Community dwelling, aged ≥70	Hospitalized, aged ≥65 (validation)	Community dwelling, aged >50	Hospitalized, aged ≥70
Risk factors				
Demographic				
Age	76–80 (1)	Age not significant and not in the index	60–64 (1)	Age not significant and not in the index
	>80 (2)		65–69 (2)	
			70–74 (3)	
			75–79 (4)	
			80–84 (5)	
			≥85 (7)	
Sex	Male (2)		Male (2)	Male (1)
Comorbidities				
Diagnoses		High-risk diagnoses (0–3)		
Diabetes mellitus			Any (1)	
Cancer			Any (2)	Solitary (3), Metastatic (8)
Lung disease			Any (2)	
Heart failure			Any (2)	Any (2)
Current tobacco use			Any (2)	
Body mass index			<25 (1)	
Laboratory values				
Albumin		≤3.5 mg/dL (0–1)		3.0–3.4 g/dL (1)
				<3.0 g/dl (2)
Creatinine		>1.5 mg/dL (0–1)		>3.0 mg/dL (2)
Functional				
ADLs	Dependence bathing (1)		Dependence bathing (2)	
Number of dependent ADLs				1–4 (2)
				All 5 (5)
Instrumental ADLs	Dependence in grocery shopping (2)		Managing finances (2)	
Physical function	Limited ability to walk (2)	Limited ability to walk (0–1)	Limited ability to walk (2)	
	Difficulty moving heavy objects (1)		Difficulty moving heavy objects (1)	
Cognition		Dementia (0–1)		
Outcome	2-year mortality	1-year mortality	4-year mortality	1-year mortality
Risk groups	Low (0–2)	Group I (0–1)	Group I (0–5)	Group I (0–1)
	Middle (3–6)	Group II (2)	Group II (6–9)	Group II (2–3)
	High (≥7)	Group III (3)	Group III (10–13)	Group III (4–6)
		Group IV (≥4)	Group IV (≥14)	Group IV (>6)

Points awarded to each clinical factor are noted in parentheses.
ADL = activity of daily living.