

Kidney Allocation for Transplantation: Some Aspects of Ethics and Comparative Law

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ABSTRACT

The allocation of organs is a crucial ethical issue. The importance attached to different allocation criteria differs considerably among the various national and international organizations. The balance between justice-centered and utility-centered systems is shifting and there are signs of a possible swing away from systems centered mainly on waiting times to others centered mainly on criteria of utility. This evolution is very significant and seems to run counter to the main stream of modern bioethics. Examples from different national policies are given herein. Particular attention is given to Europe, where national bioethics committees have tended to ignore the aspect of organ allocation. By overemphasizing the issues related to informed consent, the ethical challenges arising from the problems of resource allocation are often relegated to second place.

Organs for transplant are an example of scarce resources for which allocation policies are required. The allocation of organs is a complex process that links the procurement/retrieval of organs and their transplantation. To avoid personal bias and to ensure integrity in organ allocation systems, centralized national and international networks have been established. These networks use match programs that adopt ostensibly objective criteria to generate lists of possible recipients based on the characteristics of donor organs. The circumstances in which kidneys are allocated are different from those for other organs: Kidney transplantations are not usually life-saving operations, and candidate recipients are mostly receiving dialysis. These circumstances introduce further parameters to the selection procedure, because the criteria for inclusion in dialysis programs are influenced by various sets of guidelines.

Organ allocation should ideally be organized in accordance with transparent policies grounded on sound criteria of equity, justice, solidarity, efficiency and utility.¹ These values (particularly justice and utility) may often be in conflict.² There is no single solution to the problem of how best to balance the different values involved, because the circumstances may be complex and vary considerably.

DIFFERENT APPROACHES

Allocation decisions are based on 3 main types of criteria: biologic, clinical and organizational. The key biologic criteria include HLA compatibility, ABO compatibility, cross-match, and immunization. Clinical criteria mainly include age of the recipient, difference in age between donor and

recipient, seniority (waiting time, length of period on dialysis), urgency, and special circumstances. Organizational criteria mainly include geography (location of the transplant center, distance), reciprocal arrangements between centers, and other criteria. Although in most cases kidney transplantation is not a life-saving intervention, the choices to be made can be dramatic. The approaches adopted in the European Union are not univocal: Despite a common framework established by various European directives and recommendations, a wide range of allocation systems, protocols, procedures, criteria, and guidelines have been implemented throughout Europe. In many countries, allocation systems combine general principles to match donors and recipients, regional patient-based allocation priorities, and local center-based allocation practices. Scoring systems are an efficient and effective way to implement patient-based allocation systems: They permit a fair and impartial competition between categories of patients that cannot be achieved by means of sequentially ordered priorities. The weight given to each criterion varies remarkably in the different networks. Table 1 presents some differences regarding 2 biologic criteria, but substantial differences are also present regarding clinical and organi-

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Table 1. Examples of Differences in Allocation Criteria

	ABM	Eurotransplant	ONT	RNT	ST	UKT
HLA typing	DR>B>A	DR, A, B mismatches given equal weight	No indication	DR>B>A	DR, A, B mismatches given equal weight	DR>A>B
Blood group	ABO identical: precedence over ABO compatible	If no HLA mismatches: 0→0; B→B If 1 or more mismatches: 0→0	No indication	ABO identical (except particular conditions: full house, clinical urgency, and others)	0→0 B→B	0→0 or B

ABM = Agence de la Biomédecine (France); Eurotransplant = Austria, Belgium, Germany, Luxembourg, The Netherlands, Slovenia); ONT = Organización Nacional de Transplantes (Spain); RNT = Rete Nazionale Trapianti (Italy); ST = Scandiatransplant (Denmark, Finland, Iceland, Norway, Sweden); UKT = United Kingdom Transplant.

zational criteria. From an ethical perspective, differences in clinical and organizational criteria are the most relevant. Indeed, the importance given to each parameter determines whether a system is centered more on justice, utility, or other values. Sometimes the parameters are not only weighted differently, but also defined differently. For example, some organizations calculate the points awarded to patients for accrued waiting time from the date they are entered on the waiting list, whereas others take the date of the first dialysis as the starting point. Different approaches are adopted also regarding preemptive transplantation; only a few systems allow patients to be listed for preemptive transplantation, some of which award points for waiting time and others do not.

A SHIFTING BALANCE AND A (POSSIBLE) UNUSUAL EVOLUTION/DEVELOPMENT

The various schools of bioethics emphasize different values and propose different approaches to the allocation of scarce resources.³ The utilitarian theories are consequentialist: According to the model of social utility, resource allocation should maximize the social benefit (the subject who is most useful to the community is favored); according to the beneficence model, utility should be measured in terms of either the number of lives saved or life expectancy. Prioritarianism favors the worst-off. Personalism considers the individual and suggests that ethical choices should be based on the therapeutic principle, liberty, responsibility, sociality, and solidarity. A multiplicity of theories emphasize impartiality (eg, allocation based on waiting time, allocation by lottery).⁴

All the organizations involved in allocation constantly monitor new trends in donation and transplantation and attempt to achieve the best balance between medical efficacy and equity. This balance seems to be shifting. According to a report published in 2006 by the Canadian Council for Donation and Transplantation (CCDT), “Utility (optimising the function of the available organ supply of transplantable organs) has historically been determined by HLA matching in organ allocation schema. Although the degree of HLA matching remains an important determinant of allograft survival [...], HLA matching has been de-emphasised in many organ allocation algorithms in an effort to maintain equity with increased emphasis on waiting

time.”⁵ However, it seems that this analysis is not unanimously accepted; another report published by the CCDT in the same year noted that, “The importance given to waiting time differs among the various organisations, and no existing algorithm for the attribution of SD (Standard Donor) kidneys gives more importance to waiting times over the other factors.”⁶

Another example of the swing of the balance between justice and utility comes from the United States. According to an overview of allocation policies, “currently, deceased donor kidneys in the United States are allocated by using a point system in which waiting time has become a primary determinant of rank on the waiting list.”⁷ However, increasing attention is being paid to net survival benefit in organ allocation: “Over the last 5 years, a number of utility-based allocation systems have been proposed in an effort to increase the life-prolonging potential of deceased donor kidneys in the United States.”⁸ For example, the US United Network for Organ Sharing suggested including some form of a system based on “life years from transplant—LYFT,” which triggered a heated debate (LYFT is defined as the estimated number of years of life gained from a transplant minus the estimated number of years of life remaining on dialysis, adjusted for quality of life).^{9,10} Such a policy might preferentially allocate standard-criteria donor kidneys to candidates with relatively long life expectancies. Similarly, the Working Group for the Definition of Kidney Allocation Criteria from Deceased Donors (by the Italian National Transplant Center) seems to emphasize utility: “It is agreed that HLA compatibility remains a fundamental objective criterion in the selection of candidates [...]. Some managers (of transplant centers) attribute less importance to waiting time, using this only as a final means of discriminating between comparable candidates.”¹¹

From an ethical perspective, it is therefore possible to identify a shift from justice-centered systems to benefit-centered systems. This is particularly interesting because it appears to run counter to other trends in bioethics. According to some authors, 3 main stages can be identified in the history of bioethics¹²: When bioethics was expanding as a field of study in the 1970s, the beneficence principle inherited from a centuries-old paternalistic model of medicine was still prevalent; in the 1980s and '90s, individual freedom to choose was often considered to be the cornerstone of

medical ethics and the autonomy principle was emphasized; the new millennium witnessed increased attention to the relationship between patients and clinicians and the influence of negotiation and contractualist approaches that emphasize the justice principle.¹³ If we accept this analysis, then organ allocation seems to have followed an opposite itinerary: from an emphasis on justice (waiting time) to an emphasis on beneficence (life expectancy).

Surprisingly, despite the dramatic dilemmas necessarily involved in allocating organs, opinions from national bioethics committees (NBCs) are of little help regarding the issue of allocation. Few NBCs have addressed the problems of organ transplantation, and of those that have, most were concerned mainly with the issue of informed consent (and occasionally with the definition and determination of death). The introduction of informed consent undoubtedly marked a milestone in bioethics. However, the overemphasizing of informed consent (and related issues, such as personal data protection) could possibly distract attention from crucial issues such as organ allocation. The Australian National Health and Medical Research Council is one of the few NBCs that have addressed the problem of organ allocation.¹⁴

CONCLUSIONS

The issues related to allocating resources in organ transplantation arise at the macro (national and regional health care funding), meso (spending decisions made by local authorities and centers), and micro levels (decisions about which individuals get which resources). Approaches based on justice and equity recognize both the existence of differences among persons and the demand for fairness. In most points-based allocation systems, waiting time has generally been considered to be a primary determinant of rank, but increasing attention is being paid to life expectancy.¹⁵ The balance between these 2 criteria, which correspond roughly to justice-based and utility-based systems, seems to be fluctuating.¹⁶

A system in which the most relevant criteria are considered according to a hierarchic order—urgency, likelihood of success, time on waiting list—seems to be reasonable.¹⁷ However, because kidney transplantation is not usually a life-saving procedure (given that dialysis can compensate), in this specific case waiting time is decisive.¹⁸ To date, European NBCs have devoted scant attention to organ transplantation in general or to organ allocation in particular. Allocation policies are crucial and can not be developed by simple “majority rules”: opinions from NBCs would be very useful and are highly desirable.

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