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Ethical Criteria in the Allocation of Organs for Transplants

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Abstract

In the field of organ transplantation (especially the kidney one) one can notice a gradually bigger discrepancy between the number of patients with chronic kidney failure who are registered on the waiting lists and the number of available grafts, things that reveal a gradual rise of the renal diseases' prevalence together with a greater life expectancy and greater flexibility of the criteria that the candidates have to meet in order to be officially registered onto the waiting list (the age limit and the presence of associated chronic illnesses) while the number of donors remains relatively constant. There are usually two philosophical visions which compete which seem contradictory, at first, (utilitarianism and egalitarianism). National and international policies for the allocation of organs for transplants try to find a balance between the two ethical principles, elaborating standardized and socially accepted programmes and procedures.

Keywords: *organ donations, grafts allocation, utilitarianism, egalitarianism*

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Introduction. Utilitarianism versus Egalitarianism in organs transplantation

Due to the fact that there is an insufficient number of organs for transplantation, the policies for allocation of these organs become an extremely important and controversial problem.

The policies of allocation of organs clarify: (1) the priority given to candidates from the waiting lists regarding the transplantation of compatible organs, (2) rules which have to be followed in accepting or rejecting a different organs (the quality if the organ- donor profile index, DPI), (3) criteria for accepting candidates (in the past, patients with Type 2 diabetes or over 50 patients or under 16 patients, the problem of terminal illnesses etc.), (4) under what conditions the priority of candidates on the waiting lists can be modified for example according to the health status.

In the past, the priority rule was that of waiting time (waiting list) and a secondarily the geographical location, age and sensitivity human leukocyte antigens (HLA system is the main tissue antigen in humans, which triggers the cellular and humoral immunitary response, determining the elimination of body's own cells which had suffered antigenic modifications or the foreign cells in the body, for example, an alo graft), playing an important role in histocompatibility.

However, in present times, due to the development of immunosuppressant substances, this criteria has become less important in the allocation of organs, more efficient in predictions have become the non-immunological variables which regard the quality of alo graft (for example the age of the donor and the receiver).

That is why, the policies for the allocation of organs for transplant recognize and implement rules which standardize the fact that the organs received from older donor have a smaller life expectancy than the ones which come from younger donors, and the older receivers have a post transplant life expectancy which is lower that the younger receivers. In young people, the efficiency can be decreased by the rejection of the organ and not by the death with a successful transplant done, the way it happens in older patients who have undergone transplants.

At this time, policies for allocation of transplant organs try to make a more efficient superposition between life expectancy of the alo

graft and the survival hope of the candidate, with the aim of using the donated organs to a maximum percentage.

Stegall (2009) considered that the moment this subject is opened, one has to take into consideration two aspects:

a) The utility/justice balance; the egalitarian point of view underlines that all candidates for transplant have to have equal chances in receiving an organ, even though some patients could obtain better results after the transplantation (more years to live or professional re-inclusion which could generate profit). On the other hand, the utilitarian point of view supports the idea to obtain the maximum possible profit by using the few organs available for transplant. From this perspective, in the allocation of organs there should be taken into account the post transplant benefits as a priority. Because at the present times many states use the waiting lists (done whether according to the time of registration as donor, or the time of diagnosis of kidney failure) it can be considered that the medical practice is profoundly influenced by the equity principle. However, even the utilitarian principle transpires, taking into account that in the USA, from approximately 300.000 patients with kidney failure only 80.000 are officially registered on waiting lists, but from those registered children are a priority. In conclusion, in medical communities there is the idea that some types of patients have priority when it comes to transplants. Additionally, numerous research papers have showed that this tendency of transplant policies of directing the 'good' organs towards younger candidates is very efficient. Meier-Kriesche, Arndorfer and Kaplan (2002) pointed out that between 1990-2002, in the USA, almost 16% from the kidneys with a high DPI (donors aged between 15-25) have been transplanted to old patients (over 60), while the rest of the patients (74%) have received kidneys which came from donors aged over 50. It has been observed that the life expectancy of a young receiver who receives an organ with a high DPI is significantly bigger than that of an old receiver who receives an allograft with a high DPI. Moreover, all the candidates, no matter the characteristics (age, comorbidities), have had an quantitative improvement on average of three more years after the transplant.

The avoidance of the young organs transplantation has led to a significant rise of life expectancy of organs (in the case of approximately 27500 performed transplants) and savings of 1, 5 billion dollars (Meier-Kriesche, Schold, Gaston, Wadstrom and Kaplan, 2005).

b) OPTN Final Rules (Organ Procurement and Transplantation Network). OPTN has been founded on the basis of National Organ Transplant Act-NOTA from USA in 1984. In the present American system for allocation of organs for transplants from a deceased donor, it is taken into consideration as a priority a combination between the waiting list and the immunologic compatibility (HLA system) and on the second place other criteria: age (children), medical insurance, geographical proximity etc. (Wolfe et al., 2008).

These rules try to balance the two points of view, one being able to read statements like: 'equitable allocation of organs', 'policies for allocation of organs have to allow a better use of organs' and 'avoid loss and waste'. On the other hand, although the Final Rules are at the foundation of the general principles in some areas, they become more specific in other areas, with major implications in the development of a new policy regarding the kidney transplant. For example, it is considered that in the case of hetero grafts (tissue or organ which had been transplanted from a person to another) one will take into consideration the objective medical criteria and not the waiting list.

Having the health systems still using at a large scale the waiting list, one could understand that the system does not comply with these Rules.

Although there are these differences of attitude present towards the criteria which should be at the foundation of the procedure for allocation of grafts, there are still some areas of general agreement regarding the realization of a new policy of kidney allocation for transplant: a. the allocation of kidneys has to make a better balance between the improvement of transplant results (utilitarianism) and giving a reasonable chance to all the donors (equity); b. one of the bigger problems from the present medical system is the low post transplant life expectancy of the candidates; c. each candidate to a renal transplant should have a reasonable chance to receive an organ, no matter the age and health state; d. any new system of re-allocation of organs for transplant should be predictable, especially in the case of patient with high risk of death, with the aim of rendering clear the technical procedure of management for waiting lists.

Policies for allocation of organs for transplant

In order to respond to these difficulties and lack of clarity from the system, two new policies have been issued regarding the allocation of organs for transplant:

(1) UNOS/OPTN Kidney Transplantation Committee (2002) has proposed a donor profile index (DPI) similar to the ECD system (Expanded Criteria Donor). Candidates are put in a hierarchy according to a score (Kidney Allocation Scores-KAS) obtained according to more criteria: number of dialysis (waiting time), medical characteristics and a number of post transplant years (Life Years From Transplant-LYFT), criteria defined by the average probability of the post transplant survival and the number of years predicted without transplant for the respective patient. A confusing aspect in the system of allocation of kidneys for transplant is related to the fact that the KAS score is calculated in a different way, according to DPI. This way, the kidneys which came from donor with a low DPI score, are allocated taking into consideration the waiting list only (number of dialysis years), while the kidneys from donors with a high DPI score are allocated to candidates taking into consideration the following formula: 80% LYFT+ 20 % dialysis years. This formula of calculation could have major implications over the rate of renal transplant from donors who are alive, because a young person would be obliged to wait at least 1 or 2 years to receive an organ, this way the emotional state being modified and this has an impact on the donors who are alive. Among the advantages of this system we can point out the solution for the one of the biggest problems in the present medical system, more exactly the transplant of some organs with a high rate of survival in candidates with low post transplant life expectancy.

The most important critics of this system: (1) older candidates have less chances to receive an organ than the actual official system, (2) the methodology of LYFT calculation does not represent a sufficiently predictive factor (3) the system is too complex.

(2) American Society of Transplant Surgeons (ASTS) proposes another allocation system which takes into consideration a single criterion: all the organs which came from donors aged up to 35 will be allocated to young patients, aged maxim 35, according to the waiting list. This thing happens also in the case of kidneys which come from people aged over 35. This system has two main advantages (1) it

solves the problem of young organs which are transplanted to old candidates without impeding the transplant to old people (2) it is simple, but has received critics too: (1) choosing an age limit of 35 years relatively in an arbitrary way limits the access of candidates to transplants - a person aged 34 and 11 months is almost similar to a person aged 35 and 1 month (years of survival, LYFT, hetero graft reaction); (2) using the age factor only (even if it is a major determinant for DPI and LYFT) does not represent a too accurate prediction model, comparing to the models which take into consideration other factors as well which regard the donor and the receiver (the predictive value is significantly bigger regarding the years of post transplant survival in the matrix Age x Diabetes, Machnicki et al., 2009).

(3) Another system which started from the two above described is proposed by Stegall, 2009, which makes a number of corrections: (1) DPI should be used instead of the donor's age, this being a predictive factor which is superior to the age as far as the success of the transplant; (2) the waiting (list) time should be calculated either according to years of dialysis, or as years in which the glomerular filtration rate had been under 20mL/min (from official documents); (3) LYFT should be used instead of the candidates' age, but simplified, so that the formula comprised only 3-4 major factors (age, diabetes etc.); (4) the number of kidneys allocated using LYFT should decrease and only apply to those with a higher DPI (responding to the utilitarian principle of allocation of kidneys with the higher rate of survival to some candidates with a high rate of survival) and to increase the number of kidneys allocated only on the basis of the waiting list (maybe 50%), which would respond to the two major aims of the allocation policies of organs for transplant: allocation of some organs with a high survival rate to some candidates with a high survival rate and ensuring reasonable chances for all candidates to receive a good organ (the idea that older patients and sick with receive only organs with a low rate of survival is being counterattacked). Although it has been imposed by the policies of allocation of organs (kidneys) for transplant, LYFT is a highly predictive factor, the coefficient of correlation between this and the number of years for dialysis (waiting list) being only 0.6. The value of the coefficient rises up to 0.9 when the statistics analysis is done only in the case of patients with a high rate of survival. On the other hand, it is discussed the introduction of other predictive factors which are more valuable, for

example, the combination between the serum troponin and the ejection fraction which has a predictive value either for the waiting list or the post transplant death. (5) it is necessary the introduction of quality of life as a criteria for the evaluation of transplant's and dialysis' results, aspect which is integrated by the use of the coefficient of qualitative weighting of the number of survival years in the case of dialysis/ transplant (QALY). From the specialist literature there is a discussion about two coefficients: 1 for the person's quality of life with a functional graft and 0.8 for the dialysed patient's quality of life.

For most of the patients found in dialysis the performance of a transplant leads to the increase of quantity and quality of life, only that these benefits depend of factors which regard the quality of the organ prepared for the transplant, as well as factors with regard the receiver (age, comorbidities).

In order to dissipate this discrepancy, there have been done the following actions (Courtney & Maxwell, 2009): (1) the encouragement to receive donation from the alive volunteer donor (especially donations without family criteria; Thomphson's Organ Donation Initiative or United Network for Organ Sharing - UNOS), (2) the expansion of criteria for donors (Expanded Criteria Donor-ECD, which refers to the donor aged over 60, or between 50 and 59 who suffers from the following: Stroke, Hypertension or serum creatinine > 1.5 mg/dL at the time of death) and (3) promotion of donation from patients in cardiac death programmes. It seems that to a great extent these directions have remained unsuccessful.

When we have to rationalize a certain limited resource we can take into account the following possible criteria (Courtney & Maxwell, 2009): the social (financial) value of the patients, first come first served, chance, maximization of efficiency of use of each organ separately (the greatest benefit for most people). The problem is that when you do a good thing to a patient and at the same time you do a bad thing to a patient who had not benefited from a transplant (the Hippocrates vow is breached).

Challenges of the utilitarian perspective

1. The age. In 2006, in the UK, almost 50% of the new candidates on the waiting list were over 60. Although this age could be evaluated as 'old' it has been noticed at the same time that these people, due to the new technology and the new lifestyle they has a pretty good

health, thing that determined the recent researchers to consider that age should not be regarded as a factor itself for the evaluation of the post transplant success but more than anything else their general health state. However, it is clear that the life expectancy rate after transplant for older people is lower than the young people's. Situations have been created in which patients with a successful transplant die very quickly from other cause other than renal.

2. The type 2 diabetes. It is well know that the life expectancy after transplant for patient with previous type 2 diabetes decreases because of the cardio-vascular complications. Anyway, life expectancy for diabetics with nephropathy and transplant is bigger hat in the case of diabetics who continue therapy through dialysis.

3. Obesity. The relationship between obesity and post transplant results is not very clear. However, there are more and more studies which point out a significantly lower rate of success for patients with a high body mass index. Some health insurance companies have a clear policy regarding the financial support of this category of patients with morbid obesity, who have a high risk of death and rejection of organ. However, the risk seems to be lower than in the situation in which these remain in dialysis.

4. Other comorbidities. Knowing that the presence of any chronic complication decreases the success of the transplant, now a detailed analysis is being done for the health state of the receiver (DZ, HTA, cardio-vascular diseases, and cancer). The question that is being asked is if patients with cancer diseases should receive the right to a transplant, taking into consideration the low life expectancy, or they should be discriminated positively, only because, if they waited normally on the lists, they could dies before the transplant. The decision to use an ECD kidney for chronic patients is complex because there are data to suggest that these kidneys have a higher rate of primary nonfunction, rejection, and a greater susceptibility to preservation injury, drug toxicity, and the effects of posttransplant hypertension (Metzger et al., 2003; Stratta et al., 2004).

Challenges of the equity (equality) principle

For the calculation of the obtained efficiency for each organ and candidate, the concept 'years of life after transplant' has been proposed (Life Years From Transplant-LYFT), generic notion which points out the number of years that the patient with a terminal (renal) disease, lives

more of them than in the situation in which he would remain with a dialytic treatment. This measure is predictive and is based on the use of survival curve without and with a transplant done. These curves represent statistic analysis of some big data basis regarding the life expectancy of patients with different characteristics, with transplant or not. For example, the average number of years of survival of a diabetic person aged 50 (nephropathy) dialysed and the average number of years of survival for the same type of patient with transplant. Moreover, in this estimation of the survival time or the patient with transplant has to take into consideration the hope of survival for the transplanted organ. The calculation gets more complicated in the case of a patient who suffered a transplant, from various reasons the graft was not successful; the patient has come back to dialysis and then suffered another transplant.

In some cases it is considered absolutely necessary the introduction in this calculation of the concept of quality of life as well, point out that it is not enough to know from a quantitative point of view only what will happen to the patient, but it is important to evaluate the quality of survival time after the transplant. For this it is done an adjustment of LYFT by multiplying with an estimated quality coefficient, which varies from 0 (deceased) to 1 (healthy), 1 means a good extreme of quality of life for the patient. In fact the calculation for LYFT becomes the difference between the number of years which have been adjusted according to quality (QALY – quality adjusted life years) in the situation of dialysis and transplant. For example, a person can live 10 years in a good health state, thing that means the person will have $10 \times 1 = 10$ QALYs. Another person could live 15 years with an altered quality level, meaning there will be $15 \times 0.8 = 12$ QALYs. These values reflect the relative quality of life of patient and allow the combination in one weighted measure (indexed) of mortality and morbidity.

If one takes into consideration the calculation of cost too, a cost utility analysis can be done, using the formula:

The cost-utility rapport = $\frac{\text{transplant cost} - \text{cost of dialysis}}{\text{number of QALY produced by the transplant} - \text{number of QALY produced by the dialysis}}$ (Hyder et al., 1998).

The problem is that these data do not have any connection with what the patient himself chooses for him, thing that raises ethical problems again.

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Various variants have been developed for quality of life which would take into account the patient's perception too, for example the Time trade-off Technique (TTO) which means the presentation of some virtual cases in which the respondent could find himself and could evaluate the preferences regarding health.

For example, imagine that you suffer from the chronic fatigue syndrome and you permanently feel overwhelmed, lethargic and have headaches almost every day. You have problems when shopping and you cannot concentrate more than 1 hour in your professional activities, which lead to a decrease of your efficiency at work. You have tried to take the most common medicine prescribed for this symptoms but it seems the treatment does not have any results. Apart from this chronic fatigue syndrome you do not have any other health problem. You are 50 and life expectancy would be of 30 more years.

An extraordinary medicine has been discovered, which could eliminate all the unpleasant symptoms. At the same time, this medicine will lower your life expectancy with 5 years. Under these conditions, what do you choose: A. to live 30 more years with the chronic fatigue syndrome or B. to live 25 years in a good health state.

In a study done by Salkeld et al. (2000) there has been noticed:

- | | |
|--|---------------------|
| 1. Chronic fatigue syndrome and 30 years for 25 years | X B. perfect health |
| 2. Chronic fatigue syndrome and 30 years for 22 years | X B. perfect health |
| 3. Chronic fatigue syndrome and 30 years for 21 years | XB. perfect health |
| 4. Chronic fatigue syndrome and 30 years for 20 years | B. perfect health |
| X5. Chronic fatigue syndrome and 30 years for 19 years | B. perfect health |
| X6. Chronic fatigue syndrome and 30 years for 18 years | B. perfect health |

So, the limit which makes the difference between the 2 choices is 20 years, from which patients would not ready to decrease the life expectancy, even if they lived in perfect health.

By using the weighting formula we can evaluate as $U = \text{number of years lived in perfect health} / \text{number of years lived with symptoms} = 20/30 = 0.67$.

This coefficient allows us to come back to QALY, due to the fact that now we know that living 30 years with symptoms represents $30 \times 0.67 = 20$ QALYs, meaning 20 years of good health (Rapley, M., 2003).

As far as the Romanian legislative framework is concerned, in Law no. 95/2006 regarding the reform of health from 25/10/2006 (Methodological norm), in Chapter VI 'The removal of organs and performance of transplant, tissue and cells of human origin with therapeutic aim', in article 2, it is mentioned the fact that (1) the protocols regarding the removal of organs, tissue and human cells from deceased donors will be elaborated by the Scientific Council of the National Agency for Transplant and approved by an order of the ministry of public health and (2) the protocols mentioned in paragraph 1 will be revised periodically, according to the international progress in the field.

Article 3 states that Rules regarding the organ, tissue and cells of human origin allocation are made by the present protocols, approved by Scientific Council of the National Agency for Transplant, according to the necessities from the waiting lists, immunologic compatibility and the possibilities to use transportation as part of the time of cold ischemia.

We can observe that the procedure for the allocation of organs is poorly mentioned, the decision of the specialist in the field having the final decision as part of the National Agency for Transplant (NAT) a specific operation/algorithm, which cannot be accessed by the public because it does not appear on the NAT web site or in public official documents.

In comparison, ECD kidneys are allocated to patients on the kidney transplant waiting list in accordance with the allocation policy (United Network for Organ Sharing Policy 3.5 Allocation of Cadaveric Kidneys) put in place by the OPTN in October 2002, which states, "Kidneys procured from the ECD will be allocated to patients determined to be suitable candidates: First, for zero antigen mismatched patients among this group of patients with time limitations; and next, for all other eligible patients locally, regionally, and nationally, based on time waiting and not the HLA matching" (Rosengard, 2002).

Even though not even these rules of allocation are perfect and triggers numerous suspicions or interpretations, it about computerized

nationwide algorithm that is driven by specified allocation rules and is used to allocate all deceased donor organs. The allocation rules or algorithm is not affected by the ECD option. Whether a patient opts for an ECD does not affect his or her status or probability of receiving a standard criteria donor (SCD) kidney (a 35-yr-old man who has no history of hypertension or diabetes and for whom the cause of death is a motor vehicle accident (Rao and Ojo, 2009).

Conclusion

Under the conditions in which there is still a big discrepancy between the number of patients found on the waiting lists and the number of organs available for the transplant, increasing efficiency of using each organ separately becomes an important problem which raises ethical questions. Although up to present a solution that could respond to all the demands does not exist, we need to appreciate the effort that numerous countries make in order to create models or criteria which would decrease the weak points of the present ones. There has been observed the importance of introduction of notions of Life Years From Transplant (LYFT) and quality adjusted life years (QALY), Expanded Criteria Donor-ECD and standard-criteria donor (SCD, but the question of how to best allocate such a scarce medical resource remains unclear. Probably because of the small number of donors in Romania, this difficult issue is not discussed at all or almost at all or clarified in our country. If a person wanted to find out more regarding the way grafts are allocated in Romania, would encounter numerous difficulties. First of all, there is no information regarding the waiting lists on the web site of The National Agency of Transplant, there is not a National Register of Transplant proposed since 2009, which should ensure the continuous monitoring of the activity of transplantation according to the established procedures by National Agency of Transplant (Order 477/2009 regarding the creation of the National Register of Transplant). Moreover, people who want to become post mortem donors of organs for transplant should be able to register during their life to a national register created by the Ministry of Health (MH), on the basis of a notary declaration, aspect mentioned by the Order of the Ministry of Health no. 1158/2012 regarding the national Register of donors of organs, tissues and cells, published in December 2012, but which has not produced effects until now. From the European point of view, The Council of the

European Union, Commission "Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States identified three major policy challenges for organ donation and transplantation: ensuring the quality and safety of human organs, increasing organ availability, enhancing the efficiency and accessibility of transplantation systems in the EU (December 2012). Maybe only under the conditions in which Romania, as a member of the European Union, will have to meet these quality standards, in the near future, there will be medical services of quality information and treatment in the field of the organs transplantation.

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