Official Gazette

Miscellaneous Notices

Guidelines of the Organ Transplant Steering Committee

Pursuant to the Organ Transplant Law, 5768-2008

By virtue of its powers under section 9(b)(4) of the Organ Transplant Law, 2008[1] (hereunder - the Law), and after having received approval from the director general of the Ministry of Health under section 9(g) of the Law, the Transplant Center Steering Committee (hereunder – the Steering Committee) hereby establishes guidelines for the allocation of organs harvested under the Anatomy and Pathology Law 1953[2] (hereunder – the Anatomy and Pathology Law) or brought to Israel pursuant to section 6 of the Law:

Part A: Guidelines for the Allocation of Organs from Deceased donors

Chapter 1: General – Allocation Principles

1. The Transplant Center, as defined in section 1 of the Law, administers a data base as referred to in section 32 of the Law, which contains, *inter alia*, details of applications submitted by patients to be registered in the data base.

2. There is in existence one national waiting list, which contains all details of patients awaiting transplants (hereunder – the Waiting List).

3. Any patient who is an Israeli resident is eligible, at the recommendation of his doctor, to submit an application to be registered on the Waiting List referred to in section 24 of the Law.

4. Patient data is regularly updated and includes a range of medical details.

5. Each organ has a set of allocation criteria, which has been established according to the traits necessary for matching the donor with a recipient (such as blood type, weight and height) and according to the immunological characteristics of the organ itself (the extent to which tissue matching is necessary) and the prospects of providing quality of life and of saving life (age, waitlisted period, blood test results etc); these criteria are built into computer software specially developed and adapted for each organ.

6. Where a donor meets the conditions in the Anatomy and Pathology Law for one of his organs to be surgically removed from his body for transplant into the body of a recipient at a hospital in Israel, his details shall be forwarded to the

[1] *Sefer Hahukim* 5768, page 394
[2] *Sefer Hahukim* 5713, page 162.

Transplant Center and fed into the computerized system (hereunder – the System).

7. The System shall cross-match donor data with data of persons waiting for an organ donation and shall locate the patients most suitable for a transplant.

8. The Steering Committee shall conduct periodic control of allocations and update the allocation software as necessary and pursuant to technological advancements in the field of transplants.

Where the computer finds two or more patients equally eligible to receive organ donations, the Transplant Center shall hold medical discussions with specialists to reach a decision as to which patient shall be allocated the organ; where a decision is not reached at this level, the Transplant Center shall continue to consult with other experts specially appointed for such purpose, who are not affiliated with or employed by the hospitals in which the transplant is to take place; where necessary, the chairman of the Steering Committee, and sometimes even the director general of the Ministry of Health, shall be involved in reaching a decision.

Chapter 2: Heart Allocation

10. Principles

(a) Hearts shall be allocated according to compatibility of the recipient's blood type and body weight with that of the donor and according to the period of time he has been waitlisted for a transplant; the severity of the illness of waitlisted persons shall also be taken into account.

(b) The Waiting List is divided into two sections, pursuant to severity of illness:

(1) **Status 1** – Waitlisted persons in an urgent condition who meet the following conditions:

(a) Patients hospitalized due to the severity of their condition, and those in need of medication via continuous infusion or with mechanical pump support;

(b) Waitlisted persons with an artificial heart, even if not continuously hospitalized;

(2) **Status 2** – Waitlisted persons who are at home and are in a relatively stable condition.

11. Waiting List

A person up to 65 years of age can be registered on the heart transplant waiting list.

12. Allocation Method

(a) Where a heart is available for transplant, the donor's blood type and body dimensions (weight and height) shall be typed into the computer of the National Transplant Center, and the computer shall, pursuant to this data, generate a printout containing a list of suitable waitlisted candidates whose body dimensions vary up to 20% from the body dimensions of the donor, with priority given to persons who have been waiting longer for a transplant.

(b) The decision concerning allocation involves two considerations:

(1) First consideration – medical urgency, and as such the donated heart will be offered first to those waitlisted as status 1;

(2) Second consideration – match of blood type between the donor and the waitlisted candidate, as set out below:

The heart will first be offered to patients with the same blood type, but if none of these have are status 1 patients, it will be checked whether it is possible to transplant the heart into a waitlisted person rated status 1 whose blood type is compatible with that of the donor, subject to compatibility of body dimensions between the donor and the waitlisted candidate.

(c) Where there are two or more suitable candidates for the same heart, the patients' treating cardiologists shall discuss the matter and decide which candidate is in a more serious medical condition and will, accordingly, be allocated the donated heart; where the cardiologists do not reach agreement, an external cardiologist, who has been specified for such purpose by the National Transplant Center, who does not work with one of the hospitals in which the heart transplant is to take place, shall decide the matter after having heard the doctors; in order to reach a correct and reliable decision, the external cardiologist shall visit the urgent status 1 patients on the wards; these visits shall be conducted from time to time together with a Transplant Center representative.

Chapter 3: Lung Allocation

13. Principles

(a) Lungs shall be allocated according to blood type compatibility and severity of illness, and according to compatibility of body and height dimensions between the donor and the waitlisted candidate.

(b) Allocation method is based on the LAS - Lung Allocation Score, which is based on the following parameters: age, waitlisted period, type of lung disease and functioning of the lung, which is measured according to a number of parameters.

(c) Severity of illness: The LAS ranges between 27 and 80; the more serious the medical condition the higher the score.

14. Waiting List

Persons up to 70 years of age can be registered on the transplant waiting list.

15. Allocation Method

(a) When a lung donation is received, the patient with the most serious illness, whose blood type and body dimensions match that of the donor, shall receive the organ.

(b) A waitlisted person, whose situation has deteriorated to the extent that he requires respiration and whose LAS is above 70, shall be eligible to receive an organ from a donor with the same blood type as well as from a donor with compatible blood type.

(c) The allocation mechanism set out above shall apply whether the patient needs a transplant of one or two lungs.

16. Allocation for Combined Heart-Lung Transplant

(a) Candidates for a heart and lung transplant shall be put on the lung transplant list; a candidate defined as urgent shall be brought to the top of the lung transplant waiting list after consultation with lung specialists from other lung transplant centers; following approval, the treating lung doctor shall report to the Transplant Center.

(b) The order of priorities shall be as follows:

(1) Priority is given to status 1 heart transplant candidates over heart-lung transplant candidates;

(2) A heart-lung candidate who is at the top of the lung waiting list shall receive priority over a status 2 transplant candidate.

Chapter 4 Liver: Allocation

17. Principles

Two methods exist for liver allocations – one for adults and one for children, as set out below:

18. Liver Allocation for Adults

The adult liver allocation method is called MELD (Model for End Stage Liver Disease) and is based on the mathematical formula set out below, which was developed in one of the most important Transplant Centers in the United States;

this method was adopted by the American organ allocation organization (UNOS), and later also by western countries, including Israel:

MELD Score – a logarithm for calculating the severity of liver disease and chances of survival without transplant; scores range from 6 onwards; the greater the severity of the disease – the higher the score; registration of adults for liver transplant is conditional upon a MELD score of 10 and higher at the time of registration; if the score falls below 10 after registration, the patient is not removed from the list.

19. Liver Allocation for Children

Children up to 18 years of age shall be registered in a special children's list and rated according to severity of illness, using a method that differentiates between children up to 12 years of age and above 12 years of age, as set out below:

(1) Children up to 12 years of age – severity of illness is calculated according to the PELD score – PELD = Pediatric End-Stage Liver Disease, an arithmetical formula based on the same principles as the allocation method for adults, while for children, additional arithmetical parameters are taken into account due to the growing process: height, weight, age and date registered on the national waiting list; scores range from 6 to 40; the greater the severity of the disease – the higher the score;

(2) Children 12 to 18 years of age are included in the children's waiting list, but the severity of the disease is calculated according to the MELD method which is used for adults.

20. Waiting List

(a) There are two waiting lists – one for adults and one for children up to 18 years of age; a person up to 65 years of age can register for a transplant.

(b) The two lists are based on a score relating to severity of illness and blood type; different formulas are used for calculating severity of the disease in children as opposed to adults, due to the special characteristics of the diseases and of age; compatibility between the recipient’s body dimensions and those of the donor is taken into account.

(c) Each group has a separate list for urgent cases – status 1 patients with liver disease that is acute or severe, pursuant to set criteria, who are hospitalized in fatal condition and whose life expectancy, without transplant, is up to seven days.

21. Allocation Method

Allocation shall be according to the following method:

(1) The liver shall initially be allocated to an urgent status 1 candidate with the same or compatible blood type;

(2) In the absence of a status 1 patient, the liver shall be allocated to a patient with the same blood type as the donor and with the highest score, ie: the highest rating for severity of disease;

(3) In exceptional circumstances, involving serious patients with a MELD score higher than 30 who have a rare blood type, the patient will also be given the possibility of receiving a transplant from a donor with a blood type that is compatible and not only the same.

Chapter 5: Kidney Allocation

22. Principles

(a) No urgency criteria exist for the allocation of kidneys.

(b) Kidneys are distributed for transplant where the donor and recipient have the same blood type (O for O, B for B etc.).

23. Principles for Kidney and Pancreas Allocation to Patients with Type 1 Diabetes

Below are the principles for kidney and pancreas allocation to patients with type 1 diabetes:

(1) Blood type compatibility.

(2) Negative cross-matching results between the blood cells of the waitlisted candidate and those of the donor, and the amount of time the candidate has been on the list of diabetes patients waiting for a kidney and pancreas.

24. Waiting List

(a) There is no age limit for kidney transplants.

(b) Registration for a kidney transplant from a deceased person is only possible after commencement of dialysis.

(c) The period of time a patient has been registered on the Waiting List is calculated from the commencement of dialysis and not from the date of registration for transplant.

(d) A waitlisted dialysis patient who has advanced to a higher age group after having been waitlisted for a prolonged period shall continue to have the score given according to the age group he was in upon joining the list; a younger waitlisted person receives more points.

25. Allocation Method

Allocation is performed in the following way:

(1) Where a kidney donation is received, glands are taken from the donor and sent to the national tissue typing reference laboratory;

(2) The laboratory holds blood samples from all candidates for kidney and kidney-pancreas transplants (samples are sent there once a month);

(3) Cells taken from the glands are checked against the blood samples of waitlisted candidates who have the same blood type as the donor. This check is called "cross-matching";

(4) Candidates waiting for a transplant, whose cross-matching test with the donor's blood test is negative, can receive a kidney or kidney and pancreas from that donor.

(5) Amongst the waitlisted candidates for whom the cross-matching test with the donor is negative, priority is determined according to four criteria:

(a) Age;

(b) Waiting period, which is counted in months from the commencement of dialysis;

(c) Genetic similarity (HLA);

(d) Antibody titer (PRA);

The score for each criterion ranges from 0 – 4, except for antibody titer (PRA) – for which the score ranges from 0 to 6; the scoring method is set out in the tables in section 23.

(6) Some waitlisted candidates have a high antibody titer, which means that they have antibodies to many people, and the chance they will find a compatible kidney donor is low; to compensate for the low chance of finding a kidney, the Transplant Center has set a higher score for candidates with a higher antibody titer;

(7) A tally is made of the total score for every waitlisted candidate who has a negative cross-match with the donor, and the candidate with the highest score receives the organ.

26. Special Situations

(a) Where the donor is a child under 18 years of age, a match is first sought amongst waitlisted children less than 18 years of age.

(b) Where the donor is above 60 years of age, the transplant shall take place in patients over 60 years of age.

27. Table of Criteria and Scores for Kidney Allocation

Kidneys shall be allocated according to the criteria set out below:

(1) Table 1- Age

Age	Points
Up to 19	4
Above 19 to 41	2
Above 41 to 60	1
Above 60	0

(2) Table 2 – Antibody Titer – PRA

Antibody Levels in Percentages	Points
25	0
26 to 50	2
51 to 75	4
76 and above	6

(3) Table 3 – Waiting Time (In Months)

Genetic Similarity	Points
Up to 25	0
Above 25 to 48	1
Above 49 to 96	2
Above 96	4

(4) Table 4 – Compatibility of HLA Genetic Similarity

	Points
No incompatibility	4
Incompatibility at one site	3
No incompatibility at the DR site with incompatibility at other sites	2

(5) Table 5- Table of Blood Type Compatibility ('Compatible Blood Type')

A person with blood type:	Can receive from:	Can donate to:
O	O	AB, B, A, O
A	O, A	AB, A
B	O, B	AB, B
AB	AB, B, A, O	AB

Part B: Guidelines for Priority in Organ Allocation

28. Part B Priority

Notwithstanding that referred to in Part A, when allocating organs, priority will be given in accordance with the guidelines in this part.

29. Preamble

(a) Section 9(b)(4) of the Law provides that the Steering Committee can, as part of its duties –

"establish guidelines for the allocation of organs harvested under the Anatomical and Pathology Law or brought to Israel pursuant to section 6, provided that when the organs are allocated as aforesaid, these considerations, amongst others, are taken into account:

(1) Consent of the person, when alive, for an organ to be harvested after his death, as referred to in section 28, if he or a first degree family member needs an organ transplant;

(2) Donation of organs harvested from a person under the Anatomy and Pathology Law if a first degree family member needs an organ transplant;

(3) Donation of an organ taken from a person during his lifetime, not for a specific recipient, if that person or a first degree family member needs an organ transplant."

(b) Under section 28 of the Law, quoted in subsection (a), and based on comprehensive discussions held on the topic within the framework of a special forum of experts in the fields of ethics, philosophy, law, religious law and medicine, and in reliance on recommendations of the Transplant Center's various organ committees, the Transplant Center Steering Committee has formulated the guidelines set out below:

30. Priority Procedures

(a) A transplant candidate is eligible for priority in the allocation of organs for transplant if one of the following has been met:

(1) He or a first degree family member has signed a consent card for the donation of organs after his death pursuant to section 28 (a) of the Law; priority shall be given after three years have passed from the date he has signed the consent card;

(2) Where a first degree family member has donated organs in Israel under the Law and under the Anatomy and Pathology Law, priority shall be given from the date these guidelines have been published in the Official Gazette, onwards;

(3) Where he or a first degree family member has, during his lifetime, donated a kidney, liver lobe or lung, other than to a specific recipient under section 21 of the Law; priority shall be given from the date these guidelines have been published in the Official Gazette, onwards.

(b) A minor under 18 years of age or someone declared legally incompetent shall not be subject to the priority procedures in this chapter, and for such persons, organs for transplant shall be allocated according to the allocation procedures in existence prior to publication of the guidelines set out in Part A, without change.

(c) Where an organ is being allocated for transplant and an adult has priority status over a child or a legal incompetent just because the adult is eligible for priority under sub section (a), the organ shall be allocated to the child or the legal incompetent and not to the adult;

For the avoidance of doubt, it will be emphasized that minors under 18 years of age are excluded from priority procedures under this chapter despite the fact that under the law a minor under 17 years of age may sign an organ donor consent card.

(d) Priority for a person who has signed a donor card or the relative of such person shall be given one year following publication of these guidelines in the Official Gazette and after a waiting period of three years as specified in subsection (a)(1). However, a person who has signed a donor consent card during the said year, or his relative, as the case may be, shall be entitled to priority, even if a period of three years has not passed.

(e) In these guidelines, "first degree family member" means spouse, parent, son, daughter, brother, sister, only.

31. Breakdown of Priorities

Priority in the allocation of each of the organs donated for transplant, shall be given in the following manner:

Reasons for Giving Priority	Kidney/ Kidney-Pancreas Number of Points	Heart	Lungs LAS Number of Points	Liver MELD Number of Points
Candidate's signature on organ donor card	2	Advance to top of the status 2 list	10	2
Signature of candidate's family member (one relative only)	0.5	Advance on Status 2 list after those who have priority because they signed	2.5	0.5
Actual donation from a deceased relative or donation from someone living other than to a particular recipient	3.5	Advance to top of status 2 list before those who have priority because they signed	15	3.5

32. Further Guidelines

(a) Amongst the candidates for organ transplant who have the same number of points, priority will be given, at the time of allocation, to a candidate who has accumulated points pursuant to the medical criteria set out in Part A and not on the basis of priority procedures set out in Part B.

(b) Where the medical situation of a heart, lung or liver transplant candidate, who is eligible for advancement due to having signed a donor consent card, necessitates his advancement to the top priority list (status 1 heart, respirated patient or with an LAS above 70 for lung and status 1 or with a MELD score above 30 for liver) he shall be advanced to the top of the list pursuant to the general allocation procedures in Part A, without taking into account the fact that he is not eligible for advancement; however, if the organ allocation list for top priority candidates contains, at any particular moment, two candidates for a concrete donation who are the same from a medical perspective, allocation priority shall be given to the candidate eligible for advancement pursuant to the said advancement procedures.

(c) Priority will only be given to someone who has signed a donor card if such person has expressed a willingness to donate organs after his death, and has not limited his signature to tissue only.

(d) A transplant candidate cannot accumulate points for having met a number of advancement criteria, but if a person has met more than one criterion, the higher number of points from amongst such criteria shall be attributed to his credit.

(e) Each time organs are donated, eligibility for advancement shall be re-checked before the organs are allocated.

(f) A person who has cancels his signature on the donor card after he or a first degree family member has benefited from priority in the transplant of an organ based on such signature, shall not be eligible for priority in the future, even if he renews his signature on the donor card, provided he has been given an appropriate opportunity to be heard by a committee that is convened for such purpose.

(g) Doctors who have registered a legally incompetent patient for a transplant shall provide the Transplant Center with formal documents confirming such.

February 20, 2011.

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