الجمهورية اللبنانية
وزارة الصحة العامة

Regulations and Allocation Criteria

for Retrieved Organs from Deceased Donors

&

Transplantation from Living and Deceased Donors

As discussed during

1. **The meeting of April 29, 2014 (Kidney committee)**
2. **The meeting of June 12, 2014 (Heart committee)**
3. **The meeting of September 4, 2014 (Liver committee)**

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NOD-Lb, June 2016
1st edition
Adapted from the regulations of the "Agence de la biomédecine - France (ABM)

Reviewed and approved by
The Renal, Cardiac and Liver transplant Centers
The Lebanese Scientific Societies of Nephrology, Cardiology, Cardiovascular, Hepato-Gastro & General surgery
The National Organization for Organ and Tissue Donation and Transplantation (NOD-Lb)

Chapter I
GENERAL RULES

1. The organs that are NOW transplanted in Lebanon and are concerned by these distribution rules are: the heart, the liver, the kidneys, the pancreas, the lungs, the intestines and the corneas and all other tissues.

2. Any patient requiring organ transplantation is defined as a potential recipient.

3. Any potential recipient should be registered on the national waiting list of patients awaiting transplantation managed by NOD-Lb. To benefit from the allocation of a graft from a deceased or a living unrelated donor, the registration on the national waiting list is a mandatory prerequisite.

4. The listing of potential recipient with living related donor is just to complete the national donation and transplantation registry.

5. The registration of a potential recipient should be done by an authorized medico-surgical transplant team. The administrative record will then be reviewed by NOD-Lb before it is confirmed.

6. It is mandatory to have a copy of the ID, the blood group, the results of the serology, virology and immunology tests and the cardiac ultrasound to avoid an unintended error. The registration sheet should be complete.

7. The non Lebanese patients: They should be living in Lebanon for more than 4 years, and provide NOD-Lb in addition to all the above documents a:
   - ✓ Stay permit
   - ✓ Work permit (when applicable)

8. The registration form should be signed by the treating physician, the physician and the surgeon of the transplantation unit and the patient.

9. Updating the national waiting list:

   A. For Kidney recipients:

   - Every year: the surgeon, the physician of the transplant unit and the treating physician are responsible to reassess their patient and renew the necessary tests and send them with a medical report to NOD-Lb. If their patient has to be put temporarily out of list they (3 physicians) should send a written memo to NOD-Lb and inform their patient. When the problem is solved and the registration of the patient can be reactivated they should again inform NOD-Lb and the patient.

- ✓ To avoid extra expenses to the patients: most of the tests required are mandatorily done on a regular basis in the dialysis units (monthly, biannually and yearly). Please send these results to update the files of your patients with the above reports.

- **Every 6 months and when any serious medical problem occurs. The treating physician should send to NOD-Lb a report about the medical condition of his patient informing NOD-Lb if his patient should be put temporarily out of list. The treating physician should also inform the transplanting surgeon and the patient. When the problem is solved and the registration of the patient can be reactivated they should again inform NOD-Lb and the patient.**

B. **For heart or Liver recipients:**
Every 3 months, and when any serious medical problem occurs. The treating physician and/or the transplanting surgeon should send to NOD-Lb a report about the medical condition of his patient informing NOD-Lb if his patient should be put temporarily out of list. The treating physician should also inform the transplanting surgeon and the patient. When the problem is solved and the registration of the patient can be reactivated they should again inform NOD-Lb and the patient.

C. **Non immunized patients have to renew their historical blood sample once a year.**

D. **The immunized patients (PRA >10%) have to renew their historical blood sample twice a year.**

E. **All patients should send a new historical blood sample one month after any immunizing event (any transfusion, previous transplantation, multiparous women, acute infection, and vaccination, assist device placement...)**

10. **Patient can be listed in one accredited center only. If he wants to be released from one center to another:**
    - **He has to bring a report from the initial center and the second center to modify his file at NOD-Lb. (free of charge)**
    - **If for any reason, bringing a report from the initial center is problematic, NOD-Lb will still request a report from the second center and make sure the initial center is informed.**

11. All possible organs and tissues donors should be referred to NOD-Lb without delay. NOD-Lb is responsible to supervise the donation procedure and apply the allocation rules.

12. Any transplantation from living donors (related or unrelated) must be presented to NOD-Lb regardless of the third party payer for an administrative control before it is referred to the Ministry of Health for final approbation. (2 weeks before scheduling the surgery).

13. Every potential deceased donor must be reported without delay to NOD-Lb. NOD-Lb is responsible to supervise the donation procedure and send a letter to the ministry of health to ensure the financial coverage of the donation and the transplantation.

14. Any transplantation from living donors (related or unrelated) or deceased donors must be reported without delay to NOD-Lb. NOD-Lb is responsible for establishing a national registry of all organs and tissues transplanted in Lebanon.

15. All transplant centers are responsible to send a short report on the immediate results of any transplantation performed from a living or deceased donor, and follow-ups at: 15 days post surgery, one month, 6 months and yearly thereafter.

    For the time being we will reserve a slot for the registry in the software. Items 14 and 15 related to the donation and transplantation registry will be discussed later by the involved centers and NOD-Lb.

16. The final decision to transplant an allocated graft is the responsibility of the medico-surgical transplant team. This allocation can not contradict the general and specific rules of distribution and allocation of grafts. In case of refusal of the allocated graft, the transplanting team should send a written note to NOD-Lb to explain his decision within 24 hours.

17. Allocation is based on two levels of distribution:
    - The local level (donating hospital)
    - The national level

    The local level has always a priority.
    Emergencies apply to the national level, only.

    a) For kidney recipient: The emergency is limited to problems of access to dialysis.

    b) For the heart recipient: NOD-Lb contacts the different cardiac transplant centers to check on the presence of an extremely emergent case.

    c) For the liver recipient: acute liver failure, Hepato-Cellular carcinoma (HCC) according to the Milan criteria.

18. Unless otherwise decided by the transplanting centers, the graft is assigned to a recipient from an iso blood group.
    - If no recipient of this type is identified, the graft is offered to an ABO blood group compatible recipient according to the criteria defined for each organ by NOD-Lb and the experts committees.
    - If no compatible ABO blood group Lebanese recipient is identified, the graft is offered to a non Lebanese patient registered on the national list and then to the international level.

Potential Recipient - Blood Group				
Donor Blood Group	O	A	B	AB
O	✓	-	✓	-
A	-	✓	-	✓
B	-	-	✓	-
AB	-	-	-	✓

19. Any request for a registration in an urgent category or specific distribution and allocation of the graft should be discussed between NOD-Lb and the committee of experts chosen by the transplanting teams.

20. To reduce the risk of graft loss due to delays during the distribution:
    - Each Team should have informed NOD-LB beforehand of its unavailability.
    - Every 3 months, a message should be sent from each transplant center to NOD-Lb specifying the period of unavailability.

- In the absence of the transplanting surgeon or the treating physician, the turn will be given to the next option. The patient, who has lost his turn due to the unavailability of his transplanting team, will be given a priority with the next appropriate donor.

- In case of the unavailability of his transplanting team, a patient registered on the national emergency waiting list and chosen as the best match for an actual donor can be, at the request of NOD-Lb, transplanted by another team provided that he and the new transplanting team give their written consent to this transplantation and transmit it to NOD-Lb. In case the transplantation is refused by anyone of the concerned

persons, the patient loses his turn and will be given a priority with the next appropriate donor.

- To avoid losing grafts because of delays during the allocation phase, once all the necessary information on the donor have been received, the maximum period granted to each team to answer, is:
  - 1 h for liver and thoracic organs
  - 2 hours for kidneys.

21. After this period, NOD-Lb will propose the graft to the next chosen candidate.

22. In case of force majeure (unstable donor), teams may be advised that the period allotted for answering has been reduced.

23. Once a registered patient is transplanted, the transplanting team should remove his name from the WAITING LIST as soon as possible (No later than 24 hrs after transplantation) and update his list with NOD-Lb.

24. Simultaneous transplantation of two different organs
    a. A recipient registered on the national waiting list for the simultaneous transplantation of two different organs, one of them being the heart or the lung he has a priority at the national level.

    b. In case of proposal for simultaneous transplantation of two different organs, one of them being a kidney and the other a heart-lung, lung, heart or liver, the rules of distribution and allocation of the organ should respect the shortest duration of ischemia applicable for the: heart-lung, lung, heart, or liver.

    c. The proposition is restricted to iso group. Rh is not important.

25. NOD-Lb will publish an annual review of the national activity on organ and tissue donation and transplantation.

26. Any possible modification of the specific rules listed below must be authorized by NOD-Lb upon request of the experts committees.

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Chapter II

Specific Rules

Organ Allocation Criteria and Transplantation Regulations

Kidneys, Heart and Liver

1) **If the organ retrieval is made in a hospital performing its transplantation or in a hospital affiliated to the deceased organ system NETWORK.**

   - The heart or liver is considered the local or regional graft and is not subject to be proposed to patients belonging to priority categories at the national level.

   - The kidneys:
     - One kidney is considered the local graft and is not subject to be proposed to patients belonging to priority categories at the national level.
     - The 2nd kidney is proposed to patients belonging to priority categories at the national level.

2) At the local and national level, the allocation of a **kidney graft** is based on scores which take into account the length of the time from the registration on the waiting list, the number of HLA matching between donor and recipient, the age difference between donor and recipient's, the blood group, the degree of immunization and the medical status.

3) At the local and national level, the allocation of a **liver graft** is based on scores which take into account the length of the time from the registration on the waiting list, the age difference between donor and recipient's, the blood group, the medical status, MELD, PELD, CHILD.

The MELD/PELD Calculator

The MELD/PELD calculator collects data elements used in both the MELD and PELD score calculations. Please note the following:

The MELD score calculation uses:

- Serum Creatinine (mg/dl)*
- Bilirubin (mg/dl)
- INR

* For patients who have had 2 dialyses during the last week, or 24 hours of CVVHD, the creatinine value will be automatically set at 4 mg/dl.

The PELD score calculation uses:

- Albumin (g/dl)
- Bilirubin (mg/dl)
- INR
- Growth failure (based on gender, height and weight)
- Age at listing

4) At the local, regional and national level, the allocation of a **heart graft** is based on scores which take into account the weight (>15 kg), the blood group, the medical status, the length of the time from the registration on the waiting list.

5) **HLA**
It is mandatory for kidney transplantation, **optional for the heart.** The technique used to report the HLA should be based on **PCR with 2 decimals** (HLA A, B, DRB and DQB). Donors and Recipients awaiting organ transplantation should share the same HLA nomenclature utilized by the software of NOD-Lb.

6) **Anti-HLA antibodies (PRA): Class I & Class II**

a) It is mandatory to have a Quantitative PRA if the Qualitative PRA is positive:
- To specify the antigens to which the recipient is immunized
- and define the degree of immunization

The patient cannot be otherwise listed.

b) A patient awaiting organ transplantation is defined as immunized to class I or class II under the responsibility of the transplanting team.

c) When adequately registered, these immunized patients benefit from a national priority. **They have to repeat the PRA once a year or one month after any new immunizing event.**

d) Quantitative PRA with specification of the immunized antigens and the percentage of positivity is mandatory for: Patients have received blood, a previous transplantation, acute infection, vaccination, assist device placement... and multiparous women.

e) In case of assistant device:
- When the patient is put on an assistant device, a search for anti-HLA antibodies with the PCR technique is required (since there is almost a systematic transfusion support).
- After the installation of the assistant device:
  - If the clinical condition of the patient does not require further transfusions: two studies of antibodies anti-HLA antibodies between D15 and D21 and D30, and every six months is sufficient.
  - If the clinical condition of the patient requires blood transfusions: the frequency of search for antibodies will be modified accordingly. (one determination of PRA 3 weeks after transfusion)

7) **Age matching:**

A. **For the kidney**

The age match accepted for expanded donors: Age between 60 and 75 yrs

- Healthy old donor, i.e.:
  - ✓ Controlled Hypertension
  - ✓ GFR >70 ml/min on admission
  - ✓ Diabetic: without proteinuria
  - ✓ A baseline biopsy is preferable.

B. **For the liver:**

The age match accepted for expanded donors: Age >60 yrs

- Healthy >60 yrs old donor:
  - ✓ Accepted length of time with cardiac arrest <10 min
  - ✓ Normal enzymes on admission

C. **For the heart:**

The age match accepted for expanded donors: Age 65 yrs

- Healthy 65 yrs old donor:
  - ✓ No valvulopathy
  - ✓ EF 50%
  - ✓ No diabetes

▶ **The conditions of donor maintenance for heart allocation:**

✓ Coronary angiography and Central venous Pressure (CVP) are mandatory. If the donor has **one** of the following conditions in his past medical history:

- Segmental wall motion abnormality on echo
- Troponin elevation
- History of chest pain
- Abnormal EKG consistent with ischemia or myocardial infarction
- EF <40%
- Or **Two or three** of the followings:
  - Cocaine use
  - Diabetes
  - Hypertension
  - Hyperlipidemia
  - Intra-cerebral bleeding
  - Significant smoking
  - Strong family history of coronary artery disease

D. Age matching for standard deceased donors:

- 4-31 yrs should be matched with pediatric patients <16 yrs.
- 4-60 yrs should be matched with recipients whose age is ± 15 yrs if no matched pediatric recipient is available.
- >60 yrs see as describe above

8) **Pre-emptive transplantation: (Kidney transplantation)**

- CrCl: ≤ 20 ml/min

9) **Software selection**

For the kidney

a) The software sorts the top three recipients from the local list, according to their score. The list is proposed by NOD-Lb to the treating physician and to the transplanting team. If there is a medical contraindication, the graft is assigned to the next patient with highest score and negative cross-match.

Any exception must be justified with written report and sent within 48 hours to NOD-Lb.

b) In the absence of national priority, the software then sorts 7 patients from the national list with the highest score. The list is proposed by NOD-Lb to treating physician and to the transplanting team. If there is a medical contraindication, the graft is assigned to the next patient with highest score and negative cross-match.

c) If the donor does not match with a Lebanese recipient registered on the waiting list, the kidney can go to a matching non Lebanese patient registered on that list.

For the liver and the heart:

In the absence of national priority, the software then sorts 3 patients from the national list with the highest score. The list is proposed by NOD-Lb to treating physician and to the transplanting team. If there is a medical contraindication, the graft is assigned to the next patient with highest score and negative cross-match.

10) **Emergency**

For the kidney

a) When the transplant team requests to put his patient on the emergency list particularly when carrying on dialysis is impossible, NOD-Lb has to consult the Kidney Expert Committee on call.

b) The expert on call has to answer NOD-Lb by telephone and then send a written confirmation within 2-3 days by fax to 05955902/903 or by e-mail (info@nodlb.org).

c) NOD-Lb transmits the decision to the transplant team by fax.

d) If the agreement is given to consider the case as an emergency, NOD-Lb will put the patient on the emergency list.

e) The formalities to register a patient on the emergency list will be accepted only during the regular working hours.

For the liver: acute liver failure, HCC according to the Milan criteria.

For the heart: NOD-Lb contacts the different cardiac transplant centers to check on the presence of an extremely emergent case.

Experts Committee for the kidney, liver and heart

A. Structure of the committee of experts

1) It consists of representatives of the Kidney, liver and heart transplant centers equally divided between internists and surgeons.
2) Mandate: One-year term
3) The head of the committee will be appointed by the involved group and approved by the General Director of NOD-Lb from a list of internists and surgeons proposed by each medico-surgical team.
4) The services are provided on a free of charge basis.
5) The committees are: Kidney Experts Committee (KEC), Liver Expert Committee (LEC) and Heart Experts Committee (HEC)

B. Mission of the experts:

- Establishing an on call list for the emergency requests: name of the internist or surgeon.
- Meet 3 times a year in the presence of a representative from NOD-Lb.
- Emergency cases:

a. To be registered on the emergency national waiting list, it requires:

- **The first step** is to register the patient duly on the national waiting list. (See General Rules)
- **The next step** is to apply for registration on the emergency category, it requires:
  - ✓ The emergency accepted by the kidney transplanting teams is restricted to **poor access to dialysis.**
  - ✓ The emergency accepted by the heart transplanting teams is restricted to **the decision of the cardiac transplant teams and the HEC.**
  - ✓ The emergency accepted by the liver transplanting teams is restricted to **acute liver failure, HCC according to the Milan criteria.**
  - ✓ The emergency problem should be clarified and documented by an official medical report signed by the treating physician, the surgical and medical transplant team. If this justifies an exception from iso-group to ABO compatibility, it should also be mentioned.
  - ✓ This report will be mailed or faxed to NOD-Lb, (Fax: 05.955902/903) (info@nodlb.org)
  - ✓ NOD-Lb will transmit all the documents to the physician from the KEC or LEC or HEC on call. He will contact the committee to discuss the case and if necessary the transplant team.

b. The physician on call from the above mentioned committees transmits the written and signed decision of the concerned committee to NOD-Lb by fax or e-mail within eight days. (Within 48 hours in case of vital emergency).

c. NOD-Lb will act accordingly and transmit the signed report of the KEC, LEC and HEC to the transplant team.

d. Exceptions

These exceptions might apply at the local or national level according to the expert's opinion.

- Unless specified otherwise by the transplant team and the KEC the criteria applied for an exception of the iso-group are as follows:
  - Patients with rare blood group, for which the probability to access a graft is very low (in particular due to a previous immunization).
  - Patients of blood group AB will have access to grafts from group A.

- For the kidney:
  - Application to register a patient over 16 years in the pediatric priority category: This registration applies only to patients with growth retardation that can still benefit from an early transplantation.
  - If a patient loses his graft in ≤ than 3 months, the initial date of registration will be considered to calculate his waiting time. If the graft survives for more than 3 months, the KEC will have to decide about his waiting time and inform NOD-Lb.

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REPUBLIC OF LEBANON
GENERAL DIRECTORATE
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NOD-Lb