



## **GOVERNMENT OF KERALA**

### **Abstract**

Health & Family Welfare Department - Organ transplantation - Guidelines for altruistic and exchange donation - Judgment dated 24.11.2017 of the Hon'ble High Court of Kerala in a batch of Writ Petitions including W.P(C)No.33801 of 2017 (A) - Complied with - Orders issued.

---

### **HEALTH AND FAMILY WELFARE (B) DEPARTMENT**

G.O(Ms.)No.26/2018/H&FWD. Dated, Thiruvananthapuram, 15.02.2018.

---

- Read:-
1. G.O (Ms) No.37/2012/H&FWD dated 04.02.2012.
  2. Judgment dated 24.11.2017 of the Hon'ble High Court of Kerala in a batch of Writ Petitions including W.P(C) No.33801 of 2017 (A) .
  3. Letter No.354/18/KNOS dated 10.01.2018 of the Nodal Officer, Kerala Network for Organ Sharing.
  4. Minutes of the Cadaver Transplant Advosory Committee held on 27.01.2018 at NHM Conference Hall.
  5. Letter No.361/2018/KNOS dated 09.02.2018 of the Nodal Officer, Kerala Network for Organ Sharing.

### **ORDER**

The Hon'ble High Court, as per the Judgment read as 2<sup>nd</sup> paper above, have disposed a batch of Writ Petitions seeking permission to make advertisement in print media for kidney with the following directions:-

- (1) As per the Government Order read as 1<sup>st</sup> paper above, Government have formulated the procedure for Transplantation of Human Organs to carry out Cadaver Organ Transplantation Programme. The procedure provides for registration of intending recipients through the hospitals and a prioritization based on the condition of the patient. This shall be followed in the case of live donations also, till the Government brings out separate procedures for living altruistic donations. The KNOS can be entrusted with this onerous responsibility also, for the present, in view of the prevalent requests for transplantation.

- (2) The petitioners can register themselves with the KNOS, through the hospitals indicating their blood type or whatever details are required for organ transplantation.
- (3) The KNOS shall make periodic press releases seeking willingness for donation of organs on purely altruistic motives.
- (4) Any application received shall be processed, initially with a psychological evaluation and then finding a suitable registered individual requiring donation.
- (5) The identification of the recipient and the cross match for deciding compatibility shall be done with a team of Doctors as decided by the Nodal Officer and the expenses incurred shall be reimbursed by the intended recipient.
- (6) The entire procedure shall be carried out ensuring anonymity of the donor and the expected recipient and eventually with approval from the Authorization Committee. The Guidelines for Authorization Committees brought out by Notification No. 14931/S2/2009/H&FWD dated 19.11.2010 shall apply in these cases also.
- (7) The State can bring out fresh procedure and guidelines, in consultation with the Advisory Committee constituted as per the Government Order read as 1<sup>st</sup> paper above.
- (8) The Chief Secretary shall take expeditious steps to formulate a procedure and bring out guidelines for altruistic non-directed donations; with anonymity maintained of the donor and the recipient.
- (9) The State Government shall also ensure that there is a regular follow up of the donor and the recipient, for statistical purposes and also to provide a support system for the donor.
- (10) A fund could also be created to accept donations from the public or under Corporate Social Responsibility to provide a support system for those donors who are motivated only by altruism.

2. On the basis of the Judgment of the Hon'ble High Court, the Nodal Officer, Kerala Network for Organ Sharing, as per the letter read as 3<sup>rd</sup> paper above, have submitted draft guidelines for altruistic and exchange (SWAP) donation with the following objectives:-

- (1) To encourage altruistic organ donation.
- (2) To prevent trade in organs and to overcome organ shortage.
- (3) To safeguard the interest and welfare of living organ donors by ensuring that:

- a. Living donors receive adequate and appropriate medical, psychiatric and psychosocial evaluation before the surgical procedures.
  - b. Living donors are adequately and appropriately informed about the surgical procedures in line with the principle of informed consent.
  - c. The health needs of living donors are taken care of post surgery.
- (4) To make it possible for living donors to ensure that their near and dear ones receive organs even if their organs are incompatible for transplant.
- (5) To preserve ethical and professional standards in organ donation and transplantation in the State of Kerala.

3. The proposal was discussed in the Cadaver Transplantation Advisory Committee (CTAC) meeting held on 27.01.2018. As directed by the Committee, the Nodal Officer, KNOS, as per the letter read as 5<sup>th</sup> paper above, have submitted revised guidelines for altruistic and exchange (SWAP) donation, incorporating the modifications suggested by the Cadaver Transplantation Advisory Committee.

4. Government have examined the matter in detail and are pleased to issue the following guidelines for altruistic and exchange (SWAP) donation to encourage altruistic organ donation, to prevent organ trade and to overcome organ shortage.

### **The process of getting an organ**

Recipient registration- all end stage organ failure patients must be registered in the registry. The recipients shall get organ in four option

- i Related donation - as defined by the Transplantation of Human Organs Act, 1994 (THOA).
- ii Unrelated donation- after due approval from the Authorization Committee
- iii Exchange donation
- iv Brain death donation

### **Types of living donors who can donate organs are:**

1. Near Related Organ Donors (*As per Transplantation of Human Organs and Tissues Rules, 2014, the groups coming under this category are spouse, mother, father, brother, sister, son, daughter, grandfather, grandmother and grandchildren*)

2. Unrelated Organ Donors (Approval from Authorization Committee is mandatory)
  - a. Donors other than near relative (Uncle, Aunt, Cousin etc.)
  - b. Altruistic Organ Donor

### **Altruistic Organ Donor - Registration**

Many people donate organs to strangers in response to their appeals in print or electronic media; others donate to anyone on the waiting list or initiate a domino chain of organ donation. The current concerns on commercialization of donation can be reduced by removing the direct link between the person who offers to donate and the recipient. The link can be removed by adding all potential donors and patients who need transplant to a common pool through a registry.

(1) KNOS shall create awareness among public for altruistic live organ donation. If donors are interested in live altruistic donation, suitable recipient identification shall be done by matching algorithms. Preliminary investigation of the donor to assess the fitness for donation shall be done free of cost by any licensed transplant centres or Government hospitals. After initial screening and assessment of fitness for donation, these donors can register in the live donor registry after their HLA typing .

(2) KNOS who will maintain the registry will prioritize patients based on objectively verifiable criteria.

(3) A person who wish to donate ("prospective living donor") shall register in KNOS registry and must fulfill the following pre- requisites:

- a. He /she must be an adult as defied by law that enables a person to give consent.
- b. He/she must be able to understand and assess all the information provided to him/her.
- c. He /she has been informed and understands the potential risk of the surgical procedures, other associated interventions (e.g. investigations) and other consequences.
- d. He /she is mentally and physically fit.

(4) All potential donors must be appropriately motivated, properly informed and aware of the inherent risk of a living donor transplantation procedure.

(5) The medical and psychosocial donor evaluation should not start before the potential donor has reached an initial decision that they wish to be a donor. The medical evaluation (including a psychosocial assessment by a mental health professional, where necessary) is essential and donation cannot proceed until a full medical assessment has taken place and the donor has given written consent to surgery in a prescribed format approved by Appropriate Authority.

(6) The prospective living donor shall be given enough time to understand all the information provided to him/her and make careful considerations before making a final decision to donate.

(7) He/she shall also have the freedom to acquire advice or a second opinion from any clinician or medical institution.

(8) The intention of a prospective living donor has to be altruistic. Commercial transaction in exchange for an organ is strictly prohibited. The organ shall not be obtained from the prospective living donor by coercion or any other form of inducement. The prospective living donor and prospective recipient shall be made aware of such prohibitions.

(9) A prospective living donor shall be made aware that he/she has the right to withdraw his/her consent to donate at any time without having to state any reason.

(10) At the time of consenting, candidate living donors are adequately informed on the medical issues involved in the living donation process but are also suitably made aware of the potential financial implications associated with their generous act.

(11) Living donors should submit the application to the respective Zonal Offices (Thiruvananthapuram, Kottayam, and Kozhikode) and through said Zonal Office, the prospective donors can register in KNOS for altruistic donation.

(12) A prospective living donor shall undergo an initial evaluation process to ascertain his/her suitability for donating organ.

#### (13) Psychosocial Assessment

The psychometric tools for the psychosocial follow-up and the assessment of potential risks and protective factors:

- a) Quality of life
- b) Mental health/Psychological well-being
- c) Satisfaction with the donation process
- d) Expectations and motivation for donation
- e) Information received about the donation process
- f) Socioeconomic status
- g) Social support

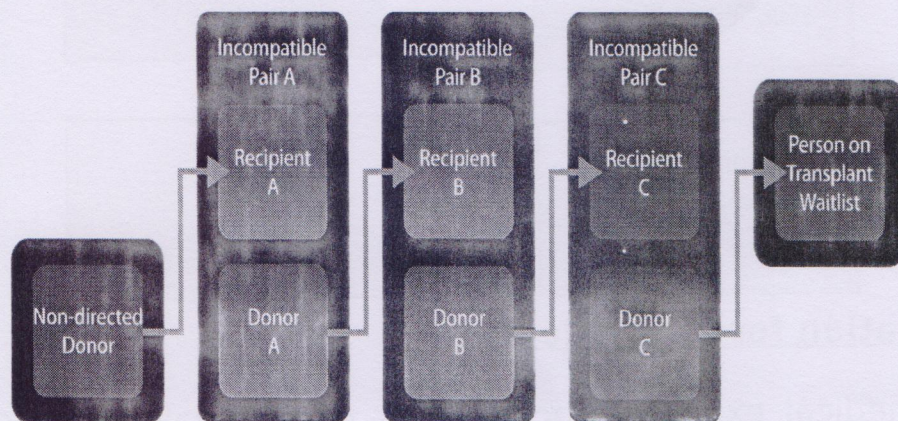
h) Employment status

(14) The preliminary examination of the donor will be done by the Zonal Office and the cost incurred by the evaluation shall be reimbursed by the recipient.

### **Altruistic Kidney Donation and Transplantation Process**

- (1) End-stage kidney patients, who needs to undergo kidney transplantation (live and deceased) should register in KNOS registry through a licenced transplant hospital.
- (2) End stage kidney patient those who wish to undergo live kidney transplantation should consult with the Regional Office of KNOS in the respective Zone.
- (3) Patients without any donor offering to donate on their behalf will only be considered for altruistic donation or deceased donor transplantation programme. Such organ recipient must fulfill the following criteria:
  - a. No compatible donor among near relatives
  - b. The recipient has a suitable living donor available among near relatives, but the donor has refused to donate in writing.
- (4) The potential live altruistic donor has full freedom to select the transplant hospital, but not the recipient.
- (5) The suitable recipient will be selected by computerized selection programme in KNOS based histo compatibility match and priority as per identified criteria.
- (6) The financial impact on the living donor is cost neutral. Living donors to receive reimbursement of expenses related to the donation, such as travel costs, additional costs (support in house etc.) and coverage (or support to meet) of loss of income, which is a direct result from the donation procedure and it should be reimbursed by the recipients.
- (7) Financial support for any complications related to donation must also be included and this bears by the recipients.
- (8) The direct costs related to living donor kidney transplantation can be broadly divided into following three major categories, according to their timing of occurrence.
  1. Direct costs incurred before donation/transplantation - These shall include the following:
    - a. Laboratory tests
    - b. Diagnostic imaging

- c. Outpatient services
  - d. Physician fees
  - e. Dialysis costs
  - f. Medications
2. Direct costs incurred at the time of donation / transplantation- These shall include the following:
- a. Laboratory tests
  - b. Diagnostic imaging
  - c. Donor/Transplant surgery
  - d. Inpatient stay
  - e. Physician fees
  - f. Dialysis costs
  - g. Medications
3. Direct costs incurred after donation/transplantation - These shall include the following
- a. Laboratory tests
  - b. Diagnostic imaging
  - c. Outpatient services
  - d. Physician fees
  - e. Medications
- (9) If a recipient have an incompatible donor by virtue of the positive cross match or incompatible blood group, who is willing to donate to a person in the waiting list, will get preference over others. This can generate chain donation system so that one altruistic donor create a chain which can help many recipients in the list as illustrated below:

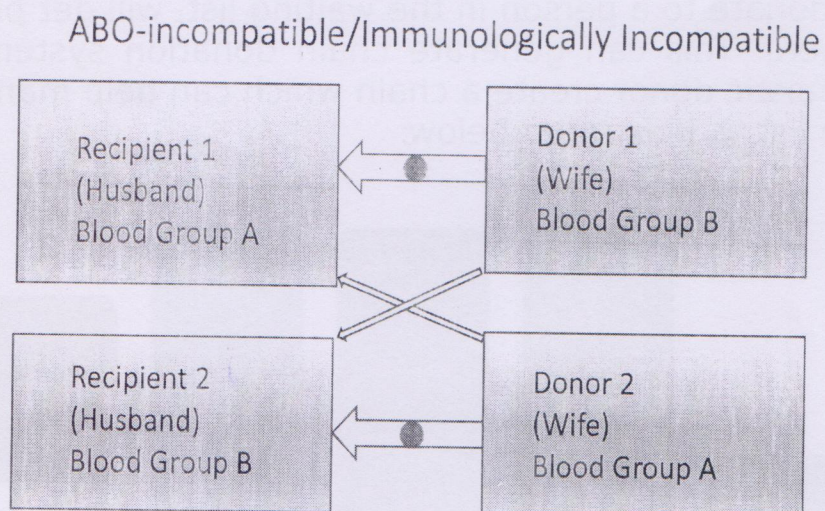


## Swap donation

The donors donate organs to strangers in exchange for getting the best matched organ for their near relatives or friends to whom they intend to donate organs. Blood group incompatible donor recipient pair can exchange donor with another blood group incompatible pair. There are more than one pair and if more than one hospital is involved, the donor will have to travel to the recipient hospital, the donor organ removal must be started simultaneously in both the hospitals. If there are more than one pair, donor recipient matching will be done by a computer assisted matching algorithm which will be designed by NIC. For this donation process KNOS will have separate Web based registry.

The patients with kidney failure, who have a blood group compatible donor (near relative). but with positive lymphocyte cross match, can be registered under Swap Donation Registry.

The cases of swap donation referred to under subsection (3A) of section 9 of the Transplantation of Human Organs Act shall be approved by Authorisation Committee of hospital or district or State in which transplantation is proposed to be done and the donation of organs shall be permissible only from near relatives of the swap recipients.



## Compensation for altruistic donor

- (1) All medical expenses incurred for donor evaluation and donor surgery must be borne by the recipients. The donor also should be compensated for loss of income which will be limited to Rs.50,000/- (Rupees Fifty thousand only) per month for three months. The donor will be provided with free health insurance



during his/her entire life time under any of the Health Insurance Scheme of Government.

- (2) The recipient, who receive organ from an altruistic donor or a swap donor must pay organ utilization fee to KNOS @ Rs.2,00,000/- (Rupees Two lakh only) for covering health expenses of altruistic donor.

### **Paired Kidney Donation- Steps to be followed**

- (1) All related living donors who are found to be incompatible with their intended recipient will be offered the option of enrolling in the Kerala Network for Organ sharing Paired Kidney Donation program.
- (2) Any patient consenting for Paired Kidney Donation will be enrolled into the KNOS Registry.
- (3) All donors enrolled in the Paired Donor program will need to have Paired Donor Typing completed (3<sup>rd</sup> Generation HLA typing in NABL accredited Lab) after initial medical and psycho social evaluation of the donor. This can be done in the hospital where the recipient is being planned for transplant surgery.
- (4) After primary evaluation of recipient and donor, the donor recipient pair shall submit formal request to KNOS through the transplant centre in respective Zonal Offices.
- (5) The team constituted in the Zonal Offices of KNOS will examine the application in detail and will register this patient in the swap registry.
- (6) The computer application will identify the best HLA compatible donor recipient pair. Upon completion of paired kidney donation match runs all potential pairs are reviewed by members of the medical staff to identify recipient/donor appropriateness.
- (7) Only patients for whom potential donors have registered as willing for paired donation will be considered to receive organs from other paired donors.
- (8) All potential donors identified by the Paired Kidney Donation match runs will be contacted to determine if they are still interested in the program.
- (9) In the event of any of the donors linked to a potential recipient refuses to donate his/her organ to the recipient who has been identified to receive the organ the patient to whom he/she was linked will be removed from the paired registry and the organ offered to the patient next in priority.
- (10) The appropriate cross matching between recipient/donor pairs also will be conducted

- (11) This identified donor recipient pairs will be interviewed and counselled on swap donation process and they are referred to the transplant centre according to their preference.
- (12) Potential donors will undergo the donor evaluation at respective transplant centre and submit to the Authorization Committee for final approval.
- (13) After due approval of the Authorization Committee, the transplant centre can proceed with transplant surgery. Both pairs must be transplanted on same day, same time. The details must be sent to the Regional Office of KNOS.

### **Recipient registration, listing and allocation**

- (1) The patient must be registered by the concerned hospital through online registration (KNOS Web Registry)
- (2) A Kidney Advisory Committee shall approve registration and urgency criteria, if any. The Committee shall confirm the need of renal transplant of every newly registered patient. Once approved, only then the patient will be put on active list in the system and Allocation Scoring for that patient will be done on the guidelines formed.
- (3) The patient should be less than or equal to 70 years of age at the time of registration.
- (4) The patient should be a case of End Stage Renal Disease on Maintenance dialysis for more than three months on regular basis.
- (5) The patient should not have an absolute contraindication for renal transplant, as follows:
  - i. Advanced untreatable cardiovascular disease
  - ii. Irreversible cerebrovascular accident
  - iii. Inoperable malignancy
  - iv. Untreatable major psychiatric illness
- (6) The status of end stage renal disease patients waiting for transplant must be updated monthly by the hospital in one of the following status:
  - i. Active
  - ii. Suspended
  - iii. Lost to follow-up
  - iv. Transplant done
  - v. Death

For recipient selection, scoring system proposed by NOTTO will be used subjected to modification later.

**SCORING SYSTEM FOR MAKING PRIORITY (adopted from NOTTO)**

Sl. No.	Criteria for scoring	Points allotted
1	Time on dialysis	(+1) for each month on dialysis
2	Previous immunological graft failure within 3 months of transplantation	(+3) for each graft failure
3	Age of recipient	(+3), if < 6 years (+2), if 6-12 years (+1), if 12-18 years
4	Age matching between donor and recipient	(-2), if >30 years difference (-1), if > 20 years difference
5	Vascular access failure	
	Failed AV Fistula	(+1) for each AVF failure
	Failed AV Graft after failed AVF	(+2) for each graft failure
6	PRA (Panel Reactive Antibody)	(+0.5) for every 10% above 20%
7	Associated diseases resulting inferior outcome	
a	Failed treatment hepatitis B and C	(-1)
b	Advanced atherosclerosis disease	(-1)
c	High risk for general anaesthesia	(-1)
8	Near relative (as per definition of THOTA) of Previous deceased donor now requiring kidney transplant	(+5)

For patients with the same score, priority will be decided based on the seniority in the waiting list.

**Miscellaneous**

- (1) KNOS shall maintain an online registry to track the details of the transplant outcome of transplant recipients along with a donor medical follow-up.
- (2) The Transplant Centres accepting a living organ donor has the responsibility for coordinating medical follow-up after surgery. The follow-up must include both medical and psychosocial assessment.

- (3) The periodic donor follow-up and medical data must be submitted to KNOS Office till web based application is ready to use.
- (4) The transplant hospital shall ensure that a register or record of the living donors is kept, in accordance with Transplantation of Human Organs Act on the protection of the personal data and statistical confidentiality.
- (5) All unrelated, related living organ transplantations and swap donation details must be reported to the KNOS State Office on a monthly basis by the transplant hospitals in the prescribed format.
- (6) To effectively run the programme KNOS shall enter in to a Memorandum of Understanding (MoU) with each Transplant Hospitals.

5. The Judgment read as 2<sup>nd</sup> paper above is complied with accordingly.

(By Order of the Governor),  
RAJEEV SADANANDAN  
Additional Chief Secretary to Government

To

The Advocate General, Ernakulam (with C/L)  
The Director of Medical Education, Thiruvananthapuram.  
The Director of Health Services, Thiruvananthapuram  
All Members of Cadavar Transplantation Advisory Committee  
(Through Director of Medical Education)  
The Principal & Chairman, District Level Authorization  
Committee, Government Medical College,  
Thiruvananthapuram/Alappuzha/ Kottayam/Thrissur /  
Kozhikode.  
The Nodal Officer, Kerala Network for Organ Sharing, Super  
Speciality Block, Government Medical College,  
Thiruvananthapuram  
All Transplantation Centres (Through Nodal Officer, KNOS)  
Information & Public Relations Department (Web & New Media)  
Stock File/Office Copy.

Forwarded/By order

  
Section Officer

✓