

IN THE HIGH COURT OF JUDICATURE AT BOMBAY CIVIL APPELLATE JURISDICTION

WRIT PETITION NO. 3048 OF 2024

Mr. Harshad Rohidas Bhoite Versus

...Petitioner

State of Maharashtra & Ors.

...Respondents

Dr. Uday Warunjikar with Mr. Jenish Jain and Mr. Dilip Pandharpate i/b. Mr. Siddhesh Pilankar for Petitioner.

Ms. Neha Bhide, GP with Ms. P. J. Gavhane, AGP for State.

Mrs. Shehnaz Bharucha i/b. Mr. A. A. Ansari for Respondent Nos.3 & 4.

CORAM: G. S. KULKARNI &

ADVAIT M. SETHNA, JJ.

30 APRIL 2025. DATE

P.C.:

1. petition involves a peculiar issue arising under the Transplantation of Human Organs and Tissues Act, 1994 (for short, "1994 Act"). The concern of the petitioner is in regard to a pre-emptive kidney transplant. He is certified to be a patient of Chronic Kidney Disease (CKD) Stage-V, but not on dialysis. The petitioner asserts that being a patient of CKD stage-V, due to polycystic kidney disease, he would require a kidney transplantation from a cadaveric donor, as the petitioner was not having a suitable donor in his family. The petitioner accordingly intended a registration for cadaveric kidney transplantation. The grievance of the petitioner is that such application of the petitioner is not being registered.

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2. The concerned authority which would register the petitioner for kidney transplant is respondent no.2-Zonal Transplant Coordination Centre at Pune. Respondent no.2, however, is not accepting the petitioner's registration for kidney transplant referring to the "Allocation Criteria for Deceased Donor Kidney Transplant Guidelines", a copy of which is annexed to the petition (page 108A of the paper-book), which inter alia provides for recipient registration, listing and scoring system in the waiting list, on the ground that the petitioner does not comply with paragraph 3 of the said guidelines namely that the patient should be a case of end stage renal disease on maintenance dialysis for more than three months on regular basis. We note the guidelines which read thus:-

" ALLOCATION CRITERIA FOR DECEASED DONOR KIDNEY TRANSPLANT (GUIDELINES)

Preamble

Organ transplant has two sources: living donor and deceased donor. In case of living denor source, donor is already decided for a specific recipient. For deceased donor source, process, influenced by a number of factors including medical urgency and donor & recipient matching Following facts need to be kept in mind for organ allocation for kidney transplantation.

CERTAIN FACTS FOR END STAGE RENAL DISEASE (ESRD)

- 1. There is disparity between number of recipients requiring kidney transplant and the deceased organs available for kidney transplantation.
- 2. Some patients need, kidney transplant on priority basis because of their medical condition, as delay in transplant may lead to mortality.
- 3. For End Stage Renal Disease (ESRD), maintenance dialysis is an acceptable and reasonably good alternate therapy so for

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majority of ESRD patients, renal transplant is not an emergency procedure.

RECIPIENT REGISTRATION, LISTING AND SCORING SYSTEM IN THE WAITING LIST (Before deceased donor availability)

- 1 Patient is to be registered by the concerned hospital through online registration form on website wawwunattaughtwingov.in
- 2. A kidney advisory committee will approve registration and urgency criteria, if any.

The kidney advisory committee will confirm need for renal transplant of every newly registered patient. Once approved, ONLY then patient will be put on active list in the system and ALLOCATION SCORING for that patient will be done based on the guidelines formed.

- 3. Patient should be a case of End Stage Renal Disease on Maintenance dialysis for more than three months on regular basis.
- 4. Patient should not have an absolute contraindication for renal transplant, as given under:
 - a. Advanced untreatable cardiovascular disease
 - b. Irreversible cerebrovascular accident
 - c. Inoperable malignancy
- d. Untreatable major psychiatric illness (to be certified by a psychiatrist)
- 5. Patient should be registered ONLY in ONE hospital registered under the Transplantation of Human Organs and Tissues Act (THOTA) with State authority.

However, he/she can change the hospital at any stage and his allocation scoring and seniority in central waiting list will not change. However, his/her seniority in the waiting list of locally available kidney, with the new Hospital will be applicable one month after date of change.

- 6. Patient can be registered for deceased donor even though patient is waiting for living donor transplant.
- 7. Status of patient must be updated regularly by the hospital in one of the following status:
 - . Active
 - . Unfit
 - . Suspended

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- . Lost to follow-up
- . Transplant done
- . Death

SCORING SYSTEM FOR MAKING PRIORITY

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) for less than 6 years (+2) for 6 to less than 12 years (+1) for 12 to less than 18 years
4	Patient on temporary Vascular access	
(a)	With Failed all AV Fistula sites	(+2)
(b)	With Failed AV Graft after all failed AVF sites	(+4)
5	PRA (Panel Reactive Antibody)	(+0.5) for every 10% above 20%
6	Previous Living donor now requiring Kidney Transplant	(+5)
7	Near relative (as per definition of THOTA) of Previous deceased donor now requiring kidney transplant	(+5)

Note: Patients with the same score, priority will be decided based on the seniority in the waiting list

ALLOCATION PRINCIPLES

1. Allocation will be done first based on city waiting list. If no recipient eligible in city waiting list then allocation will be done to state and then to other States in the ROTTO and then to other ROTTO nationally.

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In order to minimize cold ischemia time, most donated organs should be allocated within the city or at the most state, where retrieval has been done.

- 2. Kidney from Pediatric donor (less than 18 years) first will go to pediatric patient. If no pediatric patient eligible, then to adult patient.
- 3. Blood group O kidney will be allocated to recipient with group O, then to next available on waiting list of other compatible blood groups i.e. first group A, then group B and lastly group AB in that sequence.
- 4. In case of blood group A or B, the organ will be allocated to same blood group failing which to blood group AB. AB will be allocated to AB only.

ALLOCATION ALGORITHM

Once there is a call for possible deceased donor

STEP-1: Check Blood Group of available deceased donor to follow principle of allocation based on blood group as above.

STEP-2: If there is recipient in "urgent list" as per accepted criteria and approved by the appropriate committee, then one of the two available kidneys will go to the urgent case.

If there are two recipients in the urgent list, then allocation will be done to one patient with urgent criteria having more points in the scoring system.

Criteria of urgent Listing

In case of kidney transplant, urgent list is basically for a patient on following two principles

- 1. Patient who no longer has dialysis access and thus cannot be maintained on dialysis
- 2. Patients with ESRD who is unlikely to get a donor with a negative cross-match.
 - . > 90% Panel Reactive Antibody (PRA)
- . Priority/urgent list should be reviewed every 3 monthly by the SOTTO Kidney Transplant Advisory Committee
- STEP-3: Recipient requiring multi-organ transplant will get priority.

Page 5 of 10 30 April 2025 If there are more than two recipients in the multi-organ recipient list, then allocation will be done to patient having more points in the scoring system.

STEP-4: If NO urgent case and NO multi-organ recipient, then allocation will be done to patient registered for Kidney alone' transplantation based on the status of hospital doing retrieval of kidneys means whether it is transplant hospital of retrieval only hospital

If Transplant Hospital

. One kidney be used locally and other will be allocated. It is expected that the scoring system will also be followed by the hospital for local allocation of kidney.

If Retrieval Hospital

Both will be allocated

STEP-5: See Kidneys retrieval hospital, whether it is government hospital or private hospital

- 1. Kidney retrieved from a government hospital will be allocated as follows
- . First patients listed in Government ONLY hospitals list, then
- . Patients listed out of combined government and private hospital list, then
 - . Patient listed out of private ONLY hospital list
- 2. Kidney retrieved from a private hospital will be allocated as follows:
 - . First patients listed in private hospitals list, then
- . Patients listed out of combined government and private hospital list, then
 - . Patient listed out of government hospital list

INTER-STATE ISSUES

- 1. It is expected that all SOTTOs will broadly follow the same guidelines/protocols for organ allocation.
- 2. The appropriate authority of state government in consultation with SOTTOs will approve the inter-state transport of organs for transplantation."

(emphasis supplied)

3. Thus, the premise, on which the registration is denied to the

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petitioner, is on the ground that the patient should be a case of a end stage renal disease on maintenance dialysis, for more than three months on regular basis as provided for in paragraph B(3) of the aforesaid guidelines. The contention of the petitioner is to the effect that the petitioner in the near future would certainly need a kidney transplant and it is just a question of some time. It is his contention that at the time when the need for kidney transplant becomes absolutely necessary, he should not be put to a prejudice and/or an unwarrented ordeal of being required to wait in a long queue for transplant, for want of timely registration. The concern of the petitioner is that the right to life also would include right to receive an organ transplant and for which he needs to be registered so that in the event dire urgency arises, and on medical certification he becomes entitled to receive a kidney. It is the petitioner's contention that such need is not recognized by the guidelines in question, which according to the petitioner can never override the provisions of the 1994 Act and more so the requirement of Article 21 of the Constitution.

4. Dr. Warunjikar, learned counsel for the petitioner has submitted that it cannot be that only after the condition of the petitioner worsens, he would be required to adopt the procedure for registration, and only then he would be registered. His submission is that this is not a reasonable

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approach. It is hence his submission that there has to be some mechanism by which the category of patients in which the petitioner falls, need to be recognized and more particularly, being patients who would be in imminent need of kidney transplant, so that their names as per seniority (as per date of the application) as contained in such list, can be considered and recognized to be shifted in the list of already registered candidates, whenever the urgency of a transplant occurs. It is his submission that the guidelines however do not permit such course of action and resultantly, a serious prejudice is being caused to the petitioner and several such patients who would imminently need a kidney transplant.

5. Having heard learned counsel for the parties, we are of the opinion that there cannot be two opinions that the guidelines in no manner would supersede the substantive legislation, namely, the 1994 Act. Further the human need for an organ transplant is directly a facet of right to life as guaranteed under Article 21 of the Constitution of India. *Prima facie*, a situation cannot be countenanced that when for any patient there is a need of an organ transplant, which might not be immediate but is imminent and/or in a situation that the patient is immediately not on dialysis, however, it is certain that in the near future the need for a transplant would arise, considering the medical condition of the patient, such situation

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would also be required to be paid attention by the respondents. The object and intention of the Act is to provide for the regulation of removal, storage and transplantation of human organs and tissues for therapeutic purposes and for the prevention of commercial dealings in human organs and tissues and for matters connected therewith or incidental thereto. It is in the context of these objects and intention, the provisions of the 1994 Act would be required to be construed and considered, while recognizing the right to life of a patient. The provisions of the rules and any guidelines framed thereunder are required to be interpreted and recognized in such context when it concerns kidney/organ transplant. However, the consideration of these issues and/or framing of rules and guidelines is the domain of the respondents. Our concerns in the present proceedings is limited, and to the effect that the statutory and Constitutional rights of the petitioner are recognized and remain protected.

6. In the aforesaid circumstances, we are of the opinion that it would be appropriate for the respondents to consider whether a separate registration facility could be provided to those patients, who in future would imminently require an organ transplant, so that as and when the need for a transplant arises, such list can be operated on proper medical certification and such persons can be recognized to receive an organ for a transplant. In

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so observing what weighs with us is also a factor is of a ease of procedure for

such category of patients would obliviate their difficulties in having a

registration at the appropriate time and not after the patient gets critical or

his medical condition deteriorates. When the health and life at such stage

of the patient itself is rendered delicate and worrisome, any procedure for

such basic requirement of registration needs to be of absolute ease and

comfort. An appropriate response in this regard be considered and placed

before the Court on the adjourned date of hearing.

7. Accordingly stand over to 17 June 2025 (H.O.B.).

[ADVAIT M. SETHNA, J.]

[G. S. KULKARNI, J.]

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