

MEDICAL TESTS

8. The Sub-Committee-I was asked to recommend the modalities concerning tests (especially HLA, DNA tests etc) for establishing the “near relatives” and compatibility of the donor and recipient.

9. Based on the report of Sub-Committee-I, the recommendations of the Committee are as follows :

(1) If a medical practitioner, in a given case is required to ascertain the factum of ‘near relative’ through medical evidence, he should ensure the following :-

(a) that the donor has given his authorization in the appropriate Form;

(b) that the donor is in proper state of health and is fit to donate the organ, and thereafter he shall sign a certificate specified in the appropriate Form;

(c) that the Authorisation Committee has certified the relationship.

(2) Where ‘near relatives’ as defined in Section 2(i) of THOA Act, which include spouse, son, daughter, father, mother, brother and sister, are required to be tested in accordance with Rule 4 of THOA Rules, the following procedure may be followed :-

Recommended procedure for medical tests for establishing genetic relationship between the recipient and “near relatives” are as follows:-

(i) The tests for HLA, HLA-B alleles to be performed by the serological and/or PCR based DNA methods.

(ii) Test for HLA-DR beta genes to be performed using the PCR based DNA methods.

(iii) Where the above two tests does not establish a genetic relationship between the donor and the recipient, the same tests to be performed on both or at least one parent. If parents are not available, same tests to be performed on such relatives of donor and recipient as are available and are willing to be tested.

(iv) Where the tests referred to above do not establish a genetic relationship between the donor and the recipient, tests for DNA fingerprinting using single locus/multilocus polymorphic probes to be performed.

(v) The Head of the testing laboratory should state in writing whether or not he/she is satisfied that the claimed genetic relationship between the donor and the recipient is established

(3) The requisition for HLA test should be sent by the treating physician on the laboratory Proforma along with the photographs of the recipient and the potential donor duly attested by the requisitioning physician. A copy of the certificate signed by the donor that he/she is a 'near relative' of the patient should be enclosed.

(4) In case recipient is a spouse of the donor, record the statement of the recipient and the donor to the effect that they are so related and shall sign a certificate in the appropriate Form.

(5) The testing laboratory to be approved by the Director Health Services of state/UT as 'competent' both to specify and to interpret the results of the genetic tests.

1. Comment on the Availability of the tests

The HLA tests for defining genetic identity mentioned in sub-rule i) and ii) of Rule 4 are available in most centers involved in the organ transplant program. Commercial kits are available from several companies and a certified competent laboratory and the testers should have no difficulties in proper conduct of the tests and interpretation of results.

Tests mentioned in sub-rule iv) of Rule 4 which will be required only rarely are available in a few specified centers/institutions. In case of urgency on medical ground where one cannot wait for the results of tests mentioned in sub-rule iv) the case may be recommended for consideration by the Authorization Committee with request to take a decision on the basis of the available material without insisting on a test mentioned in sub-rule iv) which is not immediately available or time-consuming.

2. Comment on the cost of the tests

In a Government hospital like the AIIMS, a doctor-recipient pair testing for HLA-A, B by serology and HLA-DR by PCR based DNA based methods costs Rs.7,000/-. On the other hand,

the private hospitals like the Sir Ganga Ram Hospital charges Rs.12,000/- as a package. The cost varies further in other laboratories or hospitals.

3. Comment on the reliability of the tests.

Using serological techniques, it is possible to define 17 alleles in HLA-A locus and 31 in HLA-B locus. Similarly, the PCR-based methods can define 18 alleles at the HLA-DR locus. This number is sufficient to define genetic identity between the donor and the recipient. It is important, however that the testing should be done by only those laboratories which are infrastructurally equipped and that are approved and 'certified' by the Directorate of Health Services of State/UTs and are thus competent. Similarly, it is necessary to certify the testers.

4. Similarly the DNA finger printing tests mentioned in sub-rule iv) are highly reliable.

5. Comment on any differences in tests required to establish 'near relative' status for different organ transplants namely kidney, liver, heart.

Defining 'near relative' status by doing genetic test for organ transplants has dual purpose – one is scientific (medical) and the other ethical.

6. Genetic tests to establish the factum of relationship between the donor and the recipient are essential prior to kidney transplantation because they address both the issues, namely medical (better HLA matching translates into improved graft survival) as well as ethical (curbs commercial dealings in the transplantation of organs as required in the Act and Rules).

7. Although for liver transplants, HLA tests are not essential (although there is some debate that they may be desirable) for medical reasons, they are required for ethical reasons in situation involving live donor for liver transplantation. It may not always be possible for the medical practitioner or the "authorization committee" to ascertain the identity of the proposed donor who claims to be a 'near relative' for a transplantation of an organ like 'liver' and therefore medical tests would be advisable in all cases of 'near relative'.

8. As for Heart transplants, the organ is always from the cadaver donor. The tests to prove genetic relationship are, therefore, not required.

9. Paragraphs 8 to 16 above, thus addresses the fourth reference point as set out in Balbir Singh case.