

Pursuant to the above discussions with the committee members and the special invitees particularly, Dr. (Mrs.) Anita Roy, IPS and after perusal of the report of the sub-committee-I, the Sub-Committee-II, submitted its report, addressing all points of terms of reference as set out in Balbir Singh case. The Sub-Committee-II further suggested amendments in the Act, Rules and Forms. The recommendations of the report are based on sub committee II report and are as under:-

## **PART II – RECOMMENDATIONS**

1. The committee is of the view that the responsibility of certifying a donor as ‘near relative’ ought not to be placed on the transplant surgeon or any medical practitioner conducting the medical tests to assess the factum of ‘near relative’. The present practise puts an unnecessary and avoidable pressure on the concerned medical practitioner and he becomes vulnerable to accusations if something goes wrong. Therefore, there is a definite need to develop a mechanism where all proposed donors including ‘near relatives’ should be scrutinised by a committee (the authorization committee), particularly, keeping in view, the larger objective of ruling out commercial considerations.

2. The committee is therefore of the view that the jurisdiction of the Authorization Committees should be enlarged by bringing within its ambit the process of certifying a ‘near relative’ as well. No fruitful purpose will be served by creating another designated authority for the said purpose. Experience of the medical practitioners and police has indicated that there have been several instances where the donors are sought to be projected as near-relatives in order to avoid scrutiny by the Authorization Committees. By way of illustration, we may visualize a case where a particular proposed donor, who initially represents himself as a near relative, on a scrutiny of evidence, turns out to be a non-near-relative, whose affection or attachment with the recipient cannot otherwise be doubted. If there are two different committees then he is likely to be referred to the other Authorisation Committee. In such cases, there may be an inherent prejudice against him for initially misrepresenting himself as a near-relative and in this process a genuine case of donation of an organ for transplant may be delayed or jettisoned. Therefore, in order to maintain consistency, to save valuable time, to achieve functional efficiency and avoid duality of authority, it is desirable that scrutiny of all types of donors, both those of relatives and non-relatives should be carried out by the same authority i.e. Authorisation Committee. This will also help in eliminating the frivolous attempts laced with commercial incentives to project a non-relative as near-relative which often occurs, as indicated above, to avoid scrutiny of authorisation committee.

3. The next question that emerges is as to what should be the process of certifying the eligibility of the donor within the parameters of the legal provisions of THOA Act and THOA Rules. However, this question is interlinked with the question of the composition of the Authorisation Committees and the guidelines to govern the working of the Authorisation Committees. Once the composition and the working guidelines of the Authorization Committees are determined, the procedural aspects can easily

be identified and recommended. In order to recommend a desirable composition of the Authorisation Committee and formulate effective guidelines for the functioning of the Authorisation Committees, it will be imperative for the Committee to look into the existing legal provisions of the THOA Act and THOA Rules and include in its recommendations, the desirable modifications as well, keeping in view the observations made in the Balbir Singh case and the experiences of the medical practitioners and the law enforcing agencies.

#### 4. AUTHORISATION COMMITTEES

The committee has observed that in Metropolitan Cities, for different hospitals, providing facilities of transplantation surgery, there are distinct and independent Authorisation Committees. In the considered view of the committee, this practice of hospital based Authorisation Committees is workable and practical in Metropolitan Cities and large capital cities of states where within the city, large distances need to be traveled and it may not be possible for the medical practitioners and other members of the committee to leave hospital and go to another place for attending the meeting. The increasing vehicular traffic in such cities restricts the mobility. But, in non-metropolitan cities and smaller capital cities of states, a single Authorisation Committee for the entire district or a Division comprising of several Districts, depending upon the factors like size of population; number of transplantation centers available within the territory and other administrative exigencies, would serve the purpose.

##### A. COMPOSITION OF HOSPITAL BASED AUTHORISATION COMMITTEES :( to be proposed by institution and notified by Govt.)

- Ø The senior most person officiating as Medical Director/Medical Superintendent of the Hospital.
- Ø DM/ADM/SDM of the District which include the officers holding equivalent post in hierarchy irrespective of nomenclature of the designation. (To be nominated by concerned State/UT Govt.)
- Ø Two senior medical practitioners from the same hospital who are not part of the transplant team.
- Ø Two members being persons of high integrity, social standing and credibility, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in UGC approved University or are self-employed professionals of repute such as lawyers, chartered accountants, writers, journalists and doctors (of Indian Medical Association) etc.
- Ø One Medical Practitioner working in a Government hospital to be nominated by the Central/State Government.

##### B. COMPOSITION OF STATE/ DISTRICT LEVEL AUTHORISATION COMMITTEES (to be constituted by concerned State/UT Govt.)

- Ø A Medical Practitioner officiating as Chief Medical Officer or any other equivalent post in the main/major Government Hospital of the District.
- Ø DM/ADM/SDM of the District which include the officers holding equivalent post in hierarchy

irrespective of nomenclature of the designation.

Ø Two senior medical practitioners to be chosen from the pool of such medical practitioners who are residing in the concerned District and who are not part of any transplant team.

Ø Two senior citizens, non-medical background (one lady) of high reputation and integrity to be chosen from the pool of such citizens residing in the same district, who have served in high ranking Government positions, such as in higher judiciary, senior cadre of police service or who have served as a reader or professor in UGC approved University or are self-employed professionals of repute such as lawyers, chartered accountants, writers, journalists and doctors (of Indian Medical Association) etc.

Ø One Medical Practitioner working in a Government hospital to be nominated by the concerned State/UT Government.

(Note: Effort should be made to have most of the members' ex-officio so that the need to change the composition of committee is less frequent.)

### C. QUORUM

Quorum of the Authorisation Committee should be minimum four. However, quorum ought not to be considered as complete without the participation of the Administrative head of the hospital (for hospital based committees) or alternatively the person officiating a Chief Medical Officer of the District (for District or Division based Authorisation Committees) DM/SDM/ADM (as the case may be), one Medical Practitioner working in a Government hospital nominated by the concerned State/UT Government, and one member from the non-medical background. The members present in the meeting should be at liberty to opt/nominate any one amongst them to preside as Chairperson.

### D. FREQUENCY OF MEETINGS OF THE COMMITTEE

The frequency of meeting of authorisation committee should depend upon the work load with provisions for emergency meetings, if required. The frequency should be such that under normal circumstance, the Authorisation Committee is able to give its decision at the earliest and not later than two weeks of receiving an application completed in all respects and supported by all required documents.

### E. NOTICE OF MEETINGS TO THE MEMBERS

For the ordinary meetings, the Chairperson of the meeting shall fix a mutually agreed convenient date for each meeting and change in such date, if any, should ordinarily be communicated by the Chairperson to all the members with advance notice of minimum two days.

For emergent meetings, advance notice of two days from the office of Chairperson should be considered as adequate. However, if quorum is incomplete due to non-availability of an indispensable member, attempt should be made to hold the adjourned meeting within three days from the date for which such emergent meeting was originally fixed.

## F. JURISDICTION

The territorial jurisdiction of both types of the authorisation committees should extend to the territorial limits of the entire district or division as the case may be. Its function at jurisdiction should extend to consider and process all such cases:-

- i) where transplantation activity is proposed to be carried out at a hospital/centre located within its jurisdictional territory;
- ii) where, though the transplantation centre is not located within its territorial jurisdiction the donor or the recipient or both ordinarily reside within its jurisdiction and its receives a request from another "Authorisation Committee" to scrutinize, process, consider, determine and report such aspects/facts/issues as may be specified in such request.

## G. GUIDELINES FOR WORKING OF THE AUTHORISATION COMMITTEE

1) Secretariat of the Committee shall circulate copies of all joint applications received from the proposed donors and recipients to all members of the Committee at least three days before ordinary meetings and at least a day before the date of emergent meeting. Such applications should be circulated along with all annexures, which may have been filed along with the applications. At the time of the meeting, the Authorisation Committee should take note of all relevant contents and documents in the course of its decision making process and in the event any document or information is found to be inadequate or doubtful, explanation should be sought from the applicant and if it is considered necessary that any fact or information requires to be verified in order to confirm its veracity or correctness, the same be ascertained through the office of the jurisdictional DM/ADM/SDM or through any other competent officer, or relevant ministry of state/UT Govt., who shall ensure that such fact or information is gathered or verified from the relevant original source whether the same falls within the jurisdiction of the said district or outside the district falling under the jurisdiction of the Authorisation Committee. In case such information/fact needs verification from place outside the jurisdiction of the DM/ADM/SDM, it shall be the responsibility of the DM/ADM/SDM to use his official channel to contact his counterpart in the relevant district or any other authority to provide him the necessary information.

2. In the course, of determining eligibility of the applicant to donate the applicant should be personally interviewed by the Authorisation Committee and minutes of the interview should be recorded. Such interviews with the donors should preferably be videographed. The Authorisation Committee must focus its attention on the following :-

- a) Where the proposed transplant is between persons related genetically, (e.g. Brother, Sister, Mother, Father, Children above the age of 18 years)

The authorisation committee must evaluate:-

- i) Results of tissue typing and other basic tests.
- ii) documentary evidence of relationship e.g. relevant birth certificates and marriage certificate, certificate from Sub-divisional magistrate/ Metropolitan Magistrate/or Sarpanch of the Panchayat;
- iii) documentary evidence of identity and residence of the proposed donor e.g. Ration Card/Voters identity Card/Passport/ Driving License/ PAN Card/Bank Account and family photograph depicting the proposed donor and the proposed recipient along with another near relative.
- iv) If in its opinion, the relationship is not conclusively established after evaluating the above evidence, it may in its discretion direct further medical tests as prescribed in Rule 4(1).

b) Where the proposed transplant is between a married couple:

The authorisation committee must evaluate all available evidence to establish the factum and duration of marriage and ensure that documents such as marriage certificate, marriage photograph is placed before the committee along with the information on the number and age of children and a family photograph depicting the entire immediate family, birth certificate of children containing particulars of parents.

c) Where the proposed transplant is between persons who are related genetically but whose relationship cannot be established in accordance with rules:-

- i) results of tissue typing and other tests with the name of the HLA laboratory and if possible the statistical estimation of the probability of a genetic relationship;
- ii) documentary evidence of relationship e.g. relevant birth certificates and marriage certificate, certificate from Sub-divisional magistrate/ Metropolitan Magistrate/or Sarpanch of the Panchayat;
- iii) documentary evidence of identity and residence of the proposed donor e.g. Ration Card/Voters identity Card/Passport/ Driving License/ PAN Card/Bank Account and family photograph depicting the proposed donor and the proposed recipient along with another near relative.

d) Where the proposed transplant is between individuals who are not “near relatives”

The Authorization Committee must evaluate:-

i) That there is no commercial transaction between the recipient and the donor. That no payment of money or moneys worth as referred to in the Sections of the Act, has been made to the donor or promised to be made to the donor or any other person.

ii) that the following is specifically assessed by the Authorisation Committee :-

- a) an explanation of the link between them and the circumstances which led to the offer being made;
- b) Reasons why the donor wishes to donate?
- c) Documentary evidence of the link e.g. proof that they have lived together etc.

d) Old photographs showing the donor and the recipient together.

iii) that there is no middleman/tout involved;

iv) that financial status of the donor and the recipient is probed by asking them to give appropriate evidence of their vocation and income for the previous three financial years. Any gross disparity between the status of the two, must be evaluated in the backdrop of the objective of preventing commercial dealing.

v) that the donor is not a drug addict or a known person with criminal record;

vi) that the next of kin of the proposed unrelated donor is interviewed regarding awareness about his/her intention to donate an organ, the authenticity of the link between the donor and the recipient and the reasons for donation. Any strong views/ disagreement/objection of such kin may also be recorded and taken note of.

e) When the proposed donor or the Recipient or Both are foreigners:

i. A senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient or where they are not related the reasons as to why the proposed donor is desirous of donating his organ to the proposed recipient.

ii. Authorisation Committee can examine the cases of Indian donors consenting to donate organs to a foreign national, including a foreign national of Indian origin, with greater caution. This should be done rarely in deserving cases only.

3) In case where the donor is a woman greater precautions ought to be taken. Her identity and independent consent should be confirmed/ verified by a person other than the recipient. Any document with regard to the proof of residence/ domicile and particulars of parentage should be relatable to the photo identity of the applicant in order to ensure that the documents pertain to the same person, who is the proposed donor and in the event of any inadequate or doubtful information to this effect, the Authorisation Committee may in its discretion seek such other information or evidence as may be expedient and desirable in the peculiar facts of the case.

4) In all cases of non-near relatives, the interview of the donor should specifically deal with the aspect of affection/attachment/ other special reason, in order to rule out commercial considerations.

5) Further all donors should specifically be interviewed to rule out any element of coercion, undue influence, fraud or misrepresentation in the proposal of donation. The Authorisation Committee should state in writing its reason for rejecting/approving the application of the proposed donor and all approvals should be subject to the following conditions:-

i. that the approved proposed donor has been and would mandatorily be subjected to all such medical tests as required at the relevant stages to determine his biological capacity and compatibility to donate

the organ in question and

- ii. further that the psychiatrist clearance would also be mandatory to certify his mental condition, awareness, absence of any overt or latent psychiatric disease and ability to give free consent.
- iii. All prescribed forms have been and would be filled up by all relevant persons involved in the process of transplantation.

6) The Authorisation Committee should employ a Secretariat comprising of adequate number of employees to help it in receiving the applications and circulating it to members, informing the applicants to complete any deficiency in the application either in terms of information or in terms of supporting documents, which may be required to be submitted; to assist the Chairperson in sending notices to the members of the Authorisation Committee; to prepare minutes of the interview and providing secretarial services for dictating agenda of meetings and speaking orders.

7. The authorisation committee shall expedite its decision making process and use its discretion judiciously and pragmatically in all such cases where, the patient requires immediate transplantation.

#### H. VENUE OF THE MEETINGS & PROVISION TO MEET EXPENSES

State/UT Government, as the case may be, should ensure that a suitable venue is provided to the State/District Authorisation Committees with requisite infrastructure and appropriate facilities, conducive to the efficient functioning of the State/District Authorisation Committee. The Authorisation Committee will levy an application processing fee not exceeding Rs. 2500 per application, from which the expenses of conducting the meetings, circulating the papers and providing honorarium to the members and payment of salaries/remuneration to the secretarial staff are met. The honorarium amount may be disclosed to the members of the Committee in advance before their acceptance is sought for becoming the member of the Authorisation Committee.

I. The recommendation to include DM/ADM/SDM or equivalent Govt. officer in the Authorisation Committee is aimed to expedite the decision making process. It is a matter of common knowledge that the bigger irritants/impediments in the expeditious disposal relate the verification of facts, without which any decision, this way or that way, cannot judiciously be taken. To achieve the objective of expedience, the larger objective of eradicating commerce cannot be sacrificed. Need is to create an optimum balance between the two objective, both being equally important. Therefore, to examine the factors such as affection, attachment and special reasons and to rule out the commercial consideration, it is inevitable and absolutely imperative that the committee members proceed on the correct premise of the facts, documents, and surrounding circumstances, are able to assess the financial status of the donor and recipient which obviously cannot be done with some investigation. Therefore, the need for inclusion of the DM/ADM/SDM of equivalent Govt. officer is appropriate.

5. The above analysis, addresses the first two Points of Reference as set out by Hon'ble High Court of Delhi in Balbir Singh case.

