

The Report Of Transplant of Human Organs Act Review Committee

(as per the Delhi High Court Judgement dated 06.09.2004 in W.P. no.813/2004 to review the provisions of the Transplantation of Human Organs Act, 1994 and the Transplantation of Human Organs Rules, 1995)

Directorate General of Health Services Ministry of Health & Family Welfare Govt. of India 25th May 2005

Part I - Background Note

A Committee, hereinafter referred to as the THOA Review Committee, was constituted in terms of the judgement dated September 6, 2004 passed by Hon'ble Mr. Justice Man Mohan Sarin of High Court of Delhi in WP(C) 813/2004 titled Balbir Singh Vs. The Authorisation Committee and Others (Balbir Singh case) with direction to review the efficacy, relevance and impact of the legal provisions contained in the Transplantation of Human Organs Act, 1994 (TOHO Act) and the Transplantation of Human Organs Rules, 1994 (TOHO Rules).

The Review Committee commenced its working under the chairpersonship of Additional Secretary (Health) to the Government of India and set out to objectively and critically appraise and analyse the practical functionality of the provisions of the TOHO Act and the TOHO Rules, as defined by the Hon'ble High Court of Delhi in the Balbir Singh case.

The terms of reference are as follows: -

1. *Based on the data available on the transplantation of organs and the working of the Authorisation Committees, the Committee to examine and make its recommendations on the composition of Authorisation Committees and changes, if any, required to ensure timely permissions.*
2. *Whether the jurisdiction of the Authorisation Committees should be enlarged by bringing within its ambit the process of certifying a "near relative" or the task be assigned to another Designated authority?*
3. *Review the provisions of the Rules based on the experience of transplantation of organs as carried out and the difficulties arising due to the bottlenecks faced in the said process. The Committee to examine in particular provisions of Section 9 and requirement of carrying out the tests prescribed in Rule 4, certification in Form-3 to review the definition of "near relative" and make its recommendations in the light of the observations made.*
4. *Examine and specify the organs for transplantation of which the tests prescribed in Rule 4(1)(c) to establish the factum of being "near relative" need not be carried out when other evidence is available.*
5. *Examine the feasibility of establishing and setting up Organ Procurement Organizations with data bank to facilitate the dissemination of information on availability of organs for transplantation. To encourage organ donation especially from cadavers, cases of brain stem death and other deceased persons, who had authorized removal of organs upon demise.*
6. *Examine the feasibility of creation of a fund, the corpus to be provided partly come from the Union of India and partly by levying a fixed charge on the total bill of the hospital for transplantation and/or public donations, for providing to a donor social incentives, medical aid and facility of transplantation of organ in future, should the same be required.*
7. *Examine and recommend ways and means to give social incentives, including but not limited, to help and aid and preferred health care, recognition and honour to a donor in the community.*
8. *Examine the causes that lead to exploitation of poor and unaware persons in the process of organ donation and suggest methods to reduce, control and ultimately eradicate such mal-practices. Recommend programmes for dissemination of correct information of ethical, legal and devising procedure concerning organ donation so that a conducive atmosphere is generated and disinformation and misgivings are dispelled.*
9. *Any other matter relevant to the subject.*

The factors that gave rise to a thinking process, requiring re-appraisal of the existing provisions in TOHO Act and Rules, and which in turn contributed to and culminated in determination of the terms of reference for the Review Committee, by the Hon'ble Court of Delhi, may be summarized as under: -

(i) The determination of the fact as to whether the proposed 'donor' is the "near relative" within the meaning of section 2(i) of TOHO Act, may not necessarily require the 'donor' to undergo the prescribed medical tests in all cases and in the process consume crucial time, if relationship is otherwise ascertainable through other credible evidence.

(ii) If the factum of relationship is ascertainable from credible documents indicating the same and medical tests are not required to prove the same, then, in such cases, the requirement of a medical practitioner certifying the same may be superfluous and cosmetic.

(iii) The "Authorisation Committee" as defined under Section 2(c) of the TOHO Act may also be constituted for examining the cases of "near relatives" as well, so that the appropriate decisions are taken well in time before it is too late for the patient.

(iv) The existing legal provisions particularly Section 9 of the TOHO Act and Rule 4 of the TOHO Rules need to be harmonized with the emergent needs of the critical patients requiring immediate transplantations, without compromising the objective of TOHO Act & Rules which are aimed inter-alia to prevent unscrupulous and commercial practices in the matters relating to 'donation' of the human organs for the purposes of transplantation.

(v) The present formats of the Forms appear to be unsatisfactory and the particulars required to be filled therein may not have nexus with the objectives, which the TOHO Act and the TOHO Rules profess to achieve.

Accordingly, a high-power committee comprising of the following members was constituted by the Hon'ble High Court of Delhi: -

- (i) Secretary, Ministry of Health or his nominee being an officer not less than the rank of Additional Secretary, Ministry of Health, as the Convener.
- (ii) Director General of Health Services or the Addl. Director General of Health Services as the Member Secretary.
- (iii) The Head of Department of Surgery, AIIMS;
- (iv) Dr. Harsha Jauhari, Renal Surgeon, Sir Ganga Ram Hospital;
- (v) Secretary of the Indian Medical Association (IMA); and
- (vi) Mr. Sanjay Jain, Advocate, High Court of Delhi.

In terms of the above, Dr. S.Y. Quraishi presided over the Review Committee as its Convener, having been nominated by the Secretary (in the first meeting Smt. P. Jyoti Rao, Additional Secretary Health had presided); Prof. V.K. Arora, Additional Director General of Health Services is participating as Member-Secretary having been nominated by Director General, DGHS and Dr. S.N. Mehta is participating as Member being Head of Department, Department of Surgery, AIIMS. Dr. Vinay Agarwal participated as Member being Secretary of the Indian Medical Association (IMA).

The Committee was required to submit its report by January 5, 2005. Initially the time was extended by the Hon'ble High Court of Delhi upto 30.04.2005 and thereafter up to 26th May 2005. The Committee also availed the benefit of the following persons in the course of its deliberations, who were requested to participate in deliberation process as special invitees:-

1. Dr. (Mrs.) Anita Roy, DCP, Delhi Police
2. Shri B.P. Sharma, Joint Secretary, MOHFW
3. Dr. R.L. Icchpujani, DDG(P), DteGHS
4. Dr. S. N. Mishra, Hony. Jt. Secretary, IMA
5. Shri Dev Mehra, General Manager, IMA
6. Dr. Sudhir Gupta, CMO(NCD)

In order to collect and collate data regarding transplantation activities from some states and NCT of Delhi; a format was developed and data collected from various institutions registered in Delhi and some state Govts. The photocopy sets of replies received from various institutions containing about 624 pages have been circulated to all members before the second meeting. The meetings have taken place as follows:-

Chronological events of the THOA review committee

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| 1. Court order for constituting committee | 06-09-2004 |
| 2. Review Committee approved by Secy (H) | 23-11-2004 |
| 3. First meeting of Thoa review committee | 07.12.2004 |
| 4. Data requested from Delhi Instt. & 4 states | 08.12.2004 |
| 5. 2 nd meeting scheduled & postponed | 22.12.2004 |
| 6. 2 nd meeting scheduled & postponed | 29.12.2004 |
| 7. 2 nd meeting of Thoa review committee | 01.02.2005 |
| 8. 3 rd meeting of Thoa review committee | 14.03.2005 |
| 9. 4 th meeting of Thoa review committee | 31.03.2005 |
| 10. 5 th meeting of Thoa review committee | 21.04.2005 |
| 11. 6 th meeting of Thoa review committee | 18.05.2005 |
| 12. 7 th meeting of Thoa review committee | 25.05.2005 |
| 13. | |

Other issues which were also discussed include:-

1. Letter from Prof. Madan Mohan for cornea/eye transplantation
2. Letter from Delhi Nephrological Society
3. Offences under THOA Act to be made cognizable (as per HFM meeting 05.03.2004)
4. Extract of Rajya Sabha debate dated 13.12.2004 containing matter of public importance raised in house by Shri B. J. Panda
5. Dr. Harsha Jauhari, Member submitted a written note on the subject to appreciate the background and scope of organ transplantation activities.
6. Dr. S.N. Mehta, Head of Surgery AIIMS submitted his views in form of note.
7. Dr. Anita Roy, DCP, Delhi Police submitted a note regarding legal matters pertaining to organ transplantation.

After several rounds of preliminary discussions, the Review Committee decided to constitute two sub-committees to effectively carry out the terms of reference contained in Balbir Singh case.

SUB-COMMITTEE-I

Composition

- Dr. S.N. Mehta, Head of Department, Surgery AIIMS, New Delhi; Chairman Sub-Committee-I
- Dr. N.K. Mehra, Head of Department, Transplant Immunology & Immunogenetics, AIIMS, New Delhi;
- Dr. I.C. Verma, Immunogenetics Department, Sir Ganga Ram Hospital, New Delhi.

Work Assigned to Sub-Committee-I

To recommend the modalities concerning tests (especially HLA, DNA tests etc.) for establishing the factum of “near relative” and compatibility between the ‘donor’ and the patient; to consider the availability, costs, needs and procedure relating to such tests.

SUB-COMMITTEE-II

- Dr. S.N. Mehta, Head of Department, Surgery, AIIMS, New Delhi;- Chairman Sub-Committee-II
- Dr. Harsha Jauhari, Renal Surgeon, Sir Ganga Ram Hospital;
- Shri Sanjay Jain, Advocate, High Court of Delhi.

Work Assigned to Sub-Committee-II

The sub-committee was requested to examine and give its suggestions the following questions:-

- a) Whether the present working of Authorisation Committee is satisfactory or requires any further improvements in terms of its composition pattern, data base, scope and extent of authority and transparency?
- b) Whether the present working of the Authorisation Committee is conducive to the expeditious disposal of the cases referred to them for grant of approval to the donors to donate human organs?
- c) Whether the scope and extension of Authorisation Committee needs to be enlarged to include in its ambit the cases of near relatives as well?
- d) What steps/remedial measures can be taken to expedite the timely permissions and harmonize the functioning of the Authorisation Committee with the objectives of its existence/ construction?
- e) Whether any of the existing provisions of the Act of 1994 or Rules of 1995 or the Statutory Forms need to be modified/ amended/deleted, if so, in what manner?

Besides above, Dr. V.K. Arora, Additional Director General, DGHS, was requested to examine the data received by the Review Committee from various hospitals concerning transplantation activities and functioning of “Authorisation Committee”.

Several meetings of the Review Committee were held from time to time (as detailed earlier). The Committee took note of the entire judgement in Balbir Singh case; discussed various diverse issues emerging from and connected with the terms of reference and considered the relevance of the existing legal provisions in the backdrop of the ground realities and also reflected upon the merits and demerits of the existing laws in addressing the problems that confront the society in general and donors, recipients and surgeons in particular. The Committee also took note of the fact that TOHO Act is a special enactment to deal with the transplantation cases and therefore some changes in the Act and the Rules would be required to establish harmony between the objectives of the enactment and the rationale of the restrictions imposed therein.