

FINAL REPORT OF THE COMMITTEE, PGIMER, Chandigarh.

The appointed Expert Committee of PGIMER, Chandigarh, constituted in compliance of the orders passed by the Hon'ble Punjab and Haryana High Court with reference to writ petitions being CWP-15590-2016 and CWP-10247-2016 deliberated on issues raised in total of three meetings.

At the outset of these meetings, the Chairman emphasized that these meeting deliberations are confidential in nature, as the said Committee was constituted and thereafter, approved by the Hon'ble High Court. The report is to be given in confidentiality to the Hon'ble High Court, therefore all members and attendees should desist from releasing information of any kind about deliberations in the meeting in public or in press as that would tantamount to disrespect of the spirit in which the Hon'ble High Court has asked for an expert opinion from PGIMER, Chandigarh. The Hon'ble High Court must be appraised of the Committees' Report first before any further action by members.

The recommendations to be given to Hon'ble High Court were not finalized before this meeting on 7.5.2019. The final draft was prepared after last meeting on 7.5.2019 .

BRIEF OF MEETINGS HELD AND AGENDA DISCUSSED.

The Committee met previously on two occasions - on 11.4.2019 to outline the inputs required from attendees and again on 23.4.2019 when the Committee was briefed by the Chairman about scope of recommendations to be prepared and inputs were taken from members. The final draft was placed for approval in meeting convened on 7.5.2019 and recommendations outlined.

The 1st meeting was held on 11.4.2019 and was attended by Prof.R.K.Dhiman, Dept. of Hepatology, Prof.Kajal Jain, Dept. of Anaesthesia, Prof.Ashutosh Aggarwal, Dept. of Pulmonary Medicine, Prof.Amit Gupta, Dept. of Ophthalmology, Prof.Ajay Bahl, Dept. of Cardiology, Prof.Ashish Sharma, HOD Renal Transplant Surg., Ms.Alka Sarin as Amicus Curiae, Advocate Kanishk Lakhanpal, Advocate Shashank Bhandar, Advocate Manveen Narang, Prof.Vipin Koushal, Dept. of Hospital Admn as (Convener) with Prof.R.K.Dhiman supervising the meeting as Prof.Arunanshu Behera was engaged in the operation theatre.

The 2nd meeting was held on 23.4.2019 and attended by Prof.Arunanshu Behera, Dept. of General Surgery (Nodal Officer Liver Transplant) as **Chairman**, Prof.R.K.Dhiman, HOD, Dept. of Hepatology, Prof.H.S.Kohli, HOD, Dept. of Nephrology, Prof.Kajal Jain, Dept. of Anaesthesia, Prof.Amit Gupta, Dept. of Ophthalmology, Prof.Ajay Bahl, Dept. of Cardiology, Prof.Ashish Sharma, HOD Renal Transplant Surg, Ms.Alka Sarin as Amicus Curiae, Advocate Ranjan Lakhanpal, Sh.Deepak Balyan, Addl.A.G.Haryana, Advocate Manveen Narang, Advocate Arun Gosain (Sr.Panel Counsel for Union of India), Sh.Kuldeep Sharma, Legal Cell, PGI, Prof.Vipin Koushal, Dept. of Hospital Admn as (Convener).

The last meeting of the Committee constituted to go into the issue of transplantation of human organs out of cadaveric organ donations in this part of the country was held under the Chairmanship of Prof.Arunanshu Behera, Nodal officer Liver Transplant, Dept. of General Surgery on 7.5.2019 at 4.00 pm in the Committee Room of MS Office.

The following attended the meeting: Prof. R.K.Dhiman, HOD, Dept. of Hepatology, Prof. Kajal Jain, Dept. of Anaesthesia, Prof. Ashutosh

Aggarwal, HOD, Dept. of Pulmonary Medicine, Prof. Y.S Bansal, HOD, Forensic medicine, Prof.Ajay Bahl, Dept. of Cardiology, Prof.Ashish Sharma, HOD Renal Transplant Surg, Ms.Alka Sarin as Amicus Curiae, Sh.Deepak Balyan, Addl.A.G.Haryana, Advocate Manveen Narang, Advocate Arun Gosain (Sr.Panel Counsel for Union of India), Prof.Vipin Koushal, Dept. of Hospital Admn as **(Convener)**.

The following were special invitees/representatives of U.T. and States of Punjab and Haryana, for the meeting :

Sh.Satish Chandra, Addl.Chief Secretary, Dept. of Health & Medical Education, Govt. of Punjab

Sh.Avneesh Kumar, Director, Medical Education and Research, Govt. of Punjab

Dr.Jagdish Singh Gill, Asstt.Director, Health Services, Govt. of Punjab

•Dr.Satish K.Aggarwal, Director General of Health Services, Govt. of Haryana

•Dr.S.B.Kamboj, Asstt.Director General of Health Services, Govt. of Punjab

Dr.Jai Kishan, Health Services, Govt. of Haryana

Dr.Arvind Malhotra, HOD Neurosurgery, Rep. of DMER U.T, Chandigarh

Sh.Roshan Lal, SP Communications, Rep. of DGP U.T, Chandigarh

Sh.Gautam Cheema, IPS, Rep. of DGP, Punjab

Sh.Deepak Gahlawat, SP Law & Order, Rep. of DGP, Haryana

Dr.K.S.Raina, Rep. of DHS U.T. Chandigarh.

The Committee in all its meetings had deliberated about increasing cadaver (**deceased donor**) organ donations in this part of the country,

discussed the Transplantation of Human Organs Act, 1994 and its amendments (THO Act), the Transplantation of Human Organs and Tissues Rules, 2014 (THOA Rules), the information uploaded on the TRANSTAN website, deliberated on the Govt. of Tamil Nadu office orders regarding organ transplant and organ donation in that State, the NICE guidelines, discussed the available literature in various institutional sites such as UNOS (USA), NHS (UK), Australian and New Zealand transplant network, NOTTO (India), activities of Mohan Foundation and literature available in various Indian states website as brought forward by the Chairman and other members. The final report and its recommendations are made keeping in mind the THO Act (original and amended), the THOA Rules and TRANSTAN (Tamil Nadu) activities.

Organ and tissue donation provides hope for thousands of people with organ failure or tissue diseases and injuries. Improved surgical techniques and new anti-rejection drugs permit the successful transplantation of organs and tissues. In addition to the benefits that the transplant recipient receives, the bereaved family is presented with options that, in time, may help them cope with the sudden and tragic loss of someone special. One of the benefits for families choosing to donate organs and tissues includes knowing that their loved one's gift has provided an extension or improvement of the quality of life for another person. The decision to donate organ for others is altruistic event in case of donation after brain death. There are sensitive issues involved, some are personal, some are emotional, some are ethical and certain issues have legal aspect. The issue of DCD (donation after Cardiac death) was discussed and further directives are necessary.

As a bridge between donation and transplantation the appointed 'Transplant Coordinators' work as per the THO Act and NOTTO guidelines connecting and communicating with doctors in ICUs, hospitals, ROTTO and NOTTO and their coordinators, Retrieval Centers and Transplant Centers. Coordinators work to achieve this mission by identifying potential donors, matching donors with recipients, coordinating clinical donation activities, arranging surgical recoveries, supporting donor families and increasing public awareness about donation.

To facilitate continuous donation process improvement, certain interventions are required by the governments, institutions, hospitals at a policy level effecting SOP (Standard Operating Procedure) and help is required from public and private organizations to motivate families to take part in this altruistic event.

Deliberations were made regarding effecting a SOP for hospitals under the State Governments' jurisdictions, adhering to the spirit of THO Act and addressing the bottlenecks that hamper a healthy organ donation rate.

Detailed deliberations were also held on the issues raised by Adv.Manveen Narang representative of Ms.Manisha Gandhi regarding legalizing the sale of organs on the pattern of Iran and police Jurisdictions in facilitating organ donations. All the panel members were of the considered opinion that the sale of organs which is more so an issue for live organ donation shall not be considered at this juncture and most felt it to be unethical. All felt that all effort should be made to improve dismal rate of deceased donor organ donation and live related donation to be viewed as a supplement option for needy situations.

The THO Act has clear guidelines for a near relative to donate organs.

The suggestion that there should be implementation of organ donation for monetary consideration to reduce the role of the middle man or transplant facilitator, thus reducing risk of exploitation of both the living 'unrelated' donors as well as the recipient was not agreed upon by the experts as that will run counter to the spirit and ethics of THO Acts approved by the parliament. The members felt this issue may kindly be dealt by the Hon'ble High Court and give any directions on this issue

The issue is about the unrelated donor as 'emotional relative' donor and there was suggestion of applying a 'cooling' period of three months or a second review of the donor after 3 months by the appropriate Authorization Committee. This may address the issue of organ sale or mental coercion applied in recruiting unrelated organ donors.

The other issue of police jurisdiction in deceased donor donations was deliberated upon and it was decided that the local police must be involved to facilitate the process of organ donation and transplantation. The role of the Investigation Officer from the police in medico-legal cases was also discussed threadbare and HOD Forensic Medicine, PGIMER highlighted that it is the prerogative of the medical officers/forensic officials conducting the postmortem to decide regarding clearance in medico-legal cases for organ harvesting not the police and as such no police consent is mandatory as per the THO Act. The police has only a facilitator's role.

The other issues regarding creation of infrastructure/appointment of transplant coordinators, constitution of brain stem death certification committees and conducting awareness campaigns of organ donation for police, public and doctors was thoroughly discussed among the members and inputs from the invited representatives from Departments of Health and

Medical Education and Police from UT, Punjab and Haryana were also taken.

The Chairman also presented before the members a draft of recommendations which is to be submitted before the Hon'ble High Court and asked the members to give further suggestions, if any, in writing to the Chairman or to the Amicus Curiae, Advocate Ms. Alka Sarin within three days of the meeting.

✓ The Committee gave the mandate to the Chairman and the Amicus Curiae to prepare the final report for submission to the Hon'ble High Court.

The State Governments through their health representatives were requested to enlist support from all quarters for public support for organ donation and recruit services of NGOs in the States and issue certain orders to streamline organ procurement in their States similar to Govt. of Tamil Nadu.

✓ It was felt that a 'National Registry of Voluntary Organ Donor' be maintained of people who in their life time have expressed willingness to donate organs after death through pledging at Transplant Centers, Hospitals, through Donor Cards, Driving License, or Govt. ID Cards. This may be taken as affirmative consent after their death. This issue can easily be dealt by a centralized registry maintained by ROTTO/NOTTO with an identity number for each donor.

"Living Directive/Will" has been recognized by the Hon'ble Supreme Court of India in the case of Common Cause vs Union of India [2018(5) SCC 1]. No reason why a donor card should not be treated as a Living Directive. The registry may be maintained by ROTTOs and NOTTO with a

identifying serial number for the person and a organ card may be issued to family or individual.

Considering all of the above, the Committee in its conclusion submits the following recommendations to the Hon'ble High Court of Punjab and Haryana for consideration:

RECOMMENDATION No.1

- A. That declaration of 'brain stem death' be made mandatory for all hospitals, both private and government and autonomous institutes, in the States of Punjab, Haryana and Union Territory of Chandigarh. The THOA Rules provide for the same, however the rule is not being followed in letter and spirit.
- B. That all hospitals must provide information about possible donors in ICUs on a daily basis to the CMO/Civil Surgeon/designated District Coordinators Office and 'in hospital' Coordinators, if they are approved retrieval or transplant centers under THO Act, for necessary follow up action for organ retrieval.
- C. That monthly statistics of brain deaths and conversions be intimated to nearest SOTTO and ROTTTO centers by all hospitals having ICU facility and information about admissions, discharges and deaths, with causes, be reported monthly to both the designated SOTTO/ROTTTO/NOTTO for audit.
- D. In case 'no brain death' is declared it should also be communicated in the monthly report as 'NIL' deaths.

Explanation :

1. This model of compulsory brain death declaration is existing in TRANSTAN, Tamil Nadu.
2. It is of no use to maintain a brain dead patient involving ICU which involves high costs. The relatives may consider option of organ donation rather than continue with the line of treatment that is being provided.
3. There are many non-transplanting hospitals in the States which have intensive care facilities and have patients with brain death but these deaths are not being certified. Brain death declaration and request for organ donation should be made mandatory at all hospitals. Whether brain death declaration is being carried out or not can also be audited by a monitoring authority like SOTTO/ROTTO/NOTTO.

RECOMMENDATION No.2

There should a District level body (CMO) Civil Surgeons Office/ in all districts of states and SOTTOs of Punjab and Haryana and the UT for coordination in organ donations. If the Districts are small or number of hospitals are few 'zones' can be created by the respective States.

The Central Govt. through NOTTO gives assistance for setting up offices for the purpose for 24 hour services. They will assist in providing safe transport of donors to nearest retrieval or transplant centers with ventilator support and create green corridors for the same. The States need to issue necessary orders after consulting hospitals in their respective States.

Explanation :

1. This will be the office supervised by ROTTO, which will coordinate 24 hours a day with all hospitals private and Govt. having ICUs for

compliance to brain stem death declaration and further action in coordination with ROTTO/NOTTO.

2. They will have to employ Grief Counselors/ Transplant Coordinators in their office for the District (or zones) who will provide end of life care to potential brain dead donors and counsel relatives of potential donors and take consent for organ donation.
3. These designated SOTTOs/District level CMO/Civil Surgeon Offices will coordinate for transport of brain dead donors to the nearby organ retrieval or transplant centers as the need arises.

RECOMMENDATION No.3

The Governments must mandatorily employ Grief Counselors/ Transplant Coordinators for organ donation in all Districts (zones) attached to the designated office of CMOs or SOTTOs so created to assist ROTTOs and NOTTO set up by the Govt. of India. The qualification of Coordinators is stipulated in the THOA Rules.

Explanation :

1. Organ donation is an altruistic event and there are family sentiments and sensitive issues involved. A Transplant Coordinator can deal with the situation more appropriately as per the provisions of the THO Act.
2. The Transplant Coordinator can be an effective Grief Counsellor for the grieving family who wish to donate.
3. He/She can coordinate between Brain Death Committee, SOTTO/ROTTTO for retrieval and transportation of organs.

4. She/he can also seek information about a potential organ donor and counsel the relatives as per law and get informed consent as per the THO Act.
5. He/She can provide much needed solace to the relatives. At the same time, it will also reduce the trust deficit between the relatives and doctors, minimizing the litigation and vandalism which sometimes occur due to an untoward event. Once grief counselling has taken place, consent rates of organ donation will improve dramatically.

RECOMMENDATION No.4

It must be made mandatory for all hospitals/ICUs to give free access to designated Grief Counselors and Transplant Coordinators to assess potential donors at or below GCS level 4 and clinical information about such patients be provided to Coordinators by the treating doctors/registered medical practitioner.

P.S. : GCS stands for Glasgow Coma Score. This is the most common scoring system used to describe the level of consciousness. GCS 15 being the highest and GCS 3 being the lowest. Brain injury is classified as Severe GCS 8 or below, Moderate GCS 9-12, mild GCS 13-15. Coma is defined as GCS below score of 8.

Explanation :

1. Restricting access to trained coordinators or grief counsellors is contrary to principle of 'end of life care' in organ donation.
2. Survival of life at GCS 3 is between 4-7% worldwide, 30 days mortality is at appx 95% and they are potential brain death/brain stem

death candidates and likely to deteriorate clinically at a rapid pace thereafter.

3. Coordinators need certain time to break the sad news to relatives, show empathy and gain confidence of the family, provide end of life care and motivate family for 'brain death certification' and, if willing, proceed for organ donation.
4. This conforms to NICE guidelines for Coordinators and Organ Procurement Officers. No such guidelines are spelt out to doctors/coordinators in India.
5. Potential organ donors can be identified early in ICUs of hospitals by following such a guideline.

RECOMMENDATION No.5

All hospitals must mandatorily display a sign outside all ICUs mentioning :

1. That 'Brain Death Certification' is mandatory for patients in coma or brain stem death patients.
2. That patients have an option for 'Organ Donation' request in case of brain stem death.
3. That relatives of patients can access Grief Counselors, District/In-hospital Coordinators for organ donation and end of life care services.
4. The 24/7 helpline numbers should be displayed in all hospitals. Details of SOTTO/ROTTO contact numbers be displayed. Contact number of Grief Counselors/Coordinators be displayed outside ICUs.

Explanation :

1. This will make all stake holders and relatives aware about mandatory declaration of brain deaths.

2. That there are Grief Counselors available to them to help in making correct decisions and for 'end of life care'.
3. That there is transparency in organ donation which is visible to all.
4. It will bring about a general awareness to all attendants and public visiting hospitals.

RECOMMENDATION No.6

Committee's appeal to the Hon'ble High Court :

The Committee while deliberating on 'consent' for organ donation was faced with differing views on this. It was felt that the consent process be clarified by the Hon'ble High Court as mentioned in THO Act.

The definition of 'legal possessor' in the hospital who can give consent for organ donation and the 'near relative' for deceased donors needs to be clarified to all coordinator and doctors.

Doctors are sometimes found wanting in interpretation of law and the THO Act. Most members agreed that the term near relative of a brain dead person is same as for live related donor. However, since a 'near relative' may not be present in hospital at all times during a person's treatment, in that case the person who can give legal consent for donation be clarified for use at all levels. There is a reference in Section 3(2) and 3(3) of the THO Act to a person in lawful possession of the body.

Explanation :

1. It is some time found that only one relative/attendant is available with a patient who has come from a far off place and this relative/attendant is willing to give his consent to donate the organs of the patient. He is also the person who is to be handed over the body in the event of death.

The pertinent question here is that is this relative/attendant the legal possessor who can give consent or only a near relative living far away at that moment can give a consent for organ donation ?

2. Contacting a relative in a distant place or in another State and bringing him/her to the hospital becomes a mammoth task and the patient may proceed to cardiac death in the meantime and become unsuitable for organ procurement especially for organs like Heart, Lungs, Liver, pancreas etc.
3. Sometimes a near relative cannot be contacted.

RECOMMENDATION No.7

The Role and Jurisdiction of the IO/Police needs to be clarified to all stakeholders and police departments by respective Governments keeping in mind Govt. Orders issued by the Govt. of Tamil Nadu on this issue.

The IO/SHOs of the police station under which the hospital falls be directed to give assistance for organ procurement as mandated in THO Act. The respective Governments be also directed to instruct Police Chiefs to hold regular awareness classes for all IOs/SHOs.

Explanation :

1. The TRANSTAN/Tamil Nadu identifies the Police Station where the event of organ procurement takes place as the IO for verification of consent and facilitation of process, not the place from where the patient originated or the place the patient had an accident.
2. This brings down the consent verification time, onset of the retrieval time for the process of organ donation and allows donors who are at risk of crashing to circulatory arrest to be able to donate viable organs.

3. It also avoids unnecessary delay in the process and transport of organs and transplant procedure.
4. It also avoids unnecessary interference by distantly placed IOs/SHOs who may not be aware of the process of organ donation or provisions of the THO Act.

Please refer to Section 6 of the THO Act. Notification issued by Kerala Government may also be seen.

RECOMMENDATION No.8

The States of Punjab and Haryana must create more registered 'retrieval centers' in Government Medical Colleges complying fully with the THO Act the THOA Rules.

All future transplant/retrieval centers must mandatorily employ trained manpower for Cadaver / Deceased Donor Organ retrieval process while seeking sanction license. Transplant and retrieval team members must possess training in organ specific cadaver organ retrieval surgery for prescribed periods of training and experience as 'active member' of a transplant programme as mandated in THOA Rules for transplant surgeons.

They must be certified as being 'active member' of an established transplant center and should have been involved actively in deceased donor organ retrievals for conducting such operations in new teams .

All retrieval surgery must be done in approval and consent of ROTTO in other situations where organ specific retrieval surgeons are not available at the moment.

No transplant center should employ visiting operating surgeons for process of transplant or retrieval within the jurisdiction of the High Court in approved retrieval centers.

The organs must strictly be allocated or shared through ROTTO and NOTTO by all approved transplant centers.

Explanation :

1. Transplant centers come up without attention and commitments to cadaver (deceased donor) organ retrieval programmes.
2. This has resulted in a flourishing live donor related transplant services neglecting a cadaver donor programme and employing 'fly by night' or 'visiting' operating surgeons' for transplant activities.
3. Transplant/retrieval centers be mandated to assist retrieval procedures conducted under SOTTO/ROTTTO/NOTTO in a nearby hospital (affiliated hospital) having ICU and a well equipped operation theater.
4. As per THO Acts, organ retrieval or transplant can take place only in the hospitals which are registered for this purpose by the State Authorities. While hospitals which are conducting transplants get themselves registered for organ retrieval as well, currently no hospital has been registered as an organ retrieval centre in the States of Punjab and Haryana.

RECOMMENDATION No.9

Formation of brain death certification committee for each District having doctors based in the same District to be attached to the CMOs/Civil Surgeons or SOTTOs.

Explanation :

Brain death was recognized as a mode of death in 1994 when the THO Act was passed by the Parliament. This mode of death was recognized as these patients had no chance of recovery but could be kept on artificial support in an ICU for many days before their heart eventually stops beating. Recognition of brain death as an inevitable end of life provides an opportunity for organs to be transplanted all across the world. However, despite the THO Act, no brain death has ever been certified in the Medical Colleges across the States of Punjab and Haryana. This is despite the fact that these Colleges deal with several patients who have suffered head injuries and it is well known that head injury patients succumb from their illness by means of brain death. Even the private hospitals where these patients are admitted have not been able to declare brain death. The reason for the same is that the State has not made any brain death certification committees which can certify brain death. These committees comprise of four doctors and the committee has to examine the patient twice at an interval of six hours before the patient can be declared brain dead. In some instances, a committee has been constituted by having doctors across different cities which means that it is impossible to have them together to certify brain death at the time of death. This leads to a situation where patient has to be shifted to PGI, Chandigarh to certify brain death. Obviously, this discourages many patients from going ahead with organ donation as it leads to inconvenience to the relatives. If these donors can be certified as brain dead in the hospital where they are admitted, organ retrieval can take place at the same hospital.

RECOMMENDATION No.10

Designating hospitals with minimum of 25 beds, ICU and a clean operating theatre as 'Affiliated hospital for organ harvesting'. The brain dead patient can be maintained in such a hospital in case a local hospital is unable to provide end of life care.

Financial support for hospitals involved in maintaining an organ donor after declaration of brain death can be discussed by stake holders and Governments.

Alternatively, if the condition of a brain dead donor permits, the donor can be shifted to a nearby transplant or retrieval center on the advice of SOTTO in consultation with ROTTO for the States.

Explanation :

Maintaining brain dead donors in an ICU involves a high cost as these patients continue to require expensive medicines and ICU care till the time brain death is certified. A policy to waive off the charges of the donor family incurred after they have consented for organ donation can also promote organ donation. Similarly, for organ retrieval, operation theatre facilities are required and special solutions to preserve organs till the time they are transplanted are required. All these costs are a disincentive to a non transplanting organ retrieval centre. If organ donation is happening at a hospital where transplantation also is taking place, the cost is borne by the prospective recipient. So, some mechanism needs to be evolved so that there should be no financial disincentive for these hospitals to proceed with organ donation programme.

Even the Tamil Nadu Govt. compensates the treating hospital a certain fixed amount (appx. Rs.70,000/-) for maintenance of brain dead donors resulting in organ donation.

A local agency/NGO on the patterns of Maharashtra (Zonal Transplantation Coordination Centres, ZTCC) needs to be created. This organisation provides financial support to organ retrieval centres from the corpus of money which is collected either from registration of each patient in the Waiting List or from the hospital which accepts the donor organ.

RECOMMENDATION No.11

To involve certified NGOs, religious bodies by the States and institutions to create positive awareness about organ donation.

Explanation :

1. The process of organ donation and consent involves religious beliefs, social taboos, apprehension on part of relatives, misconceptions.
2. This can be addressed by such organizations if Governments enrolled their services to augment donation rate by public participation, pledging organs during the life time and bringing general awareness.

RECOMMENDATION No.12

Hospitals be identified in the States that have an ICU and have a well equipped operation theatre where organ procurement can take place even if these hospitals are not retrieval or transplant centers. They may be designated as 'Affiliated hospitals for organ harvesting' and a list be prepared and given to ROTTO and the transplant center for logistics assessment. In case it is required, the retrieval teams can visit these

hospitals and use their operation theatre for organ harvesting to overcome logistic issues.

Explanation :

At times the ICUs of receiving retrieval center or transplant center may wish to procure organ on site as the patient is very unstable for transport but has suitable organs to procure and brain death has been certified. The model is similar to other countries requesting organ procurement teams to procure organs in another hospital.

RECOMMENDATION No.13

A 'National Registry of Voluntary Organ Donor' be maintained by ROTTO/NOTTO for public who in their life time have expressed willingness to donate organs after death through pledging at Transplant Centers, ROTTOs Hospitals, through Donor Cards, Driving License, or Govt. ID Cards. This may be taken as affirmative consent after their death. The registry may be based on an unique national ID number given by NOTTO.

Explanation :

"Living Directive/Will" has been recognized by the Hon'ble Supreme Court of India in the case of Common Cause vs Union of India [2018(5) SCC 1]. No reason why a donor card should not be treated as a Living Directive. A centralized record of such voluntary donors who wish to donate organs after their death in the event of accident or otherwise will mitigate certain reservations expressed by the legal possessor or relative consenting for organ donation. It will also bring about transparency in the process.

RECOMMENDATION No.14

The Committee recommends that the topics of 'Organ Donation' and 'brain stem death' or brain death be taught in schools in classes 10, 11 and 12 as part of Social Science, Biology or other subjects.

Explanation :

Students who will be future citizens of the country will be well aware of brain stem death, organ donation and can advise and motivate others at home and in society.

RECOMMENDATION No.15

The Committee recommends that the States of Punjab, Haryana and UT of Chandigarh be directed by this Hon'ble Court to issue certain orders to :

1. All Hospitals including Government and private and Government Medical Institutions having ICUs to facilitate 'deceased organ donations' by mandatory declaration of brain stem death by registered practitioners in ICUs.
2. To give access to designated 'Transplant Coordinator' for grief counselling, end of life care and motivate families for organ donation in compliance of the provisions of the THO Act.
3. Instruct all Districts/zones/designated Civil Surgeon (CMO) and SOTTOs to appoint Transplant Coordinators or Grief Counselors.
4. Instruct all designated District Offices/Zone Offices or SOTTOs to coordinate with ROTTO for organ retrieval process and transport of donor or organ to centers as decided by ROTTO.
5. To instruct the Police Departments of the States of Punjab, Haryana and UT Chandigarh about responsibilities in facilitating verification of organ donation, inquest and postmortem formalities as decided by

respective States and as mandated in the THO Act and the THOA Rules.

6. To notify list of names of approved 'affiliated organ harvesting hospitals' in the State who can maintain brain stem death donors, make available their operation theatre for organ retrievals.
7. To notify list of agencies/ambulance services that can transfer a patient to the nearest center with instruction from SOTTO/ROTTO, on ventilator support and circulatory support.
8. To notify all SOPs for a) hospitals, b) Civil Surgeons/designated Zone Officers/SOTTOs, c) Affiliated organ harvest centers, d) ambulance services, e) mode of compensation to hospitals affiliated for organ harvest, f) postmortem formalities, g) availability 'end of life care' counselors and Grief Counselors for Districts and Zones.

P.S. : A standard operating procedure prepared by the committee , that can be referred to by all agencies and stake holders is annexed to these recommendations as Annexure 1-4

Explanation :

Orders from the respective State Governments are required to be issued to streamline organ donation along with the Recommendations 1 to 14 given above.

RECOMMENDATION No.16

Towards making available organs for needy patients where a unrelated living donor is required, a centralized regulatory authority(like NOTTO) be set up to channelize all transactions between genuine 'living unrelated donors' in a situation where a person is donating out of affection as "emotional relative".

To further eliminate an element of duress and prevent organ donation from becoming a channel to earn quick money, after a donor has registered himself, a cooling off period between 6 weeks to 3 months may be prescribed and only after expiration of this period, the doctors or experts in the authorization committee in a second meeting may approve such unrelated donor to be fit for donating the organ barring emergent situations that the Hon'ble court may decide.

Explanation :


For matters pertaining to living 'unrelated' donations for transplants, the Authorization Committee is appointed to regulate donations from persons who are not near relatives of the patient.

This committee ascertains that the donation is being made for "reasons of affection or attachment towards recipient or for any other special reason." However, the criteria for evaluating living donors elucidated in Rule 7 of the Transplant rules are so elaborate and thus insurmountable, rendering even the genuine donors being prevented from donating the organs to an already scant pool of the country.

Therefore, patients tend to resort to unethical and often illegal measures for their survival which is possible only through an organ transplant. Despite strict measures and laws against organ trafficking, the same is still happening at an equally rapid pace even after 2 decades of the coming into force of the Transplant Act, which thus appears to be inadequate for the purpose. According to WHO's survey in 2007, 2000 persons sell their organs yearly in India.

The Committee has made the above recommendations for the consideration of this Hon'ble Court for increasing donation rates and effective conversion

of brain death patients to an organ donor in North India. The members are ready to assist further regarding any clarifications or give additional inputs


Prof. Arunanshu Behera

(Chairman)


Advocate Ms. Alka Sarin

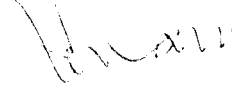
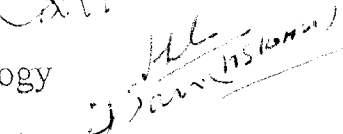

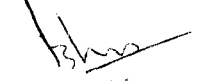


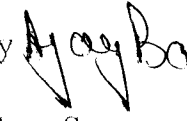

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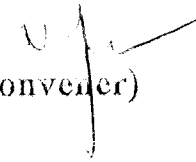
Deptt. of Gen. Surgery

(Nodal Officer Liver

Transplant, PGIMER)

Co-signatories are members of the Committee at PGIMER:

1. Prof. R.K. Dhiman, HOD, Hepatology 
2. Prof. H.S. Kohli, HOD Department of Nephrology 
3. Prof. Kajal Jain, Department of Anaesthesia 
4. Prof. Ashutosh Aggarwal, HOD, Pulmonary Medicine 
5. Prof. Amit Gupta, Department of Ophthalmology 
6. Prof. Y.S. Bansal, HOD, Forensic Medicine, PGIMER 
7. Prof. Ajay Bahl, Department of Cardiology 
8. Prof. Ashish Sharma, HOD, Renal Transplant Surgery 
9. Prof. Vipin Koushal, Hospital Administration,
Nodal Officer ROTTO, PGIMER, Chandigarh

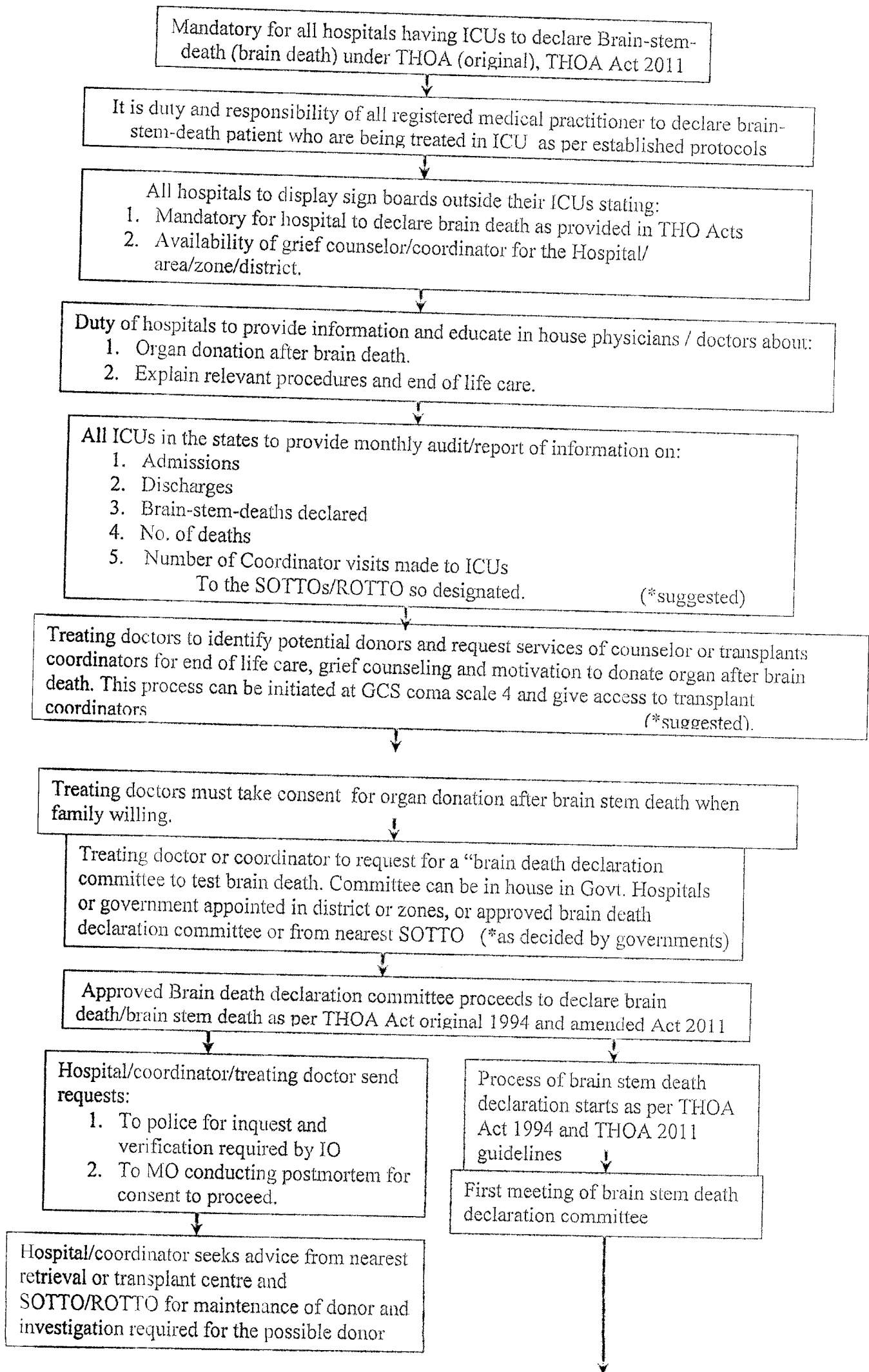

(Convener)

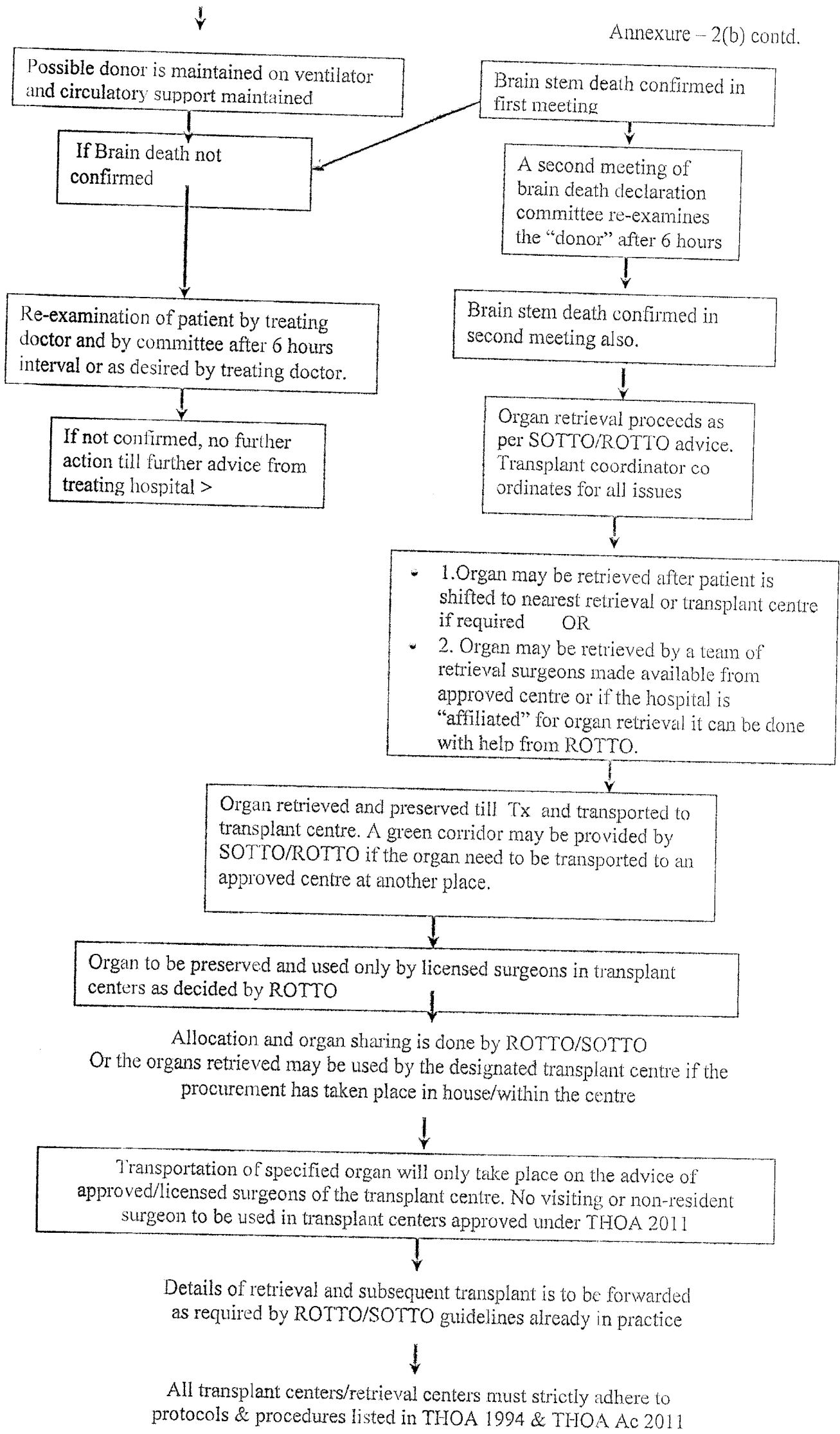
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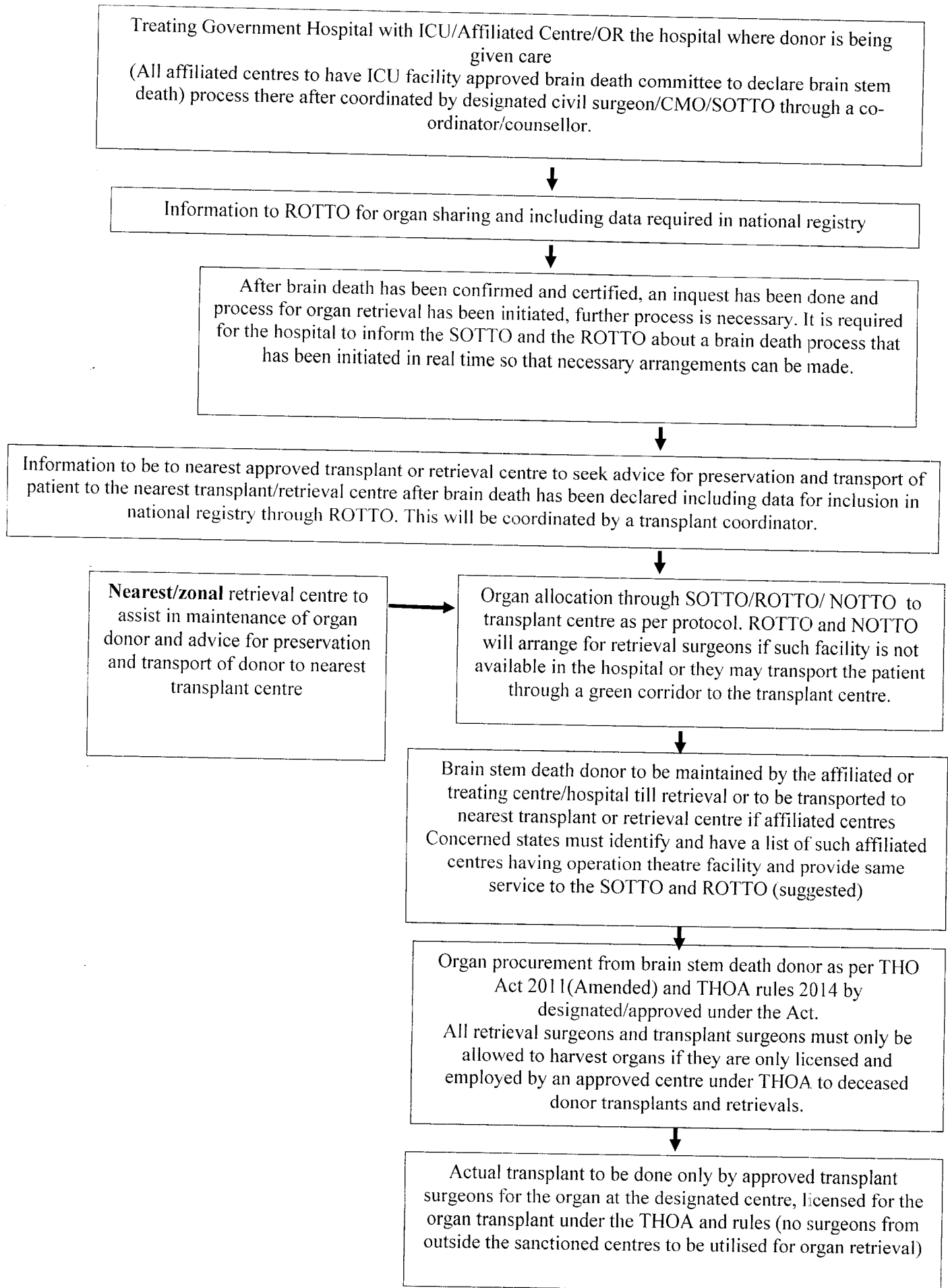
Date: 14.05.2019

(Confidential and sealed)

General information or all hospitals (Govt. And private) about brain stem death declaration and Organ Donation as per provisions of THO Acts.





SOP for Organ retrieval and transport

Form – I

Police Intimation Form

Form

Chief Medical Officer or Residential Medical Officer Civil Surgeon or
SOTTO or ROTTO Transplant Co-ordinators/ Transplant Coordinator of hospital

_____ Hospital,Address.....
.....

To

The Inspector of Police / Investigating Officer, IO

_____ Police Station. Address:.....

Sir,

Mr / Ms _____ aged _____ years of _____
_____ (Address) sustained injuries
(details) and was admitted in _____ hospital on _____ (dd/mm/yy).

2. The near relatives of the patient have expressed a positive inclination to donate the organs of the patient in the event of the person's Brain death (brain stem death). The Brain Death Certification (brain stem death certification) process is now in progress, as per the Transplantation of Human Organ Act, 1994 (Central Act 42 of 1994), Transplantation of Human Organ Act, 2011 (amended), Transplantation of Human Organ Rules, 2014.

3. You are requested to immediately come to the hospital in order to expedite the conduct of the inquest and carry out necessary procedure to enable the cadaver (deceased donor) organ donation as prescribed under THOA 1994 (original) and THO Act 2011(amended) for use in therapeutic process of organ transplantation.

Yours faithfully, (Name).....

(Date)..... (Time).....

Copy to:

Concerned commissioner of Police

Or

District Superintendent of Police

Form – II

Organ (s) functional status certificate and request for brain stem death declaration.

This is to state that Mr. / Ms. _____ S/O / D/O
_____ who had been admitted on our hospital on _____ (date)
has been declared brain stem dead/brain dead _____ A.M. / P.M. as per the THO Act, 1994 and
THOA 2011(amended). The approved brain stem death (brain death) declaration committee may
be constituted as per process described in THOA (amended) 2011 and a declaration be made.

It is certified that the following organs of this brain stem dead (brain stem death) person,
a potential organ donor are in functioning status:

- 1)
- 2)
- 3)
- 4)
- 5)

NAME.....

Designation.....

.....

(Seal)

(Date).....(Time).....

(Signature by any one of the doctors authorized by the medical superintendent of the
hospital.)

Form – III

Organ Retrieval Authorization Form

I/ We Dr. _____ here by authorize, as per Section 6 of the Transplantation Act, 1994, (Central Act 42 of 1994) for the retrieval, of the under mentioned organs, for the purpose of transplantation from the brain dead cadaver/deceased donor Mr./Mrs. _____ s/o / d/o _____ whose brain stem Death was certificated as per the said Act 1994 and the functioning status of the organ indented to be retrieved for transplantation purpose have been THOA 2011(amended) certified. Refer to relevant sections of THOA (amended) 2011 for the process of organ donation.

Organ authorized for retrieval are:

- 1)
- 2)
- 3)
- 4)
- 5)

(Signature of the Post – mortem Medical Officer who will conduct post-mortem)

Name.....
.....
Designation.....
Place.....
Date.....