Part - A

RECOMMENDATIONS

Dt. 22/07/2019

REPORT AND RECOMMENDATION OF THE COMMITTEE FOR LIVE DONATION ORGAN TRANSPLANT, PGIMER , CHANDIGARH.

This is with reference to order dated 16.05.2019 passed by the Hon'ble Punjab and Haryana High Court (CWP-15590-2016 and CWP-10247-2016) and the request sent by Director Health & Family Welfare, U.T. Chandigarh vide Endst. No.GH-III/2019/12980 dated 14.06.2019 and instruction forward by the office of Director PGIMER, Chandigarh to the Chairman of the appointed committee, Prof. Arunanshu Behera vide letter No.EKB-003568 dated 18.06.2019 the committee which looked into issue of cadaver donation has been reconvened to consider and deliberate upon the matter and issues of live organ donation.

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A meeting of the appropriate Committee constituted to go into the issue of transplantation of human organs out of Live Donor organ donations in this part of the country was held under the Chairmanship of Prof. Arunanshu Behera, Dept. of General Surgery on **18.7.2019 at 4.00pm** in the Committee Room of MS Office. Following attended the meeting:

Prof. R.K. Dhiman, Prof. H.S Kohli, Prof. Kajal Jain, Prof. Ashutosh Aggarwal, Prof. Y.S Bansal, Prof. Ajay Behl, Prof. Ashish Sharma, Prof. Vipin Koushal, Ms. Alka Sarin (Amicus Curiae), Adv. Manveen Narang, Adv. Mr. Arun Gosain

A meeting of the committee was previously held on 10.7.2019 under the Chairmanship of Prof.Arunanshu Behera, and attended by the following members.

Prof. R.K. Dhiman, Prof. Kajal Jain, Prof.Amit Gupta, Prof. Y.S Bansal, Prof. Ajay Behl, Prof. Ashish Sharma, Ms. Alka Sarin (Amicus Curiae), Adv.Ranjan Lakhanpal, Adv. Manveen Narang, Addl.A.G.Mr.Deepak Balyan,

The members had brought forward various suggestions for consideration and authorized the chairman to prepare the draft for the recommendation in consultation with the Amicus curiae appointed by Hon'ble High Court of Punjab and Haryana for next meeting for approval. The second meeting of the appointed committee was held on 18.07.2019

The Chairman prepared and brought forward the draft of recommendation which was discussed in length by the committee on 18.7.2019. The committee approved the draft recommendations.

PREAMBLE:

Transplantation of human organs or tissues in India are currently governed by the latest THOA act (amended)2011 notified by ministry of law and justice and

company affairs (legislative department) "The transplantation of human organs (amendment) at 2011 after assent of the president of India "on 27th September 2011. Under this act, chapter 7 section 24, the central government retained the power to make rules for this act.

Thereafter rules were notified in 27th march 2014 vide G.S.R 2018 (e) by ministry of health and family welfare. The current recommendations that are being given are in consonance/agreement with the THOA act 2011 and rules 2014. The transplant team/ surgeons are the first responders for conduct for the transplant when the patient and the donor seek transplant in the centre along with the donor who seeks to donate the organ or a part of organ for the recipient. Thereafter patient and the donor is clinically evaluated for eligibility, medical fitness and compatibility and evaluated for live donor transplant. In India as explained before living organ donation transplants are directed donations. i.e. the recipient and donor are known to each other. The situation as it exists is the live donor may be a near relative as defined under THOA act 2011(which includes spousal donors) or unrelated defined under section 9 (3) of the THOA act. It is the application of the section 9(3) that has led to live donors being recruited from 2nd, 3rd degree relations who are not included in the definition of near relatives OR from completely unrelated donors. The explanation given by the donors normally in their application is that there is an emotional attachment to the recipient. This section and subsection have resulted in commoditization of transplant surgery, mushrooming of transplant centres without proper expertise and infrastructures and falsification and impersonation of donors, involvement of middle man and coercive elements and trafficking in human beings as reported in UN reports and evident from various newspapers from time to time.

Live donations are being conducted for Kidney Transplants and Liver Transplants.

Kidney Transplant: Kidney transplant is a surgical procedure to place a healthy kidney from a living into a person whose kidneys no longer function properly. Since a human being can live with one Kidney, the healthy donor agrees to give one of his Kidney's to the recipient. For a donor who is healthy person there may be some short-term effects and some long-term effects. After the post-surgery cares the donor also needs periodical monitoring in order to live a healthy life.

Liver Transplant: Though each person has only one liver and would die without it, it is possible to donate a portion of the liver for transplantation into another individual. In live donations partial liver is removed and transplanted in the recipient. The partial livers in both the donor and the recipient will grow to provide normal liver function for both individuals. Possibility of Post- surgical complications are more than in Kidney Transplant.

There are other organs like part of lung, part of pancreas, part of intestine and certain body tissues can be donated when a person is willing to be a live donor.

There are two main types of Live donor organ donation that exists across the world, the Directed donation and the non- directed donation of organ or tissues. In India only Directed Live donations are recognised by law.

Directed Live donation: This applies to donation of organ donation done by a donor known to him. Under Indian scenario this includes Near relatives and spousal donors (as described in THOA) and donors who are not near relatives which include distant relatives, friend and unrelated individual who donate out of attachment and compassion. THOA Section9(3) permits distant relatives, friend and unrelated individual who donate out of attachment and affection or compassion and this has been misused in illegal transplants or trade and commoditisation.

Non-directed Live donations: This happens where the donor donates organ for altruistic beliefs and is meant for any individual not known to him/her. This has not happened in India so far. It is practiced in certain developed countries including U.S.A, some countries in Europe and Australia.

The swap donations or domino donations can be understood as an extension of Directed live organ donation.

Therefore, the issues addressed in THO Act relate only to Directed live organ donation in India, whether from near relative or not a near relative/unrelated individual.

The quantum of emotional attachment of the unrelated donor can never be evaluated prior to donor recruitment and authorization to go ahead for transplants. No psychological analysis in private is done for the unrelated donor before authorization committee meeting. The coercing involved and falsification done and commoditization of the very process therefore cannot be checked or contained if the data is not centralized for recipient and donor as envisaged in the THO Act.

Since the transplant team/ surgeons are the first responder for the request of transplant, every investigation impasse or newspapers report attributed to organ trade point the finger of suspicion to the transplant team which has enlisted the patient for treatment and aftercare. This may not be the case in fact. Medical ethics requires the transplant team only adheres to medical need and outcome of the recipient and the donor and confine themselves to the provision s that requires their participation as per THOA. Therefore, the role of treating transplant team should be limited as much permissible under the THOA 2011(amended) and Rules 2014 notified by Govt. of India.

Any exploitation of the above situation by anyone involved in the chain resulting finally in process of availing an authorization certificate from a proper authorization committee has led to corruption, organ trafficking or illegal transplants. Most of the cases again, since the surgical team was involved in the initial act of recruitment and the final act of surgery is blamed for failure to adhere to THOA act or any legality thereby absolving the responsibilities of the donor, recipient and the authorization committee/ hospital/ transplant centre, in charge of

hospital/ transplant centre which by law permitted and allowed 'these' transplant to happen. Since there are multiple levels of involvement in the sanction process, any investigation of wrong doing is very difficult to pinpoint, responsibility at a particular level to be addressed thereby creating a helpless situation to enforce the provisions of act and rules. This can be addressed by completely transparent and verifiable process and record kept each levels of involvement.

Before 1994, India had no legislation banning the sale of organs. Low costs and high availability brought in business from around the globe, and transformed India into one of the largest kidney transplant centres in the world. However, several problems began to surface. In 1994, the country passed the Transplantation of Human Organs Act (THOA), banning commerce in organs and promoting posthumous donation of organs. The law's primary mechanism for preventing the sale of organs was to restrict who could donate a kidney to another person. In particular, the THOA bars strangers from donating to one another; a person can only donate to a relative, spouse, or someone bound by "affection." In practice, though, people evade the law's restrictions to continue the trade in organs. Often, claims of "affection" are unfounded and the organ donor has no connection to the recipient.

The problem of illegal transplants not conforming to laws of the land has cropped up time and again in this country. Various news, media and U.N reports about organ trade in India has been about issues such as (I) When organ was removed without knowledge and consent of the person in pretext of some treatment, (ii) When poor people sell their organ to feed their family.iii) Coercive and forceful organ Trafficking

The disconnect between supply and demand has opened the door to a vast number of criminals and scrupulous elements who see the buying and selling of organs as a quick and relatively simple way to make tremendous profits with very little effort. The traffickers, not bound by either legal or moral imperatives, search for the cheapest sources of organs and sell in the richest of markets, making vast profits and using force and violence and duplicity without much fear of being caught.

The Transplantation of Human Organs Act, 1994, was enacted in India to stop the trade and clear the legal decks to enable a robust cadaver-based human organ donation programme to be put in place. Instead it is the live donation organ transplant that has thrived well in our country. The Hon'ble High court had emphasized earlier that a suggestion be given to improve cadaver/deceased organ donations in our country. However, cases are reported and identified about misuse of Section 9(3) of the Transplantation of Human Organs Act, 1994, which permitted a person to donate his or her kidney out of affection love or emotional attachment to the recipient as a live donor. Long titles of the Act and preamble both clarifies the intent of the Act is to prevention of commercial dealings in human organs and for matters connected therewith or incidental thereto. Further it conveys that it is intended to provide framework for the regulation of removal, storage and transplantation of human organs for therapeutic purposes and for the

prevention of commercial dealings in human organs. Section 3, 4, 5, and 6 of the Act tries regulating and monitoring commercialisation of organ donation. It had created the control of authority about when organ can be removed from the body of donor. It had also tried to monitor the act of removal of organ and lays down limitations on hospital in cases of removal of the organ. The central government again added the organisation of NOTTO and its various arms to monitor and regulate organ transplant across states who have adopted the central law and its provisions. (THOA2011- Chapter IV. National Human Organs and Tissues Removal and Storage Network: National Human Organs and Tissues Removal and Storage Network. National Registry)

The growing need by patients to get a transplant without any available robust cadaver/deceased donor programmes options, has created a situation where live donor transplant centres are sanctioned across the country. And with commoditization and large profit from the costs involved, dictated by demand and supply a large industry of private transplant centres are currently engaged in Live donor transplants completely neglecting the deceased donor transplants. This has only encouraged further trade in organs and donors as reported. The Hon'ble High Court had sought an opinion and recommendations of this committee regarding improving cadaver transplants and donation earlier. The committee had provided a report to the Hon'ble High Court.

There is also a pattern of hospitals and transplant centres employing visiting surgeons or teams to conduct organ transplants. This has encouraged commoditization of the transplant surgery as surgeons move across centres and hospitals where they are not originally registered under THO Act. The application for any organ transplant is specific about the hospital, the facility, availability of 24-hour services, name of surgeons and medical personnel in transplant team, equipments, the training and eligibility of the surgeons as per FORM 12 of the Act

There is no reason why a centre/hospital who has been inspected and found suitable for licence on all parameters will invite surgeons from other centres to operate at its own centres. It would amount to breach of transplant licence condition and also a conclusion that the team and the hospital were incapable of conducting specific organ transplants. The said licence for transplants should be revoked by appropriate authority in case of any such violation. Since this is not done and surgeons/teams conduct transplants where they are not registered. This happens more with hospitals who do not create atmosphere conducive for cadaver (deceased donor) donations and transplants but for economic reasons or to keep the programme alive and for a public gumption, image conduct such organs transplants under visiting surgeons.

The problem is even acute in government funded institutes and hospitals who either hire or sign MOU with a private hospital for conduct of transplants at the hospital. The application of Licence sanction never mentioned about the MOU nor the surgeon and the team are to be employed apart from those registered at the centre. This short-sighted practice also does not allow growth of robust transplant programmes in our country in government sectors.

It can be averred that the original team was not competent to provide transplant services at the time of sanction. Such licences are never revoked. Such a situation would have led to cancellation of licence in any other countries. It is also in contravention of and questions the basic procedure that was followed at the time of granting licence which by intent was not transferable. This kind of practice can lead to a damaging situations under consumer protection act, THOA 2011(amended), and prevent national agencies enforcing regulations of hospitals by the governments.

The above also creates a situation where government centres are neglecting cadaver donations. A situation arises where a reverse flow of patients is created by such visiting surgical teams either by reverse referrals or by 'so called patient's choice' and further commoditization and trade. This happens mostly in cases of unrelated donors across the country. The surgical team and medical team need to adhere to the spirit and intent of the provision and process under which the hospitals licence was granted. For this a definite obligation is required from the surgical team/hospital/centre, to re-register and seek a new licence if the original team is not capable of transplants. It is not safe too for patients to be operated by a team of surgeons and leave after care and donor issues and death, reporting to the hospital based team, who had expressed inability to deliver by requesting the services of a visiting surgeon, who is not registered at the centre.

Traffickers exploit the fact that states do not have transparent SOP (standard operating protocol) for live organ donations and the authorization process audited, that regulates transplant systems. Measures against trafficking for the purpose of organ removal would thus also require that systems and SOP s to be put in place that regulate and monitor organ donation and transplantation. Such SOP frameworks should function to identify potentially illegal transplant activities and potential victims of trafficking before their organs are removed. The primary objective of transplant policies and programmes should be optimal short-term and long-term medical care to promote the health of both donors and recipients in accordance with the principles of beneficence and non-malfeasance to both the donor and the recipient ("do no harm"). The donor should never be exploited emotionally and financially, coerced or intimidated or enticed into donation process.

The often-transnational nature of the crime, with donors coming from one state, recipients possibly from another, and maybe brokers from yet another one, the transplantation taking place in another state different from all these states, etc.; the crime scene would therefore be different from where donors and recipients live – an ideal setting for criminals. Adding to this is the situation where the surgical team is moving across the states to operate on patients and donors in a centre where he/team was not originally licensed to operate. The use of 'dormant' licences where the surgeons/surgeon has left employment at the specified centre and it is used by other surgeons/personnel not licensed as per provisions of FORM-12(THOA rules 2014), has made team of surgeons un accountable to post operative

care as a resident surgical team of centre. This makes investigating agency work difficult when the act has taken place in another state whose medical establishments are not directly under central government. This has allowed wrongdoers to escape law for long period of time.

The sanction of licence has three separate non transferable conditions i.e. the centre of transplant, the facility with equipment's and the personnel/meaning transplant surgeons/medical experts shown in FORM-12(THOA rules 2014).The visiting 'non resident 'surgeons or experts cannot operate at a different centres unless they are registered as per FORM-12 given for 'the' centre/hospital. It is this movement of surgeons across states and hospital where they are not employed has created many centres as front of a roaring transplant industry in our country. These centres should not have been issued licences if they were not competent by themselves to do specific organ transplants. This is also against medical ethics and following surgery when donor or recipient health issues post -operatively that are not being addressed to.

It should be mandatory for centre/teams to report donor status after live donations. The use of fly by night surgical teams who do not look after postoperative health of donors has been in practice for certain transplant centres to keep alive their programmes for public, generate considerable income or start a referral system for their own system and create a business model across states and centres. This in reality is in contravention of the provisions if Licence conditions that are there in Form-12.

Victims of organ trade , usually the donor are often reluctant to contact authorities out of fear for the safety of themselves or their families in the event that traffickers retaliate .Many States to date may have developed lists of indicators that can help law enforcement and criminal justice practitioners to better detect and identify trafficking in persons and its victims. These should be extended to include indicators to identify trafficking in persons for organ removal.

Victims are often reluctant to cooperate with law and enforcement agencies for fear of retaliations from middleman/ traffickers, for fear of being considered a criminal, out of shame and other reasons. The government in this condition have not granted witness protection for both recipient and the donor and in that scenario more violations will be reported.

The United Network for Organ Sharing (UNOS, U.S.A) defines transplant tourism as "the purchase of a transplant organ abroad that includes access to an organ while bypassing laws, rules, or processes of any or all countries involved." The term "transplant tourism" describes the commercialism that drives illegal organ trade, but not all medical tourism for organs is illegal. Australia and Singapore recently legalized monetary compensation for living organ donors. Proponents of such initiatives say that these measures do not pay people for their organs; rather, these measures merely compensate donors for the costs associated with donating an organ. For example, Australian donors receive 9 weeks' paid leave at a rate corresponding to the national minimum wage. Kidney disease advocacy organizations in both countries have expressed their support for this new initiative.

Although American federal law prohibits the sale of organs, it does permit state governments to compensate donors for travel, medical, and other incidental expenses associated with their donation. In 2004, the state of Wisconsin took advantage of this law to provide tax deductions to living donors to defray the costs of donation. In India Organ trade is prohibited under current Act, (THOA2011-Punishment for commercial dealings in human organs Section19)but the act does not address to donor compensation though a provision of "reimbursement" is exists in THOA (amended)2011 ,(Definitions)Section 2.subsection(k) where" payments" do not include any payment for defraying or reimbursing – (i) the cost of removing, transporting or preserving the human organ and tissue or both to be supplied; or (ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ and tissue or both from his body. It has not been addressed how a living donor can be compensated for above reasons.

The Guiding Principle 5 of the WHO Guiding Principles on Human Cells, Tissue and Organ Transplantation requires that Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

The 2014 UNODC Global Report on Trafficking in Persons states that despite legislative progress made concerning the crime of trafficking in persons, globally, there are still very few convictions for trafficking in persons. The low number of convictions may reflect the difficulties of the criminal justice systems to effectively respond to trafficking in persons. Experts agreed that impunity also prevails especially in the field of trafficking in persons for organ removal and especially among those medical professionals that would be involved in the crime

The committee reviewed the UNODC (United Nations Office on Drug and Crime report of 2015) on "Trafficking in Persons for the Purpose of Organ Removal" (United Nations Vienna, 2015) WHO Expert Advisory Panel on Transplantation, Organ Trafficking in India is accompanied with the menace of corruption. The Authorization Committee established under the Act which has been entrusted with granting power for organ transplantation, approved thousands of paid donor transplants after getting affidavits from donors coming under purview of Section 9(3) and to everyone's surprise it had been found in reality there was no affection or love between donor and recipient and they have never met each other to be able to donate the organs and the members of the Committee were bribed by middlemen.

Trafficking in organs and trafficking in persons for organ removal are different crimes, though frequently confused in public debate and among the legal and

scientific communities. In the case of trafficking in organs, the object of the crime is the organ, whereas in the case of human trafficking for organ removal, the object of the crime is the person. Trafficking in organs may have its origin in cases of human trafficking for organ removal, but organ trafficking will also frequently occur with no link to a case of human trafficking. The Convention defines as trafficking in human organs any of the following activities, when committed intentionally:

The illicit removal of organs: - removal without the free, informed and specific consent of the living donor, or, in the case of the deceased donor, without the removal being authorized under domestic law, OR - where in exchange for the removal of organs, the living donor, or a third party, has been offered or has received a financial gain or comparable advantage, OR - where in exchange for the removal of organs from a deceased donor, a third party has been offered or has received a financial gain or comparable advantages. The use of illicitly removed organs; The illicit solicitation or recruitment (of organ donors or recipients), or the offering and requesting of undue advantages; The preparation, preservation, storage, transportation, transfer, receipt, import and export of illicitly removed human organs; Aiding or abetting and any attempt is a crime universally.

The scarcity of evidence-based data on trafficking in persons for the purpose of organ removal can result in a lack of knowledge about the modus operandi of criminal networks, experiences of organ sellers, buyers and doctors, the criminal involvement of transplant professionals, the collusion and corruption within hospitals, possible manipulation of medical insurers, etc. Although research at the international, regional and national levels, organ removal, and this information is hardly reaching key stakeholders such as judicial authorities and law enforcement officials

As a result of the lack of existing partnerships and exchange of information, there is little awareness of the crime among criminal justice and law enforcement practitioners as well as policy makers. Consequently, trafficking in persons for organ removal does currently not seem to be on the 'enforcement agenda' of key stakeholders which under THOA1994, THOA 2011(amended) are the NOTTO, ROTTO, the Transplant centres, the Authorization committee, the treating transplant hospital, the team besides the recipient and the donor.

Under circumstances of severe organ scarcity and absence of robust cadaver transplant programmes, desperate patients may seek strategies to obtain organs illegally, outside legal transplantation frameworks. With an increased demand for organs comes their increased potential profitability, fuelling the desire of some people to trade and sell. As a result, next to altruistic procurement systems of organ supply, a black market coexists to meet the demand that altruistic systems fail to fulfil. Establishment of clinics or centres to deal with live donation transplants alone has not helped the situation.

Adding to above provision having a extraterritorial (across states or across the centres) application of employing transplant surgeons allows the relevant enforcement body and law enforcing bodies ,to lose jurisdiction over the offender,

regardless of whether they are located inside or outside of states territory. This jurisdiction includes enforcement of any action permitted by the statute, including financial remedies under consumer protection Act. In order for the offenders involved in organ trafficking to be brought to justice, extraterritorial application of the laws provided in the Act is imperative.

Teams and surgeons extending their practice across institutes or centres located outside the ambit of their licence application (FORM-12) , across government and private sectors, across centres situated in different states; across centres and facilities governed not by any single central/state authority make application of Act difficult and defeat the very purpose of the process that is required for a sanction of transplant licence. This also has impeded growth of cadaver transplant programmes in government sectors, as commoditization has attached a professional aura to live donor transplants, a medical service which was to be stringently ethical to help a needy for a good health.

People engaged in illegal Live donor organ transplants exploit the fact that centres /hospitals are not made accountable to a transparent and transparently audited regulatory transplant systems which can be centrally monitored by NOTTO in the lines of UNOS (U.S.A) and NHS (U.K).Measures against trafficking for the purpose of organ removal would thus also require that systems and frameworks be put in place that regulate and monitor organ donation and transplantation. Such frameworks should function to identify potentially illegal transplant activities and potential victims of trafficking before their organs are removed. The primary objective of transplant policies and programmes should be optimal short-term and long-term medical care to promote the health of a live donor in accordance with the principles of beneficence and non-malfeasance to both the donor and the recipient ("do no harm"). It is universally accepted truth that every technological development encompasses merits and demerits or both.

The appointed committee has deliberated on the provisions of the amended Act (THOA amended ,2011) and THOA rules 2014, and all the issues raised by the CWPs and in meetings, by various members and drafted certain recommendations. The committee feels that a complete transparency need to be maintained in donor and recipient verification, the reason or motivation of a live donor to donate organs, the Authorization process, the duties of Transplant coordinators, the duties and responsibility of the centre, responsibility and acts of treating doctors. All this must happen while protecting the rights of the recipient and donor privacy, adhering to medical ethics and fundamental rights of both donor &recipient and adhering to provisions of the THOActs and Rules.

The role of NOTTO in keeping DATA record of all live donor transplants and live donor deaths cannot be over emphasized. The committee suggests certain change to data keeping currently being followed manually and requesting a process which is digital and help in data mining or data recovery to trace any breach at any level.

Also, the committee feels that the donor detail verification should be mandatorily done with 'biometrics' as done for other services in our country. In our last recommendations to the Hon'ble high court we had suggested a 'cooling 'period of three months for a rethink on the part of the donor for his decision and allow time to address any breach as per THOAct before a transplant procedure. The committee maintains that recommendation and will mention this in one section of the current recommendation. The committee proposes to minimise the role of the transplant team in the legal process leading to authorizations and also provides the team to seek a revaluation of authorization if he/she feels, while performing the normal duty as registered medical practitioner while dealing to medical aspects of the live donor and the recipient.

The committee felt that a thorough psychological assessment of the donor be done in private prior to his appearance before the authorization committee and the transplant coordinators to be employed between transplant teams and authorization committees to prevent any conflicts of interest and alleged nexus in future. The committee also recommends that transplant centres be granted licence only in compliance to sanction conditions, a compliance statement for adherence provisions of THOAct and THOA -Rules and the CEO/director of the centre and a responsible member of transplant team like the senior most surgeon/medical expert from the

Transplant team who is conducting transplant for organ/organs licensed for the team, need to be accountable for act committed by the transplant team and for non adherence to transplant conditions and standards for which the centre was granted licence as per application in FORM-12 .

The committee recommends following after inviting comments and dissent notes with a justification from all members and invitees. The committee chairman enrolled the services a professor of Psychiatry department, PGIMER to advise the committee regarding a format to assess mandatorily issue of donor motivation and risk comprehension by donor and for an independent opinion that need to be forwarded to the authorization committee confidentially through the transplant coordinators.

FINAL RECOMMENDATIONS OF THE COMMITTEE

RECOMMENDATION 1.

BIOMETRIC VERIFICATIONS:

It is recommended that the identity of the donor and the recipient be verified through a biometric system of authentication obviating involvement of any scrupulous elements in the process and need for any officer to attest or verify ID documents.

ALL hospitals engaged in transplant procedures need to invest in a biometric system linked to national database of AADHAR and PAN numbers or any such other data base from where the identity of the Donor and Recipient can authentically be ascertained.

Justification:

All transplant performing centre need to invest in a unit for biometric verification to decrease incidences of fabrication, falsification, theft of identity of donors if we need to weed out corruption and scrupulous elements.

All such verifications are done at AADHAAR verification centres, PSKs (passport sewakendra), Driving licence issuing authority, voter id issuing authority ,PAN no issuing authority, Banks and telecom providers. There is no reason why such a process cannot be adopted at all licenced (approved)Transplant centres. The identity proof was given in a filled form format prior to 2014 and the country has progressed toward digitization since then linking AADHAAR and PAN to all services and bank accounts. This will minimize corruption at various levels as being suggested in subsequent recommendations. The centres can upload all data to NOTTO regarding all processes at various stages digitally and as scanned copies in future.

RECOMMENDATION 2.

Centralised database and registry:

Recommendation for a digital database in NOTTO/ROTTO for all live donor transplants and maintain a centralised registry and connected to AADHAAR database through NIC (National Informatics Centre).

a) It recommended that the NOTTO maintain a protected database assigning identification codes to all transplant centres across country, assigning identification codes to organ or organs, codes for live donor relation to be declared in database, assigning identification codes to state/district/U.T/hospital based authorization committees so that effective data uploading andData mining can be done by NOTTO and any competent authority under law to regulate transplant activities across states accepting and ratifying the central THOAct.

b) The ROTTO/NOTTO must maintain a database of all surgeons, medical expert mentioned in FORM -12 for sanction with their Aadhaar, PAN number, registered email id,medical council registration number and mobile number for quick redressal of breaches which may occur.

c) A database may be maintained for all employed and designated coordinators to assist in transplant protocols

d) A database needs to be maintained of various authorization committees assigning codes to the committee and its secretariat as suggested.

Justification:

All digital ID codes (as proposed herein) given to all stake holders in the process of authorization will make the decision makers and stake holders and individuals accountable to the regulating authority for transplants. It will also weed out middleman, personnel or centres making wrong data entry currently by print communications and defeating the purported regulation that was supposed to be in place. Currently there is only a monthly report sending in print to NOTTO /ROTTO about transplants conducted, manual return filing of name of donor and recipient with their hospital number, No of listed patients etc does not answer the issue of donor deaths, the issue of surgeries done by surgeons other than those listed at the centre at the time of sanction and breach that may have been committed by others but pointing the blame to the surgeon or transplant doctors. It does not take into account breaches committed during authorization process itself. Similar process of use computer algorithms for checks exists in country when citizens do not file income tax return in our country and avoid taxes.

References:*THOA2011- Chapter IV. National Human Organs and TissuesRemovalandStorageNetwork.NationalHumanOrgansandTissuesRemovalandStorageNetwork.NationalRegistry.13(C).TheCentralGovernmentmay,by notification, establish a National Human Organs and Tissues Removal and Storage Network at one or more places and Regional Network in such manner and to perform such functions, as may be prescribed.13(D). The Central Government shall maintain a national registry of the donors and recipients of human organs and tissues and such registry shall have such information as may be prescribed to an ongoing evaluation of the scientific and clinical staff". *THOA2011- Chapter VII Miscellaneous:. Section 24. Power to make rules for carrying out the purposes of this Act, (ic) the manner of establishment of a National Human Organs and Tissues Removal and Storage Network and Regional Network and functions to be

performed by them undersection13C; (id) the information in the national registry of the donors and recipients of human organs and tissues and all information under section 13D;

RECOMMENDATION 3.

DATA protection and confidentiality to be provided by NOTTO.

All confidential patient and professional data that is being forwarded as patient information and as per NOTTO requirement and requirement as underRules2014 must be protected from misuse by any one accessing the NOTTO site.

Justification:

Data protection is mandatory for protecting intellectual property rights, rights of an individual and on ethical medicine practice. This will protect doctors and individuals who may report to NOTTO about transplant related activities .The NOTTO must ensure this in consultation with NIC (National informatics centre). As the committee is recommending a verifiable digital data process at all levels, data protection is essential. Reference:*Rules 2014 – section 32 subsection (5)The Organ Donation Registry/Tissue Registry: shall include demographic information on donor (both living and deceased),hospital, height and weight, occupation, primary cause of death in case of deceased donor, associated medical illnesses, relevant laboratory tests, donor maintenance details, driving license or any other document of pledging donation, donation requested by whom, transplant coordinator, organs or tissue retrieved, outcome of donated organ or tissue, details of recipient, etc.

RECOMMENDATION 4.

Transplant coordinators to complete all formalities leading to Approval from authorization committee for live donation transplants:

The committee recommends that at all steps of required process leading up to authorization process to do live donor transplants be conducted by designated transplant co-ordinators, appointed as per THOA, leaving treating transplant doctors out from interacting directly with the authorization committees.

The transplant team member can only comply with requirements of authorization committee process as per law. The authorization committee can communicate in writing to the transplant coordinator any further requirement as per law is required from treating team.

The Hospital based Authorisation committee may have a scrutiny committee to prepare the files for putting up before the committee in place of secretariat.

Every case for Transplant should mandatorily be put up before the committee for their decision. Though the scrutiny committee may give its suggestions or observation, the ultimate decision should be that of the Authorisation committee.

Justification:

The treating team doctor is qualified in practice of medicine to attend to specific needs of the donor and recipient. They should not be engaged in responsibilities beyond their profession. Act and rules specifically provide that the operating surgeon/treating team cannot be part of the Authorisation committee. Strict adherence to the said provision will help in avoiding conflict of interest. A surgeon is an interested party in the sense that he will be conducting the surgery, hence the act mandates that he is not part of the Authorisation committee.

Involvement of treating transplant teams are prohibited under law (THOA Rules 2014) and it may lead to conflict of interests when authorization process is a legal verification of authenticity of data and intent presented by the donor and recipient. The role of authorization committee is to ensure adherence to provisions of the Act and Rules notified. The members of any hospital based scrutiny committee (whether medical or non-medical member) are in fact acting as member of secretariat to authorization committee.

RECOMMENDATION 5.

The committee recommends a uniform SOP (standard operating procedure) at all transplant centres to process live donor transplant application.

The details are provided in sequential manner of events from registration of patient till operation and discharge and data reporting at all levels as a SOP in annexure.

Justification:

This will ensure uniformity and transparency in procedures followed at all centres and their care givers for Live organ transplants. Kindly refer to SOP sheet annexed with these recommendations

Maintaining a clear and transparent standard operating protocol in current situation where allegation of wrong doing can be made is essential. It is paramount to address allegations of corruption and manipulations done by scrupulous elements in centres that are often alleged to have been committed by medical personnel/practitioners.

RECOMMENDATION 6.

The THOA and Rules (2014) provisions for Composition of authorization committees should not be overridden by centres and hospitals and no member of transplant team should be a member of any such committee or associated with it.

Justification

It is provisioned in THOA that treating member of transplant team can not be a member of any authorization committees. There is a provision for a secretariat of Authorization committee to assist the patient and process their (donor and recipient) request with a applications forwarded by transplant team member.

The Act also allows hospital-based authorization committees in case the centre conducts more than 25 transplants in a year. The Act and Rules 2014 clearly lays down norms for such a practice. It has been seen often that instead of a secretariat which scrutinizes the applications before sending them for approval from authorization committee; the centre appoint a "internal scrutiny" for same purpose.

It is also required from the intent of law in the THOAct , that no member of treating transplant team can be a member of such committee which will assist the authorization committee. This need to be strictly followed in such a scenario. The appointed transplant coordinators can present the case as it is based on application formats to the hospital-based scrutiny committee and thereafter to Hospital authorization committee. The scope of authorization committee is not clinical assessment but only to verify adherence to provisions in THOA as given in Forms1-9.This will remove alleged conflict of interest and allegations of bias often pointed towards treating doctors of transplant team. This will be also in conformity with intent of this in provisions of THOA including responsibilities of the Centre and its designated committees. It is believed and alleged that most of the transgression occurs at this level of process as per certain reports.

References:* THOA RULES 2014- SECTION 7-Authorisation Committee.—(1) The medical practitioner who will be part of the organ transplantation team for carrying out transplantation operation shall not be a member of the Authorisation Committee constituted under the provisions of clauses (a) and (b) of sub-section(4) of section 9 of the Act.*THOA RULES 2014- SECTION 11.Composition of Authorisation Committees: subsection(3) No member from transplant team of the institution should be a member of the respective Authorisation Committee.

*RULES 2014- SECTION 12.12. Composition of hospital based Authorisation Committees.—"The hospital based Authorisation Committee shall, as notified by the State Government in case of State and by the Union territory Administration in case of Union territory, consist of,...."

RECOMMENDATION 7.

The committee recommends a wait period or 'cooling period' for a live donor after his consent and psychological assessment.

This will not be applicable to emergency transplants, where the onus of urgency in transplant will rest with the surgeons/transplant team and the centre/hospital.

A second review by the authorization committee can be done and committee leaves it for the Hon'ble court to opine regarding a two-step authorization after a 'cooling' interval.

Justification:

The appointed committee had recommended a "cooling period "for live donor transplants. The committee accordingly recommends ranging from 6 weeks to three months across centres for routine live donor transplants. It also recommends that in case situations where an emergency transplant is being requested in application to authorization committee the onus must lie about indications of emergency with two treating doctors one of whom should be a physician. The onus of proving identity of donor must rest with the donor and one relative witness of the recipient. The process of uploading other details to NOTTO may be done within 2 weeks of surgery by the designated coordinator of the centre for emergency transplants.

The cooling off period will allow a rethink on the part of the live donor after re assessing risks to his health during and after donation. It will also weed our illegal donors to some extent as fear of law catching up will deter them from going ahead.

It will also give time to care givers and health professionals to report any alleged falsification or irregularities committed by the live donor or recipient. The committee has suggested that emergency transplants be kept out of cooling periods and have not compromised recipient safety in any way. Such emergency transplants should be reported to NOTTO within 2 weeks of date of surgery.

RECOMMENDATION 8.

Informed consent and right to withdraw consent.

The committee recommends that a mandatory informed consent be taken from the live donor explaining risks involved in donation surgery that are specific to organs that is to be harvested from his body ,risk of loss of life and his obligations to adhere to THO Act and laws.

The Informed Consent has to be in writing and explained in the language understood by the Donor.

And

The committee also recommends in that in consent process the donor be given an option to withdraw his consent any time before surgery or before his actual transfer to operating theatre of the facility.

Justification:

The donor may be unaware or not understood the risks involved in his live donor organ donation surgery. He can have a change of mind at any time.

It is recommended that an informed consent for a live related donor transplant be taken from both donor and recipient, which addresses the conformity to legal provisions of organ donation act 2011, explained to patient and the health risks involved in the surgery for the donor and the recipient. The sample of donor consent that is practised at PGIMER for organs (namely the liver) is being attached for court's opinion , the informed consent will differ in content for different organs in certain ways.

The donor must be explained of the risks of surgery involved including death and incapacitating morbidity which may cause loss of earnings and loss of his mental health after donation

It must be emphasised that informed consent explaining all aspects including medical and legal be explained to the recipient and especially the donor, who happens to be a perfectly healthy individual who is taking the risks involved in the surgical procedure completely unnecessary otherwise. The donor may not be aware of the risks involved in case of general type of consent taken for other surgeries. Risks and morbidity and a possible chance of mortality should be clearly understood by the donor.

Withdrawal of consent is accepted mode to ensure free and fair consenting process in surgery and give a second chance to donor to re think if he has taken the earlier decision under duress. This is in practice in many countries.

RECOMMENDATION 9.

The committee recommends a mandatory confidential psychological analysis of donor in private before presentation in person to authorization committee

Justification:

The committee recommends that a complete psychological/ psychometric evaluation be done on the donor to rule out coercion/ financial consideration while giving consents to donate his/her organs. The informed consent and a psychometric evaluation done in private with a psychologist will wipe out some of the organ trade that is being reported in UN reports (India) and most of the press reports across India about coercion, and allurement.

Aadhaar verification or PAN verification numbers, the code of organ transplanted, code of the centre, code of the authorization committee. Hence by data mining authentic outcomes can be very easily verified and discrepancies found out.

This first page of both donor and recipient discharge summary must be uploaded from the site of transplant centre and must have been signed by the nodal officer/ one in the team of licensed surgeons. This responsibility will lie with the transplant coordinator (a format is being enclosed) .Donor death reporting will be the responsibility of the centre/hospital within 72 hours.

Transplant coordinators will be assigned for specific organ/ organs for such reporting again. This formality must be completed within 6 weeks of all discharge or death either in format or scanned image.

Presently it is alleged that centres do not report donor deaths to anyone. Sometimes it is pending litigations in some courts which make regulating authorities aware of such an event. The recipient carries all risks of morbidity and acceptable mortality across the world. But donor deaths are audited as unacceptable events and are monitored in developed countries.

RECOMMENDATION 11.

The committee recommends that Up loading the result of Authorization committee for live donations approval or rejections; should be made compulsory from the hospital/ centre. This will enable regulating authority to trace rejected applications on ground of falsification as they are already AADHAAR and PAN linked in NOTTO database/registry.

Justification:

It should be mandatory for authorization committee to upload consolidated result of the authorization committee approvals and disapprovals/rejections to data base of NOTTO/ROTTO in case of live donors.

This will monitor the frequency of authorization committee meetings in a year. By a data mining process' professional' or illegal donations taking place anywhere in India or attempt to do so , or when a donor registers at a different centre after rejection from one centre ;can be traced by NOTTO. This will deter most of the organ trade. This will also point out any wrong reasons for denying a transplant to the needy. The database of members and ID codes of authorization committee, ID codes of centre facilitating transplant (or attempting) will be revealed to NOTTO by DATA mining in future. This does not stop donors who have been disallowed due to pending fitness or made to undergo a repeat assessment by authorization committee to be allowed to donate. It just makes all data accessible to NOTTO for formulation of future policies. Currently there is no modality to check functions and frequency of meetings of authorization committee. Reference:* THOA Rules

2014- Section 23 Decision of Authorisation Committee.—" (3) Every authorised transplantation centre must have its own website and the Authorisation Committee is required to take final decision within twenty four hours of holding the meeting for grant of permission or rejection for transplant.(4) The decision of the Authorisation Committee should be displayed on the notice board of the hospital o....." *THO Act 2011-restrictions on removal and transplantation of human organs and tissues or both. Section 9. 'Subsection (5)'

RECOMMENDATION 12.

Prevention of use of dormant licences and 'fly by night' or visiting surgeons who perform transplant procedures across states of India and in centres where they are not registered to practice as per FORM 12 during a grant of licence to the centre.

To practice or operate at a different centre the surgeons must register at that centre separately for a licence to operate as an employee of the centre/hospital, in form-12 and seek approval.

No member can perform duties of a transplant team unless licensed as per THO Act and without having his name in Form -12.(this excludes assistance team).

A compliance to provisions of Rules be taken from centres before granting a licence/sanction or a renewal for Sanctioning bodies must ensure standards and conditions for grant of certificate of registration for organ or tissue transplantations per the RULES -2014 , gazette of India : extraordinary [part ii—sec. 3 (26) . Conditions and standards for grant of certificate of registration for organ or tissue transplantation.

Justification:

Extraterritorial (across states or across different centres) application of employing transplant surgeons allows the relevant enforcement body and law enforcing bodies ,to lose jurisdiction over the offender, regardless of whether they are located inside or outside of states territory. This jurisdiction includes enforcement of any action permitted by the statute, including financial remedies under consumer protection Act. They are not physically present for full after care of the recipient or the live organ donor which is not ethically correct and may come as deficiency in services under CPA laws.

The competent sanctioning authorities must check the completeness of the professional ability and complete knowledge on part of the surgical or medical team about THO Acts and Rules governing organ transplants and provisions of punishments provided therein in the Acts. Otherwise laxity in interpretation about "active member" as a pre-requisite qualification in training of personnel has

resulted in certain dummy centres who only hire "visiting" surgeons to keep their programme alive.

Transplant surgeons and hospitals must comply with the conditions of Licence, sanction undertakings given while obtaining licence for a centre. NO surgical team member or surgeon is allowed by intent in law to practice in a centre where he has nor registered, sanctioned as per licence conditions in Form 12(THOA rules 2014).

The licence to a organ transplant facility cannot be violated under the Act either by the team/ facility in charge or the CEO/Director of the Hospital as that will amount to punishable offence under the THO Act. Licences are to be revoked if conditions are violated and undertakings are breached. The THOA Rules (2014) has been modified after THO Act 2011 (amended) became operational after assent from the President of India.

The licence mentions conditions such as" personnel and equipment' shown at the facility/centre. The form -12 has three condition specific to specific organ transplant i.e. the centre, facility with equipment, and the transplant surgeon/transplant team mentioned. There are conditions for the facility and an undertaking for compliance is taken along with form 12. (PGIMER sanction letter attached for Hon'ble courts perusal). These conditions are specific to the organ transplant facility as well as the transplant doctors/personnel mentioned in Form - 12 and the hospital .They cannot be treated as 'transferable' for a different centre , a centre in different/location or states.

The committee requests opinion of hon'ble High Court on above interpretation by the committee. There are surgeons who fly by night to operate in a different centre where they are not employed allegedly as good Samaritan act. The centre had taken a licence earlier by presenting asset of surgeons who have left their employment. In our view this is not in accordance with sanction condition.

The licence deemed to have expired any of the conditions in FORM-12 did not exist and afresh licence should have been sought by the centre. This is a dormant and invalid licence. In case any door death or any mishap penning it becomes difficult to point at responsibilities with respect to Informed consent, authorization process, and centres liability. This is adopted by certain centres to show to public that transplants do take place at the centre and also it helps in commoditization that we have mentioned earlier. The operating surgeon does not look after the post operative care of either donor or patient till discharge. This is the reason why Form-12 has mention of facility, equipment, and personnel. The centres also dilute conditions of sanction with respect to facility for their need.

It is the committee view that in case of violation of any conditions in sanction as stated in FORM-12 the centre must lose the licence to provide services of organ transplant . Most of the transplant trade tourism which are illegal in nature will stop. Some government establishment escape scrutiny when they borrow private surgeons to keep their transplant programme alive by showing good Samaritan act from a private centre whereas the private sector involved will not offer their

services to poor and needy. In the event of any misshapen the visiting surgeon is not available to take care of the donor or recipient at the centre where he was operated in a different jurisdictions under law.

In such a scenario the centres surgeons as per FORM12 along with CEO of the centre/hospital, must be held accountable under the THOA and CPA provisions.

References:*THO Act 2011- Chapter III Regulation of hospitals Regulation of hospitals conducting the removal, storage or transplantation of human organs and tissues or both. Section.10. subsection(b) '"no medical practitioner or any other person shall conduct, or cause to be conducted, or aid in conducting by himself or through any other person, any activity relating to the removal, storage or transplantation of any human organ and tissue or both at a place other than an place registered under this Act; and (c) no place including a hospital registered under subsection (1) of section 15 shall be used or cause to be used by any person for the removal, storage or transplantation of any human,...'" * THO Act 2011-Chapter V Registration of Hospitals: Registration of hospitals engaged in removal. Section. (14) subsection (3)." No hospital shall be registered under this Act unless the Appropriate authority is satisfied that such hospital is in a position to provide such specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed. (4). No hospital shall be registered under this Act, unless the Appropriate Authority is satisfied that such hospital has appointed a transplant co-ordinator having such qualifications and experience as may be prescribed" *THOA2011-Chapter VI Offences and Penalties Punishment for removal of human organ without authority. 18. (1)." Any person who renders his services to or at any hospital and who, for purposes of.." *THOA Rules 2014 –Section 26. Conditions and standards for grant of certificate of registration for organ or tissue transplantation centres.—"(1) No hospital shall be granted a certificate of registration for organ transplantation unless it fulfils the following conditions and standards, namely....."

RECOMMENDATION 13.

All the transplant centres must keep a copy of transplant license and copy of FORM12 at the facility offering transplants of a specific organ along with any compliance statements provided; for future inspections.

Justification:

The licence is issued with specific conditions after approval by competent authority.

The Form-12 is submitted at the time of sanction, duly signed by the CEO of the organization and in charge of the specific organ transplant officer (nodal officer)

for the organ/organs as an undertaking. They should be available to any inspecting team so appointed by the competent authority.

The sanctioning authority must validate "active member status" of the trained transplant surgeons while issuing transplant licences. An active member should have participated in Listing procedure, actual transplant surgery, post -operative care, discharge and aftercare, follow up and active training of organ harvesting, and must have adequate training in organ harvesting as all transplant centres automatically qualify as retrieval centres as per the Act. It may be noted in our view that, the certificates of registration of the facility is not transferable between the centres or for the various facilities in the centre or team of surgeon/surgeons/personnel that was shown at the time of sanction.

The patient and the donor who is undergoing transplant and donation must satisfy themselves if they so desire (see the conditions of sanction).

It has been observed that a surgeon/ team of surgeons that have been sanctioned to a particular facility is operating in a facility other than the centre (fly by night surgeons). At times surgeon moves across the state/states that are not in complete agreement of THOA rules.

In case of any mis-happening or wrongdoing, pinpointing the centre's responsibility and that of operating surgeon becomes difficult and therefore the cases that are registered on malpractices in transplant are not addressed quickly, provide any remedy to the donor in case of donor deaths or the recipient if a malpractice has occurred. The licence to do transplants by a surgeon after his met condition of THOA rules 2014 cannot be equated with degree/diploma licences, received under Indian medical council act/ state medical council act/ regional medical council act. Such degrees/ diplomas/ training can only be considered as eligible to obtain a licence for transplanting a particular organ at a specified centre according to THOA act- 2011 and THOA Rules- 2014. It must be understood at this point that from the words of the licensing authority, that the licence is specific to the centre, to the facility and the personnel (specifically the surgeons) shown by the centres.

If the surgeons chose to practice at different facilities, they must be registered through that facility/centre as per provisions of application in FORM12. It has been clarified earlier that these licenses are not transferable.

It has been seen in certain government sectors to keep a program alive; surgeons from private sectors are hired or as declared free of cost to the institution or the organization and organs of transplant. This creates an unhealthy condition which may lead to unethical situation which way refer back scenario where by from private surgeons cases are referred to the centre of the private practitioner. This may also give rise to a donor not being accepted in the government sector being accepted in private sector

The doctors in private or government sector when didn't have adequate facility or the personnel (surgeons) shouldn't have applied and given a licence for a transplant facility of any organ. This amounts to centre or institution being incompetent but holding a license to operate. In such a situation, their licences

granted should have been revoked in any other country across the world. This also creates a situation where certain surgeons merely act as a dummy (centre) for others to practice. The transplant centres sanctioned are retrieval centre for Deceased donors as per the act and their training in this aspect is mandatory and should have been assessed too while granting a licence.

It must be clarified that transplant training eligibility is not registered with any state medical councils as a medical degree but only be done with competent authority under THOA and a licence as applied for in form -12 needs to be obtained to practice at a specific centre.
References:*THOA2011-Chapter V Registration of Hospitals: Registration of hospitals engaged in removal. Section. (14) subsection (3). No hospital shall be registered under this Act unless the Appropriate authority is satisfied that such hospital is in a position to provide such specialised services and facilities, possess such skilled manpower and equipments and maintain such standards as may be prescribed. (4). No hospital shall be registered under this Act, unless the Appropriate Authority is satisfied that such hospital has appointed a transplant co-ordinator having such qualifications and experience as may be prescribed * THO Act 2011- Chapter VII Miscellaneous:. Section 24. Subsection. (2). (h) the standards as are to be enforced by the Appropriate authority for hospitals engaged in the removal, storage or transplantation of any human Page 19 of 20 and tissue or both organ under clause (iii) of subsection (3) of section 13.

RECOMMENDATION 14.

The committee recommends that a monetary reimbursement be given to a donor as a lump sum amount towards any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ and tissue or both from his body; for recuperation and travel for follow up.

This must be given to all live donors. A sum of INR 50,000 is considered by committee adequate. This sum must be deposited by the Recipient at the centre for transplant which will reimburse the donor at the time of discharge through a demand draft or RTGS. This amount would be over and above the medical expenses incurred for the Transplant viz-a-viz the donor.

Alternatively a system will need to be devised where provisions are made for medical insurance of the Donor as well as his post surgical needs be it medication, diet etc are taken care off. The States may also see the feasibility of providing free medical treatment to the Donors in a government hospital

Justification:

Recommendation for financial reimbursement as allowed under the lawfor recuperation and manpower days lost, earning lost during his time of surgery, discharge and follow up. The committee referred to THOA (amended) 2011Secton 2. (definitions) subsection(k)

(k) "payment" means payment in money or money's worth but does not include any payment for defraying or reimbursing – (i) the cost of removing, transporting or preserving the human organ and tissue or both to be supplied; or (ii) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying any human organ and tissue or both from his body;

Australia and Singapore recently legalized monetary compensation for living organ donors. Proponents of such initiatives say that these measures do not pay people for their organs; rather, these measures merely compensate donors for the costs associated with donating an organ. For example, Australian donors receive 9 weeks' paid leave at a rate corresponding to the national minimum wage. Kidney disease advocacy organizations in both countries have expressed their support for this new initiative. Reference: THOA (amended) 2011Secton 2. (definitions) subsection (k)

RECOMMENDATION 15:

The Authorisation Committee set up under the THO Act must mandatorily undergo a 4 weeks crash course/ initiation course regarding the manner in which the Donors and Donees are to be evaluated. The NOTTO and ROTTO must organise courses for candidates/members of future Authorization Committees.

Justification:

The authorization committees must undergo a course to understand their responsibilities under THOA. This orientation course must be provided by the states/NOTTO/ROTTO. The authorization committee is expected to have complete knowledge of all aspects including legal aspects of the THO Act and Rules.

RECOMMENDATION 16.

The committee keeping in view of its earlier recommendation on Deceased donor (cadaver) transplants recommends that all government hospitals and transplant centres to give priority attention to improving cadaver (deceased donor) organ donations to relieve stress on live organ donation and thus help

prevent or minimize misuse, commoditization , trade and trafficking involved with live organ donations.

Justification.

All transplants centres are automatically recognised as retrieval centres under THO Act. It is their responsibility to help governments in increasing number of cadaver transplants. The government aided hospitals with trauma centres and multiple ICU services cannot abrogate their responsibility to develop robust cadaver retrieval and transplant programmes and prevent mushrooming of 'Live organ transplants 'only centres and facility.

The very intent of THO Act 1994 and 2011(amended) was to have regulated deceased donor transplant centres and if need be to allow live organ transplants from relatives: whether near related or affectionately related. Failing to understand this intent has given rise to facilities providing only live organ donation transplants and availing publicity for same to solicit more such transplants and defeat the purpose and the very intent of government which brought in legislation through THO Act 1994(original).

The commoditization and trade that is being witnessed is the outcome of misunderstanding the purpose of these Acts.. The mainstay of organ transplants as in U.S.A (UNOS data) and U.K (NHS data) reveals that these countries perform deceased donor transplants far in excess of live donor transplants. The live donor transplants in principle simply supplement a cadaver transplant programme in case of need and not replace it.

The committee has dwelt on various issues brought forward in meetings and taken assistance from attendees from legal fraternity before drafting recommendations.

Provisions from Transplantation of Human Organ Act 1994, THOA

2011(amended) and THOA. Rules -2014 were cited as applicable by the chairman in preparing draft for approval from the committee.

The Committee has made the above recommendations regarding live donor organ transplants for the consideration of the Hon'ble High Court, in compliance to order passed by Hon'ble Court on 16-05-2019 to deliberate upon matter of live donation and to submit a report.

Prof. Arunanshu Behera
(Chairman)
20/07/2019

Advocate Ms.Alka Sarin
(Amicus Curiae)

Co –signatories to the above report 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

No. GS/CC/14/ Date: 22-07-2019

Prof. Arunanshu Behera

(Chairman)

Advocate Ms.Alka Sarin

(Amicus Curiae)

(Confidential and sealed)