Medicolegal issues in Kidney Transplantation: with updates in HOTA amendments 2014

Draft for adoption by IMA, more inputs needed

Human organs are part of national resources of a country. Organs cannot be sold or bought, organs can only be donated for therapeutic purposes. This rule of donation is applicable internationally. No country permits organ trafficking. Doctors are doing organ sale / purchase in countries where laws regulating transplantation are lenient. This has given birth to the lucrative business of transplant tourism. Indian patients in need of kidney transplant are going to Sri Lanka & Bangladesh.

Several issues hinder the process of organ transplantation.
Medical issues: HIV infection is a contraindication for kidney donation. But HIV positive donor can donate to HIV positive CKD recipient; likewise for hepatitis B and C infection.
Legal issues: Illegal organ sale & purchase.
Ethical issues: When a trauma patient suddenly dies during treatment, the treating doctors may think it very unethical to ask the grieving relatives, who are in panic state, for removal of organs.
Social issues: Poverty compels donors to sell their kidney to rich CKD patients.
Nationality issues: Transplant tourism is popular in Nigerian & Turkish youths to combat poverty.
Religious issues: Some Hindus have false belief that removal of an organ just after death will remain as defect in next birth e.g. a cadaveric cornea donor will be born blind in the next birth.
Jehovah’s Witnesses refuse all sorts of transplantation; they will die of anemia/blood loss but will never agree for even blood transfusion.
Risk factors that are highly suggestive of a kidney donation scam and/or foul play in organ transplantation: When the donor is a recently married wife (transplant marriage just for kidney); donor is not a near relative; inadequate documentary proof; DNA profile/ HLA mismatch; donor appears to be of poor financial status; donor complains of cheating and denial by Authorization Committee in other hospital / state.
Why is kidney organ transplant scam is the most reported?: Pair of vital
organs, but one can compensate another functionally; easily removable surgically; does not hamper the routine life of poor donor unlike pair of eye/ear/lungs and lifesaving for wealthy ESRD patients. So they hunt for donors in small city hospitals via touts/agents and sometimes marry the poor donor for kidney.

Donating kidney is limited to middle-class families to their dear ones. Upper class buys from lower class kidneys illegally for 5-10 lakhs.

What is the only legally permissible reason for organ donation? Donor donates one kidney “Out of affection” for the organ recipient.


Transplantation – WHO guidelines: Brain death; Consent; Transplant Authorisation Committee; Condemn organ trafficking for money; Promote non-remunerated donation and Donor advocate – NGO transplant coordinators.

Transplantation of Human Organs Act (THOA) is a special act, made by centre. Health is a state subject, each state has to adopt THOA, by passing legislation under Article 252 of constitution. Few states have adopted THOTA amendments 2014 e.g. Tamil Nadu, Goa, Delhi, West Bengal, Maharashtra, Himachal Pradesh & all union territories. THOA was initially binding in Maharashtra, Himachal Pradesh, Goa and all union territories, because they initiated the law on transplantation. THOA is still not adopted by Andhra Pradesh (?) and Jammu and Kashmir.

1994 : Transplantation of Human Organs Act (THOA) passed

No doctor or hospital will advertise that they are doing organ transplantation.

‘Donor’- means any person, not less than 18 years, who voluntarily authorizes the removal of any of his organs for therapeutic purposes.

‘Near relative’ means persons related to each other genetically, especially son, daughter, father, mother, brother, or sister. It also includes grandparents and grandchildren.

‘Next of kin’ means the ‘closest living relative’ linked by direct relationship from either blood or marriage.

No payment to donor by recipient. The cost of removing, transporting, preserving of kidney will be paid by the recipient to the hospital doing surgery. Cost incurred on maintenance of the body of brain-stem dead person for the purpose of retrieval of organs and/or tissues, will be paid by recipient.

‘Brain-stem death’ means the stage at which all functions of the brainstem have permanently & irreversibly ceased and it is so certified by panel of medical experts (other than the treating doctor)- neurologist.

2008: THOA Amendment (Transplantation of Human Organs & Tissues)

THOTA: Tissue means a group of cell, except blood. Tissue that can be
donated include the eyes, skin, bone, heart valves, eardrum, ear bones and tendons.

2014: THOTA New Rules & Amendments

Brain death can be certified by physician/surgeon/ anesthetist/ intensivist (who are not in team of transplant surgery) in the panel of medical experts.

Transplant allowed in MLC Cases too, & guidelines set for police & Hospitals in procuring organs from unclaimed dead bodies (Hospital/prison) after 24 hours.

No human organs or tissues shall be removed from the body of child<18yrs or mentally challenged person (includes person with mental illness or mental retardation) before his death, for transplantation.

Transplant swapping guidelines for mutual exchange among 2 donor families with HLA matching.

Guidelines for international donors & recipients for transplant tourism. When the proposed donor or the recipient or both are foreigners:- (i) A senior Embassy official of the country of origin has to certify the relationship between the donor and the recipient as per Form 14C. In case a country does not have an Embassy in India, the certificate of relationship, in the above format, shall be issued by the Government of that country. (ii) Authorization Committee shall examine the cases of all Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of Indian origin, with greater caution.

‘No Objection Certificate’ (NOC). When the donor is unrelated and the donor and/or recipient belong to a State/Union Territory other than the State/Union Territory, where the transplant is intended to take place, then the domicile state of the donor or recipient as the case may be, would provide the No Objection Certificate in respect of legal and residential status of donor / recipient as the case may be; while the approval for transplantation would be considered by the authorization committee of the State/District/hospital (as the case may be) where the transplantation is intended to be done. “No Objection Certificate” will not be required for near relatives including cases involving swapping of organs (permissible between near relatives only).

If the relationship is not conclusively established in donation between husband & wife, even after evaluating the documentary evidence of relationship e.g. birth certificates of children, family photographs and marriage certificates, Authorisation Committee may in its discretion, direct further medical tests- Deoxyribonucleic Acid (DNA) Profiling of kids, from a laboratory accredited with NABL.
In case the proposed transplant is between unrelated persons. Form 16 is to be provided as income proof or last 3 years Bank Statement, as appropriate evidence of vocation and income of the donor as well as the recipient for the last 3 years.

Whom to appeal if approval not granted by committee? Appeal to the State Government within 30 days. If not granted- appeal to the central Government.

In cases of research involving Donation/Transplantation of Human Organs: Donation from a live donor should be restricted to renewable tissues like bone marrow or to a paired organ whose removal will not greatly alter physiological functions, such as the kidney. The Institutional Ethics Committee has a very important role in safeguarding the rights of the research subjects.

There must be no element of commercialization or exploitation in the donation.

HOTA doesn’t regulate bone-marrow transplant or Blood donation for Blood-banks, or sperm donation for sperm-banks in IVF, or Placental-tissue banking. They are regulated under Drug & Cosmetics act.

Laws applicable: Transplant Surgeons & Medical Superintendent are charged under IPC sections 120 (B), 342, 468, 471, 34 of IPC and section-18 & 19 of the transplantation of Human Organs and Tissues Act, 1994.

S.18 of THOTA- Doctor Punished for doing illegal transplantation- 10 years prison with 20 lakhs-1 crore fine and penal erasure from Register of State Medical council for 2 years for the 1st offence & permanently for the subsequent offence.

S.19A of THOTA- Punishment for abetting false documents, negotiates or receive money, advertises or supplies organs for getting illegal transplantation- 2 years prison with Rs. 10,000/- fine.

Section 120B Indian Penal Code: Punishment of criminal conspiracy

(1) Whoever is a party to a criminal conspiracy to commit an offence punishable with death, 2 [imprisonment for life] or rigorous imprisonment for a term of two years or upwards, shall, where no express provision is made in this Code for the punishment of such a conspiracy, be punished in the same manner as if he had abetted such offence.

(2) Whoever is a party to a criminal conspiracy other than a criminal conspiracy to commit an offence punishable as aforesaid shall be punished
with imprisonment of either description for a term not exceeding six months, or with fine or with both.)

Section 342 IPC. Punishment for wrongful confinement. Whoever wrongfully confines any person shall be punished with imprisonment of either description for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both.

Section 468 IPC. Forgery for purpose of cheating: Whoever commits forgery, intending that the *(document or Electronic Record forged) shall be used for the purpose of cheating, shall be punished with imprisonment of either description for a term which may extend to seven years, and shall also be liable to fine.

Section 471 IPC. Using as genuine a forged document or electronic record: *(to prove donor a 'near-relative')*: Whoever fraudulently or dishonestly uses as genuine any *(document or electronic record) which he knows or has reason to believe to be a forged (document or electronic record), shall be punished in the same manner as if he had forged such (document or electronic record).

Section 34 IPC: Acts done by several persons in furtherance of common intention. When a criminal act is done by several persons in furtherance of the common intention of all, each of such persons is liable for that act in the same manner as if it were done by him alone.) (Input: Dr Vivekanshu, Medanta - The Medicity, Gurgaon)