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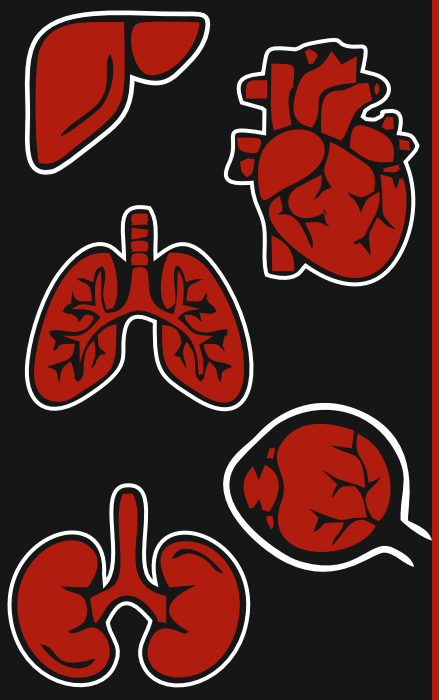

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Twenty-Five Years of Transplantation Law in India – Progress and the Way Forward

The historical Transplantation of Human Organs Act (THOA) was passed in our Lok Sabha in 1994 and completed 25 years this year.[1] The objective of the law was to stop organ commerce and accept brain stem death as a form of death to enhance the organ pool in India. However, during the first few years, neither did the unrelated organ commerce stop nor was declaring brain stem death widely practiced, and hence, very few organs were generated.[2] During the first 5 years of the law, a few hospitals had started the deceased donation program, and most others had given up on the program and labeled it as a nonstarter. The reasons given were the lack of awareness among the people and the multireligious and culturally diverse nature of the country.[3]

The law underwent amendment in 2011 and rules were framed in 2014 after recommendations of the Rajya Sabha Standing Committee on the subject. were received.[4] Certain provisions were included to ensure that the onus of responsibility for commercial organ donation was shifted to the organ donors, recipients, treating doctors and hospital administrators. The punishment for forged documents and false affidavits was considerably enhanced and could go up to ₹ 1 crore or 10 years in jail. Provisions to help push forward the deceased donation program were also included.[5] In states such as Tamil Nadu, path-breaking local government orders helped the program to take off in 2009,[6] and many of these provisions were incorporated in the 2011 amended law and its rules.[7]

The deceased donation rate went up over four times in 6 years from 2012 to 2017 [Figure 1]. Currently, not all states and union territories (UTs) have been able to perform deceased donation transplantation.[8] Among the 13 of a total of 36 states and UTs that have performed such transplants, only about five to six do it regularly and have a proper system for organ donation and allocation.[9] When we speak of India's donation rate of 0.8 PMP, the bulk of these figures reflects the donations coming from these few states.[10] The states represent less than half of the population of India, however if all 36 states and UTs of the country performed such deceased donor transplants this figure would be substantially higher. In the past 6 years, over 3100 families have said yes to donation and saved almost 9100 lives through organ and tissue donation (2012–2017)[11] The progress made has given hope to many patients suffering from organ failure; however, the demand for organs continues to exceed the supply. Most donations come from ordinary people who have the extraordinary conviction and courage to say yes to donation despite their own personal loss. This surge in deceased donation rate can be attributed to the progressive Policies of Tamil Nadu[12] as Andhra Pradesh, Telangana, Kerala and Rajasthan and due to the push provided by the private and public hospitals in states such as Maharashtra and Gujarat and UTs of Chandigarh and Puducherry.

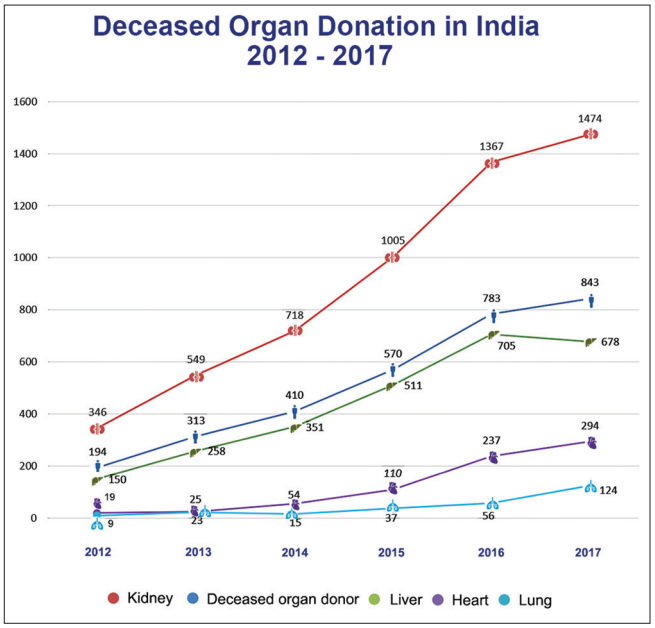

Figure 1: Deceased donation in India – 2012–2017

The key to success of the program largely depends on the availability of acute trauma services in a hospital that can identify and maintain brain deaths and support the grieving families for possible organ donation. The other challenge often faced in our intensive care is that organ donation is generally linked to brain stem death and only if family says yes to organ donation are clinicians willing to consider doing a formal brain stem death testing to declare the patient dead.

Transplant Law – The Way Forward

Our transplant law requires further amendments and clarity, if we wish to improve our numbers and it would need to ease many pain points that still exist for the clinicians, transplant coordinators, potential organ donor families, and organ distribution networks.

These are ten recommendations where either clarity is required or improvement in our law is necessary:

1. Brain stem death should be delinked from organ donation: Brain stem death as death is only mentioned in the transplant law and has been linked to organ donation. It is not mentioned in the Registration of Births and Deaths Act of 1969.[13] Therefore, in brain stem death situations where relatives refuse organ donation, the clinicians find

it difficult to disconnect the ventilator. This creates a legal and ethically challenging situation where one could be dead enough to donate when there is a yes for organ donation but continues to be unnecessarily ventilated if there is a no to the request for donation

What is required is to 'define death' in the same standard terminology in both the Registration of Births and Deaths Act and the THOA.[14] THOA defines a deceased person as one in whom permanent disappearance of all evidence of life occurs, by reason of brain stem death or in a cardiopulmonary sense at any time after live birth has taken place. It also defines "brain stem death" that means the stage at which all functions of the brain stem have permanently and irreversibly ceased. Therefore, the Registration of Births and Deaths Act should define death as "death of an individual who has sustained either (a) irreversible cessation of circulatory and respiratory functions or (b) irreversible cessation of all functions of the brain stem." Also as the first step towards delinking, it is recommended that the clause in the brain stem death certificate that states - "has the patient or next of kin agreed to any donation of organ and or tissue" (Form 10 of Rules 2014) be removed.

2. Including ancillary tests for certifying brain stem death when apnea test is not possible: In India, we follow brain stem death criteria, whereas the USA follows whole-brain death concept. In many instances where apnea test is not possible, ancillary tests such as radionuclide scan or four-vessel angiography should be included to show that there is no blood flow to the brain
3. Uniform guidelines for declaring brain stem death by hospitals: Currently, the guidelines for declaring brain stem death can vary from region to region and hospital to hospital. Recently, the robustness of testing for brain stem death has been challenged in Kerala in the high court.[15] This resulted in confusion and passing of government orders to videograph brain stem death testing process which is not only unnecessary but also a gross infringement on the privacy of the patient.[16] The World Brain Death Project recommends uniform practice with trained doctors to avoid inconsistencies in the practice of brain death declaration.[17] A uniform protocol can come as a rule of the act after obtaining consensus from the experts in the country
4. Making reporting of brain stem deaths in a hospital mandatory to the state authority: India has a high rate of road fatalities due to head injury from two- and four-wheeler vehicular accidents resulting in potentially many young organ donors.[18] Currently, there are no mechanisms in place to either identify or certify these brain deaths. Neither is there any reporting or audits of such deaths in intensive care units. Efforts are required to train intensive care staff to manage such patients and report these deaths to the state authority
5. Frame rules for donation after circulatory death: There has been remarkable progress in the area of solid organ donation after cardiopulmonary or circulatory death. In countries such as the United Kingdom, one-third of overall organ donations come from this category of organ donors[19]

The THOA law recognizes cardiopulmonary death for organ donation; however, it provides no rules to ensure that it is done ethically and legally and should not be marred by any ambiguity for misuse. For example, most countries follow 5 or 10 min "no-touch time" after cardiac arrest for surgical intervention, to ensure that death is declared and no resuscitation is possible. There needs to be consensus from the medical community on such sensitive issues, and these need to be incorporated in the rules of the law.

6. Donor pledge form (old form 5 or new form 7) requires a legal status: These are fairly elaborate forms and should be given legal validity. Currently, despite these forms, the next of kin (NOK) or near relative signature is required for organ donation to occur in the hospital. These forms need to be given a legal standing and considered as a person's living will for organ donation. The Government of India has recently introduced the clause of organ donation on the Indian driving licenses too,[20] and in future, it is hoped that this will be an important tool to check for consent of a potential donor. Taking these into consideration, these instruments need to be properly utilized to make efforts in promoting organ donation in the community more meaningful
7. Hierarchy for consent for donation requires to be defined: Who is NOK to provide consent for organ donation in an emergency situation requires to be defined. There are many instances where the NOK may not be available for consent. This delays the donation process, and sometimes, the donation itself does not happen
8. Accountability of hospitals getting license for organ donation and transplantation: The hospitals should have an obligation to share their data about short- and long-term outcomes of the transplant graft. Audits of pooled data would help in improvement and bringing in standards in the program that are evidence based. This could be made mandatory and a prerequisite when the license for transplants is being granted or renewed. Nonadherence should mean suspension of their license
9. Postmortem procedures in event of brain death need to be defined and further simplified: The process of postmortem should be uniform in all states when an organ donation takes place and a proper laid out procedure should be followed. Both the police and the forensic department should be made aware of these provisions
10. Do away with the clause of donation from unclaimed bodies: In the past 25 years, no donation has come from this category, and this should be deleted or further clarified.

The Government of India has formed the national, regional, and state bodies to overlook the program. This is a step in the right direction; however, these bodies need to focus their

efforts to improve donations and transplants in the public sector hospitals; otherwise, the large majority of both deceased and live donation transplantations would only serve the affordable class and miss out a large chunk of the population. The transplant law should universally benefit all the citizens of our country, and this is the way forward for this program.

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