Journal of Clinical and Experimental Transplantation

Vasanthi, J Clin Exp Transplant 2021, 6:5

Review Article Open Access

Legal Developments in Transplantation in India and the 2011 Amendment of THOA1994

Ramesh Vasanthi*

Department of Surgery, Safdarjung Hospital, New Delhi, India

***Correspondce to:** Ramesh Vasanthi, Department of Surgery, Safdarjung Hospital, New Delhi, India, Tel: 87564953210; E-mail: vasramesh59@gmail.com

Received date: August 02, 2021; **Accepted date:** August 16, 2021; **Published date:** August 23, 2021

Copyright: © 2021 Vasanthi R. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Abstract

In India, organ donation and transplantation dates back to over half a century when Udupa pioneered the kidney transplant in BHU. It continued gathering in its wake scandals and exploitation, witnessed worldwide. In countries with technical capability and health infrastructure, a major impetus is for framing laws to address organ shortage and amendments to increase organ recovery from individuals deceased by neurological or cardio-respiratory causes. The concept expanded to legitimize living donations without compromising donor's life. This necessitated the passage of Transplantation of Human Organs Act (THOA) on 8th July 1994, which mandated formulation of appropriate authorities, authorization committees, registration of transplant and retrieval centres, defining “near relatives” for living donation and curbing venal acts.

Keywords: Infrastructure; Udupa; THOA; Transplantation

Introduction

THOA did not achieve its full potential, with only 5855 transplants being reported in 2008. There was no national registry. Though 150 kidney, 50 liver and 5 heart transplants were reported from deceased donors, the complete statistics, deceased donors actual and utilized, organs retrieved and utilized, were not available, necessitating modifications. Goa and Himachal Pradesh, initiators of THOA 1994, acted in unison with West Bengal and 2011 Amendment known as "Transplantation of Human Organs and Tissues Act 1994 (THOTA 1994)" came into force. An important addition is equitable allocation of organs from cadaveric sources by establishment of a national network and registry. It is critical to analyze the changes brought about; its impact on organ and tissue donation and transplantation, challenges faced and reasons hampering implementation [1].

Literature Review

“Tissues” were added to the title and clauses of the Act, including penal ones. Tissue banks or biomaterial centres were recognized for recovery, testing, screening, processing, storage and distribution, and mandated, like transplant centres, to be registered under section 14A of the Act with Appropriate Authority. This straitjacketed the procedures for cornea, bone, skin, heart valve, ligament, tendon, etc. Punishment for removal of tissue without authority is imprisonment up to three years and fine up to five lakh rupees. For illicit dealings in human tissues, punishment ranges with imprisonment not less than one year extending to three years and fine not less than five lakh to twenty-five lakh rupees. There are 74 tissue transplant centres and tissue banks registered with the National Organ and Tissue Transplant Organisation (NOTTO). The importance of the central registry does not prevail on professionals who resist NOTTO registration [2]. Legally, "commodification" of organs and donations between unrelated individuals are disapproved. Israel overcame this by allowing exchange between 2 pairs of ABO incompatible donor-recipients. Thus swap transplant was born when recipients, one jewish and another muslim in May 1998, received kidneys from each other's spouse. “Swap Donation” in India was adopted in the amended act leading to 174 swap donations in 2019. ‘Near relative’ living donor definition was expanded including grandparents and grandchildren [3].

Non-transplant centres having intensive care units, designated “Non-Transplant Organ Retrieval Centres (NTORC)” were encouraged to register free with State Appropriate Authority (SAA) and provided financial assistance to improve Brain Stem Death (BSD) declaration in smaller cities. A total of 140 NTORC have been registered with SAA and 67. Transplant Coordinators (TC) mandatory in all transplant centres enabled doctors to concentrate on patient care with improved conversion rates. TC perform grief counseling, family counseling and consent taking directed to the donor family, coordinating the pre-, intra- and post-transplant with retrieval and transplant teams, including the logistics of organ transport, support to donor and recipient families. Enhanced punishment for removing human organs without authority shall be imprisonment up to ten years and fine extending to twenty lakh rupees. Commercial dealings in organs is punishable with imprisonment not less than 5 years, upto 10 years and fine of not less than 20 lakhs upto 1 crore rupees [4].

These ensured transparency, cost-effectiveness and competence that made India the favoured transplant destination, to the dismay of other nations. Our leitmotif "*Vasudeiva Kutumbakam*"-"World is one Family", behoves training surgeons or treating patients from any part of the world, except that living Indian donor can donate to a near relative but not a foreigner. Cadaveric donor organs acquired legally form a public resource warranting equitable distribution was addressed in Turkey, Brazil, Korea, Australasia and Croatia in 2001, 2005, 2006, 2008 and 2011 respectively by the establishment of national organisations, reforms and legislation, with a noticeable rise in transplantation activity. In Japan the 1997 law was amended in 2010 and the number of deceased donors increased from 7.2/year from 1999 to2010 to 53.4/year from 2010 to 2016.

Discussion

World Health Assembly (WHA) through Resolution 63.2212 urged member states 'to strengthen national and multinational authorities and/or capacities to provide oversight, organization and coordination of donation and transplantation activities, with special attention to maximizing donation from deceased persons appropriate to the transplantation needs of each country'. This is included in WHO guiding principles for human cell, tissue and organ transplantation which specified the setting up of a national organisation for supervision and affirmed by the declaration of istanbul on organ trafficking and transplant tourism. The establishment of the national human organs and tissues removal and storage network and the national registry was the most important addition of THOTA 1994, Sections 13C and 13D, leading to the setting up of NOTTO, in line with WHO recommendations. NOTTO launched its national registry NOTTR15 in November 2015 and updation is planned. States and Union Territories are reminded to upload their data real-time onto the NOTTO website for fair, equitable, digitized and transparent organ allocation [5].

Registration is not 100% since all centres have not registered with NOTTO and uploaded data. Only 428 transplant centres and 67 NTORC have registered of 550 transplant centres and 140 NTORC registered with the State Appropriate Authority (SAA). Write-ups in media and NGOs tarnishing NOTTO raise impediments in achieving targets16. Notwithstanding, NOTTO has collected data from all states and union territories. Analysis revealed 340 and 715 as the number of deceased donors 4990 and 12625 the total number of transplants in 2013 and 2019 (Table 1) respectively documenting the effects of the amendment. India is presently the third largest transplanting country in terms of the actual number of transplants done in 2019. Real-time data of deceased and live donors, recipients' Waiting List (WL) and transplants are to be shared by transplant centres, another area being worked upon. WL for organs and tissues updated real time, such that only the currently active patients are displayed, is crucial for allocation. Deaths while on waitlist and inactivity due to medical/other reasons are to be removed.

Years	Actual deceased donors	Transplants (Recipients)			
		Living	Deceased	Domino	Total
2013	340	4153	837	0	4990
2014	408	5886	1030	0	6916
2015	666	6689	1659	0	8348
2016	930	6756	2265	1	9022
2017	773	7429	2110	0	9539
2018	875	8085	2254	1	10340
2019	715	10600	2023	2	12625

Table 1. Organ donation and transplantation in India from 2013 to 2019.

State Organ and Tissue Transplant Organisations (SOTTOs) in all states are essential, achievable when the amended act is adopted. Unfortunately health being a state subject, they can adopt and modify the act. Just 16 of 28 states and 9 union territories (UT) have adopted, 12 granted funds for establishing SOTTOs and 5 for ROTTO-SOTTOs. Logistic and financial issues of organ transport remain unexploited. 'green corridors' are facilitated by some states and UT. 24 × 7 affordable air transport, access direct to cockpit, need to be brought about by co-ordination with ministries of civil aviation and home affairs. Invention of drones drone-like carriers and hybrid aerial vehicles to serve as 'Air Ambulances' are being developed and field-tested by IITs.

Training is an important activity of NOTTO to effectuate the amended act and achieve self-sufficiency. BSD declarations, majorly in medico-legal cases of neurotrauma where police officers require sensitization as also Forensic specialists to perform the postmortem along with organ retrieval or accept surgeon's findings as per the act, to avoid delay in retrieval, handing over the body for cremation and traffic police for creating green corridors for speedy organ transport. Lastly, the intensivists need training to routinely declare BSD, irrespective of organ donation, thereby convincing the next of kin for donation function as leaders of transplant coordination. A workshop Table 1. Organ donation and transplantation in India from 2013 to 2019 conducted last year by NOTTO. TC training courses, conducted by NOTTO, ROTTOs and SOTTOs ensure availability of 2 TC in each transplant centre as per the act. NOTTO has conducted 6 TC courses and has trained 337 TC since 2015.

Conclusion

In conclusion, the major impediment to uniform implementation is that health is a state subject; 16 of 28 states have adopted the amendment. There is resistance to sharing data with NOTTO, despite mandating a national network and registry under Sections 13C and 13D. THOT Rule 31, subrules 2 and 3 specify the role of state networking organization, linking on one side to hospitals, organ or tissue matching laboratories, and tissue banks within their area, and on the other side to the regional and national networking organizations. Rule 31, subrule states that the website of the transplantation centre shall be linked to state or regional-cum-state or national networks through an online system for organ procurement, sharing and transplantation. Subrules 6, 9 and 12, say the networking organizations shall coordinate with the respective state governments and shall be e-enabled and accessible through a dedicated website to maintain and update organ and tissue donation and transplantation registry at respective level. NOTTO set up to implement the act should also

implement the national organ transplant program as a statutory body and ensure accountability.

References

1. Shroff S (2009) Legal and ethical aspects of organ donation and transplantation. Indian J Urol 25: 348-355.
2. Matesanz R (1998) Cadaveric organ donation: Comparison of legislation in various countries of Europe. Nephrol Dial Transpl 13: 1632-1635.
3. Fishman RHB (1998) Israeli kidney swap unites Jews and Muslims. Lancet 351: 1641.
4. White SL, Hirth R, Mahillo B, Dominguez-Gil B, Delmonico FL, et al. (2014) The global diffusion of organ transplantation: Trends, drivers and policy implications. Bull World Health Organ 92: 826-835.
5. Dominguez-Gil B, Delmonico F L, Shaheen F A, Matesanz R, O'Connor K, et al. (2011) The critical pathway for deceased donation: Reportable uniformity in the approach to deceased donation. Transpl Int 24: 373-378.