

Information for page 94 :-

Under Medical Services Section:

- ***National Organ Transplant Programme (NOTP), Transplantation of Human Organs and Tissue Act, 1994 and Rules thereunder.***
- National Organ and Tissue Transplant Organization (NOTTO) is a national level organization set up under Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India located at 4th and 5th Floor of Institute of Pathology (ICMR) Building in Safdarjung Hospital Campus, New Delhi. The Directorate General of Health Services is implementing the National Organ Transplant Program (NOTP), through States and institutions with aim to augment organ transplant infrastructure and developing an effective mechanism for deceased organ and tissue donation. The key program components include community awareness, establishing national networking and registry, training and skilling, setting up new or upgrading existing facilities and provision of post-transplant immunosuppressant services. It is expected to not only increase the number of organ transplants but also the outcome of the transplants. The new NOTP Guidelines have been prepared to orient and sensitize States and institutions on the need of deceased organ donation, financial provisions and opportunities available under the program. The Guidelines shall help in planning, implementation, monitoring and evaluation of various components of NOTP. The successful implementation of the program requires a team approach in order to overcome the challenges associated with the need of increasing deceased organ and tissue donation and transplantation in the country.

Organ Donation and Transplantation is a Government-regulated activity in India as per the provisions of the Transplantation of Human Organs and Tissues Act, 1994 (THOTA 1994) (as amended in 2011) and rules made thereunder. The main purpose of the Act is to regulate the removal, storage, and transplantation of human organs for therapeutic purposes and for the prevention of commercial dealings in human organs & tissues. Brain stem death has been recognized as legal death in India under THOTA since 1994. In pursuance of the amended Act, the Transplantation of Human Organs and Tissues Rules were notified on 27.03.2014. The amended Act and revised rules have many provisions for the promotion of organ donation from deceased donors. The Government of India is implementing the National Organ Transplant Program (NOTP) to carry out activities as per THOTA 1994, improving awareness about a healthy lifestyle and the prevention of organ failure, raising awareness on the donation of organs and tissues from deceased persons, augmenting infrastructure for transplantation especially in government institutions, and providing training for manpower and research.

In pursuance to the mandate given under Transplantation of Human Organs & Tissues Act 1994, Government of India has setup National Organ and Tissue Transplant Organization (NOTTO), at the national level, and 5 Regional Organ and Tissue Transplant Organizations (ROTTOs), and 25 State Organ and Tissue Transplant Organizations (SOTTOs) have been established which network now with 995 hospitals/institutions, which include 716 organ transplant centers, 142 organ retrieval centers, and the remaining as tissue centers.

Dedicated website of NOTTO, URL - www.notto.mohfw.gov.in is functional to disseminate information to public. 24x7 hrs Toll free helpline no. - 1800-11-4770 is operational through dedicated Tele-Counsellors in the NOTTO call center, to provide all types of information related to organ and tissue donation and transplantation. Further, coordination for organ and tissue donation is also done through the call center.

In a nut shell NOTTO, as the apex body, plays a pivotal role in establishing and managing a fair, ethical, and transparent system for organ and tissue donation and transplantation. This involves developing policies and guidelines in line with THOTA, 1994, and THOT Rules, 2014, coordinating stakeholder activities, promoting organ donation, maintaining national registries, and monitoring compliance to prevent and assist in prosecuting illegal activities.

➤ **Parliament Questions in NOTTO:**

A parliament question with respect to NOTTO (National Organ and Tissue Transplantation Organisation) **could focus on various aspects of organ donation and transplantation in India.** It could inquire about the current state of organ donation rates, the reasons for low donation rates, and the government's efforts to address these issues.

Broadly, the Parliament Questions based on following topics:

1. Organ Donation Rates and Demand-Supply Gap:

- A question could ask about the current organ donation rate in India compared to other countries, highlighting the significant disparity between organ demand and supply.
- It could inquire about the reasons for low organ donation rates, including social, cultural, and religious barriers, red-tapism, and lack of awareness.

2. Challenges and Barriers:

- Questions could address the challenges faced by organ transplantation, such as red-tapism, lack of infrastructure, and inadequate awareness programs.
- It could explore the need for addressing myths and fears surrounding organ donation and transplantation.

3. Government Initiatives and Efforts:

- A parliament question could delve into the government's efforts to promote organ donation and transplantation, including awareness campaigns, policy changes, and infrastructure development.
- It could ask about the measures being taken to reduce costs and delays in organ transplantation, ensuring equitable access for all.

4. Specific Aspects of NOTTO:

- Questions could be directed towards NOTTO's role in coordinating organ donation and transplantation, including its activities, resources, and impact.
- It could inquire about NOTTO's efforts to streamline the process of organ donation, improve communication between hospitals and registries, and ensure ethical practices. [1]

➤ **Private Member Bills** : As per available records, none Private Member Bills with respect to THOTA 1994 and THOT Rules, 2014 has been raised in the Parliament.

➤ **Assurances** : NIL information as per available records in NOTTO.

➤ **Court Cases** : There are few ongoing court cases in Hon'ble Supreme court and various High Court. The directions of Hon'ble court are replied with and responses are submitted within the time limit. There is no contempt of court matter as on date.

NOTTO's Involvement in Court Cases

Court cases related to organ transplantation can arise from various alleged violations of THOTA, 1994, such as illegal organ removal, commercial trading, procedural lapses by hospitals or Authorization Committees, or disputes regarding consent and brain-stem death certification. Furthermore, NOTTO often oversees and responds to numerous writ petitions filed in various High Courts and the Supreme Court of India. These petitions frequently seek judicial intervention for changes in transplantation activities, challenge existing organ allocation criteria, raise concerns about procedural delays, or plea for specific relaxations under the Act. The Act establishes Appropriate Authorities at State levels (THOTA, 1994, Section 13) to enforce its provisions, and these authorities with powers of a civil court (THOTA, 1994, Section 13B).

Legal Processes and NOTTO's Role:

The cognizance of offenses under the Act is clearly defined, with courts primarily taking action based on complaints filed by the Appropriate Authority or an authorized officer (THOTA, 1994, Section 22). Individuals can also file complaints after giving due notice. The THOT Rules, 2014, further elaborate on procedures, the breach of which might lead to legal challenges. NOTTO's involvement in court cases, including writ petitions and cases stemming from violations, while State Appropriate Authorities are the primary enforcers for many direct contraventions, can be significant. NOTTO contributes by:

- Developing policies and guidance that help prevent violations and address concerns raised in petitions, thus preempting or informing legal disputes.

- Representing the national policy stance and providing expert opinions to courts or investigating agencies on technical aspects, allocation policies, or interpretations of the Act and Rules, especially in response to writ petitions.
- Leveraging data from the National Registry (mandated by THOTA, 1994, Section 13D) to assist in investigations and to provide evidence-based responses to judicial queries.
- Supporting State Authorities in complex or inter-state cases.
- Monitoring court judgments, including those on writ petitions, to understand interpretations of the law, assess the impact on allocation or other transplantation activities, and identify areas needing policy review or amendments to the Act/Rules.

Effectively responding to a multitude of writ petitions requires robust legal support and clear policy articulation. Other challenges include timely action by Appropriate Authorities in cases of violations, gathering sufficient evidence for prosecution (with penalties detailed in Chapter VI of THOTA, 1994), and adeptly handling cases with inter-state or international dimensions.

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Transplantation of Human Organs and Tissue Act (THOTA), 1994

• **Supply crisis on organ for transplant:**

India faces a significant disparity between organ demand and availability, largely due to a low deceased organ donation rate. This supply crisis can inadvertently create pressures that might lead to unethical practices. THOTA, 1994, recognizes both living and deceased donation pathways (Section 3), with specific procedures for brain-stem death certification (Section 3(6)&(7)).

Organ	Estimated Need	Transplants Done (2023)	Number of Registered Centers	Estimated Transplant Centers % in Public Sector	Type of Donor
Kidney	1,75,000-2,00,000	13426	649	<15%	LL >> DD
Liver	40,000-50,000	4491	231	<10%	LL >> DD
Heart	50,000	221	162	<20%	DD
Lung	-	197	88	<20%	DD
Pancreas	-	27	64	<10%	DD
Intestine	-	16	33	<5%	DD >> LL

The Act restricts living donations primarily to near relatives, with non-near relative donations requiring strict scrutiny by Authorization Committees to rule out commercial motives (THOTA, 1994, Section 9). The THOT Rules, 2014, detail the duties of medical practitioners regarding deceased donation, including consent and certification (Rule 5; Forms 8, 10). A key strategy to improve supply is the establishment of national, regional, and state networks (Rule 31 of THOT Rules, 2014; THOTA Section 13C) like NOTTO, ROTTOs, and SOTTOs, to coordinate and equitably allocate organs from deceased donors, tracked via the National Registry (THOTA, 1994, Section 13D).

NOTTO's role in addressing this crisis involves:

- Spearheading nationwide awareness campaigns and professional training to promote deceased donation.
- Managing national registry for fair organ allocation.
- Streamlining organ retrieval and transport processes.
- Training and Guidance of various stakeholders on ethical donation practices.
- Coordinate for research and policy analysis to overcome donation barriers.

Overcoming socio-cultural barriers to deceased donation, enhancing public and professional awareness, improving hospital infrastructure for donation, tackling logistical hurdles, and ensuring equitable organ access are major challenges.

• **Commercial Trading**

Commercial trading of human organs is a grave violation, exploiting vulnerable individuals and undermining the altruistic foundation of donation. THOTA, 1994, stringently prohibits such activities.

Section 19 of THOTA, 1994, criminalizes any form of payment for organs, seeking donors for payment, or advertising such arrangements, prescribing severe penalties including imprisonment and hefty fines. The scrutiny by Authorization Committees for non-near relative living donors, as per Section 9 of THOTA, 1994, and further detailed in the THOT Rules, 2014 (e.g., Rules 7, 19, 23; Form 11, Form 18), is specifically designed to prevent commercial transactions. These rules mandate evaluation of financial status, reasons for donation, and ensure no middlemen are involved (THOT Rule 10(3)(ix), 10(3)(vii)).

NOTTO's efforts to combat commercial trading include:

1. Monitoring registry data for patterns indicative of illegal trade.
2. Conducting awareness programs on the illegality of organ trading.
3. Collaborating with law enforcement agencies.
4. Promoting ethical conduct among transplant professionals.

Challenges: Proving direct financial transactions, addressing the exploitation of vulnerable population, countering sophisticated organ rackets, ensuring consistent rigor across all Authorization Committees, and protecting whistleblowers are significant challenges.

- **Organ Trading & Trafficking**

Organ trading and trafficking involves deceiving or coercing individuals into “donating” organs, often across borders, for commercial gain. It is a transnational crime and a serious human rights abuse.

The prohibitions against commercial dealings in THOTA, 1994 (Sections 19 and 19A), are directly applicable to commercial dealing in organ, which inherently involves trading in organs or unauthorized removal. The THOT Rules, 2014, provide specific safeguards, such as verification of residential status for unrelated inter-state donors (Rule 14; Form 20) and stringent procedures for foreign nationals involved in transplantation (Rule 20; Form 21), including embassy certifications. A critical provision (Rule 7(2) of THOT Rules, 2014) restricts Indian donors from donating to foreign recipients unless they are near relatives, acting as a key anti-trafficking measure.

NOTTO’s role in preventing organ trading & trafficking involves:

1. Engaging in international collaboration with relevant health and law enforcement bodies.
2. Ensuring strict national implementation of rules concerning foreign donors/recipients and inter-state donations.
3. Analyzing registry data to detect suspicious cross-border or inter-state activities.
4. Advocating for stronger collaborative mechanisms with immigration and border control.
5. Raising awareness among vulnerable populations.

Major Hurdles: The clandestine nature of trafficking networks, victim identification difficulties, lack of harmonized international laws, potential involvement of hospitals and personals in illegal organ transplant activities, and the high profitability of this crime pose major hurdles.

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