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The Role of Artificial Intelligence in Organ and Tissue Donation in India: A Socio-Legal Analysis

DR. LALLAN YADAV* 

ABSTRACT

Artificial intelligence (AI), long a theme of science fiction, is now reshaping the landscape of medicine, and organ and tissue donation has not been left untouched. This study undertakes an empirical and jurisprudential analysis of the role that AI presently plays in India's organ and tissue donation system, and of the performance it has shown, drawing on clinical studies, governance instruments and judicial pronouncements. It examines AI applications in five principal domains: the identification of potential deceased donors in intensive care units; intelligent organ and tissue matching and allocation; predictive modelling of graft survival and post-transplant outcomes; public engagement and consent facilitation; and AI-guided machine perfusion technologies. The paper maps these applications onto India's existing legal framework: the Transplantation of Human Organs Act, 1994 (renamed the Transplantation of Human Organs and Tissues Act on its amendment in 2011), the Digital Personal Data Protection Act, 2023, the Information Technology Act, 2000 and India's AI Governance Guidelines of 2025. It identifies critical legal gaps arising from the absence of AI-specific rules and regulation in the healthcare system, deficiencies in algorithmic accountability under THOTA, and data-sovereignty concerns that arise when clinical transplant data cross institutional and state boundaries. The paper concludes that India's aspiration to become a global leader in the transplantation of human organs and tissues, reflected in the growth of transplants between 2013 and 2025, can be advanced with the help of AI applications.

Keywords: Artificial Intelligence, Organ Donation, Machine Learning, THOTA 1994, DPDP Act 2023, NOTTO, Algorithmic Accountability, Organ Allocation, Brain Death

I. INTRODUCTION: INTELLIGENCE AT THE EDGE OF LIFE AND DEATH

Deaths from organ failure in India remain high because too few organs and tissues are available for deceased-donor transplantation. There is a wide gap between the number of donors and the number of patients who need organs: more than 63,000 patients need a kidney transplant and

* Author is an Associate Professor at Sigma University, Vadodara, Gujarat, India. ORCID: <https://orcid.org/0009-0005-8397-4787>

around 22,000 a liver transplant,¹ many die because their organ failure cannot otherwise be treated, and some die because an organ does not arrive in time. Artificial intelligence offers a way to address this systemic failure in the administration of organ donation, and it is not a futuristic abstraction: a set of tools already in use helps to identify, match, allocate and transport organs and tissues across India. Around 20,000 transplants were performed in 2025, more than four times the number performed in 2013, and India now ranks third in the world by number of transplants,² owing to advances in technology and a change in social attitudes towards organ donation. The legal framework governing this technological advance, however, remains underdeveloped and has received little attention.

The Transplantation of Human Organs Act, 1994, renamed the Transplantation of Human Organs and Tissues Act, 1994 (THOTA) when it was amended in 2011,³ was drafted in an era when the most sophisticated hospital technology was the ventilator; it says nothing about algorithms, prognostic models or digital archives. The Digital Personal Data Protection Act, 2023 (DPDP Act)⁴ provides a general-purpose framework for data governance but contains no provisions calibrated to the specific sensitivities of medical AI in life-or-death clinical contexts. India's AI Governance Guidelines, issued in 2025,⁵ articulate broad principles such as accountability, transparency and fairness, but do not treat AI in organ donation as a discrete or high-priority regulatory concern.

This paper seeks to bridge that gap. It is organised as follows. Part 2 surveys the current and emerging applications of AI in organ and tissue donation. Part 3 examines state-level innovation, exemplified by the model of the Transplant Authority of Tamil Nadu (TRANSTAN). Part 4 maps AI applications onto India's existing legal framework and identifies the gaps in

¹ PRESS INFORMATION BUREAU, MINISTRY OF HEALTH AND FAMILY WELFARE, *Union Health Minister Shri Jagat Prakash Nadda Addresses the 15th Indian Organ Donation Day Ceremony*, Release ID 2151756 (Aug. 2, 2025), <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2151756> (remarks of Nivedita Shukla Verma, Acting Secretary, Health and Family Welfare: "Over 63,000 individuals currently need kidney transplants, and around 22,000 liver transplants").

² MINISTRY OF HEALTH & FAMILY WELFARE, *Annual Report 2024–2025 of the National Organ and Tissue Transplant Organisation* (2025); for the 2025 figures, see Gautam Debroy, *With 20,138 Organ Transplants in 2025, India Recorded Highest-Ever Tally: National Organ & Tissue Transplant Organisation*, ETV BHARAT (Aug. 3, 2026), <https://www.etvbharat.com/en/bharat/with-20138-organ-transplants-india-recorded-highest-ever-tally-in-2025-enn26080305106> (reporting the NOTTO Annual Report 2025–26: 20,138 transplants in 2025 against 4,990 in 2013, with India third in the world by number of transplants).

³ The Transplantation of Human Organs Act, No. 42 of 1994, INDIA CODE (1994); The Transplantation of Human Organs (Amendment) Act, No. 16 of 2011, INDIA CODE (2011) (renaming the 1994 Act the Transplantation of Human Organs and Tissues Act, 1994); The Transplantation of Human Organs and Tissues Rules, 2014 (notified Mar. 27, 2014) (India).

⁴ The Digital Personal Data Protection Act, No. 22 of 2023, INDIA CODE (2023).

⁵ MINISTRY OF ELECTRONICS & INFORMATION TECHNOLOGY, *India AI Governance Guidelines: Enabling Safe and Trusted AI Innovation* (Nov. 2025), <https://static.pib.gov.in/WriteReadData/specificdocs/documents/2025/nov/doc2025115685601.pdf>.

governance. Part 5 addresses the ethical dimensions of AI in this context: algorithmic bias, transparency and accountability. Part 6 advances a set of reform recommendations, and Part 7 concludes.

II. AI IN ORGAN AND TISSUE DONATION: AN EMPIRICAL SURVEY

A. Automated identification of potential deceased donors

The single largest organisational failure in India's deceased donation system is not public reluctance but the under-identification of potential donors. Retrospective studies elsewhere suggest that between 30 and 60 per cent of potential organ donors are either not identified or not referred to an organ donation organisation,⁶ and in India NOTTO has itself named the poor identification and certification of brain-stem death, despite the availability of many potential donors, as a key reason why the donation rate remains below one donor per million population.⁷ In hospitals without dedicated transplant coordinators, potential donors can die unidentified, and their viable organs are lost rather than offered to patients waiting in desperation.

Machine learning offers a technically mature solution to this problem. Retrospective work using electronic health record (EHR) data from intensive care units (ICUs) has shown that temporal machine-learning models trained on routinely collected clinical data, chiefly time series of laboratory results, can automatically identify potential organ donors who might otherwise be missed. A study published in *Scientific Reports* in 2023 developed precisely such a model, which achieved high predictive accuracy (an area under the receiver operating characteristic curve of 0.966) in identifying potential organ donors among ICU admissions.⁸

Advances in AI are improving clinical practice, particularly in organ transplantation. An AI alert in the EHR system can prompt a transplant coordinator to begin family counselling and organ-preservation protocols hours earlier than under current practice, which could substantially improve the number and quality of the organs retrieved.

In India, this intervention is particularly urgent given the scale of under-identification. In Germany, a cluster-randomised trial (DETECT-IVE) has been registered to test automated

⁶ N. Sauthier et al., *Automated Screening of Potential Organ Donors Using a Temporal Machine Learning Model*, 13 SCIENTIFIC REPORTS 8459 (2023), <https://doi.org/10.1038/s41598-023-35270-w> (citing multiple retrospective cohort studies).

⁷ *Monitor Brain Stem Death Cases in ICUs to Improve Organ Donation Rate: Centre to States*, THE TRIBUNE (May 5, 2024), <https://www.tribuneindia.com/news/health/monitor-brain-stem-death-cases-in-ic-us-to-improve-organ-donation-rate-centre-to-states-618177> (PTI report quoting the letter of the Director of NOTTO to the States: "One of the key challenges identified in this is poor identification and certification of brain stem death (BSD) cases despite availability of many such potential cases").

⁸ N. Sauthier et al., *Automated Screening of Potential Organ Donors Using a Temporal Machine Learning Model*, 13 SCIENTIFIC REPORTS 8459 (2023), <https://doi.org/10.1038/s41598-023-35270-w>.

screening for the loss of cerebral functions in patients with severe brain damage;⁹ comparable research in Indian clinical settings is still emerging. The evidence base is nonetheless sufficiently established to justify pilot deployment in government teaching hospitals and trauma centres, the facilities most likely to receive road-accident victims, who are the leading source of brain-dead donors in India.

B. AI-driven organ matching and allocation

Once a deceased donor is identified and the family's consent secured, the race against organ ischaemia begins. A heart tolerates ischaemia for only four to six hours, while a kidney can remain viable for transplantation for up to about 24 hours. The organ must be matched to the most compatible and most urgent recipient within that window. In India, the matching process is currently managed through the national registry of the National Organ and Tissue Transplant Organisation (NOTTO) and the state-level databases of the State Organ and Tissue Transplant Organisations (SOTTOs). Despite the gains of digitisation, the process still relies on manual data entry, telephonic coordination and the judgment of coordinators.

The next generation of organ allocation will rest on AI-based smart matching. Such systems integrate multi-dimensional compatibility data (HLA matching, blood group, panel-reactive antibody levels and organ-specific scoring indices) with recipient urgency to generate ranked allocation scores, with greater predictive accuracy than traditional rule-based processes.

A 2024 review argues that AI-based matching promises more precise donor–recipient pairing, shorter waiting times and better use of donated kidneys, many of which are now discarded.¹⁰ In the United States, one AI developer, Valiant AI, has reported that its model raised the transplant success rate for high-risk (high-KDPI) kidneys by 19 per cent within 90 days.¹¹

NOTTO coordinates inter-state organ sharing across a vast geographic and demographic area, and an AI-driven national allocation platform would be a significant upgrade. It would reduce dependence on the judgment of individual coordinators, accelerate matching decisions and

⁹ *Automated Screening for Clinically Ascertained Loss of Cerebral Functions in Patients With Severe Brain Damage: An Interventional Cluster Randomized Trial (DETECT-IVE)*, ClinicalTrials.gov Identifier NCT06293170 (Technische Universität Dresden, Germany), <https://clinicaltrials.gov/study/NCT06293170>.

¹⁰ R. Deshpande, *Smart Match: Revolutionizing Organ Allocation Through Artificial Intelligence*, 7 FRONTIERS IN ARTIFICIAL INTELLIGENCE 1364149 (2024), <https://doi.org/10.3389/frai.2024.1364149>.

¹¹ *AI in Organ Allocation & Acceptance*, THE ALLIANCE (2025), <https://www.organdonationalliance.org/insight/ai-in-organ-allocation-acceptance/> (summarising presentations at The Alliance National Innovation Forum: Harnessing Artificial Intelligence (May 8, 2025), and reporting a 19% increase in transplant success for high-KDPI kidneys within 90 days of Valiant AI's implementation); see also D.B. Olawade et al., *The Impact of Artificial Intelligence and Machine Learning in Organ Retrieval and Transplantation: A Comprehensive Review*, 73 CURRENT RESEARCH IN TRANSLATIONAL MEDICINE 103493 (2025), <https://doi.org/10.1016/j.retram.2025.103493>; S. Naimimohasses et al., *Proceedings of the 2024 Transplant AI Symposium*, 3 FRONTIERS IN TRANSPLANTATION 1399324 (2024), <https://doi.org/10.3389/frtra.2024.1399324>.

enable real-time cross-state allocation, so that an organ can be sent to another state when no compatible recipient exists within the state of origin.

The Aadhaar-based organ donation pledge registry, launched in September 2023, had registered more than 4.8 lakh citizens by February 2026; it provides the foundational digital infrastructure upon which an AI matching layer for organs and tissues could be built.¹²

C. Predictive modelling for graft survival and post-transplant outcomes

Another important frontier of AI in transplantation is the prediction of long-term graft and patient survival. Traditional indices, such as the Model for End-Stage Liver Disease (MELD) score for liver transplantation and the Kidney Donor Profile Index (KDPI) for kidneys, provide probabilistic guidance but are limited by their reliance on a small number of discrete variables and their inability to capture complex non-linear interactions across the broader clinical picture.

Deep-learning models trained on multi-omics data, imaging biomarkers and longitudinal EHR records have shown promising predictive accuracy. A systematic review published in *BMC Medical Informatics and Decision Making* in 2025 synthesised twenty studies using machine learning for liver transplant allocation. It found that some models showed promise in predicting post-transplant survival, but that very few urgency models could outperform the MELD score, that none of the included studies offered a transplant-benefit model, and that the field remains at an exploratory stage.¹³ In kidney transplantation, the UK Live-Donor Kidney Transplant Outcome Prediction tool, an explainable machine-learning model, achieved a concordance index of 0.72 in predicting graft survival, with similar performance for more and less deprived patient subgroups (0.70 and 0.74 respectively).¹⁴

In the Indian context, predictive AI tools hold particular promise for two applications. First, they can help clinicians decide whether a marginal or extended-criteria organ, which might otherwise be discarded as unsuitable, should be used for a specific recipient. This could reduce

¹² PRESS INFORMATION BUREAU, MINISTRY OF HEALTH AND FAMILY WELFARE, *India Registers Landmark Progress in Organ Donation & Transplantation: NOTTO at the Helm of a National Transformation*, Release ID 2231563 (Feb. 22, 2026), <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2231563> (“More than 4.8 lakh citizens have registered to donate organs and tissues after death through a Aadhaar based verification system, since 17th September 2023”; “Around 18% of transplants are currently being performed with the organs donated from deceased donors”).

¹³ L. Pruinelli et al., *Transforming Liver Transplant Allocation with Artificial Intelligence and Machine Learning: A Systematic Review*, 25 *BMC MEDICAL INFORMATICS AND DECISION MAKING* art. 98 (2025), <https://doi.org/10.1186/s12911-025-02890-3>.

¹⁴ H. Ali et al., *Artificial Intelligence Assisted Risk Prediction in Organ Transplantation: A UK Live-Donor Kidney Transplant Outcome Prediction Tool*, 47 *RENAL FAILURE* 2431147 (2025), <https://doi.org/10.1080/0886022X.2024.2431147>; A. Sarasa-Cabezuelo et al., *Editorial: Enhancing Kidney Transplant Outcomes Through Machine Learning Innovations*, 8 *FRONTIERS IN ARTIFICIAL INTELLIGENCE* 1760127 (2025), <https://doi.org/10.3389/frai.2025.1760127>.

organ discard rates in a system in which about 18 per cent of transplants use organs from deceased donors.¹⁵ Second, AI monitoring tools can support the early identification of graft rejection episodes, specialist follow-up and the timing of immunosuppressive intervention, improving long-term outcomes.

D. AI in public awareness and consent facilitation

Beyond the clinical sphere, AI can transform public engagement with organ donation. NOTTO launched its Aadhaar-based online organ donation pledge website in September 2023, a system that combines digital infrastructure with targeted outreach. With public awareness growing after the Prime Minister addressed organ donation in his *Mann Ki Baat* broadcast, pledges on the portal crossed five lakh by June 2026.¹⁶ Natural language processing (NLP) tools deployed on social media platforms can identify communities in which awareness of organ donation is low, analyse sentiment around common misconceptions and personalise outreach in local languages, addressing the specific fears (of bodily disfigurement, of religious objection and of distrust of the medical system) that suppress families' consent.

AI chatbots, deployed through WhatsApp or integrated into government health portals, can relieve overstretched transplant coordinators by giving accurate, culturally sensitive answers to public queries about organ donation around the clock. Personalised, responsive digital outreach is likely to engage people more effectively than broadcast campaigns, and AI makes such personalisation possible at scale in a country of 1.4 billion people.

E. AI and machine perfusion technologies

An emerging and technically sophisticated application of AI in organ donation is its integration with machine perfusion, the *ex vivo* preservation of retrieved organs under controlled physiological conditions. Machine perfusion, particularly in normothermic and hypothermic systems, allows organs to be maintained outside the body for extended periods while perfusion parameters (temperature, flow rate, metabolic substrate concentrations and biomarker levels) are monitored in real time. AI systems can analyse the data collected during perfusion, such as

¹⁵ PRESS INFORMATION BUREAU, MINISTRY OF HEALTH AND FAMILY WELFARE, *supra* note 12.

¹⁶ PRESS INFORMATION BUREAU, MINISTRY OF HEALTH AND FAMILY WELFARE, *Union Health Minister Shri Jagat Prakash Nadda Addresses the 15th Indian Organ Donation Day Ceremony*, Release ID 2151756 (Aug. 2, 2025), <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2151756> (noting more than 3.30 lakh pledges on the Aadhaar-based NOTTO pledge website since its launch in 2023, and growing awareness after the Prime Minister addressed the issue in *Mann Ki Baat*); *India Marks Landmark Milestone with Over 5 Lakh Organ Donation Pledges*, ANI (June 22, 2026), <https://aninews.in/news/national/general-news/india-marks-landmark-milestone-with-over-5-lakh-organ-donation-pledges20260622205558/>.

flow rates, pressure, oxygen consumption and blood and urine markers, to assess the quality of the perfused organ, predict its viability and identify organs at risk of discard.¹⁷

Although machine perfusion technology remains beyond the reach of most Indian transplant centres because of its cost, government initiatives to expand transplant infrastructure under the National Organ Transplant Programme provide a policy pathway for its introduction.¹⁸ Integrating AI into future machine perfusion units would maximise the value of this expensive equipment by enabling data-driven decisions on organ acceptance and treatment.

III. THE TAMIL NADU MODEL: A CASE STUDY IN TECHNOLOGY-ENABLED DONATION

The TRANSTAN model is the most widely appreciated and instructive empirical case study of technology-enabled donation in India. TRANSTAN functions as both the State Organ and Tissue Transplant Organisation and the Regional Organ and Tissue Transplant Organisation for the southern region,¹⁹ and Tamil Nadu recorded 268 deceased donors in 2024, the highest of any Indian state.²⁰ The factors underlying this achievement offer a model for national replication. In 2021, TRANSTAN introduced an AI-based application for real-time data sharing. This application, documented in a retrospective observational study published in *BMJ Open Quality* in 2025, was intended to expedite data verification and reduce delays in organ procurement following the certification of brain death.²¹

¹⁷ E. Kotsifa & V.K. Mavroeidis, *Present and Future Applications of Artificial Intelligence in Kidney Transplantation*, 13 JOURNAL OF CLINICAL MEDICINE 5939 (2024), <https://doi.org/10.3390/jcm13195939> (§ 2.2.2, Machine Perfusion); see also M. Al Moussawy et al., *The Transformative Potential of Artificial Intelligence in Solid Organ Transplantation*, 3 FRONTIERS IN TRANSPLANTATION 1361491 (2024), <https://doi.org/10.3389/frtra.2024.1361491> (models predicting delayed graft function may help select patients who would benefit from machine perfusion).

¹⁸ PRESS INFORMATION BUREAU, MINISTRY OF HEALTH AND FAMILY WELFARE, *National Organ Transplant Programme (NOTP)*, Release ID 1739456 (July 27, 2021), <https://www.pib.gov.in/PressReleasePage.aspx?PRID=1739456> (written reply in the Rajya Sabha listing among the programme's provisions "Financial support for establishing new Organ Transplant/retrieval facilities and strengthening of existing Organ Transplant/retrieval facilities").

¹⁹ TRANSPLANT AUTHORITY OF TAMIL NADU, *About TRANSTAN*, <https://transtan.tn.gov.in/about.php> (last visited Oct. 4, 2026) (TRANSTAN "also functions as Regional Organ and Tissue Transplant Organization (ROTO) and State Organ and Tissue Transplant Organization (SOTTO) by GOI order"; the waitlist registry gives "[o]nly one Unique ID number for patients registering for any number of organs").

²⁰ K. Annadurai, G. Mani & R. Danasekaran, *Road Map to Organ Donation in Tamil Nadu: An Excellent Model for India*, 6 INTERNATIONAL JOURNAL OF PREVENTIVE MEDICINE 21 (2015), <https://doi.org/10.4103/2008-7802.153443>; for the 2024 figure, see G. Natarajan & T. Ethirajan, *Building a Sustainable Deceased Donation Ecosystem: The Tamil Nadu Experience*, 11 KIDNEY INTERNATIONAL REPORTS 106577 (2026), <https://doi.org/10.1016/j.ekir.2026.106577> (reporting 268 deceased donors in Tamil Nadu in 2024, 23.7 per cent of deceased donations in India); Veni E N, *Tamil Nadu Tops Nation in Cadaveric Organ Donations for 2024, Earns National Award*, THE SOUTH FIRST (Aug. 3, 2025), <https://thesouthfirst.com/tamilnadu/tamil-nadu-tops-nation-in-cadaveric-organ-donations-for-2024-earns-national-award/>.

²¹ S. Er, Jaisankar P & S. Nair, *Streamlining Organ Donation: Impact of an Artificial Intelligence-Based Protocol Post-Brain Death*, 14 BMJ OPEN QUALITY e003334 (2025), <https://doi.org/10.1136/bmj-oq-2025-003334>.

The application was designed to automate organ allocation from a waitlist ranked on criteria such as blood group and seniority, to verify identity and legal documentation, including the donor family's consent, and to alert hospitals and the highest-ranked patients, so speeding matching with recipients on TRANSTAN's online waitlist registry, a centralised system that assigns each patient a unique identification number irrespective of the number of organs required. The study, conducted at a single tertiary hospital in Tamil Nadu, found, however, that the median interval from the first apnoea test to organ procurement lengthened after the application was introduced, from 1,587 to 1,660 minutes, chiefly because transfer to the operating theatre after police clearance took longer.²²

Digital support in Tamil Nadu also eases the operation of the green corridor system, traffic-free routes coordinated between hospitals, TRANSTAN and the traffic police, which minimises the time lost in transporting organs. Chennai was the first city to establish a green corridor, in 2014; the system now operates across India, and several states have adopted modified versions suited to their infrastructure and geography.²³ The green corridor is not itself a digital application, but its success depends on accurate data coordination between the donor and recipient hospitals, a logistical function for which AI is well suited.

Tamil Nadu was also the first state to make the declaration of brain death mandatory, through Government Orders issued in 2008.²⁴ Its regulatory leadership and technological development have generally reinforced each other.

The Tamil Nadu model nonetheless has limitations. In 2020, it was criticised for keeping post-transplant survival rates confidential, and transplant surgeons had long demanded that the number of organs received and shared, and the outcomes of transplants, be made public.²⁵

²² Er et al., *supra* note 21 (comparing donors before the application (January 2018 to December 2021) with donors after it (January 2022 to December 2023)).

²³ Open Bureau, *When a Heart Gets the Right of Way: How India's Green Corridors Turn Traffic into Lifelines*, OPEN (Sept. 2, 2026), <https://openthemagazine.com/india/when-a-heart-gets-the-right-of-way-how-indias-green-corridors-turn-traffic-into-lifelines> (Chennai, 2014, as India's first formally organised green corridor for organ transport, later adopted in Mumbai, Pune, Delhi, Bengaluru, Hyderabad and other cities); *see also* B. Sarma et al., *Cadaveric Organ Donation: Indian Perspective*, 11 INDIAN JOURNAL OF FORENSIC AND COMMUNITY MEDICINE 44 (2024), <https://doi.org/10.18231/j.ijfcm.2024.012> (urging governments to arrange green corridors for the road transport of retrieved organs).

²⁴ G.O. (Ms.) No. 6, Health & Family Welfare Department, Government of Tamil Nadu (Jan. 8, 2008) (declaration of brain death made mandatory in Government Medical College Hospitals in Chennai); G.O. (Ms.) No. 75, Health & Family Welfare Department, Government of Tamil Nadu (Mar. 3, 2008) (procedure for declaration of brain death); Tania Goklany, *Organ Donation: What Tamil Nadu Got Right*, NDTV-FORTIS MORE TO GIVE (Nov. 17, 2016), <https://sites.ndtv.com/moretogive/india-needs-learn-tamil-nadu-organ-donation-1252/> (Tamil Nadu "is the first Indian state to make certification of brain death mandatory").

²⁵ *Organ Transplant Outcomes a Secret in Tamil Nadu*, TIMES OF INDIA (Jan. 22, 2020), <https://timesofindia.indiatimes.com/city/chennai/organ-transplant-outcomes-a-secret-in-tamil-nadu/articleshow/73514135.cms> ("For years, transplant surgeons have been demanding a transparent system, with details of the number of organs received, shared and outcomes of transplants made public.").

Existing institutional practices are not always equipped to support the introduction of AI and digital systems into organ donation, even though public expectations of digitalisation are high.

In 2025, following allegations of procedural lapses and organ trading, the Tamil Nadu Government reconstituted its authorisation committees to incorporate multi-disciplinary oversight and compulsory verification of the donor–recipient relationship.²⁶ This experience shows that technology is not a substitute for governance; it is a tool in governance's hands.

IV. MAPPING AI ONTO INDIA'S LEGAL FRAMEWORK: OPPORTUNITIES AND OMISSIONS

A. THOTA 1994 and the AI governance vacuum

THOTA, as amended in 2011, is the primary legislation governing organ donation and the transplant process in India. It was enacted to meet the problems of the 1990s: organ trafficking, the coercion of living donors and the need to certify and legalise brain death. It is silent, however, on the digital and AI transformation that has since reshaped medicine. THOTA contains no provisions on the use of algorithms in donor identification, organ allocation or outcome prediction, and the present law does not address AI tools deployed by NOTTO, SOTTOs or registered transplant hospitals.

Nor does it say who bears legal responsibility when an AI-generated allocation recommendation leads to an adverse outcome: the algorithm's developer, the hospital deploying it, the transplant coordinator who acted on it or the institutional authority that approved its use.

This legislative vacuum is not merely a theoretical concern. As AI tools become embedded in clinical workflows, through EHR-integrated donor-identification alerts, AI-assisted allocation platforms and predictive rejection-risk models, the absence of a regulatory framework creates genuine uncertainty about liability, auditability and redress. The Authorisation Committees constituted under section 9 of THOTA are designed to scrutinise human decision-making; their mandate does not extend to algorithmic accountability.²⁷ India needs either an amendment to THOTA or sector-specific AI rules under the DPDP Act that address these gaps precisely.

²⁶ Shweta Tripathi, *Tamil Nadu Revamps Organ Transplant Framework amid Kidney Sale Allegations*, THE FEDERAL (Sept. 18, 2025), <https://thefederal.com/category/states/south/tamil-nadu/tamil-nadu-revamped-organ-transplant-framework-illegal-organ-trade-207326>.

²⁷ The Transplantation of Human Organs Act, *supra* note 3, § 9(4).

B. The Digital Personal Data Protection Act, 2023

The DPDP Act is India's first comprehensive data protection law and its most significant AI-adjacent legislative instrument.²⁸ Its provisions are directly relevant to AI in organ donation. The Act requires informed consent for the processing of personal data and obliges "Data Fiduciaries", which would include hospitals, NOTTO, SOTTOs and private AI vendors processing transplant-related data, to observe the principles of purpose limitation, data minimisation, security safeguards and breach notification. Significant Data Fiduciaries, as notified by the Central Government, bear additional obligations, including Data Protection Impact Assessments, periodic audits and, under the 2025 Rules, due diligence on the algorithmic software they deploy. The Act's substantive obligations are not yet in force, however: the Digital Personal Data Protection Rules, 2025 were notified on 13 November 2025, and most of sections 3 to 17 take effect only eighteen months later, on 13 May 2027.²⁹

The Act raises several specific concerns in the organ donation context. Transplant data are among the most sensitive categories of health information: they cover not only the patient's medical condition but also HLA typing (genetic markers), demographic characteristics and the family's consent decisions. In emergency donation, obtaining consent from the right next of kin poses a practical problem, because the short window of organ viability may conflict with the procedural requirements for documented digital consent.

The Act could also complicate India's participation in international organ-sharing arrangements and its collaboration with global transplant networks on AI, since it empowers the Central Government to restrict the transfer of personal data to countries it notifies.³⁰

Finally, bias in such systems could have life-or-death consequences for disadvantaged patient groups. The Act does not specifically require AI systems deployed by Data Fiduciaries to undergo algorithmic bias audits, a gap directly relevant to organ allocation algorithms.

C. India's AI Governance Guidelines, 2025

India's AI Governance Guidelines, issued by the Ministry of Electronics and Information Technology in November 2025 as a framework for AI oversight, rest on seven guiding principles, among them fairness and equity, accountability, understandability by design, and

²⁸ The Digital Personal Data Protection Act, *supra* note 4; see also PRESS INFORMATION BUREAU, *DPDP Rules, 2025 Notified: A Citizen-Centric Framework for Privacy Protection and Responsible Data Use* (Nov. 17, 2025), <https://static.pib.gov.in/WriteReadData/specificdocs/documents/2025/nov/doc20251117695301.pdf> (the Act "creates a full framework for the protection of digital personal data in India").

²⁹ The Digital Personal Data Protection Act, *supra* note 4, §§ 10, 40; The Digital Personal Data Protection Rules, 2025, G.S.R. 846(E), rr. 1(4), 13 (Nov. 13, 2025) (India). Under the commencement notification issued the same day, §§ 3–5, 6(1)–(8) and (10), and 7–17 of the Act come into force eighteen months after notification.

³⁰ The Digital Personal Data Protection Act, *supra* note 4, § 16(1).

safety, resilience and sustainability, that are directly relevant to AI in organ donation.³¹ The Guidelines favour a graded liability system, in which responsibility is proportional to the function performed, the level of risk and the due diligence undertaken, and they contemplate additional safeguards for high-risk applications in sensitive sectors such as health. Organ allocation, in which algorithmic decisions directly determine who receives a life-saving organ, is self-evidently a high-risk, high-stakes application and should attract the highest level of governance scrutiny under this framework.

The Guidelines, however, are principle-based instruments: they create neither binding obligations nor enforceable responsibilities for specific sectors. The ethical guidelines on AI in healthcare issued by the Indian Council of Medical Research (ICMR) provide a more clinically grounded framework,³² but they too are advisory rather than mandatory. As scoping reviews have confirmed, India's AI regulatory architecture is fragmented: a principle-based national strategy operates alongside sector-specific guidelines that vary in legal force and institutional authority.³³

In organ donation, this fragmentation runs across the Ministry of Health and Family Welfare, NOTTO, individual state governments, private hospitals and international transplant networks, creating a governance vacuum that no single existing instrument fills.

V. ETHICAL DIMENSIONS: ALGORITHMIC BIAS, TRANSPARENCY AND ACCOUNTABILITY

The ethical stakes of AI in organ donation are uniquely high because the outputs of algorithmic systems translate directly into decisions about who lives and who dies. Three dimensions of ethical concern demand particular attention in the Indian context.

A. Bias and equity in algorithmic allocation

AI models trained on historical transplant data inherit the biases embedded in that data. In India, where transplant infrastructure is heavily concentrated in urban southern states and access to waitlisting is correlated with socio-economic status, an AI allocation model trained on existing registry data could systematically disadvantage rural patients, women and patients from lower-

³¹ MINISTRY OF ELECTRONICS & INFORMATION TECHNOLOGY, *supra* note 5, pt. 1 (Seven Sutras of AI Governance); *id.* at 28 (additional safeguards for high-risk applications in sensitive sectors such as health), 32 (graded liability).

³² INDIAN COUNCIL OF MEDICAL RESEARCH, *Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare* (2023).

³³ U. Joshi et al., *AI Ethics in Indian Healthcare: A Scoping Review of National and International Guidelines on Privacy, Data Protection, and Security*, 27 BMC MEDICAL ETHICS art. 86 (2026), <https://doi.org/10.1186/s12910-026-01435-1>; CMS, *AI Laws and Regulation in India*, CMS Expert Guide (2026), <https://cms.law/en/int/expert-guides/ai-regulation-scanner/india>.

income groups. A 2023 study proposing a responsible AI framework for organ donation, built around a model that predicts donation-consent outcomes, sought to reduce harm and to improve the transparency and accountability of such models.³⁴ NOTTO's ten-point advisory of August 2025, which advises States and Union Territories to give additional allocation points to women patients and to the near relatives of deceased donors, represents precisely the kind of equity intervention that AI allocation systems must be designed to honour and enforce rather than undermine.³⁵ The Supreme Court's 2025 directions for uniform national allocation criteria that address discrimination on grounds of gender, class and region, read alongside Article 14 of the Constitution, impose a constitutional responsibility to ensure that AI systems deployed in organ sharing do not reproduce or entrench existing inequities.³⁶

B. Transparency and explainability

Many high-performing AI systems in medicine are “black boxes”: they produce accurate predictions without generating explanations that clinicians or patients can interrogate. In organ allocation, where every decision implicates the fundamental rights both of the patient who receives the organ and of the patients passed over, algorithmic opacity is constitutionally untenable. The right to know why one recipient was ranked above another is an extension of the right to equality under Article 14 and the right to life under Article 21.³⁷ The emerging discipline of explainable AI (XAI) offers technical methods (SHAP values, LIME approximations and attention visualisation) for making AI decisions interpretable to non-technical users; their deployment in any AI system used for organ allocation in India should be mandatory, not aspirational.³⁸

C. Accountability and liability

When an AI allocation recommendation leads to the death of a patient who was passed over, or to a failed transplant in the recipient who received the organ, who is legally responsible? India's

³⁴ S. Tutun et al., *A Responsible AI Framework for Mitigating the Ramifications of the Organ Donation Crisis*, 25 INFORMATION SYSTEMS FRONTIERS 2301 (2023), <https://doi.org/10.1007/s10796-022-10340-y>.

³⁵ NATIONAL ORGAN & TISSUE TRANSPLANT ORGANISATION, DIRECTORATE GENERAL OF HEALTH SERVICES, ten-point advisory to States and Union Territories on organ donation and transplantation (Aug. 2025), *as reported in What Has NOTTO Said About Organ Donations to Women?*, THE HINDU (Aug. 22, 2025).

³⁶ *Indian Society of Organ Transplantation v. Union of India*, 2025 INSC 1361 (Nov. 19, 2025) (India) (requesting NOTTO to evolve model allocation criteria for a uniform national policy that addresses concerns of gender, class and regional discrimination); INDIA CONST. art. 14.

³⁷ N. Shukla, *The Constitutional Duty to Explain Automated Decisions: Towards a Right to Reasons in India's Emerging Algorithmic State*, 6 JUS CORPUS LAW JOURNAL 343, 349–51, 355–56 (2026), <https://doi.org/10.66918/juscorpus.v6i4.2026.43>; *see also* INDIA CONST. arts. 14, 21.

³⁸ K. Drabiak et al., *AI and Machine Learning Ethics, Law, Diversity, and Global Impact*, 96 BRITISH JOURNAL OF RADIOLOGY 20220934 (2023), <https://doi.org/10.1259/bjr.20220934>; A. Lebreton, *Allocating Organs Through Algorithms and Equitable Access to Transplantation: A European Human Rights Law Approach*, 10 JOURNAL OF LAW AND THE BIOSCIENCES lsad004 (2023), <https://doi.org/10.1093/jlb/lsad004>.

existing legal framework gives no clear answer. The Bharatiya Nyaya Sanhita, 2023, which replaced the Indian Penal Code, contains no provision specific to AI: harms such as identity theft are addressed by general offences and by the Information Technology Act, 2000, and the offence of causing death by a rash or negligent act, which carries a lesser punishment where a registered medical practitioner acts in the course of a medical procedure, was not framed with clinical AI in mind.³⁹ The Consumer Protection Act, 2019 protects against deficiency in services, which may extend to AI-enabled medical services, but the standard of care for AI decision-support in organ allocation has never been judicially defined.⁴⁰ A dedicated liability framework, one that distinguishes between the responsibilities of AI developers, deploying hospitals and regulatory authorities, is an urgent legislative priority. The World Health Organization's guidance on the ethics and governance of AI for health offers a useful international benchmark for calibrating such a framework.⁴¹

VI. RECOMMENDATIONS: TOWARDS A RESPONSIBLE AI FRAMEWORK FOR ORGAN DONATION IN INDIA

Realising the promise of these applications in institutional practice requires thoughtfully designed AI governance. Drawing on the empirical and jurisprudential analysis above, this study recommends the following path for India.

A. Amend THOTA to create an AI governance schedule

THOTA should be amended to include a schedule or set of rules specifically addressing the use of algorithmic systems in donor identification, organ allocation, outcome prediction and public engagement. These rules should mandate the compulsory registration with NOTTO of AI tools used in the transplant process; mandatory algorithmic audits for fairness and accuracy; explainability requirements for all AI-generated allocation recommendations; and a defined liability framework for adverse outcomes attributable to AI decision-support.

B. Specific regulations under the DPDP Act for transplant data

The DPDP Act is now law, but transplant data need sector-specific regulation. The Ministry of Health and Family Welfare, in consultation with the Data Protection Board of India, should issue regulations governing the collection, processing, storage and sharing of transplant-related personal data. These regulations should address consent in emergencies, establish a secure

³⁹ The Bharatiya Nyaya Sanhita, No. 45 of 2023, INDIA CODE (2023), § 106(1); The Information Technology Act, No. 21 of 2000, INDIA CODE (2000), § 66C.

⁴⁰ The Consumer Protection Act, No. 35 of 2019, INDIA CODE (2019), § 2(11).

⁴¹ WORLD HEALTH ORGANIZATION, *Ethics and Governance of Artificial Intelligence for Health: WHO Guidance* (2021), <https://iris.who.int/handle/10665/341996>.

national transplant data architecture with end-to-end encryption and specify the conditions under which transplant data may be shared with international research partners without compromising patient confidentiality.

C. Pilot AI-based donor identification in ICUs

NOTTO, in collaboration with the AIIMS institutions and state medical colleges, should pilot an AI-based donor identification system in ten high-volume trauma centres across five states, with structured evaluation of sensitivity, specificity and time-to-referral. TRANSTAN's 2021 AI application in Tamil Nadu provides a deployable starting point, and the procedural bottlenecks recorded in its evaluation should inform the design of the pilot. The results should be published transparently and used to inform national policy decisions.

D. Build an AI-ready national transplant registry

The National Organ and Tissue Transplant Registry is already linked with the Aadhaar-based pledge system. It should be upgraded to a fully interoperable, AI-ready digital infrastructure supporting real-time cross-state matching, automated compatibility scoring and continuous outcome monitoring. NOTTO, in consultation with the National Informatics Centre, which supports registry development, should establish an AI research institution, with data governance safeguards built in from the outset rather than retrofitted after implementation.

E. Establish an independent Transplant AI Ethics Board

The deployment of AI in organ allocation demands independent ethical oversight. NOTTO should constitute a Transplant AI Ethics Board comprising transplant clinicians, AI researchers, legal experts, bioethicists, patient representatives and members of civil society, empowered to review, approve and monitor all AI systems deployed in organ donation. Its decisions should bind all registered hospitals and coordinators and be subject to judicial review.

VII. CONCLUSION: INTELLIGENCE IN THE SERVICE OF SOLIDARITY

The relationship between artificial intelligence and organ donation calls for a humanistic approach. A machine cannot feel the grief of the donor family, the desperate hope of the patient on the waiting list or the exhaustion of the transplant coordinator who has been awake around the clock coordinating a multi-organ procurement. But it can do what human beings, fatigued and emotionally overwhelmed, sometimes cannot: process vast streams of clinical data without bias or delay; identify the patient in ICU Bed 14 who is quietly approaching brain death and whose heart could save a six-year-old in Chennai; and rank, in milliseconds, three hundred and forty potential recipients for a liver that will remain viable for only twelve more hours.

India's advances in organ donation show what coordinated governance, technological investment and public mobilisation can achieve together.

The Aadhaar-based donor pledge registry, the Tamil Nadu green corridor, TRANSTAN's AI application and the NOTTO digital network are not cold bureaucratic instruments. By supplying organs to patients in need, they help to reduce deaths from organ failure, so that death, when it comes, leaves something of value behind.

India nonetheless stands at a crossroads. Raising the deceased donation rate from its current level of under one donor per million population towards that of Spain, the highest in the world at around 48 per million,⁴² cannot be achieved through institutional goodwill alone. It requires AI systems that are robust, equitably designed, legally accountable and embedded in a regulatory framework that inspires public trust. Building that framework is not merely a technical or legislative task; it also calls for a sense of moral obligation and social awareness about organ and tissue donation among the general public.

VIII. SIGNIFICANCE OF THE STUDY

This study holds academic, legal and practical significance in the growing intersection of artificial intelligence and the law on organ and tissue transplantation in India:

1. **Bridging technology and law.** The study highlights how AI is transforming organ donation systems while existing law remains inadequate to regulate rapid digitalisation and technological advance, and how the gap between the legal framework and modern medical technologies can be bridged.
2. **Addressing the organ shortage crisis.** By examining AI's role in improving donor identification, HLA matching and organ allocation, the study offers insights into India's persistent organ shortage and into strengthening the transplantation framework. AI can also support hospitals and transplant coordinators in the transplant process.
3. **Contribution to legal scholarship.** The article adds to the limited doctrinal literature on AI in healthcare law in India through a critical analysis of the legal provisions, ethical principles and constitutional dimensions of organ donation.

⁴² India's Organ Donation Rate Remains Below One Per Million: Government Report, ETV BHARAT (Aug. 2, 2025), <https://www.etvbharat.com/en/!health/indias-organ-donation-rate-remains-below-one-per-million-government-report-enn25080203679> (reporting the NOTTO Annual Report 2024–2025: India's rate “remains low at less than one per million population”, against “around 48 per million population in Spain”).

4. **Identification of legal gaps.** The article examines the lacunae in the current legal regime, including deficiencies in algorithmic accountability, data protection and transparency, to inform future law reform.
5. **Policy and law reform implications.** The study offers a foundation for policymakers and legislators designing AI-specific healthcare regulation that makes ethical, transparent and equitable organ allocation the basis of the organ donation process.
6. **Protection of fundamental rights.** The study examines how the use of AI in organ allocation must align with equality (Article 14), the right to life (Article 21) and privacy, ensuring the protection of human dignity and rights.
7. **Guidance for stakeholders.** The study offers medical professionals, legal practitioners and the authorities involved in transplantation a perspective on the value of AI, while emphasising the accountability of digital technology.

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