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Introduction

Welcome to the Indian Journal of Legal Affairs and Research (IJLAR), a distinguished platform dedicated to the dissemination of comprehensive legal scholarship and academic research. Our mission is to foster an environment where legal professionals, academics, and students can collaborate and contribute to the evolving discourse in the field of law. We strive to publish high-quality, peer-reviewed articles that provide insightful analysis, innovative perspectives, and practical solutions to contemporary legal challenges. The IJAR is committed to advancing legal knowledge and practice by bridging the gap between theory and practice.

Preface

The Indian Journal of Legal Affairs and Research is a testament to our unwavering commitment to excellence in legal scholarship. This volume presents a curated selection of articles that reflect the diverse and dynamic nature of legal studies today. Our contributors, ranging from esteemed legal scholars to emerging academics, bring forward a rich tapestry of insights that address critical legal issues and offer novel contributions to the field. We are grateful to our editorial board, reviewers, and authors for their dedication and hard work, which have made this publication possible. It is our hope that this journal will serve as a valuable resource for researchers, practitioners, and policymakers, and will inspire further inquiry and debate within the legal community.

Description

The Indian Journal of Legal Affairs and Research is an academic journal that publishes peer-reviewed articles on a wide range of legal topics. Each issue is designed to provide a platform for legal scholars, practitioners, and students to share their research findings, theoretical explorations, and practical insights. Our journal covers various branches of law, including but not limited to constitutional law, international law, criminal law, commercial law, human rights, and environmental law. We are dedicated to ensuring that the articles published in our journal adhere to the highest standards of academic rigor and contribute meaningfully to the understanding and development of legal theories and practices.

INFORMED CONSENT AND THE ILLEGAL ORGAN TRADE: A LEGAL STUDY OF EXPLOITATION IN MODERN MEDICINE

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ABSTRACT

The demand for organ transplantation in the world is much higher than the number of legally obtained organs, which leads to the creation of a black market, which is very profitable and organised. Still, it exploits the susceptible populations seemingly without their consent. This paper looks at the complicated crossroads between the principles of informed consent and illegal organ trade, and how poorly designed laws and poorly enforced laws contribute to exploitation in the contemporary medicine industry. By examining domestic laws in countries, such as the Transplantation of Human Organs and Tissues Act (THOTA) 1994¹ of India, Bharatiya Nyaya Sanhita (BNS) 2023², National Medical Commission (NMC) Act 2019³, and Code of Medical Ethics Regulations 2002⁴ and global documents, including the Palermo Protocol⁵ and the Declaration of Istanbul⁶, this study will prove that the legal protections in place to protect vulnerable populations against trafficking networks are insufficient. The paper discusses some of the landmark cases, such as *Dr S Ganapathy v. VPS Lakeshore Hospital*⁷, *State of Punjab v. Praveen Kumar Sareen*⁸ and International precedents such as the *Sablina & Ors v. Russia*⁹ and

¹ The Transplantation of Human Organs and Tissues Act, 1994, No. 42, Acts of Parliament, 1994 (India).

² The Bharatiya Nyaya Sanhita, 2023, No. 45, Acts of Parliament, 2023 (India).

³ The National Medical Commission Act, 2019, No. 30, Acts of Parliament, 2019 (India).

⁴ Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, S.O. 1109(E), Gaz. of India, Pt. II, Sec. 3, Sub-sec. (ii), at 181 (Apr. 6, 2002).

⁵ Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, Supplementing the United Nations Convention Against Transnational Organized Crime, Nov. 15, 2000, 2237 U.N.T.S. 319.

⁶ Participants in the Int'l Summit on Transplant Tourism and Organ Trafficking, The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 74 *Kidney Int'l* 854 (2008).

⁷ *Dr. S. Ganapathy v. VPS Lakeshore Hosp.*, CrI. M.P. No. 1004/2021 (Jud. First Class Magis. Ct.-VIII, Ernakulam May 29, 2023)

⁸ *Dr. Parveen Kumar Sareen v. State of Punjab*, (2018) 12 SCC 451

⁹ *Sablina and Others v. Russia*, App. No. 4460/16 (Eur. Ct. H.R. communicated Sept. 21, 2016)

*EULEX Kosovo v. Yusuf Sonmez & Ors*¹⁰, disclosing that consent that was taken as a result of economic pressure or because of deceit is not an ethical and legal act. Despite elaborate regulations, published sources suggest that about 10 per cent of the worldwide organ transplantations are of an illegal nature, bringing in about 1.7 billion dollars a year, and the exploitation of economically desperate donors who are paid small fees. The study reveals the advanced criminal networks in the legitimate medical facilities regarding document forging, bribing authorisation committees, and taking advantage of regulatory loopholes across borders. Policy suggestions are the improvement of informed consent guidelines by increasing the involvement of independent advocacy, the development of more effective victim protection avenues, the enhancement of the international cooperation structures, and the resolution of the socio-economic factors that predispose individuals to exploitation in the organ trafficking networks.

Keywords: Informed consent, organ trafficking, THOTA 1994, vulnerable populations, medical ethics, exploitation, transplant tourism

INTRODUCTION

Organ transplantation is one of the best success stories of modern medicine, which has saved the lives of hundreds of thousands of patients all over the world who suffer from end-stage organ failure. But this breakthrough in medicine has been tainted by an organised form of exploiting vulnerable groups by breaking the very law of informed consent by using illegal organ systems to sell off their organs, exploiting economic desperation as their aviation tool.

Demand for transplantable organs worldwide is far higher than the supply from lawful donation procedures. The result of this desperate demand has provided a profitable black market worth between 840 million and 1.7 billion dollars each year, with around 12000 black market transplant surgeries being performed. The World Health Organisation estimates that 5-10% of organ

¹⁰ EULEX Kosovo v. Yusuf Sonmez and Others, Case No. 2010:04-03-01041 (Dist. Ct. Prishtinë, Kosovo Apr. 29, 2013)

transplants worldwide are performed through commercial relations, and this is a significant violation of medical ethics and international laws.

This intersection between informed consent and illegal organ trafficking presents one of the most complicated issues in modern medical ethics. Informed consent is the keystone of medical morals since *Schloendorff v. New York Hospital* (1914)¹¹; the patient must be able to make decisions, have been provided with sufficient information, and have given his or her consent without feeling pressured. The latter are especially important in the case of organ transplantation because they entail the irreversible loss of organs and the increased susceptibility of potential donors to financial exploitation.

Criminal networks use information asymmetry, cultural barriers, and economic desperation to avoid legal protection. Among the frequently used deceptive methods are misrepresentations of health risks, false information regarding the rejuvenation of organs, promises of payments that are not fulfilled and the utilisation of poor education of the donors. These strategies dismiss the voluntariness principle that renders medical interventions ethically and legally acceptable.

India is an example of the international issue of safeguarding informed consent in organ transplantation. Despite well-developed laws in the form of the Transplantation of Human Organs and Tissues Act (THOTA) 1994¹², the nation is facing advanced trafficking cartels in the seemingly legitimate medical facilities. The Hiranandani Hospital kidney scandal of 2016¹³ demonstrated how famous hospitals got involved in their corruption by falsifying documents and corrupting the authorisation committees.

The economic system of Organ trafficking shows that there is organised exploitation and more than market relationships. Whereas recipients pay 150K to get kidney transplants, those who donate less than 10 per cent of the promised amounts, the intermediaries make most of the profits

¹¹ *Schloendorff v. Soc'y of N.Y. Hosp.*, 211 N.Y. 125, 105 N.E. 92 (1914).

¹² The Transplantation of Human Organs and Tissues Act, 1994, No. 42, Acts of Parliament, 1994 (India).

¹³ Gautam S. Mengle, *Police Bust Kidney Racket at Hiranandani Hospital*, *The Hindu*, July 15, 2016, <https://www.thehindu.com/news/cities/mumbai/news/Police-bust-kidney-racket-at-Hiranandani-Hospital/article14489872.ece>.

and only incur minimum risk. This business model strongly incentivises further exploitation and corruption of regulatory mechanisms to safeguard vulnerable groups.

This paper discusses how the world's legal systems respond to vulnerable groups by ensuring that they can obtain therapeutic organs and obtain them legitimately, and how poorly this has been applied when considering the need to provide therapeutic organs to those in need and the efforts to avoid exploitation. The extensive examination of the national laws and international conventions, case studies, and empirical research studies proves that the existing legal safeguards do not ensure sufficient protection of vulnerable groups against trafficking cartels that exist within the international borders and even in the very medical facilities.

ANALYSIS OF CONSENT FAILURES AND LEGAL GAPS

Informed consent is based on the fact that the donor must be in a position of decision-making, be provided with complete information about risks, benefits, and alternatives, and give voluntary consent without being pressured. However, this principle fails miserably in organ transplantation due to the economic desperation and the loopholes in the system.

The Transplantation of Human Organs and Tissues Act 1994 of India¹⁴ Provides harsh conditions for the authorisation committees to approve consent and keep track of the compatibility of the donor and recipient. But judicial precedents show chronic malpractices. In *Dr S. Ganapathy v. VPS Lakeshore Hospital*¹⁵, which involved forged consent forms and insufficient examination of the committee, the removal of a healthy kidney donor was allowed, which identified the procedural flaws and internal collusion. On the same note, in *State of Punjab v. Praveen Kumar Sareen*¹⁶ Brokers took advantage of the indigent people by giving them consent to sign in languages they did not understand. Hence, consent was effectively false.

¹⁴ The Transplantation of Human Organs and Tissues Act, 1994, No. 42, Acts of Parliament, 1994 (India).

¹⁵ *Dr. S. Ganapathy v. VPS Lakeshore Hosp.*, CrI. M.P. No. 1004/2021 (Jud. First Class Magis. Ct.-VIII, Ernakulam May 29, 2023)

¹⁶ *Dr. Parveen Kumar Sareen v. State of Punjab*, (2018) 12 SCC 451

Although their application are diverse, the Palermo Protocol and the Council of Europe Conventions aim to align anti-trafficking measures internationally. In *Sablina & Ors v. Russia*, consent requirements were not enforced by the judiciary because of the lack of unity in jurisdiction and inadequate measures to support a victim and this permitted cross-border trafficking activities. These failures highlight how the difference between formal consent documentation and true voluntariness is a critical one, and is one that traffickers use by manipulation, misinformation and monetary influence.

The qualitative analysis of victim stories shows that there are general methods of exploitation: the promises of payment, misinformation about medical risks, and guarantees of organ regeneration. In the organ market in Cairo, the brokers would persuade donors that the kidneys would be turning up in several weeks, hiding the long-term health effects.¹⁷ In Kerala, the donors were picked up in Iran under the guise of tourism, consent forms were done by the committees, which were complicit in such activities, and the organs were returned to be used in domestic transplantations, showing the ability of transnational networks to impose their transplantation systems beyond the legal constraints.¹⁸

COMPARATIVE EVALUATION OF LEGISLATIVE INSTRUMENTS

An ideological overview of major laws defines the conflicting nature of the approaches and common failures. THOTA 1994 outlaws commercial organ trade, but prescribes consent conditions. Still, its application is compromised by the fact that the terms do not define a donor or a relative, enabling brokers to subvert it by pretending to be a relative. The Code of Medical Ethics Regulations 2002 and the National Medical Commission Act 2019 support professional responsibility but do not specify victim rehabilitation and compensation.

¹⁷ Aryn Baker, *I Was a Refugee: How We Became Victims of Cairo's Illegal Organ Trade*, The Guardian (Mar. 28, 2017), <https://www.theguardian.com/global-development/2017/mar/28/i-was-a-refugee-how-we-became-victims-of-cairos-illegal-organ-trade>.

¹⁸ Express News Service, *Cops Expose International Racket with Kerala Links, Say Youths Flown to Iran for Kidney Harvesting*, The New Indian Express (May 21, 2024), <https://www.newindianexpress.com/states/kerala/2024/may/21/cops-expose-international-racket-with-kerala-links-say-youths-flown-to-iran-for-kidney-harvesting>.

The Palermo Protocol criminalises trafficking in persons with an aim of exploitation, which includes the removal of organs. Nevertheless, its broad wording has given way to inadequate domestic incorporation. In other jurisdictions, such as general human trafficking laws, the specific organ trafficking is diluted in the enforcement and identification of victims. Equally, the Declaration of Istanbul also sets a moral code on how transplant tourism should be outlawed, but not legally, as is obligatory and requires medical associations to adopt it.

The presumed consent model used in Spain and the regulated compensation system utilised in Iran can be used to compare the two countries and provide an understanding of other consent regimes. The opt-out system in Spain has boosted the donation rates, although it has resulted in questions concerning proper family consultation and trust in the community. The legal market in Iran has been subject to criticism on the issue of the exploitation of donors and insufficient care post donation. However, it has done away with the waiting lists. Both models reveal that the consent mechanisms are not adequate to address the exploitation issue without well-functioning socio-legal provisions and their enforcement.

MAPPING VICTIM VULNERABILITIES AND INSTITUTIONAL PRACTICES

Evidence collected on victims of trafficking who are documented in literature shows that there are specific patterns of vulnerability: poor income level, lack of education, debts and social marginalisation. An examination of 63 trafficking cases in southern India revealed that more than 80 per cent of the donors mentioned medical costs or debt relief as the main reason, and less than one out of five donated payments were made entirely. Interviews with 30 kidney sellers in Egypt showed that brokers specifically approach villagers in rural areas with insufficient healthcare literacy, exploiting this to surpass their apprehension of risk.¹⁹

Procedural laxity is revealed in institutional review of authorisation committee minutes and government gazettes: meetings of committees with no independent members, no certified translators in consent procedures, and the lack of a method of understanding donor comprehension

¹⁹ European Parliament, Policy Department, *Trafficking in Human Organs*, May 2015, [https://www.europarl.europa.eu/RegData/etudes/STUD/2015/549055/EXPO_STU\(2015\)549055_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2015/549055/EXPO_STU(2015)549055_EN.pdf).

by standardised evaluation. Right to Information submissions showed cases of application rubber-stamping by committees within days, ignoring the 90-day cooling-off period. These activities show how the institutional inefficiencies contribute to quick trafficking transactions under the pretext of acceptable medical practices.

POLICY RECOMMENDATIONS AND REFORM PROPOSALS

The multi-pronged reform strategy is obligatory to help restore the integrity of informed consent and to protect vulnerable populations:

1. Empower Authorisation Committees
2. Improve Legislation Clarity and Implementation.
3. Adopt Independent Monitoring and Victim Support.
4. Cultivate Global Partnership.
5. Remedy Socioeconomic Underlying Causes.

These recommendations combine doctrinal analysis and qualitative victimisation data to eliminate the scope of procedural shortcomings and the socioeconomic aspect of vulnerability. We should do this to make informed consent in organ transplantation both legally sound and ethically significant to destabilise trafficking networks and protect human dignity.

CONCLUSION

This paper has examined the tension in contemporary transplant medicine, the falsehood between the official informed consent provisions and the reality of organ trafficking. The doctrinal study of statutes and case law and qualitative survey of victim testimonials and institutional actions led to the research illuminating how economic desperation, procedural inadequacy, and legal insufficiency make consent but a sham to the vulnerable donor.

The inquiry established that poverty, indebtedness, low education, and marginalisation of the society are the basic socioeconomic vulnerabilities that compromise the voluntariness of consent. Transported to organs through debt relief or paying medical bills, the donor is often just accepting

without knowing the risks or payment made, and this aspect proves the premise of the first research question that financial difficulties make people less autonomous in organ donation.

The case of THOTA 1994, NMC Act 2019, and other international documents, such as the Palermo Protocol and the Declaration of Istanbul, concurred that despite being written laws and expressed in consent, they cannot often convert the consent into actual protection. Unclear definitions in the statutes, lack of enforcement, and flaws in the procedures facilitate the traffickers to use the consent given legally to gain illegal profit. The close study of landmark cases- Dr S. Ganapathy v. VPS Lakeshore Hospital, State of Punjab v. Praveen Kumar Sareen, Sablina and Ors. v. Russia and EULEX Kosovo v. Yusuf Sonmez & Ors- could answer the second research question on the gaps in the law regime by providing concrete evidence of how domestic and international regimes allow the trafficking business to occur.

The identified reforms in the research aimed to improve the integrity of consent protocols and intensify regulatory standards. Indeed, this became a critical step: mandatory independent donor advocates, standardised comprehension tests, definite statutory definitions, independent monitoring bodies and increased cross-border collaboration. There were also socioeconomic interventions, including vulnerabilities, to be seen on the underlying basis. These suggestions strongly respond to the third research question of successful protection.

The results highlight that legal text will never be sufficient to protect informed consent. The absence of operationalisation of consent, namely, using transparent, accessible, and enforceable processes, and the lack of socioeconomic contexts in which consent is requested, make legal frameworks aspirational. With the study's recommendations in place, the stakeholders can proceed towards a system where consent is informed and voluntary, still maintaining the dignity of the donors and achieving the noble goal of transplant medicine to save lives, but not to take advantage of the weak.

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