

The Study of Current Legislative Statement of Organ Transplantation

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Abstract

The main purpose of our research highlights a lack of awareness about donor laws, inadequate implementation, and critical challenges that require legal reform, enhanced support for donors, and better training for healthcare professionals. The legislative framework for organ transplantation varies widely across Asian countries, reflecting differences in cultural, ethical, and legal perspectives.

Organ transplantation involves transferring organs, tissues, or cells from donors to recipients, with a significant global demand surpassing the available supply. Biomedical ethics, as outlined by Beauchamp and Childress, and further examined by Veatch and Harris, provide a framework for addressing the moral dilemmas associated with transplantation. In Mongolia, the organ transplantation framework is guided by international standards, though there are gaps in legislation, social welfare, and insurance coverage, which impact the effectiveness of the transplant system.

Keywords: Organ Transplantation, Biomedical Ethics, Consent, Legal Framework, Donor Law.

1. Introduction

Transplantation is a surgical procedure in which an organ/s, tissue or a group of cells are removed from one person (the donor) and surgically transplanted into another person (the recipient), or moved from one site to another site in the same person. There are 40,000 transplants take place any given year in the world.

Organ transplantation is one of the great advances in modern medicine. It offers a second chance at life to people of all ages who have life-threatening diseases or injuries to their vital organs. Other donated tissues, like corneas, tendons and bones, can enhance lives by helping restore sight, movement and other physical functions. But the need for organ donations far exceeds the available supply. In the U.S., over 100,000 people are waiting for a life-saving organ transplant on any given day.

Effective ways to treat illnesses are progressively being put into practice, and new therapeutic and diagnostic innovations and

technologies are emerging quickly in the field of modern medicine. An example of this is the medical practice of transplanting cells, tissues, and organs from living or deceased donors.

2. The Legal Theoretical Framework of Organ Transplantation

Patients with end-stage organ failure have hope through organ transplantation, a potentially life-saving medical procedure. To guarantee fair and effective access to these crucial medical services, it is crucial to address the ethical, legal, and practical aspects of organ donation and transplantation.

The organ transplantation legislation aimed to enhanced the organ transplantation system by promoting donation, ensuring ethical practices, improving efficiency, and providing necessary support for donors and recipients.

The purpose of organ transplantation legislation is to: Promote implement nationwide campaigns to educate the public about the importance of organ donation. Ensure ethical practices in organ

procurement and transplantation. Ensure that potential donors and their families receive comprehensive information about the donation process and provide informed consent.

Improve the efficiency and transparency of the organ transplantation process. Develop a fair and transparent system for organ allocation based on medical need, urgency, and compatibility. Provides support and protection for both donors and recipients. Provide medical and psychological support for living donors and transplant recipients.

Establish a national oversight body to monitor and regulate organ donation and transplantation activities. Work with hospitals and healthcare providers to ensure adherence to ethical and procedural standards.

Tom L. Beauchamp and James F. Childress (1979) introduced the four principles of biomedical ethics: autonomy, beneficence, non-maleficence, and justice. These principles are often applied to issues of organ transplantation. They argued that due to the limited number of available organs and the difficulties in matching donors and recipients, applying these concepts to organ transplantation can be difficult. When weighing the needs and rights of various patients, such as allocating priority on the transplant waiting list, ethical quandaries frequently come up. Healthcare professionals endeavor to navigate these ethical challenges and deliver optimal care to donors and recipients by upholding the principles of autonomy, beneficence, non-maleficence, and justice.

Robert M. Veatch (2000) explored the ethical issues in organ transplantation, including allocation, consent, and the ethics of living donors. His work on the ethical issues in organ transplantation is a critical examination of the various ethical dilemmas that arise in the field. The exploration encompasses three main areas: allocation, consent, and the ethics of living donors and of ethical issues in organ transplantation provides a comprehensive framework for addressing the moral dilemmas associated with organ allocation, consent, and living donors.

John Harris (1985) discusses the moral and ethical implications of life-saving treatments, including organ transplantation. John Harris's discussion on the moral and ethical implications of life-saving treatments, including organ transplantation, provides a robust ethical framework for understanding and addressing these critical issues. His focus on the value of life, equitable resource allocation, informed consent, and the ethics of living donors contributes significantly to the ethical discourse surrounding life-saving medical interventions. By incorporating Harris's ethical principles into policy and practice, we can work towards a more just and compassionate healthcare system that respects the value of human life and the autonomy of individuals.

Charlotte Johnson-Webber, Jasmine Mah and et all (2023), explained that solid organ donation and transplantation is a good example of a complex healthcare process, as it involves multiple,

frequently time-limited steps and requires high-level coordination and collaboration between distinct stakeholders. Moreover, trust and confidence from the general public must be established and maintained in order to achieve success. The challenges involved in this process extend far beyond those associated with basic clinical practice or a single healthcare system alone. Many interrelated factors must be addressed to develop and sustain a high-quality program that meets the needs of the population.

3. The Current Situation of Organ Transplantation in Mongolia

The World Organ Transplantation Association's and the World Health Organization's guidelines, protocols, and standards, as well as the Law on Donors, serve as the foundation for Mongolia's legal framework surrounding organ, tissue, and cell transplantation. For doctors who treat patients undergoing organ transplantation and donate, tissue, and cell donations, there is insufficient support from insurance companies and laws regarding personal privacy, social welfare, protection, and insurance coverage, even in the case of applicable laws and regulations.

In Mongolia, hemodialysis or kidney replacement therapy is used for chronic kidney failure in 80–100 persons out of every million, and more than 80% of these individuals have kidney transplant surgery. Ten percent of them have been exposed to the hepatitis B and C viruses. The annual number of cases of liver cancer is over 2,000, with 80% of cases dying in the year of diagnosis. The incidence of cancer is six times higher than the world average.

Our research was motivated by the lack of analysis and research activities in the fields of medicine and law due to the development of cell, tissue, and organ transplantation treatment methods, rationalization of laws and legal issues regulating them, raising issues, and significant research.

The law defines donors and recipients, which are the primary cases studied by our research team. This comprises: The donor must follow the non-profit, non-receivable, voluntary donation principle when giving blood, cells, tissues, or organs in order to preserve human health and save lives. Donors can fall into one of two categories.

I. "Living donor" is defined as an individual who freely donates organs, tissues, cells, and parts of organs in order to maintain their health and save lives; II. "Inanimate donor" is outlined as a deceased person whose brain has completely died, whose function has been irreversibly lost, or whose function is normal after it has been verified that some organs, tissues, and cells can be transplanted.

II. A "inanimate donor" is a deceased person whose brain has entirely gone dead, whose function has been irreversibly lost, or whose function is normal after it has been established that certain organs, tissues, and cells can be transplanted. In medicine, non-living donors are utilized as death donors, cadaver donors, or cadaver donors.

- "recipient" means, as defined by law, an individual who requires a transfusion of blood or blood products, or a transplant of donor cells, tissues, or organs in order to preserve his life or health.

The first organ transplant surgery was performed in Mongolia in 1956 when a corneal transplant was performed, and again in 1996 when a kidney transplant was performed. This kind of treatment is constantly evolving. The process of transferring a human cell, tissue, or organ—in whole or in part—to another individual is known as organ transplantation. The donor is the individual who freely gives away cells, tissues, and organs; the recipient is the person who receives those donations. Organs including the heart, liver, pancreas, kidney, lung, intestine, cornea, spinal cord, bones, cartilage, tendons, skin, blood vessels, and heart valves are transplanted; as of right now, the aforementioned services are offered in 86 countries .

There is a significant risk of donor expectations and unofficial false news and information spreading due to a lack of knowledge, information, and attitudes regarding the voluntary donation of cells, tissues, and organs, as well as the inadequacy of health institutions and qualified human resources. The Health Development Center's organ donation waiting list typically has between 100 and 110 persons waiting for liver donation and between 100 and 120 people in need of kidney transplants.

According to a World Health Organization study, there were 290 stroke cases diagnosed for every 100,000 people in Mongolia, of which 142 (49%) resulted in death. Additionally, there were 400–500 traffic accident deaths annually and 1,007 cases of cardiovascular disease for every 10,000 people. It is possible to convert 300–400 deaths from the aforementioned illnesses into non-living donors. From a single brain-dead donor (cadaver), 7-8

lives are saved abroad, and 3–4 people in our nation benefit from organ, tissue, and cell transplants.

Considering that it is a relatively new technology for our nation, it is nevertheless developing quickly. In the Mongolian Center for Health Development's 2023 report, claims:

- Through the National First Central Hospital, 340 patients have undergone kidney transplant treatment since 1996. In 2011, 242 patients underwent liver transplants; in 1964, 32 patients underwent corneal transplants; and in 2020, tendon transplants were performed. 170 cases were filed in total.
- This year at the National Cancer Research Center, 128 patients received liver transplants.
- Since its founding in 1964, the National Trauma and Orthopedic Research Center has successfully performed skin transplant surgery on 700 patients annually;
- In 2021, the General Hospital of State Special Employees successfully completed tendon transplantation from a cadaver donor.

4. The Situation of Organ Transplantation in The World

The world has been running organ transplant programs since 1960, and associated laws and regulations have been created. The US Congress passed the "Organ Transplantation Act" in 1984 to address the organ shortage as well as ethical concerns pertaining to the quick development, accessibility, and outcomes of tissue and organ transplantation. Approved initially as the National Law on Transplantation.

The OPT-in and OPT-out legal models are the two that the contract governs in terms of authorization and strategy for organ transplantation. The features of these two models are displayed in Figure 1, along with the nations in which they are used

Models	The principles of law	Ethical concepts	Individual	Family Prohibition
OPT-in	Based on individual rights	Independence	Obtain consent from the patient and family	Regenerate organs. (Ethically, it aims to inspire trust and confidence)
OPT-out	Based on social duties and responsibilities	Social density and benefits	If you don't refuse to be a donor	the organ will not be restored
OPT-in	Country	Mongolia, USA, Australia, Canada, Chile, Cuba, Denmark, Estonia, Ireland, Japan, Malaysia, Mexico, Venezuela, New Zealand, Germany, Holland, Denmark, Great Britain, South Korea, South Africa, Thailand		
OPT-out		Sweden, Argentina, Croatia, Austria, Belgium, France, Italy, Czech Republic, Finland, Norway, Turkey, Greece, Portugal, Poland, Spain, Panama, Prague, Luxembourg, Latvia, Hungary, Singapore, Estonia		

Figure 1. A comparison of models for contract law.

According to the above model, the Organ Procurement Organization (OPO) organizes general regulations and the OPT-IN model is widely used in the United States; as a result, the relevant laws and regulations are relatively developed. In the Republic of Turkey, however, the potential or OPT-OUT model is more advanced. Determining factors such as population size, religion, medical professionals, legal knowledge of the public, and the rationality of organ, tissue, and cell transplantation, low expectations are held for donors, including deceased ones, in foreign nations as below:

- Based on the idea of acceptance if one does not refuse to become a donor, and on the OPT-OUT system in the framework of the authorization and approach to organ transplantation, which views the process of becoming a donor as a social duty and responsibility.
- In 2007, it was declared that Christians have an obligation to voluntarily donate their organs to the Church of England. The majority of Protestants and Anglicans consider organ donation to be a charitable act.

- Muslims in Britain are not uncommonly in possession of donor cards. They regard being a living donor as a virtue, and their holy religion teaches them to be compassionate, helpful, and to donate their organs as a good deed in order to save the lives of others.

It is divided into two categories under international law and legal norms: principles of cell, tissue, and organ transplantation experiments and methodological principles of cell, tissue, and organ transplantation. Stated differently, the foundation lies in the principles of experimental research, treatment, and transplantation of cells, tissues, and organs.

As a result, the Helsinki Declaration of 1964 and the Nuremberg Codes of 1947 both stipulate in their preambles that monitoring is required when conducting medical research leading to the transplantation of human blood, tissues, or organs. A number of documents, including the 1987 Declaration on Transplantation of Human Tissues and Organs, contain guidelines for following the World Medical Association's Declaration of Helsinki when performing experiments involving the transplantation of human organs and blood.

The World Health Organization's research indicates that over 100,000 organ transplant cases are carried out on average every year. Human cells, tissues, and organs are illegally taken and sold as donors due to high demand, high-cost sales regulations in some countries, and a lack of available donors. Crimes and violations like human trafficking for organ harvesting are on the rise. While the laws governing the transplantation of human cells, tissues, and organs vary from nation to nation, there are many shared features in terms of the aims, purposes, and paths taken. Combating the illegal harvesting, trafficking, and use of human cells, tissues, and organs is one of its shared objectives.

Because it will be more common in practice to transplant cells, tissues, and organs from living donors, there will be a decrease in the transplantation of tissues and organs from living donors in the future. Instead, the system for transplanting cells, tissues, and organs from non-living donors will be further developed, and the

laws governing this process will be optimized. It's now a major concern in the legal and health fields. Because of this, global trends (such as the World Health Organ, the Istanbul Declaration, and the Madrid Declaration) advocate for organ transplantation from "brain-dead donors," which is thought to be essential to protect living donors.

The world has formally adopted organ transplant programs since 1960, and the drafting of relevant laws and regulations has started. The Donor Law, originally approved in 2000 and consisting of 24 articles spread over 6 chapters, regulates the legal acquisition and transplantation of human blood, cells, tissues, and organs in our nation. It was updated in 2022 and became a significant law to safeguard living donors, assist silent donors, and enhance the donor-friendly legal framework.

5. The Research Methodology and Results of Study

We conducted between 2019 and 2023 in Third State Central Hospital and the National Trauma and Orthopedic Research Center in our study. This study used standard sociological research methods, including fact research methods, observation-descriptive methods, and quantitative methods (questionnaire, content analysis), to gather data on pre-made questionnaire cards with 12–17 questions. The data were then analyzed and the findings were demonstrated.

A total of 67 physicians and nurses from donor hospitals made up our research team; 64.2% were employed by the Third State Central Hospital, and 35.8% (85.1%) and 14.9%, by the National Trauma and Orthopedic Research Center 50.7% of the participants were female and 49.3% of the participants were male.

When asked what year the Law on Donors revision, which is the primary focus of the research, was implemented, 59.7% of respondents said it was 2018, while 28.4% said they were unsure. Of the donors, 44.8 percent are knowledgeable, and 55.2 percent are not knowledgeable about donors. Furthermore, according to 52.2 percent of the respondents, they learned about the law from pertinent laws and regulations, 34.3 percent from medical professionals and hospital staff, and 13.4 percent from the media and mass media.

In addition, 56.7 percent of respondents said they knew about the illegal organ trade, compared to 43.3 percent who did not. Regarding the adequacy of the current law's implementation regarding donors, 61.2% of respondents stated it was insufficient, 6.0% said it was sufficient, 32.8% were unsure, and the law's implementation conflicted with their activities. The following are the answers to the research's open questions. It consists as below:

- Unclear Donor Law provisions,
- Donor expectations are high; there is no social security or welfare support for the recipient or the individual who voluntarily donates tissues and organs; there is a lack of human resources in management and organizational departments and units for cell, tissue, and organ transplantation;
- There are no specifically regulated provisions in the law supporting

citizens who have donated their cells, tissues, or organs;
- The majority provided insufficient information, training, and advertising.

6. Conclusion

The surgical process of transplanting organs, tissues, or cells from a donor to a recipient, or within the same individual, is known as organ transplantation. Even though 40,000 transplants take place globally each year, there is a far greater need for organ donations than there is availability.

Numerous scholars studied organ transplantation. The four guiding concepts of biomedical ethics—autonomy, beneficence, non-maleficence, and justice—were first presented by Tom L. Beauchamp and James F. Childress. Robert M. Veatch (2000) examined the moral dilemmas surrounding organ transplantation, emphasizing consent, allocation, and living donor ethics. A strong ethical framework for discussing the moral and ethical ramifications of life-saving procedures, such as organ transplantation, is offered by John Harris (1985).

According to Charlotte Johnson-Webber, Jasmine Mah, and colleagues (2023), solid organ donation and transplantation entail a number of intricate, time-sensitive processes that call for close coordination and cooperation between a number of stakeholders. The World Organ Transplantation Association's and the World Health Organization's guidelines, protocols, and standards form the basis of Mongolia's legal framework for organ, tissue, and cell transplantation.

Legislation pertaining to social welfare, privacy, and insurance coverage for organ donation and transplantation is lacking in Mongolia, as is support from insurance companies. Around 80% of Mongolians with chronic kidney failure receive kidney transplant surgery, while the remaining 80–100 people per million use hemodialysis or kidney replacement therapy. Liver cancer incidence in Mongolia is significantly higher than the global average, and many of these patients have been exposed to hepatitis B and C. "Inanimate donors" are deceased people whose organs can be transplanted, and "living donors" are people who freely donate organs, tissues, or cells, according to the law. A corneal transplant was performed in Mongolia for the first time in 1956. A kidney transplant was performed there in 1996. Currently, 86 countries offer organ transplant services.

In Mongolia, 340 kidney transplants, 242 liver transplants, and a variety of other organ and tissue transplants have been carried out since 1996; noteworthy developments have been documented in the last few years.

We concluded from our results of research as below:
The data reveal a significant gap in awareness regarding the Law on Donors, with 28.4% of respondents unsure of its implementation year and 55.2% lacking knowledge about donor regulations. This highlights a crucial need for enhanced educational initiatives and

training for healthcare professionals to ensure comprehensive understanding and compliance with the law.

A majority of respondents (61.2%) believe that the current implementation of the donor law is inadequate. This suggests that while the law may be in place, its practical execution and the support it provides to both donors and recipients may be falling short. There is a clear demand for a review and possible revision of the law to address these deficiencies."

The study identifies several critical challenges, including unclear provisions in the donor law, insufficient social security for donors, and a lack of human resources in transplant management. To improve the system, it is essential to address these gaps by providing better legal clarity, enhancing support mechanisms for donors, and investing in adequate training and resources for healthcare personnel involved in transplantation.

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